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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED
10/22/2020 3:39 PM
ARCHIVES DIVISION
SECRETARY OF STATE

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

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/24/2020 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)

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

DATE: 11/24/2020

TIME: 8:30 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 11/24/2020.

Oral comment can be offered at the hearing on the date and time listed above.

NEED FOR THE RULE(S):

ORS 689.645 and ORS 689.649 permit a pharmacist to provide approved patient care services pursuant to a statewide drug therapy management protocol, developed by the PHPFAC, and adopted by rule of the Board. Described in recent meeting minutes, a statewide protocol may incorporate a standardized process with required utilization of a Patient Intake form and Treatment Care Pathway under which a pharmacist may identify a patient's medical need, issue a

prescription, and dispense a drug or device to a patient. All must be in accordance with the protocol. Rules have been revised to incorporate recent PHPFAC recommendations.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

Draft Protocol "package" is available on the board's website:

https://www.oregon.gov/pharmacy/Documents/PrEP_Protocol_Package.pdf

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.

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. Approximately 1648 pharmacy outlets registered in Oregon identify as 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.

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.

AMEND: 855-020-0300

RULE SUMMARY: Adds one new patient care protocol to the compendia.

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) Vulvovaginal candidiasis (VVC) Protocol (v. August 2020)¶¶

(3) Preventative care ¶¶

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

(b) Male and female condoms.¶¶

(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.¶¶

(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.]

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.645, ORS 689.649