



Rules – January 2025

For filing with CSI and JCARR.

Rule 4729:8-1-01 | Ohio Automated Rx Reporting System - Definitions. (AMEND)

As used in division 4729:8 of the Administrative Code:

(A) "Controlled substance" has the same meaning as in section [3719.01](#) of the Revised Code.

(B) “Central fill pharmacy” has the same meaning as in rule 4729:5-5-19 of the Administrative Code.

(B ~~C~~) "Distributor of dangerous drugs" or "drug distributor" means the following persons licensed in accordance with section [4729.52](#) of the Revised Code and division 4729:6 of the Administrative Code:

- (1) Wholesale distributors of dangerous drugs, including virtual wholesalers.
- (2) Manufacturers of dangerous drugs.
- (3) Outsourcing facilities.

(D) “Designated representative” means the dispensary key employee responsible for acting in compliance with agency 3796 of the Administrative Code.

(E) “Dispense” means the final association of a drug with a particular patient pursuant to a prescription, drug order, or other lawful order of a prescriber and the professional judgment of and the responsibility for interpreting, preparing, compounding, labeling, and packaging a specific drug.

(F) “Dispensary” means a holder of a valid retail dispensary license in accordance with Chapter 3796. of the Revised Code.

(G) “Originating pharmacy” has the same meaning as in rule 4729:5-5-19 of the Administrative Code.

(H) “Opioid treatment program” has the same meaning as in Chapter 4729:5-21 of the Administrative Code.

(~~C~~ ~~H~~) "Outpatient" means any person who receives drugs for use outside of an institutional facility as defined in agency 4729 of the Administrative Code.

~~(D-G)~~ "Peer review committee" has the same meaning as in section [2305.25](#) of the Revised Code, except that it includes only a peer review committee of a hospital or a peer review committee of a nonprofit health care corporation that is a member of the hospital or of which the hospital is a member.

~~(E-H)~~ "Personally furnish" means the distribution of drugs by a prescriber to the prescriber's patients for use outside the prescriber's practice setting.

~~(F-I)~~ "Pharmacy" has the same meaning as in section [4729.01](#) of the Revised Code.

~~(G-J)~~ "Prescriber" or "licensed health professional authorized to prescribe drugs" have the same meaning as in section [4729.01](#) of the Revised Code.

~~(H-K)~~ "Terminal distributor of dangerous drugs" or "terminal distributor" has the same meaning as in section [4729.01](#) of the Revised Code.

~~(I-L)~~ "Sale" and "sell" has the same meaning as in section [4729.01](#) of the Revised Code.

~~(J-M)~~ "Wholesale sale" and "sale at wholesale" have the same meaning as in section [4729.01](#) of the Revised Code. Wholesale sale also includes the following:

- (1) An occasional sale conducted in accordance with section [4729.51](#) of the Revised Code;
- (2) The sale of a sample or complimentary supply, as defined in rule [4729:6-3-08](#) of the Administrative Code, to a prescriber or terminal distributor;
- (3) The transfer or sale of a non-patient specific dangerous drug to a prescriber or terminal distributor.

~~**(K) "Zero report" means a report documenting that none of the drugs listed in Chapter 4729:8-2 of the Administrative code were sold, dispensed or personally furnished during the required reporting period.**~~

(N) "Zero report" means either:

(1) A report documenting that none of the drugs listed in Chapter 4729:8-2 of the Administrative Code were sold, dispensed or personally furnished during the required reporting period; or

(2) For a dispensary, a report documenting that no medical marijuana was sold or dispensed.

Rule 4729:8-3-02 | Information required for submission. (AMEND)

(A) Pharmacies pursuant to paragraphs (A) and (B) of rule [4729:8-3-01](#) of the Administrative Code that dispense drugs listed in Chapter 4729:8-2 of the Administrative Code to outpatients shall report the following dispensing information to the board of pharmacy in accordance with rule [4729:8-3-03](#) of the Administrative Code:

(1) Pharmacy drug enforcement administration registration number. If not applicable, another mutually acceptable identifier;

(2) Pharmacy name;

(3) Pharmacy address;

(4) Pharmacy telephone number;

(5) Pharmacy dispensing software vendor or proprietary software;

(6) Pharmacy license number, if both the drug enforcement administration registration and national provider identifier are not provided;

(7) Type of pharmacy or dispenser;

(8) Indication if entity is a mail order pharmacy;

(5 ~~9~~) Patient full name;

(6 ~~10~~) Patient residential address;

(7 ~~11~~) Patient telephone number;

(8 ~~12~~) Patient date of birth;

(9 ~~13~~) Patient gender;

(14) Species code;

(15) Owner's name for veterinary patients;

(16) Owner's date of birth for veterinary patients;

(17) Owner's gender for veterinary patients;

(18) Name of animal;

(19) Veterinary species code for veterinary patients that is either:

(a) For small animals: 03;

(b) For large animals, including livestock: 06.

(10 ~~20~~) Prescriber's full name (first name and last name);

(21) Transmission form of prescription (e.g., written, verbal, electronic, etc.);

(~~11~~ **22**) Prescriber's drug enforcement administration registration number. If not applicable, another mutually acceptable identifier;

(~~12~~ **23**) Date prescription was issued by the prescriber;

(~~13~~ **24**) Date the prescription was dispensed ~~or sold~~ by the pharmacy;

(25) Date the prescription was sold by the pharmacy, which shall be the date the prescription is sold, picked up, or otherwise left the pharmacy;

(~~14~~ **26**) Indication of whether the prescription dispensed is new or a refill;

(~~15~~ **27**) Number of the refill being dispensed;

(~~16~~ **28**) National drug code of the drug dispensed;

(29) Indication if the product is compounded in accordance with division 4729:7 of the Administrative Code;

(~~17~~ **30**) Quantity of the drug prescribed;

(~~18~~ **31**) Quantity of drug dispensed;

(~~19~~ **32**) Number of days' supply of the drug dispensed as indicated by the prescriber pursuant to agency 4729 of the Administrative Code, except as follows:

(a) If a days' supply is not indicated by the prescriber, the pharmacy shall calculate and report the number of days' supply of the drug dispensed;

(b) If the quantity of drug dispensed is different from the quantity indicated on the prescription, the pharmacy shall calculate and report the number of days' supply of the drug dispensed.

(~~20~~ **33**) Serial or prescription number assigned to the prescription order;

(~~21~~ **34**) Source of payment for the prescription that indicates one of the following: private pay (cash), medicaid, medicare, commercial insurance, or workers' compensation. Use of discount cards shall be reported as private pay;

(~~22~~ **35**) Pharmacy national provider identification (NPI) number;

(~~23~~ **36**) Prescriber's national provider identification (NPI) number, if prescriber does not have an NPI, **then the prescriber's state license number or** another mutually acceptable identifier;

(37) Pharmacist national provider identifier (NPI).

(a) If a pharmacist, other than the dispensing pharmacist, conducted the drug utilization review per rule 4729:5-5-08 of the Administrative Code, report the NPI of the pharmacist who conducted the drug utilization review;

(b) If a pharmacist does not have an NPI, report the pharmacist's license number or another mutually acceptable identifier;

(38) Name of pharmacist. If a pharmacist other than the dispensing pharmacist conducted the drug utilization review per rule 4729:5-5-08 of the Administrative Code, report the full name of the pharmacist who conducted the drug utilization review;

(24 **39**) Any of the following as indicated by the prescriber pursuant to agency 4729 of the Administrative Code:

(a) The ICD-10-CM medical diagnosis code of the primary disease or condition that the controlled substance drug is being used to treat. The code shall, at a minimum, include the first four alpha-numeric characters of the ICD-10-CM medical diagnosis code, sometimes referred to as the category and the etiology (ex. M 16.5);

(b) For dentists licensed pursuant to Chapter 4715. of the Revised Code, the "Code on Dental Procedures and Nomenclature" (CDT code), as published by the American dental association, of the dental treatment requiring the controlled substance prescription;

(c) If no such code is indicated on the prescription, the pharmacy shall indicate "NC" in the diagnosis data field.

(B) Prescribers pursuant to paragraph (E) of rule [4729:8-3-01](#) of the Administrative Code that personally furnish drugs listed in Chapter 4729:8-2 of the Administrative Code shall report the following information to the board of pharmacy in accordance with rule [4729:8-3-03](#) of the Administrative Code:

(1) Prescriber drug enforcement administration registration number. If not applicable, another mutually acceptable identifier;

(2) Prescriber full name (first and last name);

(3) Prescriber address;

(4) Prescriber telephone number;

(5) Patient full name;

(6) Patient residential address;

(7) Patient telephone number;

(8) Patient date of birth;

(9) Patient gender;

- (10) Date the drug was personally furnished by the prescriber;
- (11) National drug code of the drug personally furnished;
- (12) Quantity of drug personally furnished;
- (13) Number of intended days' supply of drug personally furnished;
- (14) Source of payment for the prescription that indicates one of the following: private pay (cash), medicaid, medicare, commercial insurance, or workers' compensation. Use of discount cards shall be reported as private pay;
- (15) Either of the following:
 - (a) The ICD-10-CM medical diagnosis code of the primary disease or condition that the controlled substance drug is being used to treat. The code shall, at a minimum, include the first four alpha numeric characters of the ICD-10-CM medical diagnosis code, sometimes referred to as the category and the etiology (ex. M 16.5);
 - (b) For dentists licensed pursuant to Chapter 4715. of the Revised Code, the "Code on Dental Procedures and Nomenclature" (CDT code), as published by the American dental association, of the dental treatment requiring the controlled substance prescription.
- (C) Drug distributors and terminal distributors pursuant to paragraphs (C) and (D) of rule [4729:8-3-01](#) of the Administrative Code that sell at wholesale drugs listed in Chapter 4729:8-2 of the Administrative Code shall report the following information to the board of pharmacy in accordance with rule [4729:8-3-03](#) of the Administrative Code:
 - (1) Drug distributor or terminal distributor drug enforcement administration registration number. If not applicable, then another mutually acceptable identifier;
 - (2) Purchaser's drug enforcement administration registration number. If not applicable, then another mutually acceptable identifier;
 - (3) National drug code number of the drug sold;
 - (4) Quantity of the drug sold;
 - (5) Date of sale; and
 - (6) Transaction identifier or invoice number.
- (D) Drug distributors shall report suspicious orders and customer information pursuant to rule [4729:6-3-05](#) of the Administrative Code to the drug database established in section [4729.75](#) of the Revised Code.

Rule 4729:8-3-03 | Electronic format required for the transmission of drug sales.
(RESCIND CURRENT / NEW)

(A) All prescription dispensing information or prescriber personally furnishing information required to be submitted to the board pursuant to rule 4729-8-3-02 of the Administrative Code must be transmitted in the following format specified by the "American Society for Automation in Pharmacy" (ASAP) for prescription monitoring programs:

(1) ASAP Version 5.0 Standard for Prescription Drug Monitoring Programs (1/1/2024); or

(2) Until **December 1**, 2025, ASAP Version 4.2A Standard for Prescription Drug Monitoring Programs (3/15/2017).

(B) The board's executive director or the director's designee may authorize up to a six-month extension to the implementation of ASAP Version 5.0 beyond April 1, 2025. Such extensions may only be considered if the pharmacy or prescriber has made all reasonable and prudent attempts to meet the deadline.

(C) In the event that a pharmacy or a prescriber cannot electronically transmit the required information pursuant to paragraph (A) of this rule, the pharmacy or prescriber may request a variance from the board's executive director or the director's designee to submit drug sales information in a mutually acceptable format.

(D) All wholesale data required to be submitted to the board of pharmacy pursuant to rule 4729-8-3-02 of the Administrative Code shall be transmitted in the report format used when transmitting controlled substance data to the federal drug enforcement administration via the "Automation of Reports and Consolidated Orders System" (ARCOS) or other mutually acceptable format.

(E) In the event that a drug distributor or terminal distributor cannot electronically transmit the required information pursuant to paragraph (D) of this rule, the drug distributor or terminal distributor may request a variance from the board's executive director or the director's designee to submit drug sales information in a mutually acceptable format.

Rule 4729:11-1-01 | Definitions - home medical equipment. (AMEND)

As used in this division:

(A) "24/7 coverage" means that facilities that provide HME services must have a telephone number that is operational twenty-four hours a day, seven days a week that clients can call to seek assistance. The telephone line may be an answering service that is monitored on a regular basis by the HME provider and should also alert clients to contact 911 in an emergency.

(B) "Abandoned application" means an application submitted for licensure or registration where an applicant fails to complete all application requirements within thirty days after being notified of the incomplete application by the board. An applicant forfeits all fees associated with an abandoned application. The board shall not be required to act on any abandoned application and the application may be destroyed by board staff. If an application is abandoned, the applicant shall be required to reapply for licensure or registration, submit the required fee and comply with the licensure or registration requirements in effect at the time of reapplication.

An application shall not be deemed abandoned if the application is subject to any of the following:

(1) An administrative proceeding; or

(2) If there is discipline pending against the applicant.

(C) "Accrediting body" means an agency recognized by the board under rule [4729:11-2-04](#) of the Administrative Code.

~~**(D) "Act of moral turpitude" means an act or behavior that gravely violates moral sentiment or accepted moral standards of the community and is a morally culpable quality held to be present in some criminal offenses as distinguished from others.**~~

(D) "Addicted to or abusing alcohol or drugs" means the chronic and habitual use of alcohol or the use of a drug of abuse as defined in section [3719.011](#) of the Revised Code by an individual to the extent that the individual no longer can control the individual's use of alcohol or drugs, the individual is physically or psychologically dependent on alcohol or drugs, or the individual's use or abuse of alcohol or drugs endangers the health, safety, or welfare of the individual or others.

(E) "Board" means the state board of pharmacy.

(E) "Business day" means any day other than Saturday, Sunday or a holiday recognized by the state of Ohio on which the offices of the board of pharmacy are not open for business.

(G) "Certificate of registration" or "registration" means a person holding a valid certificate of registration issued under Chapter 4752. of the Revised Code.

(H) "Client" or "patient" means a person who receives HME services from an HME services provider.

(I) "CMS" means the centers for medicare and medicaid services.

(J) "Contact hour" means a period of sixty minutes with a minimum of fifty minutes of instruction. For credit hours earned on an academic quarter system, one credit hour is equivalent to ten contact hours. For credit hours earned on an academic trimester system, one credit hour is equivalent to twelve contact hours. For credit hours earned on an academic semester system, one credit hour is equivalent to fifteen contact hours.

(K) "Disciplinary action" means any of the following by a federal agency or licensing agency of any state or jurisdiction, regardless of whether the action occurred by formal proceeding, consent, settlement, or other agreement:

- (1) An action to revoke, suspend, restrict, limit, or refuse to grant or renew a license, registration or certification;
- (2) A summary or emergency suspension of a license, registration or certification, of any length, and any subsequent revision to the action;
- (3) An administrative fine or monetary penalty, taken as a result of a formal proceeding, to include any fine or money penalty connected to the delivery of health care services or taken in conjunction with other adverse licensure, registration or certification actions, such as revocation, suspension, censure, reprimand, or probation;
- (4) An action to reprimand or place the license, registration, or certification holder on probation;
- (5) The issuance of a corrective action plan only if such issuance is in conjunction with other adverse licensure, registration or certification actions, such as revocation, suspension, reprimand, probation, or surrender;
- (6) The withdrawal of a renewal application for licensure, registration or certification while under investigation;

(7) The non-renewal of a license, registration or certification while under investigation or to avoid an investigation;

(8) The surrender of a license or other relinquishment, registration or certification in lieu of a formal sanction against a person's license, registration or certificate, whether permanent or temporary;

(9) In lieu of an adverse licensure, registration or certification action, a licensing agency issues a consent order in which a person agrees not to re-apply for a license in the future.

(10) An enforceable agreement not to practice or to be placed into inactive or other equivalent status while under investigation or in exchange for not conducting an investigation.

(L) "Disqualifying offense" has the same meaning as defined in rule 4729-3-01 of the Administrative Code.

(M) "Expired certificate of registration" means the holder of a certificate of a registration under Chapter 4752. of the Revised Code has failed to fulfill all requirements of certificate renewal and has failed to request that the board place the certificate into inactive status.

(N) "Expired license" means the holder of a license under Chapter 4752. of the Revised Code has failed to fulfill all requirements of licensure renewal, and who has failed to request that the board place the certificate on inactive status.

(O) "Home medical equipment" or "HME" has the same meaning as defined in section [4752.01](#) of the Revised Code. Pursuant to division (B)(3) of that section, HME shall also include the following equipment:

(1) Hospital grade pulse oximeters pursuant to a prescription issued by a prescriber;

(2) Home photo therapy (bili lights or blankets);

(3) Individually sized or customized accessories that are an integral part of equipment defined in this paragraph and paragraphs (T) and (DD) of this rule;

(4) Transcutaneous electronic nerve stimulators (TENS), excluding devices labeled by the federal food and drug administration for over-the-counter use and are identified with the federal food and drug administration product code "NUH.OTC TENS";

(5) Drop foot stimulators;

(6) Bone growth stimulators;

(7) Vision restoration therapy devices;

(8) In-home patient lifts;

(9) Life-sustaining equipment as defined in paragraph (T) of this rule; and

(10) Technologically sophisticated medical equipment as defined in paragraph (DD) of this rule.

(P) "Home medical equipment services" or "HME services" has the same meaning as defined in section [4752.01](#) of the Revised Code.

(Q) "Home medical equipment services provider" or "HME services provider" has the same meaning as defined in section [4752.01](#) of the Revised Code.

(R) "Inactive status" means the status of a license or registration issued under Chapter 4752. of the Revised Code of a facility that has made a request, in a manner determined by the board, that the board place the license or registration into inactive status. A facility with an inactive license does not hold a current, valid license or certificate of registration under Chapter 4752. of the Revised Code.

(S) "In-service education" means that a continuing education program is offered by a HME service provider organization and not an approved peer review organization.

(T) "Joint commission on accreditation of healthcare organizations," as used in section [4752.12](#) of the Revised Code, means "the joint commission" or its predecessor organization.

(U) "Life sustaining equipment" has the same meaning as defined in section [4752.01](#) of the Revised Code and includes the following:

(1) Ventilators;

(2) Oxygen concentrators;

(3) Oxygen liquid systems;

(4) Oxygen compressed gas systems;

(5) Non-invasive ventilator system (e.g. bi-level, iron lungs, rocking beds, diaphragmatic pacers, etc.);

(6) Any other life sustaining equipment as determined by the board.

(V) "Person" includes any individual, partnership, association, limited liability company, or corporation, the state, any political subdivision of the state, and any district, department, or agency of the state or its political subdivisions. It also includes any individual member,

regardless of the percentage of ownership, of any partnership, association, limited liability company, or corporation.

(W) "Place on probation" means to take action against a license or registration for a period of time determined by the board which imposes conditions or other requirements, or suspends or otherwise restricts some or all of the activities in which the licensee or registrant may engage.

(X) "Readily retrievable" means that records maintained in accordance with this chapter shall be kept in such a manner that, upon request, they can be produced for review no later than three business days to an agent, officer, or inspector of the board.

(Y) "Refuse to grant or renew" means to deny original or continued licensure or registration for a period of at least twenty-four months. After twenty-four months, or such period of time as the individual board order may require, a person licensed or registered by the board or a person seeking to attain such status by licensure or registration, and whose license or registration the state board of pharmacy has refused to grant or renew, may make application to the board for issuance of a new license. A person that seeks to attain such status by licensure or registration, whose license the state board of pharmacy has refused to grant or renew must meet all requirements established by the board in rule and as may be set forth in the person's board order.

(Z) "Registered" and "licensed" mean that a person has met the initial qualifications for a certificate of registration (registered) or license (licensed) with the state board of pharmacy under Chapter 4752. of the Revised Code and rules adopted thereunder and have complied with renewal procedures, including payment of applicable fees.

(AA) "Revoke" means to take action against a license or registration rendering such license or registration void and such license or registration shall not be reissued. Revoke is an action that is permanent against the licensee or registrant.

(BB) "Staff" means employees or their representatives of a licensee or registrant.

(CC) "Suspend" means to take action against a license or certificate of registration rendering such license or registration without force and effect for a period of time as determined by the state board of pharmacy.

(DD) "Summary suspension" means to take immediate action against a license or registration without a prior hearing rendering such license or registration without force and effect for a period of time as indicated in section [4752.09](#) of the Revised Code. The board may suspend a

license or registration issued pursuant to Chapter 4752. of the Revised Code by utilizing a telephone conference call to review the allegations and take a vote.

(EE) "Technologically sophisticated medical equipment" has the same meaning as defined in section [4752.01](#) of the Revised Code and includes the following:

- (1) Oxygen conservation devices;
- (2) CPAP (continuous positive airway pressure) devices;
- (3) High frequency chest wall oscillators (vests);
- (4) Intrapulmonary percussive ventilation (IPV) devices;
- (5) Intermittent positive pressure breathing (IPPB) devices;
- (6) Cough-assist mechanical in-exsufflator;
- (7) Apnea monitors;
- (8) Percussors for chest physiotherapy;
- (9) Suction machines;
- (10) Feeding pumps;
- (11) Infusion pumps;
- (12) Continuous passive motion (CPM) devices;
- (13) Custom seating or positioning systems;
- (14) Custom rehab equipment (e.g. standers & gait trainers);
- (15) Vacuum assisted wound closure devices;
- (16) Electric wheelchairs and custom scooters;
- (17) Auto-titrating airway devices; and
- (18) Any other technologically sophisticated medical equipment as determined by the board.

Rule 4729:11-2-01 | Licensure, registration and renewal.

(A) An applicant applying for licensure as a HME services provider shall:

(1) File an application with the board pursuant to rule 4729:11-2-03 of the Administrative Code; and

(2) Submit the required fee as established in paragraph (F) of this rule.

(3) To be licensed as a HME services provider, the applicant shall comply with the following:

(a) The applicant shall be physically located in Ohio. A HME services provider located outside the boundaries of the state of Ohio may only apply for a certificate of registration pursuant to paragraph (B) of this rule.

(b) Meet the minimum standards set forth in rule 4729:11-3-01 of the Administrative Code.

(c) Comply with all recordkeeping requirements in accordance with rule 4729:11-3-02 of the Administrative Code.

(d) Submit to an on-site inspection pursuant to rule 4729:11-3-03 of the Administrative Code.

(B) An applicant applying for a certificate of registration as a HME services provider shall:

(1) File an application with the board pursuant to rule 4729:11-2-03 of the Administrative Code.

(2) Submit the required fee as established in paragraph (F) of this rule.

(3) The applicant shall be accredited by the joint commission on accreditation of healthcare organizations or another national accrediting body recognized by the board in accordance with rule 4729:11-2-04 of the Administrative Code. Part of the registration process shall be an inquiry to the accrediting agency with which the entity is accredited. This information will be used as a part of the consideration in granting a registration.

(C) The persons listed in paragraphs (A) and (B) of this rule shall be a natural person that owns and/or operates the business entity applying for licensure or registration. In the event the applicant is not owned by a natural person, each business entity with an ownership interest in the applicant must be disclosed on the application up to and through the entity that is owned by a natural person.

(D) A license or registration expires at the end of the period for which it is issued and may be renewed. For purposes of issuing and renewing licenses, the board shall use a biennial licensing period that begins on the first day of July of each even-numbered year and ends on the thirtieth day of June of the next succeeding even-numbered year.

(E) A person who seeks to renew a license or registration shall submit an application for renewal, containing information as required by the board, and pay the required fee in accordance with paragraph (F) of this rule on or before the thirtieth day of June each even-numbered year.

(F) The board establishes the following non-refundable fees:

(1) All applications for initial and biennial renewal of a license shall include a fee no greater than one thousand two hundred dollars;

(2) All applications for initial and biennial renewal of a certificate of registration shall include a fee no greater than five hundred dollars.

(3) If an application for renewal of a license or certificate of registration is filed with the board after the renewal date, the applicant will be charged an additional late fee of two hundred dollars.

(4) If a complete application for renewal has not been submitted by the sixty-first day after the renewal date specified in this rule, the license or certificate of registration is considered void and cannot be renewed, but the holder may reinstate the licensure or registration in accordance with procedures specified by the board.

(G) A person that fails to renew a license or certificate or registration in accordance with this rule is prohibited from engaging in the provision of HME services.

(H) ~~On or before June 30, 2022, a~~ **A** HME services provider located outside the boundaries of the state of Ohio currently licensed under Chapter 4752. of the Revised Code shall obtain a registration as a HME services provider.

(J) Except as provided in division (B) of section 4752.02 of the Revised Code, no person shall provide home medical equipment services or claim to the public to be a home medical equipment services provider unless either of the following is the case:

(1) The person holds a valid license issued under this division;

(2) The person holds a valid certificate of registration issued under this division.

Rule 4729:1-3-02 | Immunization administration by pharmacists. (AMEND)

(A) A course in the administration of immunizations developed pursuant to division (B)(1) of section [4729.41](#) of the Revised Code shall meet 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 shall be conducted by an accreditation council for pharmacy education (ACPE) accredited provider.

(4) The course must be a minimum of five hours in length and include the following:

(a) A review of immunology that includes a discussion of the body's immune system reaction to immunizations.

(b) A review of each immunization recommended by the **advisory** committee on immunization practices of centers for disease control and prevention in the United States department of health and human services (~~8/5/2022~~) (6/28/2024) that includes the following:

(i) Disease states associated with the immunization;

(ii) Type or nature of activity of the immunization;

(iii) Administration schedules;

(iv) Routes of administration;

(v) Injection sites;

(vi) Dosages;

(vii) Monitoring and treatment of the patient for adverse reactions, including the use of diphenhydramine and epinephrine;

(viii) Patient populations;

(ix) Precautions and contraindications; and

- (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.

(5) The course must provide a method to evaluate the successful comprehension of the content.

(6) The course must provide a method to demonstrate the participant has successfully completed the course.

(B) Courses on immunization administration may be reviewed by the state board of pharmacy. A training course that fails to comply with the requirements set forth in this rule shall be considered in violation of this rule.

(C) Failure to adhere to the standard of care for administration of an immunization shall be considered a violation of this rule and may subject a pharmacist to discipline in accordance with rule [4729:1-4-01](#) of the Administrative Code.

(D) Pursuant to section [4729.41](#) of the Revised Code, a **physician prescriber**-established protocol for the administration of immunizations shall include the following:

- (1) For each immunization authorized:
 - (a) Name and strength;
 - (b) Precautions and contraindications;
 - (c) Intended audience or patient population;
 - (d) Dosage;
 - (e) Administration schedules;
 - (f) Routes of administration; and
 - (g) Injection sites.

(2) The length of time the pharmacist, ~~or a~~ pharmacy intern, **certified pharmacy technician or registered pharmacy technician** 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 **authorizing prescriber physician**. The location of the observation shall be in the general vicinity of the administering pharmacist, ~~or~~ pharmacy intern, **certified pharmacy technician or registered pharmacy technician** 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 primary care provider or the applicable board of health within thirty days after administering an immunization, except for influenza immunizations administered to individuals eighteen years of age and older.

(5) The locations that a pharmacist, ~~or~~ pharmacy intern, **certified pharmacy technician or registered pharmacy technician** under the direct supervision of a pharmacist may engage in the administration of immunizations.

(E) All **prescriber-physician**-established protocols must be signed and dated by the **physician prescriber** prior to implementation and maintained by the terminal distributor of dangerous drugs. The protocols shall be renewed by a **physician prescriber** on a biennial basis.

(1) A **physician prescriber** may sign one protocol for multiple locations licensed as terminal distributors of dangerous drugs.

(2) Each location licensed as a terminal distributor of dangerous drugs shall maintain a copy of the protocol on-site for inspection by an agent, inspector or employee of the state board of pharmacy.

(F) Upon the request of the state board of pharmacy, a pharmacist or terminal distributor of dangerous drugs shall immediately provide the protocols for immunizations. The state board of pharmacy, after review, may approve the protocol or return it to the pharmacist or terminal distributor for revision without approval. If a protocol has been returned for revision without approval, it may not be implemented until the board has granted approval.

(G) A pharmacist may administer the following immunizations in accordance with section 4729.41 of the Revised Code and this rule:

(1) ~~In the case of administer to an individual who is seven five years of age or older but not more than thirteen years of age, administer to the individual an immunization for any of the following:~~

~~(a) Influenza;~~

~~(b) COVID-19;~~

~~(c) Any other disease, but only pursuant to a prescription.~~

~~(2) In the case of an individual who is thirteen years of age or older, administer to the individual an immunization for any disease, including an immunization for influenza or COVID-19.~~

(G) A pharmacist, in accordance with section 4729.41 of the Revised code and this rule, may administer to an individual who is five years of age or older an immunization for any disease, including an immunization for influenza or COVID-19.

(H) A pharmacist shall obtain informed consent pursuant to rule [4729:5-5-04](#) of the Administrative Code to administer an immunization.

(I) Immunization records shall be maintained in accordance with rule [4729:5-5-04](#) of the Administrative Code.

(J) A pharmacist shall comply with the vaccine information statement requirements of the National Vaccine Childhood Injury Act, 42 USC Section 300aa-26 (12/14/1993).

(K) For each immunization administered to an individual by a pharmacist, other than an immunization for influenza administered to an individual eighteen years of age or older, the pharmacist shall notify the individual's primary care provider or, if the individual has no primary care provider, 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. Notification shall be conducted using one of the following methods that is capable of confirming delivery of the required notification:

(1) Electronic mail;

(2) Interoperable electronic medical records system;

(3) Facsimile;

(4) Electronic prescribing system;

(5) Electronic pharmacy record system;

(6) Documented verbal communication;

(7) Reporting to the state's immunization registry; or

(8) Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.

(L) For each immunization administered by a pharmacist to an individual who is younger than eighteen years of age, the pharmacist shall inform the individual's parent or legal guardian of the importance of well child visits with a pediatrician or other primary care provider and shall refer patients when appropriate.

~~(L)~~ **(M)** A pharmacist administering immunizations in accordance with this rule shall receive and maintain certification to perform basic life-support procedures by successfully completing a basic life-support training course certified by the American red cross, American heart association, **American safety and health institute**, or other training course approved by the board. Certification shall be obtained and maintained through courses that are conducted in-person or, at a minimum, offer an in-person or electronic hands-on training component.

~~(M)~~ **(N)** A pharmacist who completed a course in the administration of immunizations that complied with the training requirements in effect immediately prior to the adoption of this rule shall be deemed in compliance with division (B)(1) of section [4729.41](#) of the Revised Code.

~~(N)~~ **(O)** A pharmacist shall maintain the following records on file at the location(s) where the pharmacist administers immunizations in accordance with this rule:

(1) Proof of successful completion of a training course specified in paragraph (A) of this rule; and

(2) Proof of maintenance of certification to perform basic life-support procedures in accordance with paragraph (M) of this rule.

~~(O)~~ **(P)** As part of engaging in the administration of immunizations or supervising an individual authorized to administer immunizations, a pharmacist may administer epinephrine or diphenhydramine, or both, to individuals in emergency situations resulting from adverse reactions to the immunizations administered by the pharmacist or other authorized individuals under the supervision of the pharmacist.

(Q) As used in this rule, "prescriber" means either:

(1) A physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery or

(2) A certified nurse-midwife, clinical nurse specialist, or certified nurse practitioner licensed under Chapter 4723. of the Revised Code.

Rule 4729:2-3-03 | Immunization administration by pharmacy interns. (AMEND)

(A) Pharmacy interns working under the direct supervision of a pharmacist may administer immunizations listed in paragraph (C) of this rule if an intern complies with the following:

(1) Successfully completes a course in the administration of immunizations that meets the requirements set forth in rule [4729:1-3-02](#) of the Administrative Code.

(2) Practices in accordance with a definitive set of treatment guidelines specified in a protocol established by a **physician prescriber** that complies with the requirements of rule [4729:1-3-02](#) of the Administrative Code.

(3) Receives and maintains certification to perform basic life-support procedures by successfully completing a basic life-support training course certified by the American red cross, American heart association, **American safety and health institute**, or other training course approved by the board. Certification shall be obtained and maintained through courses that are conducted in-person or, at a minimum, offer an in-person or electronic hands-on training component.

(4) The supervising pharmacist has completed all of the training necessary to administer immunizations in accordance with rule [4729:1-3-02](#) of the Administrative Code.

(B) Failure to adhere to the standard of care for administration of an immunization shall be considered a violation of this rule and may subject a pharmacy intern to discipline in accordance with rule [4729:2-4-01](#) of the Administrative Code.

(C) A pharmacy intern working under the direct supervision of a pharmacist may administer the same immunizations authorized for pharmacist administration as authorized by section [4729.41](#) of the Revised Code and rule [4729:1-3-02](#) of the Administrative Code.

(D) A pharmacy intern shall obtain informed consent pursuant to rule [4729:5-5-04](#) of the Administrative Code to administer an immunization.

(E) A pharmacy intern shall comply with the vaccine information statement requirements of the National Vaccine Childhood Injury Act, 42 USC Section 300aa-26 (12/14/1993).

(F) For each immunization administered to an individual by a pharmacy intern, other than an immunization for influenza administered to an individual eighteen years of age or older, the pharmacy intern shall notify the individual's primary care provider or, if the individual has no primary care provider, 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. Notification shall be conducted using one of the following methods that is capable of confirming delivery of the required notification:

- (1) Electronic mail;
- (2) Interoperable electronic medical records system;
- (3) Facsimile;
- (4) Electronic prescribing system;
- (5) Electronic pharmacy record system;
- (6) Documented verbal communication;
- (7) Reporting to the state's immunization registry; or
- (8) Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.

(G) For each immunization administered by a pharmacy intern to an individual who is younger than eighteen years of age, the pharmacy intern shall inform the individual's parent or legal guardian of the importance of well child visits with a pediatrician or other primary care provider and shall refer patients when appropriate.

~~(G)~~ (H) A pharmacy intern shall maintain the following records on file at the location(s) where the pharmacy intern administers immunizations in accordance with this rule:

- (1) Proof of successful completion of a training course specified in paragraph (A)(1) of this rule; and
- (2) Proof of maintenance of certification to perform basic life-support procedures in accordance with paragraph (A)(3) of this rule.

Rule 4729:3-3-06 | Immunization administration by certified and registered pharmacy technicians. (AMEND)

~~(A) A certified or registered pharmacy technician who meets the requirements of paragraph (B) of this rule and is working under the direct supervision of a pharmacist who meets the requirements of rule 4729:1-3-02, may do any of the following:~~

~~(1) In the case of administer to an individual who is seven five years of age or older but not more than thirteen years of age, administer to the individual an immunization for any of the following:~~

~~(a) Influenza;~~

~~(b) COVID-19;~~

~~(c) Any other disease, but only pursuant to a prescription.~~

~~(2) In the case of an individual who is thirteen years of age or older, administer to the individual an immunization for any disease, including an immunization for influenza or COVID-19.~~

(A) A certified or registered pharmacy technician who meets the requirements of paragraph (B) of this rule and is working under the direct supervision of a pharmacist who meets the requirements of rule 4729:1-3-02 of the Administrative Code, may:

(1) Administer to an individual who is five years of age or older an immunization for any disease, including an immunization for influenza or COVID-19.

~~(3) (2) The pharmacist on duty who is supervising the technician may prohibit, limit, or restrict the type of immunizations administered, including the age of the patient, by the technician.~~

(B) For a certified or registered pharmacy technician to be authorized to engage in the administration of immunizations, comply with all the following requirements:

(1) Complete a practical training program that meets the requirements set forth in paragraph (C) of this rule.

(2) Administer immunizations authorized by a **physician prescriber**-established protocol that meets the requirements of rule 4729:1-3-02 of the Administrative Code.

(3) Be authorized by the supervising pharmacist to administer immunizations. The supervising pharmacist may restrict the type of immunizations provided by a certified or registered technician.

(4) Receive and maintain certification to perform basic life-support procedures by successfully completing a basic life-support training course certified by the American red cross, American heart association, **American safety and health institute**, or other training course approved by the board. Certification shall be obtained and maintained through courses that are

conducted in- person or, at a minimum, offer an in-person or electronic hands-on training component.

(5) The pharmacist on duty who is supervising the technician shall be on-site to administer epinephrine or diphenhydramine, or both, to individuals in emergency situations resulting from adverse reactions to the immunizations administered by the registered or certified pharmacy technician.

(6) The pharmacist on duty who is supervising the technician determines if the technician is competent to administer immunizations.

(C) A course in the administration of immunizations developed pursuant paragraph (B) of this rule shall meet 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 shall be conducted by an accreditation council for pharmacy education (ACPE) accredited provider.

(4) The course must be a minimum of six hours in length and include, at a minimum, the following topic areas:

(a) A review of immunology that includes a discussion of the body's immune system reaction to immunizations.

(b) A review of each immunization 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 **(6/28/2024)**~~(8/5/2022)~~:

(i) Disease states associated with the immunization;

(ii) Type or nature of activity of the immunization;

(iii) Administration schedules;

(iv) Routes of administration;

(v) Injection sites;

(vi) Dosages;

(vii) Monitoring and treatment of the patient for adverse reactions;

(viii) Patient populations;

(ix) Precautions and contraindications; and

- (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.
- (5) The course must provide a method to evaluate the successful comprehension of the content.
- (6) The course must provide a method to demonstrate the participant has successfully completed the course.
- (D) Courses on immunization administration may be reviewed by the state board of pharmacy. A training course that fails to comply with the requirements set forth in this rule shall be considered in violation of this rule.
- (E) The pharmacy employing the technician shall ensure informed consent is obtained pursuant to rule 4729:5-5-04 of the Administrative Code prior to the administration of an immunization.
- (F) The pharmacy employing the technician shall ensure the technician maintains the competency and skills necessary to safely administer immunizations. The pharmacy shall ensure the technician has initial and annual documented assessment of competency in immunization administration.
- (G) Immunization records shall be maintained in accordance with rule 4729:5-5-04 of the Administrative Code.
- (H) The pharmacy where a technician is administering immunizations in accordance with this rule shall comply with the vaccine information statement requirements of the National Vaccine Childhood Injury Act, 42 USC Section 300aa-26 (12/14/1993).
- (I) For each immunization administered to an individual by a certified or registered pharmacy technician, other than an immunization for influenza administered to an individual eighteen years of age or older, the pharmacy employing the technician shall be responsible for ensuring the notification of the individual's primary care provider or, if the individual has no primary care provider, 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. Notification shall be conducted using one of the following methods that is capable of confirming delivery of the required notification:
 - (1) Electronic mail;

- (2) Interoperable electronic medical records system;
- (3) Facsimile;
- (4) Electronic prescribing system;
- (5) Electronic pharmacy record system;
- (6) Reporting to the state's immunization registry;
- (7) Documented verbal communication; or
- (8) Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.

(J) For each immunization administered by a certified pharmacy technician or registered pharmacy technician to an individual who is younger than eighteen years of age, the certified pharmacy technician or registered pharmacy technician shall inform the individual's parent or legal guardian of the importance of well child visits with a pediatrician or other primary care provider and shall refer patients when appropriate.

~~(J)~~ **(K)** The pharmacy employing a certified or registered technician authorized to provide immunizations in accordance with this rule, shall maintain, or have immediate access to, the following records on file at the location(s) where the pharmacy technician administers immunizations in accordance with this rule:

- (1) Proof of successful completion of a training course specified in paragraph (C) of this rule;
- (2) Proof of maintenance of certification to perform basic life-support procedures in accordance with paragraph (B)(4) of this rule; and
- (3) Proof of competency assessments as required in paragraph (F) of this rule.

~~(K)~~ **(L)** A pharmacist practicing within an outpatient pharmacy shall not supervise more than three pharmacy personnel engaged in the administration of immunizations pursuant to this rule and rule 4729:2-3-03 of the Ohio Administrative Code.

~~(L)~~ **(M)** A pharmacist supervising an immunization clinic outside of an outpatient pharmacy shall not supervise more than six pharmacy personnel engaged in the administration of immunizations pursuant to this rule and rule 4729:2-3-03 of the Ohio Administrative Code.