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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

10/19/2023 5:03 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Pharmacist, Certified Oregon Pharmacy Technician and Pharmacy Technician Administration of Vaccines

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/21/2023 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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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: 11/21/2023

TIME: 9:30 AM

OFFICER: Rachel Melvin

HEARING LOCATION

ADDRESS: Oregon Board of Pharmacy - Virtual Mtg , 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: 343868791

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 November 21, 2023. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

NEED FOR THE RULE(S)

Beginning 1/1/2024, proposed rule amendments will permit a Pharmacist to administer an influenza vaccine to persons who are six months of age or older pursuant to 2023 HB 2278 and permit a Certified Oregon Pharmacy Technician

(COPT) or Pharmacy Technician (PT) to administer a vaccine under the supervision of a Pharmacist pursuant to 2023 HB 2486.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

2023 HB 2278 <https://olis.oregonlegislature.gov/liz/2023R1/Downloads/MeasureDocument/HB2278/Enrolled>

2023 HB 2486 <https://olis.oregonlegislature.gov/liz/2023R1/Downloads/MeasureDocument/HB2486/Enrolled>

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

Part of the proposed rules may favorably impact racial equity making it easier for Black, Indigenous, people of color, and American Indian/Alaska Native people (BIPOC-AI/AN) to access vaccines in a pharmacy. Permitting pharmacists to administer influenza vaccine to patients aged 6 months and older and pharmacy technicians to administer vaccines may contribute to closing disparities in vaccination rates between white persons and BIPOC-AI/AN. Pharmacies are often located in communities where BIPOC-AI/AN live and are more accessible than other healthcare settings. Pharmacists and pharmacy technicians are also trained to provide culturally competent care.

FISCAL AND ECONOMIC IMPACT:

The proposed rules have no anticipated fiscal and economic impact as the rules do not require a Pharmacist, COPT or PT to provide vaccinations.

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).

(1) The proposed rules will have no additional economic impact on state agencies, units of local government, or the public.

(2)(a) The proposed rule amendments apply to pharmacy registrants of the Oregon Board of Pharmacy. Approximately 30% of Drug Outlet Pharmacy (RP & IP) registrants identify as a small business.

(b) The rulemaking imposes no additional mandatory reporting, recordkeeping or other administrative requirements on small businesses.

(c) The rulemaking imposes no additional requirements regarding equipment, supplies, labor or administration.

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

Licensees and registrants who identify as a small business will receive an email notice of proposed rulemaking via GovDelivery and will have an opportunity to provide public comment on the proposed rules for the board's consideration.

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

The board did not direct staff to convene a Rules Advisory Committee or Workgroup to advise on the proposed rule amendments. Recent legislation informed the proposed rule amendments. Pursuant to 2023 HB 2278, proposed amendments will permit a Pharmacist to administer an influenza vaccine to persons who are six months of age or older. Pursuant to 2023 HB 2486, proposed amendments will permit a Certified Oregon Pharmacy Technician (COPT) or Pharmacy Technician (PT) to administer a vaccine under the supervision of a Pharmacist.

RULES PROPOSED:

ADOPT: 855-115-0305

RULE SUMMARY: Revises and relocates OAR 855-019-0270, OAR 855-019-0280 and OAR 855-019-0290. Adds administration requirements for Pharmacists who provide administration of a drug, device or vaccine and/or supervise an Intern, COPT or PT in the administration of a vaccine, including training, verification and documentation requirements.

CHANGES TO RULE:

855-115-0305

Services: Administration of Vaccines, Drugs, or Devices

(1) In accordance with ORS 689.645 and ORS 689.655, a Pharmacist may administer a vaccine, drug or device as specified in this rule. The Pharmacist must be acting:

(a) Under the direction of or pursuant to a lawful prescription or order issued by a licensed practitioner acting within the scope of the practitioner's practice; or

(b) In accordance with a statewide drug therapy management protocol per OAR 855-115-0345; or

(c) In accordance with a clinical pharmacy agreement or collaborative drug therapy management agreement per OAR 855-115-0315.

(2) A Pharmacist who administers a vaccine, drug or device must:

(a) Prior to administration of an injectable drug or device, receive practical training on the injection site and administration technique that is utilized. For orally administered drugs, training is not required.

(b) Hold 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 is specific to the age and population receiving the vaccine, drug or device, contains a hands-on training component, and is valid for not more than three years. The most current CPR certification record must be retained according to OAR 855-104-0055.

(c) Ensure that any drug administered to a patient was stored in accordance with the drug storage rules for pharmacies in ORS 855-041-1036;

(d) Observe, monitor, report, and otherwise take appropriate action regarding desired effect, side effect, interaction, and contraindication associated with administering the vaccine, drug or device;

(e) Ensure that vaccine, drug or device administration is documented in the patient's permanent record; and

(f) Ensure records and documents are retained according to OAR 855-104-0055. Records of administration must include but are not limited to:

(A) Patient identifier;

(B) Vaccine, drug or device and strength;

(C) Route and site of administration;

(D) Date and time of administration; and

(E) Pharmacist identifier.

(3) For vaccines only, the requirements in (2) and the following apply, and the Pharmacist who administers or supervises each administration of a vaccine to a patient must:

(a) Complete training that includes hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines. The training 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; and

(b) Make vaccine recommendations;

(c) Select each vaccine to be administered;

(d) Ensure compliance with (1);

(e) Ensure the appropriate Vaccine Information Statement (VIS) is provided to the patient or patient's agent prior to each dose of vaccine.

(f) Perform verification prior to administration that includes but is not limited to:

(A) Prescription order accuracy verification; and

(B) Vaccine product accuracy review;

(g) Advise or counsel on therapeutic values, content, hazards and use of each vaccine;

(h) Manage adverse events;

(i) Report adverse events as required by the Vaccine Adverse Events Reporting System (VAERS) and to the primary care provider as identified by the patient;

(j) Verify accuracy and completeness of documentation for vaccine administration;

- (k) Ensure all persons administering vaccines under their supervision are appropriately trained and qualified.¶
 - (l) Follow the guidance in the Centers for Disease Control and Prevention (CDC) Vaccine Storage and Handling Toolkit (v. 4/12/2022); and¶
 - (m) Have access to a current edition of the CDC reference, "Epidemiology and Prevention of Vaccine-Preventable Diseases" (v. 8/2021);¶
 - (5) The Pharmacist may administer a drug or device in conjunction with training the patient or the patient's agent on how to administer or self-administer the drug or device. ¶
 - (6) Records and documents must be retained according to OAR 855-104-0055.¶
 - (7) 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 855-120-0150.¶
 - (b) Certified Oregon Pharmacy Technician or Pharmacy Technician to conduct the physical act of administering a vaccine in accordance with OAR 855-125-0305.¶
 - (8) 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 in the case of an adverse reaction and any other issue that may arise.
- Statutory/Other Authority: ORS 689.205, 2023 HB 2278, 2023 HB 2486
- Statutes/Other Implemented: ORS 689.655, 2023 HB 2486

ADOPT: 855-125-0305

RULE SUMMARY: Permits an appropriately trained and qualified COPT and PT to perform the physical act of administering vaccines under the supervision of an appropriately trained and qualified Pharmacist pursuant to 2023 HB 2486 beginning 1/1/2024, adds training and certification requirements prior to administering vaccines, adds documentation requirements, adds notification and record retention requirements.

CHANGES TO RULE:

855-125-0305

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 or 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