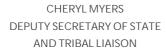
OFFICE OF THE SECRETARY OF STATE

LAVONNE GRIFFIN-VALADE SECRETARY OF STATE





ARCHIVES DIVISION

STEPHANIE CLARK DIRECTOR

800 SUMMER STREET NE SALEM, OR 97310 503-373-0701

NOTICE OF PROPOSED RULEMAKING INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855 BOARD OF PHARMACY **FILED**

12/22/2023 9:21 AM ARCHIVES DIVISION SECRETARY OF STATE

FILING CAPTION: Repeals Division 20; Pharmacist Prescriptive Authority

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 01/24/2024 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

800 NE Oregon St., Suite 150

Filed By:

971-673-0001

Portland, OR 97232

Rachel Melvin

pharmacy.rulemaking@bop.oregon.gov

Rules Coordinator

HEARING(S)

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

DATE: 01/24/2024 TIME: 9:30 AM

OFFICER: Rachel Melvin

HEARING LOCATION

ADDRESS: Oregon Board of Pharmacy - Virtual Hearing, 800 NE Oregon St., Suite 150, Portland, OR 97232

REMOTE MEETING DETAILS

MEETING URL: Click here to join the meeting

PHONE NUMBER: 503-446-4951 CONFERENCE ID: 618712182 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 January 24, 2024. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

NEED FOR THE RULE(S)

Repeals Division 020 Pharmacist Prescriptive Authority rules in its entirety, effective at 11:59PM on 2/29/2024.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Division 115 Pharmacists Permanent Administrative Order

https://www.oregon.gov/pharmacy/Documents/Div_115_Pharmacists_BP_16-2023TrackedChanges.pdf

https://www.oregon.gov/pharmacy/Documents/Div_115_Supervision_Counseling_PIC_Qualifications_BP_31-2023TrackedChanges.pdf

https://www.oregon.gov/pharmacy/Documents/855-115-0350_Short-acting_Opioid_Antagonists_BP_26-2023TrackedChanges.pdf

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

The proposed rule repeal is not expected to affect racial equity in this state.

FISCAL AND ECONOMIC IMPACT:

The proposed rule repeal has no anticipated fiscal and economic impact.

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).

The proposed rule repeal will have no additional economic impact on state agencies, units of local government, the public or registrants or licensees who identify as a small business.

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

Small businesses were not involved in determining to repeal the rule. A notice of rulemaking hearing will be sent to interested parties, some of whom may identify as a small business and will have an opportunity to provide public comment on the proposed rule repeal.

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

The board adopted new Division 115 Pharmacists rules in August, October and December 2023, effective 3/1/2024. The nature of the proposed rule repeal does not require input from an advisory committee.

RULES PROPOSED:

855-020-0110, 855-020-0120, 855-020-0200

REPEAL: 855-020-0110

RULE SUMMARY: Repeals Division 020 Pharmacist Prescriptive Authority rules. The board adopted Division 115 Pharmacists rules in August, October and December 2023, which replaces Division 020. Division 020 needs to be repealed effective at 11:59PM on 2/29/2024 to allow Division 115 rules to become effective at 12:00AM on 3/1/2024.

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 must 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 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 via the Formulary or Protocol Compendia, the Pharmacist must:¶
- (a) Ensure training and education requirements have been met prior to engaging in prescribing activities. An attestation of or certificate of completion of all required training and education must be retained for 6 years or uploaded into the Pharmacist's electronic licensing record with the board; ¶
- (b) 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 physical assessment must be performed in a face-to-face, in-person interaction and not through electronic means; ¶
- (c) 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; ¶
- (d) Implement the care plan, to include appropriate treatment goals, monitoring parameters, and follow-up; and ¶
 (a) Provide notification to the national's identified primary care provider or other care providers when applicable
- (e) 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 Formulary or Protocol Compendia drug or device.¶
- (5) The Pharmacist must maintain all records associated with prescribing and other related activities performed for a minimum of 7 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 must be written, electronic or a combination of the two.¶
- (6) If consultation is provided through an electronic means, the Oregon licensed Pharmacist must use an audiovisual communication system to conduct the consultation.

Statutory/Other Authority: ORS 689.205, ORS 689.689

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

REPEAL: 855-020-0120

RULE SUMMARY: Repeals Division 020 Pharmacist Prescriptive Authority rules. The board adopted Division 115 Pharmacists rules in August, October and December 2023, which replaces Division 020. Division 020 needs to be repealed effective at 11:59PM on 2/29/2024 to allow Division 115 rules to become effective at 12:00AM on 3/1/2024.

CHANGES TO RULE:

855-020-0120

Prescribing Prohibited Practices

A Pharmacist must not prescribe a drug or device: ¶

- (1) To self or a spouse, domestic partner, parent, guardian, sibling, child, aunt, uncle, grandchild and grandparent, including foster, in-law, and step relationships or other individual for whom a Pharmacist's personal or emotional involvement may render the Pharmacist unable to exercise detached professional judgment in prescribing pursuant to the Formulary and Protocol Compendia.¶
- (2) An Intern must not prescribe a drug or device. ¶
- (3) A Pharmacist must not require, but may allow, a patient to schedule an appointment with the Pharmacist for the prescribing or administering of an injectable hormonal contraceptive or the prescribing or dispensing of a self-administered hormonal contraceptive.

Statutory/Other Authority: ORS 689.205

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

REPEAL: 855-020-0200

RULE SUMMARY: Repeals Division 020 Pharmacist Prescriptive Authority rules. The board adopted Division 115 Pharmacists rules in August, October and December 2023, which replaces Division 020. Division 020 needs to be repealed effective at 11:59PM on 2/29/2024 to allow Division 115 rules to become effective at 12:00AM on 3/1/2024.

CHANGES TO RULE:

855-020-0200

Formulary Compendium

A pharmacist may prescribe, according to rules in this Division, an FDA-approved drug and device listed in the following compendium, pursuant to a diagnosis by a health care practitioner who has prescriptive authority and who is qualified to make the diagnosis. The diagnosis must be documented.¶

Devices and supplies:¶

- (1) Diabetic blood sugar testing supplies;¶
- (2) Injection supplies;¶
- (3) Nebulizers and associated supplies;¶
- (4) Inhalation spacers;¶
- (5) Peak flow meters;¶
- (6) International Normalized Ratio (INR) testing supplies;¶
- (7) Enteral nutrition supplies; ¶
- (8) Ostomy products and supplies; and ¶
- (9) Non-invasive blood pressure monitors
- Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.645, ORS 689.649