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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**

01/02/2024 2:59 PM ARCHIVES DIVISION SECRETARY OF STATE

FILING CAPTION: Repeals Division 019 and 025 Vaccination rules effective 2/29/2024

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 02/22/2024 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.

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Filed By:

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Portland, OR 97232

Rachel Melvin

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Rules Coordinator

HEARING(S)

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

DATE: 02/22/2024 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: 700559800 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 February 22, 2024. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

NEED FOR THE RULE(S)

Repeals rules in Division 019 Pharmacist and Division 025 Certified Oregon Pharmacy Technician and Pharmacy Technician rules related to vaccinations effective 11:59PM on 2/29/2024. The board adopted Division 115 Pharmacists rules in August, October and December 2023, which replace Division 019. The board adopted Division 125 Pharmacy

Technicians rules in August 2023 and December 2023 which replace Division 025. Divisions 019 and 025 need to be repealed effective at 11:59PM on 2/29/2024 to allow Division 115 and 125 rules to become effective at 12:00AM on 3/1/2024. These repeals are being filed separately from the other Division 019 and 025 repeals due to limitations in the online rule filing system that would not permit the rules to be repealed until after amendments adopted by the board in December 2023 became effective on 1/1/2024.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Div 019 Pharmacist 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/Div_115_125_RPH_COPT_PT_Admin_Vaccines_BP_30-2023TrackedChanges.pdf

Division 125 Pharmacy Technicians Permanent Administrative Order

https://www.oregon.gov/pharmacy/Documents/Div_125_Pharmacy_Technicians_BP_18-2023TrackedChanges.pdf https://www.oregon.gov/pharmacy/Documents/Div_115_125_RPH_COPT_PT_Admin_Vaccines_BP_30-2023TrackedChanges.pdf

https://www.oregon.gov/pharmacy/Documents/Div_125_Prohibited_Practices_BP_32-2023TrackedChanges.pdf

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

The proposed rule repeals are not expected to affect racial equity in this state.

FISCAL AND ECONOMIC IMPACT:

The proposed rule repeals have 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 repeals 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 board adopted new Division 125 Pharmacy Technicians rules in August 2023 and December 2023, effective 3/1/2024. The nature of the proposed rule repeals does not require input from an advisory committee.

RULES PROPOSED:

855-019-0270, 855-019-0280, 855-019-0290, 855-025-0024

REPEAL: 855-019-0270

RULE SUMMARY: Repeals Division 019 Pharmacists rules related to vaccination. The board adopted Division 115 Pharmacists rules in August, October and December 2023, which replaces Division 019. Division 019 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:

855-019-0270

Vaccination: Qualifications ¶

A Pharmacist may administer vaccines if the Pharmacist:¶

- (1) Has completed a course of training approved by the board and maintained competency that includes, injection site, and Cardiopulmonary Resuscitation (CPR) specific to the age and population of patients being vaccinated by the Pharmacist:¶
- (2) Holds active CPR certification issued by the American Heart Association or the American Red Cross or any other equivalent program intended for a healthcare provider that contains a hands-on training component and is valid for not more than three years;¶
- (3) Has access to the current edition of the CDC reference, "Epidemiology and Prevention of Vaccine-Preventable Diseases."

Statutory/Other Authority: ORS 689.205, ORS 689.645

Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.645

REPEAL: 855-019-0280

RULE SUMMARY: Repeals Division 019 Pharmacists rules related to vaccination. The board adopted Division 115 Pharmacists rules in August, October and December 2023, which replaces Division 019. Division 019 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:

855-019-0280

Vaccination: Protocols, Policies and Procedures ¶

- (1) Prior to prescribing, administering or dispensing a vaccine, a Pharmacist:¶
- (a) Until January 31, 2024, must follow protocols written and approved by the Oregon Health Authority (OHA) for vaccines and the treatment of severe adverse events following administration of a vaccine. ¶
- (b) Effective February 1, 2024, must follow a statewide drug therapy management protocol per OAR 855-020-0300 or a collaborative drug therapy management agreement per OAR 855-019-0260.¶
- (2) A Pharmacist may administer vaccines: ¶
- (a) To a person who is seven years of age or older; ¶
- (b) To a person who is six months of age or older if the vaccine administered is an influenza vaccine; and \$\Pi\$
- (c) To a person who is at least three years of age when:¶
- (A) The Governor declares a state of public health emergency and authorizes the reduced age limitation; or ¶
- (B) The Public Health Director, during a declared disease outbreak, authorizes a reduction in the age limit.¶
- (3) A Pharmacist who administers or supervises administration of any vaccine must: ¶
- (a) Make vaccine recommendations:¶
- (b) Select each vaccine to be administered:¶
- (c) Ensure compliance with (1);¶
- (d) Ensure the appropriate Vaccine Information Statement (VIS) is provided to the patient or legal representative prior to each dose of vaccine;¶
- (e) Perform verification prior to administration that includes but is not limited to:¶
- (A) Prescription order accuracy verification; and ¶
- (B) Vaccine product accuracy review; ¶
- (f) Advise or counsel on therapeutic values, content, hazards and use of each vaccine; ¶
- (g) Manage adverse events;¶

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- (h) Report adverse events as required by the Vaccine Adverse Events Reporting System (VAERS) and to the primary care provider as identified by the patient:¶
- (i) Verify accuracy and completeness of documentation for vaccine administration; and ¶
- (i) Ensure all persons administering vaccines under their supervision are appropriately trained and qualified. ¶
- (4) An appropriately trained and qualified Pharmacist may permit an appropriately trained and qualified: ¶
- (a) Intern to perform the same duties as a Pharmacist except as prohibited in OAR 855-019-0200(6).¶
- (b) Certified Oregon Pharmacy Technician or Pharmacy Technician to conduct the physical act of administering a vaccine in accordance with OAR 855-025-0024.¶
- (5) The appropriately trained and qualified Pharmacist who is supervising an Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician in administering a vaccine must be immediately available to the vaccinator to respond to adverse reactions and any other issues that may arise.

Statutory/Other Authority: ORS 433.441, ORS 433.443, ORS 689.205, ORS 689.645, 2023 HB 2278, 2023 HB 2486

Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.645, 2023 HB 2278, 2023 HB 2486

REPEAL: 855-019-0290

RULE SUMMARY: Repeals Division 019 Pharmacists rules related to vaccination. The board adopted Division 115 Pharmacists rules in August, October and December 2023, which replaces Division 019. Division 019 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:

855-019-0290

Vaccination: Record Keeping and Reporting ¶

- A Pharmacist who administers or supervises each administration of a vaccine to a patient must: ¶
- (1) Fully document the administration in the patient's permanent record.
- (2) Report the following elements to the OHA ALERT Immunization Information System in a manner prescribed by OHA within 15 days of administration. ¶
- (a) The name, address, gender and date of birth of the patient;¶
- (b) The date of administration of the vaccine;¶
- (c) The NDC number of the vaccine, or other acceptable standardized vaccine code set: ¶
- (d) The address of the pharmacy where vaccine was administered unless automatically embedded in the electronic report provided to the OHA ALERT Immunization System;¶
- (e) The phone number of the patient when available;¶
- (f) The dose amount, manufacturer, site of administration, lot number and expiration date of the vaccine when available:¶
- (3) Keep documentation of current CPR training. This documentation will be kept on site and available for inspection.¶
- (4) Follow storage and handling guidance from the vaccine manufacturer and the Centers for Disease Control and Prevention (CDC).¶
- (5) For the purpose of participation in the Oregon Vaccines for Children program,¶
- (a) The vaccine eligibility code for each dose must be reported to the ALERT Immunization Information System in the manner prescribed by OHA, and ¶
- (b) The Pharmacist is recognized as a prescriber.¶
- (c) If providing state or federal vaccines during a pandemic as determined by the CDC, the event and priority code as specified by OHA must be provided upon request in the manner prescribed by OHA.

 Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.645, 2023 HB 2278, 2023 HB 2486

REPEAL: 855-025-0024

RULE SUMMARY: Repeals Division 025 Certified Oregon Pharmacy Technician and Pharmacy Technicians rules related to vaccination. The board adopted Division 125 Pharmacy Technicians rules in August 2023 and December 2023 which replaces Division 025. Division 025 needs to be repealed effective at 11:59PM on 2/29/2024 to allow Division 125 rules to become effective at 12:00AM on 3/1/2024.

CHANGES TO RULE:

855-025-0024

Services: Vaccine Administration

- (1) A Certified Oregon Pharmacy Technician or Pharmacy Technician may perform the physical act of administering vaccines under the supervision of an appropriately trained and qualified Pharmacist:¶
 (a) To a person who is seven years of age or older:¶
- (b) To a person who is at least three years of age when;¶
- (A) The Governor declares a state of public health emergency and authorizes the reduced age limitation; or ¶
- (B) The Public Health Director, during a declared disease outbreak, authorizes a reduction in the age limit.¶
- (2) A Certified Oregon Pharmacy Technician or Pharmacy Technician must:¶
- (a) Prior to administration of a vaccine, receive practical training that includes infection control, recognition of anatomical landmarks and competency in hands-on administration technique.¶
- (b) Prior to administration of a vaccine, hold active CPR certification issued by the American Heart Association or the American Red Cross or any other equivalent program that is specific to the age and population receiving the vaccine, contains a hands-on training component, and is valid for not more than three years. ¶
- (3) Document the vaccine administration including but not limited to the vaccine administered, dose, expiration date, lot number, and injection site. ¶
- (4) Notify the supervising Pharmacist immediately in the event of a suspected adverse reaction to a vaccine.¶ (5) The training required in (2) may include programs approved by the ACPE, curriculum-based programs from an ACPE-accredited college or school of pharmacy, state or local health department programs, training by an appropriately qualified practitioner, or programs approved by the board.¶
- (6) The records and forms required by this section must be filed in the pharmacy, made available to the board for inspection upon request, and must be retained for three years.

Statutory/Other Authority: ORS 689.205, 2023 HB 2486

Statutes/Other Implemented: ORS 689.151, 2023 HB 2486