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**NOTICE OF PROPOSED RULEMAKING**  
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855  
BOARD OF PHARMACY

**FILED**  
08/13/2019 2:54 PM  
ARCHIVES DIVISION  
SECRETARY OF STATE

FILING CAPTION: Prescribing practice rules updated to reflect statutory authority and incorporate Committee recommendations.

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 09/24/2019 4:30 PM

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

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Filed By:  
Rachel Melvin  
Rules Coordinator

HEARING(S)

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

DATE: 09/24/2019

TIME: 1:30 PM

OFFICER: Rachel Melvin

ADDRESS: Portland State Office

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Portland, OR 97232

NEED FOR THE RULE(S):

ORS 689.645 and 689.649 describe intent and legal scope for the Public Health and Pharmacy Formulary Advisory Committee (PHPFAC) efforts. Per law, the Committee shall recommend a formulary of drug and devices that a pharmacist may prescribe and dispense to a patient; items must be pursuant to a diagnosis by a health care practitioner qualified to make the diagnosis and who has prescriptive authority. In Oregon, this includes physicians, nurse practitioners and PAs. The Committee shall periodically review the formulary and recommend revisions to the board and "The formulary may include post-diagnostic drugs and devices such as diabetic testing supplies, emergency refills of insulin, albuterol inhalers, epinephrine autoinjectors, smoking cessation aids, discharge medications for transitions of care, rapid strep tests and spacers."

The law also states that a pharmacist may provide approved patient care services pursuant to a statewide drug therapy management protocol, developed by the PHPFAC; and adopted by rule of the Board. These patient care services include smoking cessation and travel health services. For the purposes of the conversation and past minutes, a statewide protocol consists of a standardized patient assessment process and treatment care plan under which a pharmacist may prescribe and dispense a drug or device to a patient.

Rules have revisions (1) to appropriately reflect statutory authority, including repeal of OAR 855-019-0264; (2) provide clarity for documentation expectations; (3) incorporate recent PHPFAC recommendations; and (4) implement directives of 2019 SB 9.

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DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

2019 SB 9 (2019 OL Ch. 95)

Documents are available on the Boards website at:

<https://www.oregon.gov/pharmacy/Pages/PharmacyFormularyAdvisoryCommittee.aspx>

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FISCAL AND ECONOMIC IMPACT:

The fiscal and economic impact is dependent upon whether or not a pharmacist chooses to participate in patient care and prescribing services, and if a pharmacy outlet chooses to offer these services. Participation is voluntary.

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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.

2. a. Of the approximately 1500 pharmacy outlets registered in Oregon, about 50 to 100 are residential and may be considered small businesses. 2.b and c. 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.

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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.

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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.

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RULES PROPOSED:

855-019-0264, 855-019-0470, 855-020-0110, 855-020-0200, 855-020-0300

REPEAL: 855-019-0264

RULE SUMMARY: Repeals outdated language related to OHA protocols.

CHANGES TO RULE:

~~855-019-0264~~

~~State Drug Therapy Management Protocols~~

~~(1) A pharmacist may participate in statewide drug therapy management protocols developed by the Oregon~~

Health Authority to provide approved patient care services including but not limited to:¶¶

(a) Smoking cessation therapy;¶¶

(b) Travel health services; and¶¶

(c) Immunizations.¶¶

(2) The pharmacy must maintain written or electronic policies and procedures for each state drug therapy management protocol in which it participates.¶¶

(3) A pharmacist who participates in a state drug therapy management protocol must:¶¶

(a) Retain the required training documentation set forth by the protocol and make available to the Board upon request; and¶¶

(b) Document the prescription, administration, and patient interaction in the patient's record, and provide notification to the patient's primary care provider when available.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, 2015 OL Ch. 362

ADOPT: 855-019-0470

RULE SUMMARY: Implements 2019 SB 9 related to pharmacists prescribing emergency insulin.

CHANGES TO RULE:

855-019-0470

Emergency Insulin

Emergency Insulin. A pharmacist who has completed a Board approved ACPE accredited training program may prescribe and dispense emergency refills of insulin and associated insulin related devices and supplies, not including insulin pump devices, to a person who has evidence of a previous prescription from a licensed health care provider; in such cases, a pharmacist shall prescribe the lesser of a 30-day supply or the smallest available package size, and not more than three emergency refills and associated supplies in a calendar year.

Statutory/Other Authority: ORS 689 205

Statutes/Other Implemented: 2019 OL Ch. 95

AMEND: 855-020-0110

RULE SUMMARY: Rules have revisions to appropriately reflect statutory authority and to provide clarity for documentation expectations.

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 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) Prescribing drugs and devices pursuant to the formulary and protocol compendia;¶

(e) Patient education; and¶

(f) Provider notification.¶

(3) The pharmacist is responsible for recognizing limits of knowledge and experience and for resolving situations beyond his or her pharmacist expertise by consulting with or referring patients to another health care provider.¶

~~(34) At a minimum, f~~For each drug or device the pharmacist prescribes, the pharmacist must document the following, which constitutes the Visit Summary:¶

~~(a) Create, approve, and maintain a drug therapy management protocol based on current and referenced clinical guidelines that must include:¶~~

~~(A) Patient inclusion and exclusion criteria; and¶~~

~~(B) Explicit medical referral criteria; and¶~~

~~(b) Collect subjective and objective information.¶~~

(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¶

(eb) Utilize information obtained in the assessment to evaluate and develop an individualized patient-centered care plan, pursuant to the pharmacist's established statewide drug therapy management protocol and policies and procedures; and¶

(edc) Implement the care plan, to include appropriate treatment goals, monitoring parameters, and follow-up; and¶

(ed) 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.¶

(45) The pharmacist shall maintain all records associated with prescribing for a minimum of 10 years, including but not limited to the drug therapy management protocol, the prescription record, consultation, and Visit Summary, and a copy must be made available to the patient, provider, and Board upon request 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: 855-020-0200

RULE SUMMARY: Rules have revisions to incorporate recent Public Health and Pharmacy Formulary Advisory Committee recommendations.

CHANGES TO RULE:

855-020-0200

Formulary Compendium

A pharmacist may prescribe, according to regulations outlined 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 on the Visit Summary.

~~(1)~~

Devices and supplies:

~~(a)~~ Diabetic blood sugar testing supplies;

~~(b)~~ Pen needles;

~~(c)~~ Syringe/Injection supplies;

~~(d)~~ Nebulizers and associated supplies;

~~(e)~~ Inhalation spacers;

~~(f)~~ Peak flow meters;

~~(g)~~ International Normalized Ratio (INR) testing supplies;

~~(h)~~ Enteral nutrition supplies; and

~~(i)~~ Ostomy products and supplies.

~~(2) Placeholder~~

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.645, ORS 689.649

AMEND: 855-020-0300

RULE SUMMARY: Revisions incorporate recent Public Health and Pharmacy Formulary Advisory Committee recommendations.

CHANGES TO RULE:

855-020-0300

Protocol Compendium

A pharmacist may prescribe, via statewide drug therapy management protocol and according to regulations 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; ¶¶

(D) Intranasal corticosteroids.¶¶

(~~b~~3) Preventative care¶¶

(a) Emergency Contraception, not including abortifacients.¶¶

(b) Male and female condoms.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.645, ORS 689.649