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SECRETARY OF STATE & LEGISLATIVE COUNSEL

PERMANENT ADMINISTRATIVE ORDER

BP 56-2022 CHAPTER 855 BOARD OF PHARMACY

FILING CAPTION: Compendia and prescribing practices amendments; incorporates Public Health and Pharmacy Formulary Advisory Committee (PHPFAC) recommendations

EFFECTIVE DATE: 02/01/2023

AGENCY APPROVED DATE: 12/15/2022

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RULES:

855-010-0018, 855-019-0400, 855-019-0405, 855-019-0410, 855-019-0415, 855-019-0425, 855-019-0430, 855-019-0435, 855-020-0105, 855-020-0110, 855-020-0120, 855-020-0300

ADOPT: 855-010-0018

NOTICE FILED DATE: 10/21/2022

RULE SUMMARY: Relocates OAR 855-020-0105 to OAR 855-010-0018. This rule concerns the Public Health and Pharmacy Formulary Advisory Committee (PHPFAC) and delineates the members, terms, process to submit a concept, recommendations to the board for adoption, and recommendations for protocol and compendium review and revisions of the PHPFAC. Relocating these rules to board administration and policies in OAR 855-010 improves rule organization.

CHANGES TO RULE:

855-010-0018

Public Health and Pharmacy Formulary Advisory Committee

(1) The Public Health and Pharmacy Formulary Advisory Committee must consist of:

(a) Two physicians licensed to practice medicine under ORS 677.100 to 677.228;¶

(b) Two advanced practice registered nurses who have prescriptive authority and who are licensed by the Oregon State Board of Nursing; and ¶

(c) Three Pharmacists licensed by the State Board of Pharmacy, at least one of whom is employed as a community Pharmacist and one of whom is employed as a health system Pharmacist.¶

(2) A Pharmacist may submit a concept, on a form prescribed by the board to the committee for consideration, for the development of a protocol or the addition of a drug or device to the formulary.

(3) The committee must recommend to the board, for adoption by rule, a protocol or formulary of drugs and devices from which a Pharmacist can prescribe and dispense to a patient pursuant to a diagnosis by a qualified healthcare practitioner.

(4) The committee must periodically review the formulary and protocol compendium and recommend the revisions to the board for adoption by rule.

Statutory/Other Authority: ORS 689.205

NOTICE FILED DATE: 10/21/2022

RULE SUMMARY: Repeals OAR 855-019-0400 related to contraceptive prescribing purpose. Striking these specific contraceptive rules in OAR 855-019 is necessary in order to add Contraception to the Protocol Compendium in OAR 855-020-0300.

CHANGES TO RULE:

855-019-0400 Contraceptives - Purpose ¶

The purpose of rules OAR 855-019-0400 through 855-019-0435, is to develop standard procedures for the prescribing of injectable hormonal contraceptives and self-administered hormonal contraceptives by an Oregon licensed pharmacist, providing timely access to care. To ensure public safety and provide a consistent level of care, a pharmacist may participate upon completion of a Board approved training program. Under the rules of this section, a qualified pharmacist may prescribe hormonal contraceptives to a patient pursuant to a self-screening risk assessment questionnaire and standard procedural algorithm.

Statutory/Other Authority: ORS 689.205

NOTICE FILED DATE: 10/21/2022

RULE SUMMARY: Repeals OAR 855-019-0400 related to contraceptive prescribing purpose. Striking these specific contraceptive rules in OAR 855-019 is necessary in order to add Contraception to the Protocol Compendium in OAR 855-020-0300.

CHANGES TO RULE:

855-019-0405 Contraceptives - Definitions ¶

In OAR 855-019-0400 through 855-019-0435:¶

(1) "Clinical visit" means a consultation with a healthcare provider, other than a pharmacist, for women's health, which should address contraception and age-appropriate screening.¶

(2) "Injectable hormonal contraceptive" means a drug composed of a hormone or a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy and that a health care practitioner administers to the patient by injection.¶

(3) "Self-administered hormonal contraceptive" means a drug composed of a hormone or a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy and that the patient to whom the drug is prescribed may administer to oneself.

Statutory/Other Authority: ORS 689.205

NOTICE FILED DATE: 10/21/2022

RULE SUMMARY: Repeals OAR 855-019-0410 related to prescriptive practice consultation. Striking these specific contraceptive prescribing rules in OAR 855-019 is necessary in order to add Contraception to the Protocol Compendium in OAR 855-020-0300.

CHANGES TO RULE:

855-019-0410

Prescriptive Practice Consultation

In an effort to clarify, improve, and support appropriate pharmacist prescribing, the Board shall periodically review prescribing standards, practices, and scope in consultation with designated representatives from the Oregon Medical Board, Oregon State Board of Nursing, and Oregon Health Authority. The Board will seek recommendations from these representatives to be considered in conjunction with American Congress of Obstetricians and Gynecologists (ACOG) guidelines and other evidence-based standards, as it seeks to evaluate and improve prescribing practices within pharmacy. To the extent that developed standards are incorporated into practice, the forms, screening tools, or requisite training materials shall be prepared by the Board in consultation with these designated representatives.

Statutory/Other Authority: ORS 689.205

NOTICE FILED DATE: 10/21/2022

RULE SUMMARY: Repeals OAR 855-019-0410 related to prescriptive practice consultation. Striking these specific contraceptive prescribing rules in OAR 855-019 is necessary in order to add Contraception to the Protocol Compendium in OAR 855-020-0300.

CHANGES TO RULE:

855-019-0415 Contraceptive - Training Program ¶

(1) Only a pharmacist, who has completed a Board approved Accreditation Council for Pharmacy Education (ACPE) accredited educational training program related to the prescribing of contraceptives by a pharmacist, may prescribe injectable hormonal contraceptives and self-administered hormonal contraceptives for a patient.¶ (2) A pharmacist must submit a copy of the certificate of completion of training to the Board within 15 days of completion.¶

(3) A pharmacist must maintain the certificate of completion and make available upon request.

Statutory/Other Authority: ORS 689.205

NOTICE FILED DATE: 10/24/2022

RULE SUMMARY: Repeals OAR 855-019-0425 related to contraceptive procedural mandates. Striking these specific contraceptive prescribing rules in OAR 855-019 is necessary in order to add Contraception to the Protocol Compendium in OAR 855-020-0300.

CHANGES TO RULE:

855-019-0425

Contraceptive - Procedural Mandates ¶

(1) For each new patient requesting contraceptive services and, at a minimum of every twelve months for each returning patient, a participating pharmacist must:¶

(a) Obtain a completed Oregon Self-Screening Risk Assessment Questionnaire; and ¶

(b) Utilize and follow the Oregon Standard Procedures Algorithm to perform the patient assessment; and¶ (c) Prescribe, if clinically appropriate, the self-administered or injectable hormonal contraceptive, or refer to a healthcare practitioner: and¶

(d) Provide the patient with a Visit Summary; and ¶

(e) Advise the patient to consult with a primary care practitioner or women's health care practitioner; and ¶ (f) Document the encounter and maintain records pursuant to OAR 855-019-0435.¶

(2) If the self-administered hormonal contraceptive is dispensed or the injectable hormonal contraceptive is administered, it must be done as soon as practicable after the pharmacist issues the prescription and shall include any relevant educational materials.¶

(3) Nothing in this rule shall prohibit the partial filling or transferring of a drug prescribed pursuant to this process, per the request of the patient.¶

(4) A pharmacy must:¶

(a) Keep records of the encounter, including but not limited to, the Oregon Self-Screening Risk Assessment Questionnaire for a minimum of five years; and¶

(b) Keep records of the medication dispensed for a minimum of three years; and ¶

(c) Establish, maintain and enforce written procedures for the provision of care under this section, including, but not limited to:¶

(A) Providing a workflow process and physical location that maintains confidentiality and is not susceptible to distraction; and¶

(B) Documentation and recordkeeping.

Statutory/Other Authority: ORS 689.205

NOTICE FILED DATE: 10/21/2022

RULE SUMMARY: Repeals OAR 855-019-0430 related to contraceptive prohibited practices. Striking these specific contraceptive prescribing rules in OAR 855-019 is necessary in order to add Contraception to the Protocol Compendium in OAR 855-020-0300.

CHANGES TO RULE:

855-019-0430

Contraceptive - Prohibited Practices ¶

A pharmacist must not:¶

(1) Require a patient to schedule an appointment with the pharmacist for the prescribing, administering or dispensing of a hormonal contraceptive;¶

(2) Continue to prescribe a hormonal contraceptive to a patient beyond three years from the initial prescription without evidence of a clinical visit;¶

(3) Prescribe in instances that the Oregon Standard Procedures Algorithm requires referral to a provider; and ¶ (4) Prescribe to self or immediate family members.

Statutory/Other Authority: ORS 689.205

NOTICE FILED DATE: 10/21/2022

RULE SUMMARY: Repeals OAR 855-019-0435 related to contraceptive records. Striking these specific contraceptive prescribing rules in OAR 855-019 is necessary in order to add Contraception to the Protocol Compendium in OAR 855-020-0300.

CHANGES TO RULE:

855-019-0435 Contraceptive - Records ¶

(1) A pharmacist must document the encounter and the prescription, and maintain records.¶

(2) A pharmacy must maintain records of the encounter, including but not limited to, the Oregon Self-Screening Risk Assessment Questionnaire for a minimum of five years and maintain records of the medication administered or dispensed for a minimum of three years.¶

(3) Prescriptions are valid for one year pursuant to OAR 855-041-1125.

Statutory/Other Authority: ORS 689.205

REPEAL: 855-020-0105

NOTICE FILED DATE: 10/21/2022

RULE SUMMARY: Relocates OAR 855-020-0105 to OAR 855-010-0018. This rule concerns the Public Health and Pharmacy Formulary Advisory Committee (PHPFAC) and delineates the members, terms, process to submit a concept, recommendations to the board for adoption, and recommendations for protocol and compendium review and revisions of the PHPFAC. Relocating these rules to board administration and policies in OAR 855-010 improves rule organization.

CHANGES TO RULE:

855-020-0105

Public Health and Pharmacy Formulary Advisory Committee

(1) The Public Health and Pharmacy Formulary Advisory Committee shall consist of: ¶

(a) Two physicians licensed to practice medicine under ORS 677.100 to 677.228; ¶

(b) Two advanced practice registered nurses who have prescriptive authority and who are licensed by the Oregon State Board of Nursing; and ¶

(c) Three pharmacists licensed by the State Board of Pharmacy, at least one of whom is employed as a community pharmacist and one of whom is employed as a health system pharmacist.¶

(2) A pharmacist may submit a concept, on a form prescribed by the Board to the committee for consideration, for the development of a protocol or the addition of a drug or device to the formulary.¶

(3) The committee shall recommend to the Board, for adoption by rule, a protocol or formulary of drugs and devices from which a pharmacist may prescribe and dispense to a patient pursuant to a diagnosis by a qualified healthcare practitioner.¶

(4) The committee shall periodically review the formulary and protocol compendium and recommend the revisions to the Board for adoption by rule.

Statutory/Other Authority: ORS 689.205

AMEND: 855-020-0110

NOTICE FILED DATE: 10/21/2022

RULE SUMMARY: Rule amendments in OAR 855-020 include adding language related to ensuring training and education requirements have been met prior to engaging in prescribing and requirements for retaining copies of the training and education. The amendments in OAR 855-020 are necessary for compliance, provide clarity to licensees and were recommended by the PHPFAC.

CHANGES TO RULE:

855-020-0110

Prescribing Practices

(1) A <u>pP</u>harmacist located and licensed in Oregon may prescribe and dispense FDA-approved drugs and devices included on either the Formulary or Protocol Compendia, set forth in this Division. A <u>pP</u>harmacist mayust only prescribe a drug or device consistent with the parameters of the Formulary and Protocol Compendia, and in accordance with federal and state regulations.¶

(2) A <u>pP</u>harmacist must create, approve, and maintain policies and procedures for prescribing post-diagnostic drugs and devices or providing patient care services pursuant to statewide drug therapy management protocols. The policies and procedures must describe current and referenced clinical guidelines, and include but not be limited to:¶

- (a) Patient inclusion and exclusion criteria;¶
- (b) Explicit medical referral criteria;¶
- (c) Care plan preparation, implementation, and follow-up; \P
- (d) Patient education; and ¶
- (e) Provider notification; and \P
- (f) Maintaining confidentiality.¶

(3) The <u>pP</u>harmacist is responsible for recognizing limits of knowledge and experience and for resolving situations beyond their expertise by consulting with or referring patients to another health care provider.¶
(4) For each drug or device the pPharmacist processibles with the pharmacist must ¶

(4) For each drug or device the <u>pP</u>harmacist prescribes<u>, via</u> the pharmacist must:¶

(aFormulary or Protocol Compendia, the Pharmacist must:¶

(a) Ensure training and education requirements have been met prior to engaging in prescribing activities. An attestation of or certificate of completion of all required training and education must be retained for 6 years or uploaded into the Pharmacist's electronic licensing record with the board; ¶

(b) Assess patient and collect subjective and objective information, including the diagnosis for Formulary Compendia items, about the patient's health history and clinical status. The pPharmacist's physical assessment must be performed in a face-to-face, in-person interaction and not through electronic means; and ¶ (bc) Utilize information obtained in the assessment to evaluate and develop an individualized patient-centered care plan, pursuant to the statewide drug therapy management protocol and policies and procedures; and ¶ (ed) Implement the care plan, to include appropriate treatment goals, monitoring parameters, and follow-up; and ¶ (de) Provide notification to the patient's identified primary care provider or other care providers when applicable within five business days following the prescribing of a Formulary or Protocol Compendia drug or device.¶ (5) The pPharmacist must maintain all records associated with prescribing and other related activities performed for a minimum of 402 years, and a copy must be made available to the patient and provider upon request. Pharmacy records must be retained and made available to the Board for inspection upon request. Records must be stored onsite for at least one year and then may be stored in a secure off-site location if retrievable within three business days. Records and documentation mayust be written, electronic or a combination of the two.•¶ (6) If consultation is provided through an electronic means, the Oregon licensed Pharmacist must use an audiovisual communication system to conduct the consultation.

Statutory/Other Authority: ORS 689.205, ORS 689.689

AMEND: 855-020-0120

NOTICE FILED DATE: 10/21/2022

RULE SUMMARY: Rule amendments in OAR 855-020 include adding language that prohibits prescribing drugs or devices when the Formulary and Protocol Compendia requires a referral to another non-Pharmacist provider and adds that a Pharmacist must not require, but may allow, a patient to schedule an appointment with the RPH for prescribing or administering of an injectable hormonal contraceptive or the prescribing or dispensing of a self-administered hormonal contraceptive. The amendments in OAR 855-020 are necessary for compliance, provide clarity to licensees and were recommended by the PHPFAC.

CHANGES TO RULE:

855-020-0120

Prescribing Prohibited Practices

(1) A pPharmacist mayust not prescribe a drug or device t: ¶

(1) To self or a spouse, domestic partner, parent, guardian, sibling, child, aunt, uncle, grandchild and grandparent, including foster, in-law, and step relationships or other individual for whom a <u>pP</u>harmacist's personal or emotional involvement may render the <u>pP</u>harmacist unable to exercise detached professional judgment in prescribing pursuant to the Formulary and Protocol Compendia.¶

(2) An $ilntern may ust not prescribe a drug or device. <math>\P$

(3) A Pharmacist must not require, but may allow, a patient to schedule an appointment with the Pharmacist for the prescribing or administering of an injectable hormonal contraceptive or the prescribing or dispensing of a self-administered hormonal contraceptive.

Statutory/Other Authority: ORS 689.205

AMEND: 855-020-0300

REPEAL: Temporary 855-020-0300 from BP 44-2022

NOTICE FILED DATE: 10/21/2022

RULE SUMMARY: Adds COVID-19 Antiviral (PAXLOVID) and Contraception protocols to the compendium. Amends Travel Medications, HIV Post and Pre-Exposure Prophylaxis (PEP & PrEP) protocols as recommended by the PHPFAC.

CHANGES TO RULE:

855-020-0300

Protocol Compendium

A Pharmacist may prescribe, via statewide drug therapy management protocol and according to rules outlined in this Division, an FDA-approved drug and device listed in the following compendium:

(1) Continuation of therapy (v. 06/2021)¶

(2) Conditions¶

(a) Cough and cold symptom management¶

(A) Pseudoephedrine (v. 06/2021);¶

(B) Benzonatate (v. 06/2021);¶

(C) Short-acting beta agonists (v. 06/2021); \P

(D) Intranasal corticosteroids (v. 06/2021);¶

(b) Vulvovaginal candidiasis (VVC)-Protocol (v. 06/2021);¶

(c) COVID-19 Monoclonal Antibody (mAb)-Protocol (v. 12/2021); and ¶

(d) COVID-19 Antigen Self-Test Protoco(v. 12/2021); ¶

(e) COVID-19 Antiviral (v. 12/20212).¶

(3) Preventative care¶

(a) Emergency Contraception (v. 06/2021);¶

(b) Male and female condoms (v. 06/2021);¶

(c) Tobacco Cessation, NRT (Nicotine Replacement Therapy) and Non-NRT $\frac{Protocol}{v}(v.\,06/2022);\P$

(d) Travel Medications Protocol (v. 0612/20212);¶

(e) HIV Post-exposure Prophylaxis (PEP) Protocol (v. 12/20212); and ¶

(f) HIV Pre-exposure Prophylaxis (PrEP) Protocol(v. 12/2022); and ¶

(g) Contraception (v. <u>612</u>/2022).¶

[Publications referenced are available for inspection in the office of the Board of Pharmacy per OAR 855-010-0021.]

Statutory/Other Authority: ORS 689.205