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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED
10/25/2021 5:11 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Compendia and prescribing practices updated incorporating recent Public Health and Pharmacy Formulary Advisory Committee recommendations

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/23/2021 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)

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

DATE: 11/23/2021
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.

Alternatively, you may dial (503) 446-4951 Phone Conference ID: 472 815 435# for audio only.

You may file written comments before 4:30PM on November 23, 2021 by emailing your comments to pharmacy.rulemaking@bop.oregon.

NEED FOR THE RULE(S)

Permanently adopts the COVID-19 monoclonal antibody (mAb) therapy protocol for the treatment and post-exposure prophylaxis of COVID-19. Improving the supply of prescribers and administrators will facilitate increased accessibility to COVID-19 mAb therapy is in the interest of public health.

Adopts revisions to PEP and PrEP protocols as recommended by the committee.

Clarifies that face-to-face requirement only applies to physical assessment components of patient care process (collect, assess, plan, implement, and follow-up). Additional revisions are minor corrections.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

ORS 689.645 and 689.649 state 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. A statewide protocol consists of a standardized patient assessment process and treatment care plan under which a pharmacist may assess and identify a patient's medical need, then prescribe and dispense a drug or device to the patient.
Statewide drug therapy management protocol for COVID mAb:
https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-hcp.pdf Emergency Use Authorization (EUA) of REGEN-COV
https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-patient.pdf Emergency Use Authorization (EUA) of REGEN-COV
Statewide drug therapy management protocol for PEP and PrEP:
2021 HB 2958 https://olis.oregonlegislature.gov/liz/2021R1/Downloads/MeasureDocument/HB2958/Enrolled
CDC Pre-exposure Prophylaxis (PrEP) Care System https://www.cdc.gov/hiv/effective-interventions/prevent/prep/index.html
AASLD/IDSA HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C
https://www.hcvguidelines.org/evaluate/testing-and-linkage

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 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. 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.

RULES PROPOSED:
855-020-0110, 855-020-0300

AMEND: 855-020-0110

RULE SUMMARY: Clarifies that face-to-face requirement only applies to physical assessment components of patient

care process (collect, assess, plan, implement, and follow-up).

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~~may 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 pursuant to statewide drug therapy management protocols. The policies and procedures ~~shall~~must 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) Patient education; and¶
(e) Provider notification; and¶
(f) Maintaining confidentiality.¶
(3) The pharmacist is responsible for recognizing limits of knowledge and experience and for resolving situations beyond their expertise by consulting with or referring patients to another health care provider.¶
(4) For each drug or device the pharmacist prescribes, the pharmacist must:¶
(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 p~~atient~~hysical assessment ~~shall~~must be performed in a face-to-face, in-person interaction and not through electronic means; and¶
(b) Utilize information obtained in the assessment to evaluate and develop an individualized patient-centered care plan, pursuant to the statewide drug therapy management protocol and policies and procedures; and¶
(c) Implement the care plan, to include appropriate treatment goals, monitoring parameters, and follow-up; and¶
(d) Provide notification 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.¶
(5) The pharmacist ~~shall~~must maintain all records associated with prescribing 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.¶
(6) If consultation is provided through an electronic means, the Oregon licensed Pharmacist must use real-time audio-visual communication to conduct the consultation.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645, ORS 689.649

AMEND: 855-020-0300

RULE SUMMARY: Permanently adopts new COVID mAb to the protocol compendia. Amends protocol versions in the protocol compendia.

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.09/2021)¶
(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. 0~~6~~9/2021); and ¶
(f) HIV Pre-exposure Prophylaxis (PrEP) Protocol (v. 0~~6~~9/2021)¶
[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