

OFFICE OF THE SECRETARY OF STATE

SHEMIA FAGAN
SECRETARY OF STATE

CHERYL MYERS
DEPUTY SECRETARY OF STATE



ARCHIVES DIVISION

STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

PERMANENT ADMINISTRATIVE ORDER

BP 39-2021

CHAPTER 855
BOARD OF PHARMACY

FILED

12/16/2021 3:48 PM
ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

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

EFFECTIVE DATE: 03/31/2022

AGENCY APPROVED DATE: 12/09/2021

CONTACT: Rachel Melvin

971-673-0001

pharmacy.rulemaking@bop.oregon.gov

800 NE Oregon St., Suite 150

Portland, OR 97232

Filed By:

Rachel Melvin

Rules Coordinator

RULES:

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

REPEAL: 855-043-0405

NOTICE FILED DATE: 10/25/2021

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(7) related to Supervising Physician Dispensing Outlets (SPDOs) 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

NOTICE FILED DATE: 10/25/2021

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(7) related to Supervising Physician Dispensing Outlets (SPDOs) 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

NOTICE FILED DATE: 10/25/2021

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(7) related to Supervising Physician Dispensing Outlets (SPDOs) 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

NOTICE FILED DATE: 10/25/2021

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(7) related to Supervising Physician Dispensing Outlets (SPDOs) 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

NOTICE FILED DATE: 10/25/2021

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(7) related to Supervising Physician Dispensing Outlets (SPDOs) 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

NOTICE FILED DATE: 10/25/2021

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(7) related to Supervising Physician Dispensing Outlets (SPDOs) 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

NOTICE FILED DATE: 10/25/2021

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(7) related to Supervising Physician Dispensing Outlets (SPDOs) 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) Notwithstanding 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

NOTICE FILED DATE: 10/25/2021

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(7) related to Supervising Physician Dispensing Outlets (SPDOs) 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

NOTICE FILED DATE: 10/25/2021

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(7) related to Supervising Physician Dispensing Outlets (SPDOs) 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

NOTICE FILED DATE: 10/25/2021

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(7) related to Supervising Physician Dispensing Outlets (SPDOs) 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

NOTICE FILED DATE: 10/25/2021

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(7) related to Supervising Physician Dispensing Outlets (SPDOs) 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

NOTICE FILED DATE: 10/25/2021

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(7) related to Supervising Physician Dispensing Outlets (SPDOs) 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~~