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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
10/25/2021 5:11 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: 2021 HB 3036 allows physician assistant to dispense prescription drugs and proactive procedural rule review

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/23/2021 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.

CONTACT: Rachel Melvin
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800 NE Oregon St., Suite 150
Portland,OR 97232

Filed By:
Rachel Melvin
Rules Coordinator

HEARING(S)

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

DATE: 11/23/2021
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 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.

Alternatively, you may dial (503) 446-4951 Phone Conference ID: 472 815 435# for audio only.

You may file written comments before 4:30PM on November 23, 2021 by emailing your comments to pharmacy.rulemaking@bop.oregon.

NEED FOR THE RULE(S)

Revisions to Division 043 are necessary to incorporate changes to physician assistant (PA) scope set forth in 2021 HB 3036, related to dispensing prescription drugs.

To ensure rules reflect updates to statutes, including ORS 678.390 concerning the authority of a nurse practitioner and clinical nurse specialist to dispense drugs.

To appropriately references and reflects current regulations, amends and repeals outdated regulations in alignment with the board's 2020-2024 strategic plan.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

2021 HB 3036 https://olis.oregonlegislature.gov/liz/2021R1/Downloads/MeasureDocument/HB3036/Enrolled
Oregon State Board of Nursing: ORS
678.390 https://www.oregonlegislature.gov/bills_laws/ors/ors678.html
Poison Prevention Packaging Act: https://www.govinfo.gov/content/pkg/CFR-2021-title16-vol2/pdf/CFR-2021-title16-vol2-chapII-subchapE.pdf
16 CFR 1700 (XX/XX/XXXX)Poison Prevention
16 CFR 1701 (XX/XX/XXXX) Statements of Policy and Interpretation
16 CFR 1702 (XX/XX/XXXX) Petitions for Exemptions from Poison Preventing Packaging Act Requirements; Petition Procedures and Requirements

FISCAL AND ECONOMIC IMPACT:

OAR 855-043-0002(7), OAR 855-043-0405 through OAR 855-043-0455: There are 52 Supervising Physician Dispensing Outlets (SPDO) and 49 Dispensing Practitioner Dispensing Outlets (DPDO) currently active. As a result of 2021 HB 3036, SPDO will be discontinued effective 3/31/2022. 6 SPDOs also have an active DPDO registration. The discontinued SPDOs may now meet the requirements for registration as a "DPDO". The current SPDO registration fee is $175/$275 with CS annually and the current DPDO registration fee is $100 annually. There are currently 6 locations that hold both registrations. The transition from SPDO Registration to DPDO registration has a net biennial revenue reduction of 17,400.

OAR 855-043-0002(2) and (4), OAR 855-043-0003, OAR 855-043-0004, OAR 855-043-0005, OAR 855-043-0210, OAR 855-043-0505 through OAR 855-043-0560, OAR 855-043-0705 and OAR 855-043-0740: No anticipated fiscal.

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).

The Oregon Board of Pharmacy will have a net biennial revenue reduction of $17,400 for the transition from SPDO Registration to DPDO registration. There are are no known economic impacts to 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?

Legislative directive of 2021 HB 3036

RULES PROPOSED:

855-043-0002, 855-043-0003, 855-043-0004, 855-043-0005, 855-043-0210, 855-043-0405, 855-043-0410, 855-

043-0415, 855-043-0420, 855-043-0425, 855-043-0430, 855-043-0435, 855-043-0436, 855-043-0440, 855-043-0445, 855-043-0450, 855-043-0455, 855-043-0505, 855-043-0510, 855-043-0530, 855-043-0540, 855-043-0545, 855-043-0555, 855-043-0560, 855-043-0705, 855-043-0740

AMEND: 855-043-0002

RULE SUMMARY: Revisions to Division 043 are necessary to incorporate changes to PA scope set forth in 2021 HB 3036, related to dispensing prescription drugs. Repeal of OAR 855-043-0405 through 855-043-0455 and 855-043-0002(9) effective 3/31/2022. Appropriately references and reflects current regulations, amends and repeals outdated regulations in alignment with the board's 2020-2024 strategic plan.

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) "Counseling" means an oral or other appropriate communication process between a practitioner and a patient or a patient's agent in which the practitioner obtains information from the patient or patient's agent, and, where appropriate, the patient's medical records, assesses that information and provides the patient or patient's agent with professional advice regarding the safe and effective use of the drug or device for the purpose of assuring therapeutic appropriateness.¶
(3) "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~~4) "Expedited Partner Therapy (EPT)" means the practice of prescribing or dispensing an antibiotic drug for the treatment of a sexually transmitted disease to the partner of a patient without first examining that partner.¶
(5) "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 ~~B~~board or by the ~~Department of Human Services (DHS~~Oregon Health Authority (OHA).¶
(~~4~~6) "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) "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~~OHA.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

AMEND: 855-043-0003

RULE SUMMARY: Appropriately references and reflects current regulations, amends and repeals outdated regulations in alignment with the board's 2020-2024 strategic plan.

CHANGES TO RULE:

855-043-0003
Expedited Partner Therapy ¶

(1) ~~Expedited Partner Therapy (EPT) means the practice of prescribing or dispensing an antibiotic drug for the treatment of a sexually transmitted disease to~~There is substantial evidence that rates of re-infection with certain sexually transmitted diseases can be reduced by treating all sexual partners for the disease, even when the treating clinician has not examined those partners. This practice is known as Expedited Partner Therapy.¶
(2) Because of the important public health implications, the 2009 Oregon Legislature passed HB 3022 authorizing the ~~partner of a patient without first examining that partner~~is practice. This law permits health professional regulatory boards to adopt rules permitting practitioners to practice Expedited Partner Therapy.¶
(~~2~~3) ~~An EPT prescription may only be dispensed for a drug and a disease that has been determined by DHS to be appropriately addressed by EPT~~The law specifies that a prescription issued in the practice of Expedited Partner Therapy is valid, even if the name of the patient the prescription is intended for is not on the prescription.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ~~2009 OL Ch 522~~ORS 689.505

ADOPT: 855-043-0004

RULE SUMMARY: Appropriately references and reflects current regulations, amends and repeals outdated regulations in alignment with the board's 2020-2024 strategic plan.

CHANGES TO RULE:

855-043-0004
Expedited Partner Therapy (EPT) - Procedures
(1) Notwithstanding any other rules in this division that mandate requirements for a valid prescription and for labeling, when a prescription is marked EPT or a similar notation by the prescribing practitioner, this rule governs.¶
(2) An EPT prescription may only be dispensed for a drug that has been determined by the Oregon Health Authority to be appropriately used for EPT.¶
Prescription¶
(3) An EPT treatment protocol must conform to the following:¶
(a) It must include a prescription for each named or unnamed partner of the patient;¶
(b) It must contain a hand written or electronic signature of the prescribing practitioner;¶
(c) The practitioner must identify the prescription in the following manner:¶
(A) Write "for EPT," or a similar notation, on the face of the prescription;¶
(B) For a verbal order, the practitioner must identify the prescription as an "EPT Prescription," or similar identification;¶
(C) The practitioner must identify the prescription for each partner either by including the name of the patient, such as "John Doe - Partner 1" or by labeling the prescription as "EPT Partner"¶
(d) An EPT Prescription expires 30 days after the date written;¶
(e) An EPT Prescription may not be refilled;¶
(f) If any component of the prescription is missing, the DPDO must contact the prescriber or the prescriber's agent and must record the additional information on the prescription.¶
(4) A patient may give the prescription to each unnamed partner for that person to fill at a pharmacy of their choice; or the patient may elect for a DPDO to dispense all prescriptions and then give the dispensed drugs to each unnamed partner.¶
Labeling¶
(5) The DPDO must label the drug for the named patient in accordance with normal procedures as specified in the other rules of this division, however when either the patient or partner is unnamed, the DPDO may create a unique identifier and use that instead of a name for both labeling and record keeping purposes.¶
(6) The DPDO must assign a separate and unique identifier to each prescription and clearly identity this number on each corresponding prescription label.¶
Counseling¶
(7) The DPDO is not required to obtain an EPT patient's or partner's name, address, or demographics; however, the DPDO must:¶
(a) Provide counseling in the form of written patient information to accompany each prescription for each partner and ask the patient about any known allergies or other drugs being taken by each partner. The DPDO should advise the patient to encourage each partner to call the DPDO before taking the drug if they have experienced any adverse effect from a drug in the past or if they are taking other drugs;¶
(b) Document counseling.¶
Records¶
(8) All documentation required by this rule must be attached to the prescription and must be referenced to each partner's prescription. Such documentation must be retained in accordance with the other rules in this division and must be made available to the board upon request.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505

REPEAL: 855-043-0005

RULE SUMMARY: Appropriately references and reflects current regulations, amends and repeals outdated regulations in alignment with the board's 2020-2024 strategic plan.

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) Not withstanding 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~~

REPEAL: 855-043-0210

RULE SUMMARY: Ensure rules reflect updates to statutes, including ORS 678.390 concerning the authority of a nurse practitioner and clinical nurse specialist to dispense drugs.

CHANGES TO RULE:

~~855-043-0210~~
~~Purpose and Scope~~
~~The Oregon State Board of Nursing may grant to a certified nurse practitioner or Clinical Nurse Specialist the privilege of writing prescriptions described in the formulary under ORS 678.385. A certified nurse practitioner or Clinical Nurse Specialist may submit an application to the Oregon State Board of Nursing to dispense prescription drugs. An application for the authority to dispense prescription drugs as authorized by ORS 678.385 shall include evidence of completion of a prescription drug dispensing training program jointly developed and adopted by rule by the Oregon State Board of Nursing (851-050-0162) and the State Board of Pharmacy. The training program shall be as follows:¶~~
~~(1) Documented review of content regarding safe dispensing listed below:¶~~
~~(a) Board of Nursing handbook "Prescriptive Authority in Oregon for Nurse Practitioners and Clinical Nurse Specialists";¶~~
~~(b) The Drug Enforcement Administration Pharmacist's Manual (2004);¶~~
~~(c) OAR 851, division 56;¶~~
~~(d) ORS Chapter 689 and OAR chapter 855;¶~~
~~(e) US Consumer Product Safety Commission publication "Poison Prevention Packaging: A Text for Pharmacist's and Physicians;"¶~~
~~(f) The Institute for Safe Medication Practices (ISMP) "List of Error-Prone Abbreviations, Symbols, and Dose Designations" (Nov. 2006); and¶~~
~~(g) Information on available electronic or hard copy prescription drug references which provide information to professionals authorized to dispense prescription medications¶~~
~~(2) Successful self examination as provided by the Board of Nursing on these materials.¶~~
~~[Publications: Publications referenced are available from the agency.]~~
~~Statutory/Other Authority: ORS 678.390, 689.205~~
~~Statutes/Other Implemented: ORS 689.205~~

REPEAL: 855-043-0405

RULE SUMMARY: Revisions to Division 043 are necessary to incorporate changes to PA scope set forth in 2021 HB 3036, related to dispensing prescription drugs. Repeal of OAR 855-043-0405 through 855-043-0455 and 855-043-0002(9) effective 3/31/2022.

CHANGES TO RULE:

~~855-043-0405~~
~~Purpose and Scope~~
~~A supervising physician or supervising physician organization that supervises a physician assistant with dispensing authority must register the dispensing site with the Board as a Supervising Physician Dispensing Outlet (SPDO) and must comply with the rules in OAR chapter 855, division 43.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, 689.305, 2012 OL Ch 34~~

REPEAL: 855-043-0410

RULE SUMMARY: Revisions to Division 043 are necessary to incorporate changes to PA scope set forth in 2021 HB 3036, related to dispensing prescription drugs. Repeal of OAR 855-043-0405 through 855-043-0455 and 855-043-0002(9) effective 3/31/2022.

CHANGES TO RULE:

~~855-043-0410~~
~~Registration~~
~~(1) A Supervising Physician Dispensing Outlet must register with the Board as a SPDO in the category of Retail Drug Outlet on a form provided by the Board, and must renew its registration annually on a renewal form provided by the Board.¶~~
~~(2) The initial application must state the location of the SPDO and the name of the person applying for registration. When the person applying for registration is not the owner of the dispensing site, the application must disclose the name and address of the owner and the applicant's affiliation with the owner.¶~~
~~(a) If more than one individual owns the dispensing site, the names and addresses of the partners or persons holding the three largest ownership interests in the dispensing site must be disclosed on the application.¶~~
~~(b) If the owner is a corporation, the application must state the name of the corporation as filed with the Corporation Division of the Oregon Secretary of State, including the names of the corporation's officers.¶~~
~~(3) Upon request by the Board, the applicant must furnish such information as required by the Board regarding the partners, stockholders, or other persons not named in the application.¶~~
~~(4) An initial application must be accompanied by the fee established in division 110 of this chapter.¶~~
~~(5) A certificate of registration will be issued upon Board approval of the application.¶~~
~~(6) All registration renewal applications must be accompanied by the annual renewal fee established in Division 110 of this chapter and must contain the information required in sections (2) and (3) of this rule.¶~~
~~(7) The SPDO registration expires March 31, annually. If the annual renewal fee referred to in section (5) of this rule is not paid by February 28 of the current year, the applicant for renewal must submit the delinquent fee established in division 110 of this chapter with the renewal application.¶~~
~~(8) The registration is not transferable and the registration fee cannot be prorated.¶~~
~~(9) The registrant must notify the Board, within 15 days, of any substantial change to the information provided on the registration application. Substantial change shall include but not be limited to: change of ownership; change of business address; change of normal business hours; any disciplinary action taken or pending by any state or federal authority against the registrant, or any of its principals, owners, directors, officers, consultant pharmacist or supervising physician.¶~~
~~(10) A new registration form is required for a change of ownership or location and must be submitted to the Board with the fees as specified in division 110 of this chapter within 15 days of the change.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, 689.305, 2012 OL Ch 34~~

REPEAL: 855-043-0415

RULE SUMMARY: Revisions to Division 043 are necessary to incorporate changes to PA scope set forth in 2021 HB 3036, related to dispensing prescription drugs. Repeal of OAR 855-043-0405 through 855-043-0455 and 855-043-0002(9) effective 3/31/2022.

CHANGES TO RULE:

~~855-043-0415~~
~~Consulting Pharmacist~~
~~(1) A SPDO must retain a pharmacist licensed in Oregon for consultation purposes.¶~~
~~(2) The consulting pharmacist must conduct and document an annual inspection of the outlet on a form provided by the Board. The completed inspection report form must be filed in the outlet, retained on file for three years and be available to the Board for inspection.¶~~
~~(3) The duties of the consulting pharmacist shall be clearly defined in writing within the organization. The consulting pharmacist must:¶~~
~~(a) Develop policies and procedures for the outlet in collaboration with the supervising physician; and¶~~
~~(b) Work in consultation with the supervising physician in the development of the formulary of drugs and classes of drugs for the outlet.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, 689.305, 2012 OL Ch 34~~

REPEAL: 855-043-0420

RULE SUMMARY: Revisions to Division 043 are necessary to incorporate changes to PA scope set forth in 2021 HB 3036, related to dispensing prescription drugs. Repeal of OAR 855-043-0405 through 855-043-0455 and 855-043-0002(9) effective 3/31/2022.

CHANGES TO RULE:

~~855-043-0420~~
~~Policies and Procedures~~
~~The registered SPDO must:¶~~
~~(1) Maintain written policies and procedures for drug management, including storage, security, integrity, access, dispensing, disposal, record keeping and accountability;¶~~
~~(2) Maintain all drug records required by federal and state law;¶~~
~~(3) Establish procedures for procurement of drugs; and¶~~
~~(4) Establish procedures to train physician assistants who dispense drugs and to ensure the continued competence of physician assistants who dispense drugs.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, 689.305, 2012 OL Ch 34~~

REPEAL: 855-043-0425

RULE SUMMARY: Revisions to Division 043 are necessary to incorporate changes to PA scope set forth in 2021 HB 3036, related to dispensing prescription drugs. Repeal of OAR 855-043-0405 through 855-043-0455 and 855-043-0002(9) effective 3/31/2022.

CHANGES TO RULE:

~~855-043-0425~~
~~Security~~
~~(1) All drugs must be kept in a locked drug cabinet or designated drug storage area that is sufficiently secure to deny access to unauthorized persons. The drug cabinet or designated drug storage area must remain locked and secured when not in use.¶~~
~~(2) No drug dispensing machine may be placed in a waiting room or an area that is accessible by the public.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, 689.305, 2012 OL Ch 34~~

REPEAL: 855-043-0430

RULE SUMMARY: Revisions to Division 043 are necessary to incorporate changes to PA scope set forth in 2021 HB 3036, related to dispensing prescription drugs. Repeal of OAR 855-043-0405 through 855-043-0455 and 855-043-0002(9) effective 3/31/2022.

CHANGES TO RULE:

~~855-043-0430~~
~~Storage of Drugs~~
~~All drugs, including drug samples, must be stored under conditions that ensure proper sanitation, temperature, light, ventilation, moisture control, and any other condition recommended by the manufacturer.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, 689.305, 2012 OL Ch 34~~

REPEAL: 855-043-0435

RULE SUMMARY: Revisions to Division 043 are necessary to incorporate changes to PA scope set forth in 2021 HB 3036, related to dispensing prescription drugs. Repeal of OAR 855-043-0405 through 855-043-0455 and 855-043-0002(9) effective 3/31/2022.

CHANGES TO RULE:

~~855-043-0435~~
~~Labeling~~
~~(1) A prescription must be labeled with the following information:¶~~
~~(a) Unique identifier;¶~~
~~(b) Name of patient;¶~~
~~(c) Name of prescriber;¶~~
~~(d) Name, address, and phone number of the clinic;¶~~
~~(e) Date of dispensing;¶~~
~~(f) Name and strength of the drug. If the drug does not have a brand name, then the generic name of the drug and the drug manufacturer must be stated;¶~~
~~(g) Quantity dispensed;¶~~
~~(h) Directions for use;¶~~
~~(i) Initials of the physician assistant or practitioner dispensing;¶~~
~~(j) Cautionary statements, if any, as required by law; and¶~~
~~(k) Manufacturer's expiration date, or an earlier date if preferable, after which the patient should not use the drug; and¶~~
~~(l) Any dispensed prescription medication, other than those in unit dose or unit of use packaging, shall be labeled with its physical description, including any identification code that may appear on tablets and capsules.¶~~
~~(2) Not withstanding any other requirements in this rule, when a drug is dispensed in the practice of an Expedited Partner Therapy treatment protocol, as described in OAR 855-041-4000 through 4005, the name of the patient may be omitted.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, 689.305, 2012 OL Ch 34~~

REPEAL: 855-043-0436

RULE SUMMARY: Revisions to Division 043 are necessary to incorporate changes to PA scope set forth in 2021 HB 3036, related to dispensing prescription drugs. Repeal of OAR 855-043-0405 through 855-043-0455 and 855-043-0002(9) effective 3/31/2022.

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~~

REPEAL: 855-043-0440

RULE SUMMARY: Revisions to Division 043 are necessary to incorporate changes to PA scope set forth in 2021 HB 3036, related to dispensing prescription drugs. Repeal of OAR 855-043-0405 through 855-043-0455 and 855-043-0002(9) effective 3/31/2022.

CHANGES TO RULE:

~~855-043-0440~~
~~Dispensing and Drug Delivery~~
~~(1) Drugs dispensed from a SPO by a physician assistant with dispensing authority or a practitioner must be personally dispensed by the practitioner or physician assistant.¶~~
~~(2) Prior to dispensing a medication a drug utilization review must be performed by the physician assistant or practitioner which includes but is not limited to drug interactions, drug allergies and duplicate drug therapy.¶~~
~~(3) The physician assistant or practitioner must orally counsel the patient concerning all new drugs, unless circumstances would render oral counseling ineffective.¶~~
~~(4) When dispensed, a drug must be accompanied by written information that contains at least the following information:¶~~
~~(a) Drug name, class and indications;¶~~
~~(b) Proper use and storage;¶~~
~~(c) Common side effects;¶~~
~~(d) Precautions and contraindications; and¶~~
~~(e) Significant drug interactions.¶~~
~~(5) Each authorized dispenser of a prescription drug product for which a Medication Guide is required must provide the Medication Guide directly to each patient or patient's agent when the product is dispensed, unless an exemption applies.¶~~
~~(6) Any other requirement of State or federal law.¶~~
~~(7) A SPDO must dispense a drug in a new container that complies with the current provisions of the Federal Consumer Packaging Act (Public Law 91-601, 91st Congress, S. 2162) and rules or regulations and with the current United States Pharmacopoeia/National Formulary monographs for preservation, packaging, storage and labeling.¶~~
~~(8) Drugs must be prepackaged by a pharmacy or manufacturer registered with the Board.¶~~
~~(9) A SPDO may not accept the return of drugs from a previously dispensed prescription and must maintain a list of sites in Oregon where drugs may be disposed.¶~~
~~(10) 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.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, 689.305, 2012 OL Ch 34~~

REPEAL: 855-043-0445

RULE SUMMARY: Revisions to Division 043 are necessary to incorporate changes to PA scope set forth in 2021 HB 3036, related to dispensing prescription drugs. Repeal of OAR 855-043-0405 through 855-043-0455 and 855-043-0002(9) effective 3/31/2022.

CHANGES TO RULE:

~~855-043-0445~~
~~Drug Dispensing Training Program~~
~~A physician assistant must complete a drug dispensing training program jointly developed by the Oregon Medical Board and the Board of Pharmacy before dispensing drugs to patients.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, 689.305, 2012 OL Ch 34~~

REPEAL: 855-043-0450

RULE SUMMARY: Revisions to Division 043 are necessary to incorporate changes to PA scope set forth in 2021 HB 3036, related to dispensing prescription drugs. Repeal of OAR 855-043-0405 through 855-043-0455 and 855-043-0002(9) effective 3/31/2022.

CHANGES TO RULE:

~~855-043-0450~~
~~Disposal of Drugs~~
~~Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be documented, quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, 689.305, 2012 OL Ch 34~~

REPEAL: 855-043-0455

RULE SUMMARY: Revisions to Division 043 are necessary to incorporate changes to PA scope set forth in 2021 HB 3036, related to dispensing prescription drugs. Repeal of OAR 855-043-0405 through 855-043-0455 and 855-043-0002(9) effective 3/31/2022.

CHANGES TO RULE:

~~855-043-0455~~
~~Record Keeping~~
~~(1) A dispensing record must be maintained separately from the patient chart and kept for a minimum of three years. The record must show, at a minimum, the following:¶~~
~~(a) Name of patient;¶~~
~~(b) Unique identifier;¶~~
~~(c) Dose, dosage form, quantity dispensed and either the brand name of drug, or generic name and name of manufacturer or distributor;¶~~
~~(d) Directions for use;¶~~
~~(e) Date of dispensing; and¶~~
~~(f) Initials of person dispensing the prescription.¶~~
~~(2) All records of receipt and disposal of drugs must be kept for a minimum of three years.¶~~
~~(3) Records documenting training required by OAR 855-043-0445 must be kept for three years.¶~~
~~(4) All records required by these rules or by other State and federal law must be readily retrievable and available for inspection by the Board.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, 689.305, 2012 OL Ch 34~~

AMEND: 855-043-0505

RULE SUMMARY: Revisions to Division 043 are necessary to incorporate changes to PA scope set forth in 2021 HB 3036, related to dispensing prescription drugs. Repeal of OAR 855-043-0405 through 855-043-0455 and 855-043-0002(9) effective 3/31/2022. Ensure rules reflect updates to statutes, including ORS 678.390 concerning the authority of a nurse practitioner and clinical nurse specialist to dispense drugs. Appropriately references and reflects current regulations, amends and repeals outdated regulations in alignment with the board's 2020-2024 strategic plan.

CHANGES TO RULE:

855-043-0505
Dispensing Practitioner Drug Outlets - Purpose
~~A~~Unless subject to an exemption in OAR 855-043-0510(2), a practitioner~~'s facility~~ that engages in dispensing ~~certain FDA-approved~~ human prescription drug therapies ~~greater than a 72 hours supply or any medication refill~~ must register their dispensing site ~~as a drug outlet~~ with the ~~B~~board as a Dispensing Practitioner Drug Outlet (DPDO).
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.305

AMEND: 855-043-0510

RULE SUMMARY: Revisions to Division 043 are necessary to incorporate changes to PA scope set forth in 2021 HB 3036, related to dispensing prescription drugs. Repeal of OAR 855-043-0405 through 855-043-0455 and 855-043-0002(9) effective 3/31/2022. Ensure rules reflect updates to statutes, including ORS 678.390 concerning the authority of a nurse practitioner and clinical nurse specialist to dispense drugs. Appropriately references and reflects current regulations, amends and repeals outdated regulations in alignment with the board's 2020-2024 strategic plan.

CHANGES TO RULE:

855-043-0510
Dispensing Practitioner Drug Outlets - Registration
(1) ~~A~~Unless subject to an exemption in OAR 855-043-0510(2), a practitioner~~'s facility~~ that engages in dispensing ~~FDA-approved~~ human prescription drug therapies ~~greater than a 72 hours supply or any medication refill~~ must register the~~ir~~ dispensing site ~~as a drug outlet~~ with the ~~B~~board as a DPDO on a form pr~~ovid~~escribed by the ~~B~~board, and must renew its registration annually on a renewal form pr~~ovid~~escribed by the ~~B~~board.¶
(2) A practitioner's facility is exempt from this registration requirement if the practitioner and facility only engages in:¶
(A) Dispensing FDA approved drug samples; or¶
(B) Dispensing Medication Assistance Program (MAP) drugs; or¶
(C) Dispensing homeopathic products; or¶
(D) Dispensing natural thyroid supplemental products; or¶
(E) Dispensing a small amount of drugs to start therapy or incidental to a procedure or office visit, up to a 72 hour supply; or¶
(F) An amount greater than a 72 hour supply if the drug is:¶
(i) A drug in the manufacturer's original unit-of-use packaging, such as a metered-dose-inhaler or bottle of fluoride rinse; or¶
(ii) A full course of therapy, if in the professional judgment of the practitioner would be in the patient's best interest, such as a course of antibiotic therapy.¶
(3) The initial and renewal applications must state the location of the DPDO and the name of the person applying for registration. When the person applying for registration is not the owner of the dispensing site, the application must disclose the name and address of the owner and the applicant's affiliation with the owner.¶
(a) If more than one individual owns the dispensing site, the names and addresses of the partners or persons holding the three largest ownership interests in the dispensing site must be disclosed on the application.¶
(b) If the owner is a corporation, the application must state the name of the corporation as filed with the Corporation Division of the Oregon Secretary of State, including the names of the corporation's officers.¶
(4) Upon request by the ~~B~~board~~,~~ the applicant must furnish such information as required by the ~~B~~board regarding the partners, stockholders, or other persons not named in the application.¶
(5) An initial and renewal applications must be accompanied by the fee established ~~in division 110 of this chapter.~~ OAR 855-110.¶
(6) A certificate of registration will be issued upon ~~B~~board approval of the application.¶
(7) ~~All registration renewal applications must be accompanied by the annual renewal fee established in Division 110 of this chapter and must contain the information required in sections (2) and (3) of this rule. ¶~~
~~(8)~~ The DPDO registration expires March 31, annually. If the annual renewal fee is not paid by ~~February 28~~March 31 of the current year, the applicant for renewal must submit the ~~delinquent~~late renewal fee established in ~~division 110 of this chapter~~OAR 855-110 with the renewal application.¶
(~~9~~8) The registration is not transferable and the registration fee cannot be prorated.¶
(~~10~~9) The registrant must notify the ~~B~~board~~, within 15 days, of~~ 15 days prior to any substantial change to the information provided on the registration application. Substantial change ~~shall~~ include~~s~~ but is not ~~be~~ limited to: change of ownership; change of business name; change of business address; change of normal business hours; any disciplinary action taken or pending by any state or federal authority against the registrant, or any of its principals, owners, directors, or officers~~, or supervising practitioner. .~~¶
(1~~1~~0) A new registration form is required for a change of ownership or location and must be submitted to the ~~B~~board with the fees as specified in ~~division 110 of this chapter within 15 days of~~OAR 855-110 15 days prior to the change.¶
(1~~2~~1) The ~~B~~board may grant a time-limited waiver exempting DPDO registration when a practitioner licensing board submits a request to the ~~B~~board with a plan to annually inspect the dispensing facility to the standards of the ~~Board~~board.¶
(12) All Supervising Physician Dispensing Outlet registrations expire on March 31, 2022. Outlets that utilize

dispensing Physician Assistants must apply for and be granted registration as a Dispensing Practitioner Drug Outlet upon the expiration of the Supervising Physician Dispensing Outlet Registration unless subject to an exemption in OAR 855-043-0510(2).
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.305

AMEND: 855-043-0530

RULE SUMMARY: Revisions to Division 043 are necessary to incorporate changes to PA scope set forth in 2021 HB 3036, related to dispensing prescription drugs. Repeal of OAR 855-043-0405 through 855-043-0455 and 855-043-0002(9) effective 3/31/2022. Ensure rules reflect updates to statutes, including ORS 678.390 concerning the authority of a nurse practitioner and clinical nurse specialist to dispense drugs. Appropriately references and reflects current regulations, amends and repeals outdated regulations in alignment with the board's 2020-2024 strategic plan.

CHANGES TO RULE:

855-043-0530
Dispensing Practitioner Drug Outlets - Drug ~~Acquisition~~Procurement
The registered DPDO m~~ust verify that all drugs are acquired from a registrant of the Board~~ay only receive drugs from an Oregon Registered Drug Outlet (e.g. Wholesaler, Manufacturer or Pharmacy).
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.305

AMEND: 855-043-0540

RULE SUMMARY: Revisions to Division 043 are necessary to incorporate changes to PA scope set forth in 2021 HB 3036, related to dispensing prescription drugs. Repeal of OAR 855-043-0405 through 855-043-0455 and 855-043-0002(9) effective 3/31/2022. Ensure rules reflect updates to statutes, including ORS 678.390 concerning the authority of a nurse practitioner and clinical nurse specialist to dispense drugs. Appropriately references and reflects current regulations, amends and repeals outdated regulations in alignment with the board's 2020-2024 strategic plan.

CHANGES TO RULE:

855-043-0540
Dispensing Practitioner Drug Outlet - Labeling
(1) A prescription must be labeled with the following information:¶
(a) Name of patient;~~-~~¶
(b) Name of prescriber;~~-~~¶
(c) Name, address, and phone number of the clinic;~~-~~¶
(d) Date of dispensing;~~-~~¶
(e) Name and strength of the drug. If the drug does not have a brand name, then the generic name of the drug and the drug manufacturer must be stated;~~-~~¶
(f) Quantity dispensed;~~-~~¶
(g) Directions for use;~~-~~¶
(h) Cautionary statements, if any, as required by law; and~~-~~¶
(i) ~~Manufacturer's e~~An expiration date after which the patient should not use the drug or medicine. Expiration date~~,~~s o~~r an earlier date if preferable, aft~~n prescriptions must be the same as that on the original container or one year from the date the drug was originally dispensed and placed in the new containe~~r~~r, which~~ the patient should not use the drug; and~~ever date is earlier. Any drug expiring before the expected length of time for course of therapy must not be dispensed. ¶
(j) Any dispensed prescription medication, other than those in unit dose or unit of use packaging, ~~shall~~must be labeled with its physical description, including any identification code that may appear on tablets and capsules.~~-~~¶
(2) Not withstanding any other requirements in this rule, when a drug is dispensed in the practice of an Expedited Partner Therapy treatment protocol, as described in OAR 855-04~~1-4000 through 4005~~3-0004, the name of the patient may be omitted.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.305

AMEND: 855-043-0545

RULE SUMMARY: Revisions to Division 043 are necessary to incorporate changes to PA scope set forth in 2021 HB 3036, related to dispensing prescription drugs. Repeal of OAR 855-043-0405 through 855-043-0455 and 855-043-0002(9) effective 3/31/2022. Ensure rules reflect updates to statutes, including ORS 678.390 concerning the authority of a nurse practitioner and clinical nurse specialist to dispense drugs. Appropriately references and reflects current regulations, amends and repeals outdated regulations in alignment with the board's 2020-2024 strategic plan.

CHANGES TO RULE:

855-043-0545
Dispensing Practitioner Drug Outlets - Dispensing and Drug Delivery
(1) ~~Drugs dispensed from DPDO~~Prescription drugs must be personally dispensed by the practitioner unless otherwise authorized by ~~a~~the practitioner ~~shall~~'s licensing board.¶
(2) Drugs dispensed from the DPDO must be dispensed in compliance with the requirements of the practitioner's licensing ~~B~~board.¶
(~~2~~3) A DPDO must comply with all requirements of State or federal law.¶
(~~3~~4) A DPDO must dispense a drug in a new container that complies with the current provisions of the ~~Federal Consumer Packaging Act (Public Law 91-601, 91st Congress, S. 2162) an~~Poison Prevention Packaging Act in 16 CFR 1700 (XX/XX/XXXX), 16 CFR 1701 (XX/XX/XXXX) and 16 CFR 1702 (XX/XX/XXXX).¶
(5) Dispensed dru~~les or regulations and with the current United States Pharmacopoeia/National Formulary monographs for preservation, packaging, storage and labeling.¶~~
~~(4) Drugs must be packaged by the practitioner, a pharmacy, or a manufacturer registered with the Board.~~ gs must be packaged by the DPDO, a pharmacy, or a manufacturer registered with the board.¶
(6) A DPDO may not accept the return of drugs from a previously dispensed prescription and must maintain a list of sites in Oregon where drugs may be disposed.¶
(7) A DPDO may deliver or mail prescription to the patient if:¶
(a) Proper drug storage conditions are maintained; and¶
(b) The DPDO offers in writing, to provide direct counseling, information on how to contact the practitioner, and information about the drug, including, but not limited to:¶
(A) Drug name, class and indications;¶
(B) Proper use and storage;¶
(C) Common side effects;¶
(D) Precautions and contraindications; and¶
(E) Significant drug interactions.¶
(~~5~~8) ~~A~~The DPDO m~~ay not accept the return of drugs from a previously dispensed prescription and shall maintain a list of sites in Oregon where drugs may be~~ust ensure that all prescriptions, prescription refills, and drug orders are correctly dispensed in accordance with the prescribing practitioner's authorization and any other requirement of State or federal law.¶
(9) Each authorized dispenser of a prescription drug product for which a Medication Guide is required must provide the Medication Guide directly to each patient or patient's agent when the product is dispo~~o~~ensed, unless an exemption applies.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.305

AMEND: 855-043-0555

RULE SUMMARY: Revisions to Division 043 are necessary to incorporate changes to PA scope set forth in 2021 HB 3036, related to dispensing prescription drugs. Repeal of OAR 855-043-0405 through 855-043-0455 and 855-043-0002(9) effective 3/31/2022. Ensure rules reflect updates to statutes, including ORS 678.390 concerning the authority of a nurse practitioner and clinical nurse specialist to dispense drugs. Appropriately references and reflects current regulations, amends and repeals outdated regulations in alignment with the board's 2020-2024 strategic plan.

CHANGES TO RULE:

855-043-0555
Dispensing Practitioner Drug Outlets - Record ~~Keeping~~s
(1) A unique dispensing record ~~shall~~must be maintained, be readily retrievable, and kept for a minimum of three years. The record must show, at a minimum, the following:¶
(a) Name of patient;¶
(b) Dose, dosage form, quantity dispensed and either the brand name of drug, or generic name and name of manufacturer or distributor;¶
(c) Directions for use;¶
(d) Date of dispensing; and¶
(e) Initials of person dispensing the prescription.¶
(2) All records of receipt and disposal of drugs must be kept for a minimum of three years.¶
(3) All records ~~required by these rules or by other State and federal law must~~and documents required by ORS 475, ORS 689, and OAR 855:¶
(a) Must be stored on-site for 12 months and must be provided to the board immediately upon request at the time of inspection; ¶
(b) May be ~~readily retrievable and available for inspection by the Board~~stored in a secured off-site location after 12 months of on-site storage and must be provided to the board upon request within three business days; and ¶
(c) May be in written or electronic format.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.305

AMEND: 855-043-0560

RULE SUMMARY: Revisions to Division 043 are necessary to incorporate changes to PA scope set forth in 2021 HB 3036, related to dispensing prescription drugs. Repeal of OAR 855-043-0405 through 855-043-0455 and 855-043-0002(9) effective 3/31/2022. Ensure rules reflect updates to statutes, including ORS 678.390 concerning the authority of a nurse practitioner and clinical nurse specialist to dispense drugs. Appropriately references and reflects current regulations, amends and repeals outdated regulations in alignment with the board's 2020-2024 strategic plan.

CHANGES TO RULE:

855-043-0560
Dispensing Practitioner Drug Outlets - Inspections
(1) The DPDO must complete the ~~B~~board Self Inspection Form by February 1, annually.¶
(2) Each DPDO will be inspected per OAR 855-001-0040 on a routine basis and ~~shall~~must be scheduled in advance with the ~~practitioner~~DPDO, to occur during normal business hours.¶
(3) The inspection ~~shall~~must focus on the acquisition, storage, labeling and recordkeeping of drugs intended for dispensing and any violation will apply to the DPDO registration and not to the practitioner.¶
(4) The Board of Pharmacy ~~shall~~must notify the practitioner's licensing ~~B~~board of any disciplinary action taken against a DPDO.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.305

AMEND: 855-043-0705

RULE SUMMARY: Appropriately references and reflects current regulations, amends and repeals outdated regulations in alignment with the board's 2020-2024 strategic plan.

CHANGES TO RULE:

855-043-0705
Community Health Clinic (CHC) - Registration ¶

(1) A Community Health Clinic Drug Outlet must register with the ~~B~~board on a form prescribed by the ~~B~~board, and must renew its registration annually on a renewal form prescribed by the ~~B~~board.¶
(2) An initial application and renewal application must be accompanied by the fee established in ~~division 110 of this Chapter~~OAR 855-110.¶
(3) A certificate of registration will be issued upon ~~B~~board approval of the application.¶
(4) The CHC Drug Outlet registration expires March 31, annually. If the annual renewal fee is not paid by ~~February 28~~March 31 of the current year, the applicant for renewal must submit the ~~delinquent~~late renewal fee established in ~~division 110 of this Chapter~~OAR 855-110 with the renewal application.¶
(5) The registration is not transferable and the registration fee cannot be prorated.¶
(6) The registrant must notify the ~~B~~board, within 15 days, of any substantial change to the information provided on the registration application. A substantial change shall include but not be limited to: a change of ownership; change of business address; change of normal business hours; any disciplinary action taken or pending by any state or federal authority against the registrant, or any of its principals, owners, directors, officers, or Medical Director.¶
(7) A new registration form is required for a change of ownership or location and must be submitted to the ~~B~~board with the fees as specified in ~~division 110 of this Chapter~~OAR 855-110 within 15 days of the change.¶
(8) A CHC Drug Outlet may be inspected by the ~~B~~board.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305

AMEND: 855-043-0740

RULE SUMMARY: Appropriately references and reflects current regulations, amends and repeals outdated regulations in alignment with the board's 2020-2024 strategic plan.

CHANGES TO RULE:

855-043-0740
Community Health Clinic (CHC) - Dispensing and Drug Delivery ¶

(1) A drug may only be dispensed by a practitioner who has been given dispensing privileges by their licensing Board or by a Registered Nurse.¶
(2) A Registered Nurse may only provide over-the-counter drugs pursuant to established CHC protocols.¶
(3) A Registered Nurse may only dispense a drug listed in, or for a condition listed in, the formulary.¶
(4) Nonjudgmental dispensing functions may be delegated to staff assistants when the accuracy and completeness of the prescription is verified by a practitioner who has been given dispensing privileges by their licensing Board, or by a Registered Nurse, prior to being delivered or transferred to the patient.¶
(5) The CHC will provide appropriate drug information for medications dispensed to a patient, which can be provided by the Registered Nurse or practitioner at the time of dispensing.¶
(6) A~~ll drugs~~ CHC must ~~be~~ dispense~~d~~ a drug in a new container that complies with the current provisions of the ~~Federal Consumer Packaging Act (Public Law 91-601, 91st Congress, S. 2162) and rules or regulations and with the current United States Pharmacopoeia/National Formulary monographs for preservation, packaging, storage and labeling.¶~~
~~(7) D~~Poison Prevention Packaging Act in 16 CFR 1700 (XX/XX/XXXX), 16 CFR 1701 (XX/XX/XXXX) and 16 CFR 1702 (XX/XX/XXXX).¶
(7) Dispensed drugs must be ~~re~~packaged by the practitioner, Registered Nurse, a pharmacy; or a manufacturer registered with the ~~B~~board.¶
(8) A CHC may not accept the return of drugs from a previously dispensed prescription and must maintain a list of sites in Oregon where drugs may be disposed.¶
(9) A CHC must have access to 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.¶
(10) A CHC may deliver or mail prescription to the patient if:¶
(a) Proper drug storage conditions are maintained; and¶
(b) The CHC offers in writing, to provide direct counseling, information on how to contact the practitioner, and information about the drug, including, but not limited to:¶
(A) Drug name, class and indications;¶
(B) Proper use and storage;¶
(C) Common side effects;¶
(D) Precautions and contraindications; and¶
(E) Significant drug interactions.¶
(11) The CHC must ensure that all prescriptions, prescription refills, and drug orders are correctly dispensed in accordance with the prescribing practitioner's authorization and any other requirement of State or federal law.¶
(12) Each authorized dispenser of a prescription drug product for which a Medication Guide is required must provide the Medication Guide directly to each patient or patient's agent when the product is dispensed, unless an exemption applies.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305