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CHAPTER 855
BOARD OF PHARMACY

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

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RULES:

855-019-0270, 855-019-0280, 855-019-0290, 855-025-0024, 855-041-1040, 855-139-0600

AMEND: 855-019-0270

NOTICE FILED DATE: 10/19/2023

RULE SUMMARY: Amends by relocating existing rules related to supervision of an immunizing Intern, protocols and to whom a pharmacist can administer vaccines to 855-019-0280.

CHANGES TO RULE:

855-019-0270

Vaccination: Qualifications ¶¶

~~(1) In this rule and in OAR 855-019-0280, an intern who is appropriately trained and qualified in accordance with Section (3) of this rule may perform the same duties as a pharmacist, provided that the intern is supervised by an appropriately trained and qualified pharmacist.¶¶~~

~~(2) A pharmacist may administer vaccines to persons who are at least 7 years of age as provided by these rules. For the purposes of this rule, a person is at least 7 years of age on the day of the person's seventh birthday.¶¶~~

~~(3) A pharmacist may administer vaccines under section (1) or section (2) of this rule only if A Pharmacist may administer vaccines if the Pharmacist:¶¶~~

~~(a) 1) The pharmacist has completed a course of training approved by the Board and maintained competency;¶¶~~

~~(b) The pharmacist training that includes, injection site, and Cardiopulmonary Resuscitation (CPR) specific to the age and population the pharmacist treats;¶¶~~

~~(c) Tof patients being vaccinated by the pPharmacist h;¶¶~~

~~(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, and documentation of the certification is placed on file in the pharmacy;¶¶~~

~~(d) 3) The vaccines are administered in accordance with an administration protocol written and approved by the Oregon Health Authority (OHA); and¶¶~~

~~(e) The pharmacist has a current copy of the CDC reference, "Epidemiology and Prevention of Vaccine-Preventable Diseases."¶¶~~

(4) A pharmacist otherwise in compliance with section three of this rule may, during a declared emergency, administer a vaccine to a person who is at least three (3) 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.¶¶
(5) A pharmacist may not delegate the administration of vaccines to another person. Has access to the current edition of the CDC reference, "Epidemiology and Prevention of Vaccine-Preventable Diseases."
Statutory/Other Authority: ~~ORS 689.205-433.441, 433.443, 2015 OL Ch 29, ORS 689.645~~
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.645, 2015 OL Ch 295

AMEND: 855-019-0280

NOTICE FILED DATE: 10/19/2023

RULE SUMMARY: Amends by adding language relocated from OAR 855-019-0270; Adds that a Pharmacist may administer to a person who is six months of age or older if the vaccine administered is an influenza vaccine per 2023 HB 2278 beginning 1/1/2024; Moves requirements for a pharmacy to 855-041-1040; Adds rules related to the Pharmacist duties for administration or supervision of vaccination; Removes requirement for Pharmacist to 'give' Vaccine Information Statement (VIS) to patient and ensure it was read by/to patient and alternatively requires Pharmacist to 'ensure' patient receives VIS; Adds pharmacist requirements for supervising Interns, COPTs and PTs who administer a vaccine, which includes the Pharmacist being immediately available to the vaccinator.

CHANGES TO RULE:

855-019-0280

Vaccination: Protocols, Policies and Procedures ¶

- (1) ~~Prior to prescribing, administering a vaccine to a person who is at least 7 years of age or dispensing a vaccine, a Pharmacist:~~ ¶
- ~~(a) Until January 31, 2024, must follow protocols written and approved by the Oregon Health Authority (OHA) for administration of vaccines and the treatment of severe adverse events following administration of a vaccine.~~ ¶
- ~~(2b) A pharmacist during a declared emergency may administer a vaccine.~~ 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~~ ¶
- (c) ~~To a person who is at least three (3) 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) ~~The a Pharmacy must maintain written policies and procedures for handling and disposal of used or contaminated equipment and supplies.~~ ist who administers or supervises administration of any vaccine must: ¶
- (a) Make vaccine recommendations; ¶
- (b) Select each vaccine to be administered; ¶
- (4c) ~~The pharmacist must give~~ Ensure compliance with (1); ¶
- (d) Ensure the appropriate Vaccine Information Statement (VIS) is provided to the patient or legal representative with prior to each dose of vaccine covered by these forms. The pharmacist must ensure that the patient or legal representative is available and has read, or has had read to them, the information provided and has had their questions answered prior to administering the; ¶
- (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; ¶
- (5g) ~~The pharmacist must r~~ Manage adverse events; ¶
- ¶
- (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 ¶
- (6j) ~~The pharmacist may prescribe, administer or dispense immunizations, including oral vaccines, as established by written protocols approved by OHA~~ 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 689.205, 433.441, ORS 433.443, 2015-OL Ch 295~~ ORS 689.205, ORS 689.645,

2023 HB 2278, 2023 HB 2486

Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.645, 2015 OL Ch 295 2023 HB 2278, 2023 HB 2486

AMEND: 855-019-0290

NOTICE FILED DATE: 10/19/2023

RULE SUMMARY: Adds the phrase "or supervises each administration of" to OAR 855-019-0290(1). Removes "former requirement" language from (2).

CHANGES TO RULE:

855-019-0290

Vaccination: Record Keeping and Reporting

~~(1) 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) A pharmacist who administers any vaccine must report the following elements to the OHA ALERT Immunization Information System in a manner prescribed by OHA within 15 days of administration. This replaces the former requirement to notify the primary health care provider. A pharmacist is not required to notify the primary health care provider.~~

~~(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) A pharmacist who administers any vaccine will keep documentation of current CPR training. This documentation will be kept on site and available for inspection.~~

~~(4) A pharmacist who administers any vaccine will 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

ADOPT: 855-025-0024

NOTICE FILED DATE: 10/19/2023

RULE SUMMARY: Adopts new rule permitting 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.

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

AMEND: 855-041-1040

NOTICE FILED DATE: 10/19/2023

RULE SUMMARY: Amends (2)(i) by adding requirements for the outlet to have policies and procedures for COPT/PT vaccination; Adds (2)(l) "Disposal of drugs and/or devices including hazardous and pharmaceutical waste" which is relocated from OAR 855-019-0270.

CHANGES TO RULE:

855-041-1040

Outlet: Policies and Procedures ¶¶

(1) The drug outlet pharmacy and its Pharmacist in Charge is accountable for establishing, maintaining, and enforcing written policies and procedures for the drug outlet pharmacy in compliance with federal and state regulations. The written policies and procedures must be maintained at the drug outlet pharmacy and must be available to the board upon request.¶¶

(2) The written policies and procedures must include at a minimum the responsibilities of the drug outlet pharmacy including;¶¶

(a) Security;¶¶

(b) Operation, testing and maintenance of pharmacy systems and equipment;¶¶

(c) Sanitation;¶¶

(d) Storage of drugs;¶¶

(e) Dispensing;¶¶

(f) Pharmacist supervision, direction and control of non-Pharmacists;¶¶

(g) Documenting the date, time and identification of the licensee and the specific activity or function of the person performing each step in the dispensing process;¶¶

(h) Utilization of Certified Oregon Pharmacy Technicians or Pharmacy Technicians;¶¶

(i) Certified Oregon Pharmacy Technician or Pharmacy Technician final verification and/or vaccination, if utilized;¶¶

(j) Drug and/or device procurement;¶¶

(k) Receiving of drugs and/or devices;¶¶

(l) Disposal of drugs and/or devices including hazardous and pharmaceutical waste;¶¶

(m) Delivery of drugs and/or devices;¶¶

(~~nn~~) Utilization of Oregon licensed Pharmacist (i.e. DUR, Counseling);¶¶

(~~oo~~) Recordkeeping;¶¶

(~~pp~~) Patient confidentiality;¶¶

(~~qq~~) Continuous quality improvement;¶¶

(~~rr~~) Plan for discontinuing and recovering services in the event of a pharmacy closure;¶¶

(~~rs~~) Training: initial and ongoing; and¶¶

(~~st~~) Interpretation, translation and prescription reader services.

Statutory/Other Authority: ORS 689.205, 2022 HB 4034

Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.508, 2022 HB 4034

AMEND: 855-139-0600

NOTICE FILED DATE: 10/19/2023

RULE SUMMARY: Amends (1) by revising language in (a) to match proposed language in OAR 855-125-0150 and adding (b) which prohibits a COPT/PT at a RDSP to "Administer a vaccine." as a pharmacist is not present to respond to an adverse reaction.

CHANGES TO RULE:

855-139-0600

Prohibited Practices: General

A Retail Drug Outlet RDSP must not: ¶

(1) Allow a Certified Oregon Pharmacy Technician or Pharmacy Technician to ask questions of: ¶

~~(a) Refuse a request from a patient or, patient's agent which screen and/or limit, or practitioner to interaction with the Oregon licensed Pharmacist; a Pharmacist; and ¶~~

(b) Administer a vaccine. ¶

(2) Advertise or otherwise purport to operate as a pharmacy or to advertise or purport to provide pharmacy services unless the person is registered with the board pursuant to ORS 689.305; ¶

(3) Compound sterile preparations; or ¶

(4) Repackage drugs.

Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305, ORS 689.315, ~~2022 HB 4034~~ 700

Statutes/Other Implemented: ~~ORS 689.155, 2022 HB 4034~~ 315, ORS 689.155, ORS 689.700, 2023 HB 2486