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

NOTICE OF PROPOSED RULEMAKING

INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED
04/16/2021 2:52 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Compendia updated to incorporate recent Public Health and Pharmacy Formulary Advisory Committee (PHPFAC) recommendations

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 05/26/2021 4:30 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

CONTACT: Rachel Melvin
971-673-0001
pharmacy.rulemaking@oregon.gov

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: 05/26/2021
TIME: 9:30 AM
OFFICER: Rachel Melvin
ADDRESS: Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232
SPECIAL INSTRUCTIONS:
This hearing meeting will be held via telephonic conference call. To participate, call 1-877-873-8017, participant code 139360#. Email written comment to pharmacy.rulemaking@oregon.gov by 4:30PM on 5/26/2021. Oral comment can be offered at the hearing on the date and time listed above.

NEED FOR THE RULE(S):

Appropriately references and reflects current standards incorporated in statewide drug therapy management protocols by reference, amends and repeals outdated regulations. Additional revisions to the proposed rules are a result of input from the Public Health and Pharmacy Formulary Advisory Committee.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

Statewide drug therapy management protocols

https://www.oregon.gov/pharmacy/Documents/RMH_Protocol_Package.pdf, ORS 689.645 and ORS 689.649 https://www.oregonlegislature.gov/bills_laws/ors/ors689.html

FISCAL AND ECONOMIC IMPACT:

None anticipated

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).

State agencies and local government are not impacted by these rules. Pharmacy stakeholders and the public may be impacted by these rules if utilized. Provision of formulary prescribing services by a pharmacist/pharmacy is voluntary. The professional time to offer these services and comply with record keeping requirements may increase costs to the outlet, which may possibly be passed on to the public for prescribing services. Outlets will be required to establish and enforce policies and procedures and pharmacists must comply with the rules if they offer the services.

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

Participation is voluntary and a pharmacist is not mandated to offer patient care and prescribing services.

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

The statutorily mandated Public Health and Pharmacy Formulary Advisory Committee informed the content of these rules.

RULES PROPOSED:
855-020-0110, 855-020-0120, 855-020-0200, 855-020-0300

AMEND: 855-020-0110

RULE SUMMARY: Updates all protocols in the protocol compendia. Adds one new item to the formulary compendia

CHANGES TO RULE:

855-020-0110
Prescribing Practices
(1) A pharmacist 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 pharmacist shall 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 pharmacist must create, approve, and maintain policies and procedures for prescribing post-diagnostic drugs and devices or providing patient care services ~~via implementation of~~pursuant to statewide drug therapy management protocols. The policies and procedures shall 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;¶
(d) P~~rescribing drugs and devices pursuant to the formulary and protocol compendia;¶~~
~~(e) Patient education; and¶~~

~~(f) Provider notification~~atient education; and¶
(e) Provider notification; and¶
(f) Maintaining confidentiality.¶
(3) The pharmacist is responsible for recognizing limits of knowledge and experience and for resolving situations beyond ~~his or her pharmacist~~their expertise by consulting with or referring patients to another health care provider.¶
(4) For each drug or device the pharmacist prescribes, the pharmacist must:¶
(a) 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 pharmacist's patient assessment shall be performed in a face-to-face, in-person interaction and not through electronic means; and¶
(b) 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¶
(c) Implement the care plan, to include appropriate treatment goals, monitoring parameters, and follow-up; and¶
(d) Provide notification, ~~preferably via an interoperable information technology system,~~ to the patient's identified primary care provider or other care providers when applicable, within five business days following the prescribing of a Compendia drug or device.¶
(5) The pharmacist shall maintain all records associated with prescribing and other related activities performed for a minimum of 10 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 may be written, electronic or a combination of the two.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645, ORS 689.649

AMEND: 855-020-0120

RULE SUMMARY: Updates all protocols in the protocol compendia. Adds one new item to the formulary compendia.

CHANGES TO RULE:

855-020-0120
Prescribing Prohibited Practices
~~The responsibility and authority to prescribe pursuant to the Formulary and Protocol Compendia is upon the pharmacist. A pharmacist shall not prescribe a drug or device to self or immediate family members~~(1) A pharmacist may not prescribe a drug or device 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 pharmacist's personal or emotional involvement may render the pharmacist unable to exercise detached professional judgment in prescribing pursuant to the Formulary and Protocol Compendia.¶
(2) An intern may not prescribe a drug or device.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645, ORS 689.649

AMEND: 855-020-0200

RULE SUMMARY: Updates all protocols in the protocol compendia. Adds one new item to the formulary compendia

CHANGES TO RULE:

855-020-0200
Formulary Compendium
A pharmacist may prescribe, according to r~~egulations outlined~~ules in this Division, an FDA-approved drug and device listed in the following compendium, pursuant to a diagnosis by a health care practitioner who has prescriptive authority and who is qualified to make the diagnosis. The diagnosis must be documented.~~¶~~
Devices and supplies: ¶
(1) Diabetic blood sugar testing supplies;¶
(2) Injection supplies;¶
(3) Nebulizers and associated supplies;¶
(4) Inhalation spacers;¶
(5) Peak flow meters;¶
(6) International Normalized Ratio (INR) testing supplies;¶
(7) Enteral nutrition supplies; ~~and~~ ¶
(8) Ostomy products and supplies~~.~~; and¶
(9) Non-invasive blood pressure monitors
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645, ORS 689.649

AMEND: 855-020-0300

RULE SUMMARY: Updates all protocols in the protocol compendia. Adds one new item to the formulary compendia.

CHANGES TO RULE:

855-020-0300
Protocol Compendium
A pharmacist may prescribe, via statewide drug therapy management protocol and according to r~~egulation~~ules outlined in this Division, an FDA-approved drug and device listed in the following compendium:¶
(1) Continuation of therapy¶
~~(a) A pharmacist may prescribe any non-controlled medication to extend a patient's prescription therapy to avoid interruption of treatment; and ¶~~
~~(b) In such cases, a pharmacist shall only prescribe a drug quantity sufficient for the circumstances, not to exceed a 60-day supply, and no more than two extensions in a 12-month period per medication.¶~~
~~(2) Conditions¶~~
~~(a) Cough and cold symptom management¶~~
~~(A) Pseudoephedrine products for patients 18 years of age and older, verified by positive identification, not to exceed 3.6 grams or a 60-count quantity per prescription, whichever is less, or a total of three prescriptions in a 12-month period. Pharmacist must review PDMP prior to issuing prescription and retain documentation of PDMP review; ¶~~
~~(B) Benzonatate, for the treatment of cough, not to exceed a 7-day supply;¶~~
~~(C) Short-acting beta agonists, not to exceed 1 inhaler with or without a spacer, or 1 box of nebulizer ampules, per year;~~ (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); and¶
(D) Intranasal corticosteroids~~.~~ (v. 06/2021)¶
(b) Vulvovaginal candidiasis (VVC) Protocol (v. ~~August~~ 06/202~~0~~1)¶
(3) Preventative care ¶
(a) Emergency Contraception~~, not including abortifacients.~~ (v. 06/2021);¶
(b) Male and female condoms~~.~~ (v. 06/2021);¶
(c) Tobacco Cessation, NRT (Nicotine Replacement Therapy) and Non-NRT Protocol (v. ~~August 2020). A pharmacist is permitted to provide patient care services pursuant to this protocol only upon documented completion of a minimum of 2 hours of tobacco cessation continuing education.¶~~
~~(d) Travel Medications Protocol (v. August 2020). A pharmacist who meets criteria to immunize pursuant to OAR 855-019-0270 is permitted to provide patient care services pursuant to this protocol only upon documented completion of: minimum of 4 hour certificate for pharmacy-based travel medicine services intended for the pharmacist (one-time requirement), and minimum of 1 hour of travel medication continuing education every 24 months.¶~~
~~(e) HIV Post-exposure Prophylaxis (PEP) Protocol (v. August 2020). A pharmacist is permitted provide patient care services pursuant to this protocol only upon documented completion of a comprehensive training program for the prescribing and dispensing of HIV prevention medications, to include related trauma-informed care.~~ 06/2021);¶
(d) Travel Medications Protocol (v. 06/2021) ¶
(e) HIV Post-exposure Prophylaxis (PEP) Protocol (v. 06/2021); and ¶
(f) HIV Pre-exposure Prophylaxis (PrEP) Protocol (v. ~~December 2020). A pharmacist is permitted provide patient care services pursuant to this protocol only upon documented completion of a comprehensive training program for the prescribing and dispensing of HIV prevention medications, to include related trauma-informed care.¶~~

~~[Publications referenced are available from the agency~~06/2021)¶

[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

Statutes/Other Implemented: ORS 689.645, ORS 689.649