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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED

04/19/2023 8:33 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Repeals COVID-19 Monoclonal Antibody & Antiviral protocols; Repeals Emergency Insulin rule and amends Protocol Compendium

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 05/23/2023 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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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: 05/23/2023

TIME: 9:30 AM

OFFICER: Rachel Melvin

HEARING LOCATION

ADDRESS: Virtual Hearing, 800 NE Oregon St., Portland, OR 97232

SPECIAL INSTRUCTIONS:

This hearing meeting will be held virtually via Microsoft Teams.

If you wish to present oral testimony virtually during this hearing, sign up on our website at www.oregon.gov/pharmacy/pages/rulemaking-information or email your first and last name, email address and phone number to

pharmacy.rulemaking@bop.oregon.gov to receive a calendar invitation to join the virtual hearing. Please indicate which

rule(s) you would like to comment on.

You must submit written comments before 4:30PM on May 23, 2023. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

REMOTE MEETING DETAILS

MEETING URL: [Click here to join the meeting](#)

PHONE NUMBER: 503-446-4951

CONFERENCE ID: 518898073

NEED FOR THE RULE(S)

Repeals statewide drug therapy management protocols for COVID-19 Monoclonal Antibody and COVID-19 Antiviral. Repeals OAR 855-019-0470 related to emergency insulin. Amends the Protocol Compendium with revisions to Continuation of Therapy now including emergency refills of insulin, Contraception, PEP, PrEP and Travel Medications

as recommended by the Public Health and Pharmacy Formulary Advisory Committee (PHPFAC).

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Determination of Public Health Emergency <https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency>

Emergency Use Authorization of Medical Products and Related Authorities

<https://www.fda.gov/media/97321/download>

REGEN-COV EUA <https://www.fda.gov/media/145610/download>, <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs>

Paxlovid EUA <https://www.fda.gov/media/155050/download>

Frequently Asked Questions on the Emergency Use Authorization for Paxlovid for Treatment of COVID-19

<https://www.fda.gov/media/155052/download>

References for Pharmacist Prescriptive Authority ORS 689.645, ORS 689.649, ORS 689.689

https://www.oregonlegislature.gov/bills_laws/ors/ors689.html

References for each protocol are included in the protocol.

Proposed Statewide Drug Therapy Management Protocol – Continuation of Therapy v. 06/2023

https://www.oregon.gov/pharmacy/Documents/A2a-_Continuation_of_Therapy_Protocol.pdf

Proposed Statewide Drug Therapy Management Protocol – Contraception v. 06/2023

https://www.oregon.gov/pharmacy/Documents/A2b-_PrevCare_Contraception_Protocol.pdf

Proposed Statewide Drug Therapy Management Protocol – HIV Post-Exposure Prophylaxis (PEP) v. 06/2023

https://www.oregon.gov/pharmacy/Documents/A2c-_PrevCare_PEP_Protocol.pdf

Proposed Statewide Drug Therapy Management Protocol – HIV Pre-Exposure Prophylaxis (PrEP) v. 06/2023

https://www.oregon.gov/pharmacy/Documents/A2d-_PrevCare_PrEP_Protocol.pdf

Proposed Statewide Drug Therapy Management Protocol – Travel Medications v. 06/2023

https://www.oregon.gov/pharmacy/Documents/A2e-_PrevCare_Travel_Medications_Protocol.pdf

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

The impact is unknown on how or who the removal of COVID-19 Monoclonal and COVID-19 Antiviral protocols may impact. By making treatment for continuation of therapy including emergency refills of insulin, contraception, PEP, PrEP and travel medications easily accessible to patients at their local pharmacy, it may improve access for patients who are not 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).

There are no known economic impacts to the agency, other state or local government, or small businesses. Pharmacy stakeholders and the public may be impacted by these rules if utilized. Provision of formulary and protocol compendia 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 be passed on to the public or payors 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 the proposed rules.

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

The FDA Emergency Use Authorizations for COVID-19 Monoclonal Antibody and COVID-19 Antiviral changed, making them no longer appropriate for prescribing by Oregon pharmacists under OAR 855-020 . The statutorily mandated PHPFAC informed the content of the proposed draft protocols and proposed amendments to existing protocols.

RULES PROPOSED:

855-019-0470, 855-020-0300

REPEAL: 855-019-0470

RULE SUMMARY: Repeals OAR 855-019-0470 related to Emergency Insulin which will now be located within the Continuation of Therapy statewide drug therapy management protocol in OAR 855-020-0300.

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 supplies in a calendar year.~~

~~Statutory/Other Authority: ORS 689.205~~

~~Statutes/Other Implemented: 2019 OL Ch. 95~~

AMEND: 855-020-0300

RULE SUMMARY: Permanently repeals statewide drug therapy protocols for COVID-19 Monoclonal Antibody and COVID-19 Antiviral. COVID-19 Monoclonal Antibody- REGENCOV: REGEN-COV (casirivimab and imdevimab) is not currently authorized in any U.S. region. COVID-19 Antiviral- Paxlovid: Under Oregon state laws, pharmacists cannot diagnose. The current Paxlovid EUA (2/2023) requires a COVID-19 diagnosis to prescribe Paxlovid, which cannot be required in the Board's protocol making it inconsistent with federal law.

Proposed amendments include revised protocol versions of Continuation of Therapy now including emergency refills of insulin, Contraception, PEP, PrEP, and Travel Medications as recommended by the PHPFAC.

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 including emergency refills of insulin (v. 06/2021~~3~~);¶

(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) (v. 06/2021);¶

(c) COVID-19 Monoclonal Antibody (mAb) (v. 12/2021);¶

~~(d) COVID-19 Antigen Self-Test (v. 12/2021);¶~~

~~(e) COVID-19 Antiviral (v. 12/2022); Antigen Self-Test (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 (v. 06/2022);¶

(d) Travel Medications (v. ~~12/06/2022~~);¶

(e) HIV Post-exposure Prophylaxis (PEP) (v. ~~12/06/2022~~);¶

(f) HIV Pre-exposure Prophylaxis (PrEP) (v. ~~12/06/2022~~); and¶

(g) Contraception (v. ~~12/06/2022~~).¶

[Publications referenced are available for inspection in the office of the Board of Pharmacy per OAR 855-010-0021 from the agency.]

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.645, ORS 689.649, ORS 689.689, ORS 689.696