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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED

02/23/2022 2:52 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Compendia amended to include COVID-19 Antigen Self-Test

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 03/29/2022 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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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: 03/29/2022

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: 414 724 81# for audio only.

You may file written comments before 4:30PM on March 29, 2022 by emailing your comments to pharmacy.rulemaking@bop.oregon.gov

NEED FOR THE RULE(S)

Permanently adopts the COVID-19 antigen self-test protocol for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 of COVID-19.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

ORS 689.645 and ORS 689.649 state that a pharmacist may provide approved patient care services pursuant to a statewide drug therapy management protocol and adopted by rule of the board. A statewide protocol consists of a standardized patient assessment process and treatment care plan under which a pharmacist may assess and identify the need for a patient care service, then prescribe and dispense a drug or device to the patient.

EUA: Instructions for COVID-19 Antigen Self-Test (Home Test)<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2>

OHA Fax to Pharmacies: Fee-for-service coverage of COVID-19 home testing policy update.
https://www.oregon.gov/oha/HSD/OHP/Announcements/Pharmacy-Home-Tests-Update1121.pdf?utm_medium=email&utm_name=providermatters11192021&utm_source=govdelivery

Testing and Medicaid Coverage of Habilitation Services State Health Official letter- Medicaid and CHIP Coverage and Reimbursement of COVID-19 Testing under the American Rescue Plan Act of 2021 and Medicaid Coverage of Habilitation Services <https://www.medicaid.gov/federal-policy-guidance/downloads/sho-21-003.pdf>

Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 43 (pg. 6)- FAQs <https://www.cms.gov/files/document/FFCRA-Part-43-FAQs.pdf>

COVID-19 Antigen Self Test Protocol https://www.oregon.gov/pharmacy/Documents/COVID-19_Antigen_Self_Test_Protocol.pdf

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

Inequity in access to free COVID-19 antigen self-tests is yet another example of the consistent theme of inequities over the course of the COVID-19 pandemic. Compared to their white counterparts, people of color have faced increased risk of exposure to the virus, suffered more illness and death, and faced more barriers to accessing protective equipment, testing, care, and treatment, as well as vaccines. According to the 2019 Oregon Health Insurance Survey (OHIS), 94% of Oregon residents had health insurance coverage (95.2% Asian, 93.3% White, 92.2% Black, 87.7% Two or more/Other, 83.4% Hispanic). By making these self-test kits easily accessible to patients at their local pharmacy and then billed to their health plan for no charge, it may possibly improve access for patients who may not be able to otherwise access or afford the kits.

FISCAL AND ECONOMIC IMPACT:

The proposed rule may have the fiscal and economic impact of assisting with early confirmation of COVID-19 infection and thus decrease of transmission due to quarantine and treatment options.

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).

OBOP: The rulemaking imposes minimal additional requirements regarding professional services and increased administration for maintenance of the protocol and convening the Public Health and Pharmacy Formulary Committee as needed to make updates to the protocol.

Other State Agencies/Units of Local Government/Public or Stakeholders: The rule may have a positive impact on the work of the Oregon Health Authority Public Health Division and County Health Departments along with providing members of the public to access COVID-19 test kits more easily.

Effect on Small Businesses – None anticipated. The rulemaking imposes no additional mandatory reporting, recordkeeping, or other administrative requirements on small businesses.

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

Small businesses were not involved in the development of proposed amendments to these rules.

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

No, a RAC was not consulted. The Public Health and Pharmacy Formulary Advisory Committee adopted a new protocol and recommended amending the proposed rule to align with the protocol.

AMEND: 855-020-0300

RULE SUMMARY: Permanently adopts a COVID-19 antigen self-test protocol and amends the current protocol compendia. Increases equitable access to COVID-19 antigen self-tests and reduces barriers to obtaining COVID-19 antigen self-tests.

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); and¶¶

(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. 06/2021);¶¶

(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. 12/2021).¶¶

[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