OFFICE OF THE SECRETARY OF STATE

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ARCHIVES DIVISION

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NOTICE OF PROPOSED RULEMAKING INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855 BOARD OF PHARMACY

FILED

04/25/2022 4:56 PM ARCHIVES DIVISION SECRETARY OF STATE

FILING CAPTION: Protocol compendia updated with new protocol versions for Tobacco Cessation and PrEP

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 05/24/2022 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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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: 05/24/2022 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 virtually via Microsoft Teams.

If you wish to present oral testimony during this hearing, sign up on our website at www.oregon.gov/pharmacy/pages/rulemaking-information or email your contact information to pharmacy.rulemaking@bop.oregon.gov to receive the link to join the virtual meeting. Please indicate which rule(s) you would like to comment on.

Alternatively, you may dial (503) 446-4951 Phone Conference ID: 114 068 944# for audio only.

You may file written comments before 4:30PM on May 24, 2022 by emailing your comments to pharmacy.rulemaking@bop.oregon.gov

NEED FOR THE RULE(S)

Permanently adopts amended statewide drug therapy management protocol for Tobacco Cessation – NRT (Nicotine Replacement Therapy) and Non-NRT v. 6/2022 and statewide drug therapy management protocol for HIV Pre-Exposure Prophylaxis (PrEP) v. 6/2022 as recommended by the Public Health and Pharmacy Formulary Advisory Committee.

Tobacco Cessation protocol v. 6/2021 https://www.oregon.gov/pharmacy/Documents/Tobacco_Protocol.pdf HIV Pre-Exposure Prophylaxis (PrEP) protocol v. 12/2021 https://www.oregon.gov/pharmacy/Documents/PrEP_Protocol.pdf

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

Although tobacco use has declined significantly since 1964, disparities in tobacco use remain across groups defined by race, ethnicity, educational level, and socioeconomic status and across regions of the country. In 2015, 16.8% of African-Americans, 21.9% of American Indians/Alaska Natives, 7% of Asian-Americans, 10.1% of Hispanics and 16.6% of non-Hispanic Whites used tobacco. Although African Americans usually smoke fewer cigarettes and start smoking cigarettes at an older age, they are more likely to die from smoking-related diseases than Whites. During 2010–2015, racial/ethnic disparities in HIV incidence increased among men who have sex with men (MSM); in 2015, rates among black and Hispanic MSM were 10.5 and 4.9 times as high, respectively, as the rate among white MSM (compared with 9.2 and 3.8 times as high, respectively, in 2010). Pre-exposure prophylaxis (PrEP) reduces the risk for sexual human immunodeficiency virus transmission by approximately 99%. By making tobacco cessation and PrEP therapies easily accessible to patients at their local pharmacy, it may improve access for patients who may not be able to otherwise access these services.

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 proposed protocols or the draft rule. 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):

Small businesses were not involved in the development of these rules. 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 the proposed amended protocols.

AMEND: 855-020-0300

RULE SUMMARY: Minor edits to Tobacco Cessation Assessment and Treatment Care Pathway for clarity. Edits to PrEP Patient Intake Form, Assessment and Treatment Care Pathway and Provider Fax documents to align with CDC's Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update Clinical Practice Guideline.

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);¶
- (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 Protocol (v. 12/2021).¶
- (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 Protocol (v. 06/20212);¶
- (d) Travel Medications Protocol (v. 06/2021); ¶
- (e) HIV Post-exposure Prophylaxis (PEP) Protocol (v. 12/2021); and ¶
- (f) HIV Pre-exposure Prophylaxis (PrEP) Protocol (v. 126/20212).¶

[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