

4729-5-36

Course requirements in the administration of immunizations.

- (A) A course in the administration of immunizations developed pursuant to division (B)(1) of section 4729.41 of the Revised Code shall meet at least the following requirements:
- (1) The instructor shall be a licensed health care professional and have the appropriate education and experience to teach a course in the administration of immunizations.
 - (2) The content must meet the standards established for such courses by the centers for disease control and prevention in the public health service of the United States department of health and human services.
 - (3) The course must be a minimum of five hours in length and include at least the following:
 - (a) A review of immunology that includes a discussion of the body's immune system reaction to the immunizations.
 - (b) A review of each medication listed in division (A)(3) of section 4729.41 of the Revised Code and each immunization or vaccination pursuant to ~~to~~ rule 4729-5-38 of the Administrative Code that includes the following:
 - (i) Disease states associated with the immunization;
 - (ii) Type or nature of activity of the immunization;
 - (iii) Appropriate administration schedules;
 - (iv) Appropriate routes of administration;
 - (v) Appropriate injection sites;
 - (vi) Appropriate dosages;
 - (vii) Appropriate monitoring and treatment of the patient for adverse reactions, including the use of diphenhydramine and epinephrine;
 - (viii) Appropriate patient populations;

- (ix) Precautions and contraindications;
 - (x) Proper storage requirements for the immunization.
- (c) A review of sterile technique in injectable dosage preparation and administration.
- (d) A minimum of one hour of instruction and physical participation in administration techniques.
- (e) A review of the proper disposal procedures for contaminated needles and immunizations.
- (f) A review of the proper procedures for accidental needle sticks.
- (4) The course must provide a method to evaluate the successful mastery of the content.
- (B) All courses in immunizations must be submitted to the state board of pharmacy for approval. The courses may be reviewed with the state medical board and the board of nursing, as appropriate. Any subsequent revisions to the course, after the initial approval, must be submitted to the state board of pharmacy for approval.
- (C) A pharmacist or pharmacy intern acting under the direct supervision of a pharmacist who has not successfully completed a course in immunization administration that meets the requirements set forth in this rule, must complete a course that meets the requirements in this rule prior to the administration of any immunization listed in rule 4729-5-38 of the Administrative Code.

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4729-5-37

Protocols for the administration of immunizations.

(A) To be considered an approved protocol pursuant to division (B)(3) of section 4729.41 of the Revised Code, the physician-established protocol for the administration of immunizations must include at least the following:

(1) For each medication listed in division (A)(3) of section 4729.41 of the Revised Code and ~~in~~ each immunization or vaccination pursuant to rule 4729-5-38 of the Administrative Code:

- (a) Name and strength;
- (b) Precautions and contraindications;
- (c) Intended audience or patient population;
- (d) Appropriate dosage;
- (e) Appropriate administration schedules;
- (f) Appropriate routes of administration;
- (g) Appropriate injection sites;

(2) The length of time the pharmacist or pharmacy intern under the direct supervision of a pharmacist must observe an individual for adverse effects, which shall be based on appropriate standards of care established by the physician. The location of the observation shall be in the general vicinity of the administering pharmacist or pharmacy intern to allow for on-going evaluation.

(3) A method to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks.

(4) A method to notify an individual's physician or the applicable board of health within thirty days after administering medication, except for influenza immunizations administered to individuals eighteen years of age and older.

(5) The locations that a pharmacist or pharmacy intern under the direct supervision of a pharmacist may engage in the administration of immunizations.

(B) All physician-established protocols must be signed and dated by the physician prior

to implementation and maintained by the administering pharmacist. The pharmacist must renew the protocol annually with the physician.

- (C) Upon the request of the state board of pharmacy, a pharmacist shall immediately provide the protocols for immunizations pursuant to division (B)(3) of section 4729.41 of the Revised Code and rule 4729-5-38 of the Administrative Code. The state board of pharmacy, after review, may approve the protocol or return it to the pharmacist for revision without approval. If a protocol has been returned for revision without approval, it may not be implemented until the board has approved it. The state board of pharmacy may review the protocols with the state medical board and the board of nursing, as appropriate.

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4729-9-08

Change in description of terminal or wholesale dangerous drug facility.

For the purpose of division (E) of section 4729.51 and division (D) of section 4729.52 of the Revised Code, any change in the ownership, business or trade name, category, or address of a terminal or wholesale distributor of dangerous drugs requires a new application, required fee, and license. The new application and required fee shall be submitted within 30 days of any change in the ownership, business or trade name, category, or address.

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4729-5-38

Immunization & Vaccine Administration.

(A) A pharmacist or pharmacy intern acting under the direct supervision of a pharmacist may administer in accordance with section 4729.41 of the Revised Code the following:

(1) Any immunization or vaccine that is included in either of the following schedules and is administered according to those schedules:

(a) The immunization schedule for persons aged zero through eighteen years recommended by the advisory committee on immunization practices of the centers for disease control and prevention in the United States department of health and human services (8/17/2015).

(b) Except as listed in paragraph (A)(2) of this rule, the adult immunization schedule recommended by the advisory committee on immunization practices of the centers for disease control and prevention in the United States department of health and human services (8/17/2015).

(2) The zoster vaccine according to the age criteria specified in the F.D.A. approved labeling.

(3) Except as provided in paragraph (A)(4) and (A)(5) of this rule, any other immunization or vaccine recommended by the advisory committee on immunization practices of the centers for disease control and prevention in the United States department of health and human services if administered in accordance with the recommendations adopted by the committee.

(4) The rabies vaccine for post exposure if all the following are met:

(a) A pharmacist or pharmacy intern does not provide the initial dose of the rabies post exposure vaccine;

(b) Follow-up doses are administered pursuant to a prescription issued by a prescriber; and

(c) The follow-up doses are administered in accordance with recommendations adopted by the advisory committee on immunization practices of the centers for disease control and prevention in the United States department of health and human services (8/17/2015).

(5) The requirements listed in paragraph (A)(4) of this rule do not apply to the rabies vaccine for preexposure if administered in accordance with recommendations adopted by the advisory committee on immunization practices of the centers for disease control and prevention in the United States department of health and human services (8/17/2015).

(B) A pharmacist or pharmacy intern shall obtain informed consent to administer an

immunization or vaccination pursuant to paragraph (O) of rule 4729-5-27 of the Administrative Code.

(C) A pharmacist or pharmacy intern shall comply with the vaccine information statement requirements of the National Vaccine Childhood Injury Act, 42 U.S.C. Section 300aa-26 (8/17/2015).

(D) A pharmacist or pharmacy intern who engages in the administration of an immunization or vaccination shall do so in accordance with rules 4729-5-36 and 4729-5-37 of the Administrative Code.

(E) An immunization or vaccine specified in this rule shall not be administered to any individual who is less than thirteen years of age, except in the following situations:

(1) The immunization for influenza is administered to individuals who are seven years of age or older; or

(2) Pursuant to a prescription from a licensed prescriber, an immunization or vaccine is administered to individuals who are seven years of age or older but not more than thirteen years of age.

(F) For each immunization administered to an individual by a pharmacist or pharmacy intern, other than an immunization for influenza administered to an individual eighteen years of age or older, the pharmacist or pharmacy intern shall notify the individual's family physician or, if the individual has no family physician, the board of health of the health district in which the individual resides or the authority having the duties of a board of health for that district under section 3709.05 of the Revised Code. The notice shall be given not later than thirty days after the immunization is administered.

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4729-9-12

Verification of license as a distributor of dangerous drugs or exempt status of a prescriber.

- (A) Before a wholesale distributor of dangerous drugs may make a sale of a dangerous drug to a terminal distributor of dangerous drugs, the wholesale distributor must obtain a copy of the current certificate of license as a terminal distributor from the purchaser pursuant to division (A) of section 4729.60 of the Revised Code.
- (1) The purchaser shall furnish a copy of the certificate of license as a terminal distributor to the wholesale distributor of dangerous drugs. If the certificate of license indicates a limited category I, II, or III license, the terminal distributor shall furnish the wholesale distributor a copy of the current license addendum listing those drugs the purchaser is authorized to possess.
 - (2) If no certificate of license as a terminal distributor is obtained or furnished before the sale, both the seller and the purchaser shall be considered to be in violation of section 4729.60 of the Revised Code.
- (B) Before a terminal distributor of dangerous drugs may make a purchase of dangerous drugs at wholesale, the purchaser must obtain from the seller the wholesale distributor registration number pursuant to division (B) of section 4729.60 of the Revised Code.
- (1) The seller shall furnish the wholesale distributor registration number and registration expiration date to the terminal distributor of dangerous drugs.
 - (2) If no registration number of the wholesale distributor is obtained or furnished before the purchase, both the purchaser and the seller shall be considered to be in violation of section 4729.60 of the Revised Code.
- (C) Before a wholesale distributor of dangerous drugs may make a sale of a dangerous drug to a prescriber as defined in division (I) of section 4729.01 of the Revised Code, the wholesale distributor must obtain:
- (1) A copy of the current certificate of license as a terminal distributor from the prescriber pursuant to division (A) of section 4729.60 of the Revised Code and, if the license is limited, a copy of the addendum listing the drugs the licensee is authorized to purchase and possess; or
 - (2) Unless the prescriber meets the terminal distributor of dangerous drugs licensing requirements in section 4729.541 of the Revised Code, Copies ~~Copies~~ copies of all documents required to establish that the prescriber is exempt from licensure as a terminal distributor of dangerous drugs pursuant to

divisions (B)(1)(a), (B)(1)(j), and (B)(1)(k) of section 4729.51 of the Revised Code and is authorized by federal and state laws to purchase the dangerous drugs for use in the course of his/her professional practice. The required documents are as follows:

- (a) An individual prescriber doing business as a sole proprietor (not incorporated in any manner) as set forth in division (B)(1)(a) of 4729.51 of the Revised Code, an individual prescriber doing business as a sole shareholder of a corporation or a limited liability company pursuant to division (B)(1)(j) of section 4729.51 of the Revised Code, and a dentist pursuant to division (B)(1)(k) of 4729.51 of the Revised Code must provide a copy of his/her current license to practice and the license must authorize the use of the drugs requested from the wholesaler in his/her practice. Also, a prescriber doing business as a sole shareholder of a corporation or a limited liability company must also provide official documentation that states he/she is the sole shareholder;
 - (b) The address of all sites of practice where the drugs will be delivered to and stored for use by the prescriber in his/her professional practice pursuant to federal and state laws;
 - (c) Verification from the licensing board that the prescriber's license is in good standing and that there are no restrictions on his/her license to practice and use drugs in his/her practice. If the license has been restricted by the licensing board, a copy of the official documents restricting the license to practice and use drugs in the course of professional practice must be furnished to the wholesaler and maintained by the wholesaler with all other documents establishing the prescriber's exemption from licensure as a terminal distributor of dangerous drugs;
 - (d) If an exempted prescriber wishes to purchase and possess dangerous drugs which are also controlled substances, the prescriber must submit a copy of his/her current registration with the federal drug enforcement administration and provide verification that the DEA registration and authority to use controlled substances in the course of professional practice has not been restricted by the appropriate professional licensing board or the federal drug enforcement administration.
- (D) Dangerous drugs may not be shipped by a wholesale distributor of dangerous drugs to any address other than those listed by the business entity meeting the definition of a prescriber and filed with the wholesale distributor in paragraph (B) of this rule. Controlled substances may only be shipped to those addresses registered with the

federal drug enforcement administration for the purpose of storing controlled substances.

- (E) All documents establishing the fact that a prescriber is exempt from licensure as a terminal distributor of dangerous drugs shall be current and maintained for a period of three years by the wholesale distributor of dangerous drugs.
- (F) Copies of licenses to practice and verification that there are no restrictions on a prescriber's license by either the appropriate professional licensing board or the federal drug enforcement administration shall be obtained within fifteen days of the date of renewal of such licenses. No dangerous drugs may be sold and delivered to a prescriber until the required documentation has been obtained by the wholesale distributor.
- (G) Each wholesale distributor of dangerous drugs registered with the state board of pharmacy shall report any suspicious purchases of any dangerous drugs by a prescriber exempted from licensure as a terminal distributor of dangerous drugs. A suspicious purchase includes, but is not limited to, any drugs that the prescriber is not authorized to use in the course of his/her professional practice.
- (H) Before a terminal distributor of dangerous drugs may make a sale of dangerous drugs pursuant to rule 4729-16-07 of the Administrative Code, the terminal distributor of dangerous drugs must confirm a current certificate of license as a terminal distributor from the purchaser.

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4729-9-19

Violations as evidence for denial or discipline of terminal, wholesale, or manufacturer license.

(A) The state board of pharmacy may consider as evidence of a person not meeting the requirements provided in sections 4729.53 and 4729.55 of the Revised Code, and may deny or discipline a person registration as a wholesale distributor of dangerous drugs or licensure as a terminal distributor of dangerous drugs in Ohio if such person:

(1) Has been convicted of a felony;

~~(2)~~ (3) Commission of an act that constitutes a felony in this state, regardless of the jurisdiction in which the act was committed;

~~(2)~~~~(3)~~ Has been convicted of violating any state or federal pharmacy or drug law;

~~(3)~~~~(4)~~ Is not of good moral character and habits;

~~(4)~~~~(5)~~ Is addicted to or abusing ~~liquor~~ alcohol or drugs;

~~(5)~~~~(6)~~ Has been disciplined by the Ohio state board of pharmacy pursuant to section 4729.16 of the Revised Code; or

~~(6)~~~~(7)~~ Has been disciplined by any professional licensing board.

(B) When a request for licensure as a terminal distributor of dangerous drugs, a wholesale distributor of dangerous drugs, or as a wholesaler or manufacturer of controlled substances is made, the state board of pharmacy may consider as evidence of the facility not meeting the requirements for licensure as provided in Chapters 3719. and 4729. of the Revised Code, or may deny issuance of such licensure, if:

(1) The ownership of such facility, or pharmacy previously located in such facility, has been transferred from a licensee whose license has been revoked or disciplined by the state board of pharmacy or any other professional licensing board to the spouse or other family member;

(2) The ownership of such facility, or pharmacy previously located in such facility, has been transferred from a licensee whose license has been revoked or disciplined by the state board of pharmacy or any other professional licensing board to another who employs the former owner or who allows the former owner to be present within the physical confines of the location to be licensed.

(3) The facility knowingly employs a person who: ~~has been denied the right to work in such a facility by the state board of pharmacy as part of an official order of the board.~~

(a) Has been denied the right to work in such a facility by the state board of pharmacy as part of an official order of the board;

(b) Has been denied the right to work in such a facility by another professional licensing board as part of an official order of that board;

(c) Has been convicted of a felony;

(d) Has committed an act that constitutes a felony in this state, regardless of the jurisdiction in which the act was committed;

(e) Has been convicted of violating any state or federal pharmacy or drug law;

(f) Is not of good moral character and habits;

(g) Is addicted to or abusing alcohol or drugs;

(h) Has been disciplined by the Ohio state board of pharmacy pursuant to section 4729.16 of the Revised Code; or

(i) Has been disciplined by any professional licensing board.

(C) "Person" has the same meaning as in 4729.01(S) of the revised code and also includes any individual member, regardless of the percentage of ownership, of any partnership, association, limited liability company, or corporation.

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4729-5-23**Therapeutic Diabetic Shoes.**

(A) Pursuant to section 4779.02 of the Revised Code, a pharmacist or pharmacy intern acting under the direct supervision of a pharmacist, may fit and measure individuals for therapeutic diabetic shoes and shoe inserts and may dispense those shoes and shoe inserts.

(B) A pharmacist or pharmacy intern acting under the direct supervision of a pharmacist shall not provide any other services that are authorized under chapter 4779 of the Revised Code.

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