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FULL TEXT SHOWING CHANGES

UNDERLINED = Add New Language

LINED THROUGH = ~~Remove~~ Old Language

4729-4-01 Definitions. (Effective 6-21-09)

As used in Chapter 4729-4 of the Administrative Code:

- (A) "Compounding" has the same meaning as defined in division (C) of section 4729.01 of the Revised Code.
- (B) "Package or label any drug" means the placement of a drug into a container or package and the affixing of a drug label or drug information to the immediate drug container or drug package.
- (C) "Prepare or mix any intravenous drug to be injected into a human being" has the same meaning as "Compounding" as defined in division (C) of section 4729.01 of the Revised Code.
- (D) "Qualified pharmacy technician" has the same meaning as defined in section 4729.42 of the Revised Code.

4729-4-02 Board approved examination for qualified pharmacy technicians.

(Effective 7-25-09)

A board approved examination for qualified pharmacy technicians required in section 4729.42 of the Revised Code means either of the following:

- (A) An examination provided by a national pharmacy technician certification program that is accredited by the National Commission for Certifying Agencies. Information regarding these examinations will be posted on the board's web site (www.pharmacy.ohio.gov).
- (B) An examination provided by an employer after being approved by the board of pharmacy.
 - (1) The employer shall ensure that the examination is of appropriate breadth and depth, clearly addressing the competencies required for a technician to safely and effectively work in that particular setting and shall include at a minimum the following:
 - (a) The applicable employer practice areas specified in division (B) of section 4729.42 of the Revised Code;
 - (b) Pharmacy terminology;

- (c) Basic drug information;
- (d) Basic calculations;
- (e) Quality control procedures;
- (f) State and federal laws, rules, and regulations regarding:
 - (i) Qualified pharmacy technician duties;
 - (ii) Pharmacist duties;
 - (iii) Pharmacy intern duties;
 - (iv) Prescription or drug order processing procedures;
 - (v) Drug record keeping requirements;
 - (vi) Patient confidentiality;
 - (vii) Security requirements;
 - (viii) Storage requirements.
- (2) An examination provided by an employer shall only be considered as an approved examination for that employer.
- (3) The employer shall have procedures that ensure the security and integrity of the examination materials, describe the testing format, and define the successful completion of an examination which must be at least seventy-five percent. The administration of an examination shall be supervised by a proctor and at a minimum shall consist primarily of multiple choice, essay, or short answer questions. The questions on the examination shall not be given to the examinee prior to taking the examination. The answers to the examination must not be given to the examinee prior to or during the examination. The examinee shall agree in writing not to share the questions or answers to the examination with any other person.
- (4) The employer shall maintain the examinations and scores of all of the employees who successfully passed an examination for a minimum of three years after the employee ceases employment.
- (5) An employer shall provide the examination procedures and the examination materials to the board for review and approval. The board, after reviewing the examination procedures and materials, may approve the examination program or return it to the employer for revision without approval. If an examination program has been returned for revision without approval, the board will indicate the reasons for the rejection and it may not be used further until the board has approved it. If requested by the state board of pharmacy, an employer shall

provide the examination results to the board within three working days, excluding weekends and holidays.

4729-4-03 Qualified pharmacy technician training program. (Effective 6-21-09)

A pharmacy technician training program pursuant to division (E) of section 4729.42 of the Revised Code shall be of appropriate breadth and depth, clearly addressing the competencies for a technician to safely and effectively work in that particular setting and shall include at a minimum the following:

- (A) The applicable practice areas specified in division (B) of section 4729.42 of the Revised Code;
- (B) Pharmacy terminology;
- (C) Basic drug information;
- (D) Basic calculations;
- (E) Quality control procedures;
- (F) State and federal laws, rules, and regulations regarding:
 - (1) Qualified pharmacy technician duties;
 - (2) Pharmacist duties;
 - (3) Pharmacy intern duties;
 - (4) Prescription or drug order processing procedures;
 - (5) Drug record keeping requirements;
 - (6) Patient confidentiality;
 - (7) Security requirements;
 - (8) Storage requirements.

4729-4-04 Criminal records check for qualified pharmacy technicians.

(Effective 6-21-09)

- (A) Pursuant to sections 4729.42 and 4776.02 of the Revised Code, the criminal records check performed by the Ohio bureau of criminal identification and investigation (BCI&I) shall consist of both a BCI&I criminal records check and a federal bureau of investigation (FBI) criminal records check. BCI&I shall send the results of the BCI&I criminal records check directly to the employer or potential employer. BCI&I shall provide a letter regarding the FBI criminal records check to the employer or potential

employer stating that there is either no record of any conviction or a letter stating that the request may not meet the criteria. When an employer or potential employer receives a letter stating that the request may not meet the criteria, they may share this information with the employee or potential employee. In order to complete the criminal records check, the employee or potential employee must then complete a "Request for Release-FBI Rapsheet" and send it to BCI&I to request a copy of the FBI criminal record results be sent directly to the employee or potential employee. The employee or potential employee is then responsible for providing the FBI criminal records check results to the employer or potential employer. The employee or potential employee must provide the results to the employer or potential employer in the original sealed envelope received from BCI&I.

(B) The criminal records check shall be based on electronic fingerprint impressions that are submitted directly to BCI&I from a "WebCheck" provider agency located in Ohio. The employer may accept the results of a criminal records check based on ink impressions from a "WebCheck" provider agency only in the event that readable electronic fingerprint impressions cannot be obtained.

4729-5-36 Course requirements in the administration of immunizations.

(Effective 6-21-09)

(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) of section 4729.41 of the Revised Code and in 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;
 - (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.

4729-5-37 Protocols for the administration of immunizations. (Effective 6-21-09)

- (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) of section 4729.41 of the Revised Code and in 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. 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.

4729-5-38 Immunization administration. (Effective 6-21-09)

In addition to the immunizations and medications listed in section 4729.41 of the Revised Code and pursuant to the requirements noted in section 4729.41 of the Revised Code and rules 4729-5-36 and 4729-5-37 of the Administrative Code, a pharmacist may administer the zoster vaccine according to the following requirements:

- (A) The pharmacist must receive a patient specific prescription prior to administration of the drug:

- (B) The vaccine must be administered within thirty days of the issuance of the prescription;
- (C) The patient must meet the age criteria specified in the F.D.A. approved labeling; and
- (D) The pharmacist must be able to document meeting the training criteria required by rule 4729-5-36.

4729-37-07 Frequency requirements for submitting drug database information.
(Effective 6-21-09)

- (A) ~~At~~ Until August 31, 2009, all drug dispensing information required to be submitted to the board of pharmacy pursuant to rules 4729-37-02 and 4729-37-04 of the Administrative Code must be submitted twice a month as follows:
 - (1) During the first through the fifth day of each month; and
 - (2) During the fifteenth through the twentieth day of each month; and
 - (3) The information shall be consecutive and inclusive from the last date and time information was submitted and shall be reported no later than twenty-one days after the date of the dispensing.
- (B) Starting on September 1, 2009, all drug dispensing information required to be submitted to the board of pharmacy pursuant to rules 4729-37-02 and 4729-37-04 of the Administrative Code shall be submitted at least weekly. The information shall be consecutive and inclusive from the last date and time information was submitted and shall be reported no later than eight days after the date of the dispensing.
- (C) If a pharmacy has no drug dispensing information required to be submitted to the board of pharmacy pursuant to rules 4729-37-02 and 4729-37-04 of the Administrative Code, the pharmacy shall submit a "Zero Report" during the regular reporting cycle.
- ~~(B)~~(D) All wholesale drug sale information required to be submitted to the board of pharmacy pursuant to rules 4729-37-02 and 4729-37-04 of the Administrative Code must be submitted monthly as follows:
 - (1) During the first through the tenth day of each month; and
 - (2) The information shall be consecutive and inclusive from the last date and time information was submitted and shall be reported no later than forty days after the date of the wholesale sale.
- ~~(C)~~(E) In the event that a wholesaler or pharmacy cannot submit the required information as described in this rule they must immediately contact the board of pharmacy to determine a mutually acceptable time for submission of information. The wholesaler

or pharmacy must document in writing to the board of pharmacy the reasons for their inability to submit the required information.