Mike DeWine, Governor Jon Husted, Lt. Governor Steven W. Schierholt, Executive Director

## **Rules & Resolutions - July 2024**

#### Resolutions

\*Indicates resolutions was authorized by the Board President in accordance with a Board resolution adopted on May 5, 2020.

## \*1) Temporary Authorization for the Use of Non-Ohio Licensed Pharmacy Personnel by Walgreens

To mitigate any possible delays due to the closure of Ohio Rite Aid stores, the Ohio Board of Pharmacy hereby authorizes non-Ohio licensed pharmacy personnel employed by Walgreens licensed in other states to work in Ohio Walgreens or Rite Aid stores under certain conditions. This authorization is being issued in accordance with a Board resolution adopted on May 5, 2020.

For the purposes of this authorization, "non-Ohio licensed pharmacy personnel" means an individual who is licensed or registered as a pharmacist, pharmacy intern, or pharmacy technician in another state or jurisdiction, but who does not hold an active Ohio license or registration.

This authorization shall be in effect from the date it is signed by a representative of Walgreens and shall remain in effect until July 31, 2024, upon which all Walgreens pharmacists, pharmacy interns, and pharmacy technicians must be appropriately licensed in accordance with Chapter 4729. of the Revised Code.

Pharmacy personnel employed by Walgreens who are not licensed/registered in Ohio, but currently licensed and in good standing in another state, may practice pharmacy in this state under the following conditions:

1. Walgreens shall verify that all non-Ohio licensed personnel are in good standing prior to commencing work in this state. Verification may be done using the online licensing system of the state in which the pharmacy personnel were originally licensed or registered. If licensed/registered in multiple states, verification must be conducted in the state where the individual primarily practices.



**NOTE:** "In good standing" means the pharmacist does not have a license, registration or certificate limited, on probation, suspended, or revoked by any public agency or licensing agency. "State" means a state of the United States, the District of Columbia, the Commonwealth of Puerto Rico or a territory or insular possession subject to the jurisdiction of the United States.

Verification documentation must be maintained by Walgreens for three years in a readily retrievable manner (i.e. must be produced for review no later than three business days to an agent, officer or inspector of the Board).

- **2.** Walgreens acknowledges that any non-Ohio licensed pharmacy personnel shall be the responsibility of the terminal distributor of dangerous drugs that employs the personnel. Any violations of Ohio laws and rules by non-Ohio licensed pharmacy personnel shall be attributed to the pharmacy licensed as a terminal distributor of dangerous drugs.
- **3.** Walgreens is responsible for training non-Ohio licensed pharmacy personnel to comply with the requirements of Ohio laws and rules governing the practice of pharmacy and the distribution of dangerous drugs.
- **4.** A non-Ohio licensed pharmacy technician may only practice as a registered pharmacy technician, unless the technician holds a current certification from <a href="NHA">NHA</a> (ExCPT) or <a href="PTCB">PTCB</a>.
- **5.** Walgreens must submit notification to the Board prior to the start of non-Ohio licensed pharmacy personnel starting work in Ohio. Notification must be submitted using the <u>Out of State Pharmacy Personnel Notification Form</u> (included with this authorization).

**IMPORTANT:** The notification form must be submitted in advance. Pharmacies that have identified potential personnel are encouraged to submit these individuals now rather than waiting until operational needs necessitate out-of-state personnel.

## 2) Licensure Verification for Institutional Pharmacies Restocking EMS Organizations

To ensure compliance with the licensure verification requirements of OAC 4729:5-3-04 and to reduce operational burden, the Ohio Board of Pharmacy hereby adopts the following resolution for institutional pharmacies owned or operated by Ohio hospitals:

An institutional pharmacy that is owned or operated by a hospital for purposes of restocking an emergency medical services vehicle may satisfy the licensure verification requirements of OAC 4729:5-3-04 by conducting an annual query to ensure the EMS organization is properly licensed as a terminal distributor of dangerous drugs. This resolution shall remain in effect until rescinded by the Board or upon amendment of OAC 4729:5-3-04.

## For filing with CSI and JCARR

## Rule 4729:5-3-04 | Verification of licensure prior to sale or purchase. (AMEND)

- (A) Before a terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor shall query the **boards board's** online roster (available on the **boards board's** website: www.pharmacy.ohio.gov) to confirm any of the following:
- (1) The seller is licensed to engage in the sale of dangerous drugs in accordance with section <u>4729.52</u> of the Revised Code; or
- (2) The seller is licensed to engage in the occasional sale or distribution of dangerous drugs at wholesale in accordance with rule <u>4729:5-3-09</u> of the Administrative Code.
- (B) If no documented query is conducted before a purchase is made, it shall be presumed that the purchase of dangerous drugs by the terminal distributor is in violation of section 4729.51 of the Revised Code.

If a licensed terminal distributor of dangerous drugs conducts a documented query at least annually and relies on the results of the query in purchasing dangerous drugs, the terminal distributor shall be deemed not to have violated section <u>4729.51</u> of the Revised Code in making the purchase.

- (C) Before a terminal distributor of dangerous drugs may make a sale of dangerous drugs pursuant to rule <u>4729:5-3-09</u> of the Administrative Code, the terminal distributor shall query the **boards board's** online roster (available on the **boards board's** website: www.pharmacy.ohio.gov) to determine if the purchaser is licensed as either:
- (1) A terminal distributor of dangerous drugs.

For a limited terminal distributor of dangerous drugs license, a terminal distributor shall also review a current version of the <u>licensee's</u> <del>licensees</del> drug list to ensure the purchaser is authorized to possess the drugs ordered.

- (2) A distributor of dangerous drugs in accordance with division 4729:6 of the Administrative Code.
- (D) Paragraph (C) of this rule does not apply when a terminal distributor sells or distributes dangerous drugs at wholesale to any of the following:
- (1) A terminal distributor, manufacturer, outsourcing facility, third-party logistics provider, repackager, or wholesale distributor that is located in another state, is not engaged in the sale

of dangerous drugs within this state, and is actively licensed to engage in the sale of dangerous drugs by the state in which the distributor conducts business; or

- (2) Any of the exempted persons described in section <u>4729.541</u> of the Revised Code.
- (3) The sale, transfer, or distribution of dangerous drugs to an EMS organization from an institutional pharmacy licensed as a terminal distributor of dangerous drugs that is owned or operated by a hospital for purposes of restocking an emergency medical services vehicle if the institutional pharmacy conducts an annual query to ensure the EMS organization is properly licensed as a terminal distributor of dangerous drugs.
- (E) A terminal distributor of dangerous drugs may make a sale of a dangerous drug to any of the exempted persons described in section <u>4729.541</u> of the Revised Code in accordance with rule <u>4729:5-3-09</u> of the Administrative Code and shall ensure the purchaser meets the exemption criteria. To confirm a purchaser meets the exemption criteria, the terminal drug distributor shall comply with the all the following:
- (1) Provide the purchaser, in a manner determined by the board, the requirements in Ohio law of when a purchaser shall hold a license as a terminal distributor of dangerous drugs;
- (2) If the purchaser is a prescriber, verify the prescriber is appropriately licensed in this state to prescribe drugs or dangerous drugs or drug therapy related devices in the course of the individual's professional practice;
- (3) Require the purchaser who claims an exemption to the terminal distributor of dangerous drug licensing requirement to annually attest in writing, which may include an electronic signature, that the purchaser meets the licensing exemptions in section <u>4729.541</u> of the Revised Code; and
- (4) Ensure that all attestations are maintained by the terminal distributor for a period of three years following the date the attestation is signed by the purchaser.

#### Rule 4729:5-5-04 | Record keeping. (AMEND)

- (A) There shall be positive identification of the licensed or registered individuals responsible for performing the following activities authorized under Chapter 4729. of the Revised Code and agency 4729 of the Administrative Code:
- (1) Prescription information entered into the record keeping system. This provision shall take effect one-year from the effective date of this rule.
- (2) Verification by the pharmacist of the prescription information entered into the record keeping system.
- (3) Prospective drug utilization review, which shall be captured as a standalone action or as part of either:
- (a) The pharmacist verification of prescription information in paragraph (A)(2) of this rule; or
- (b) The dispensing process in paragraph (A)(4) of this rule.
- (4) Dispensing.
- (5) Compounding.
- (6) Administering immunizations pursuant to section <u>4729.41</u> of the Revised Code.
- (7) Administering injectable drugs pursuant to section <u>4729.45</u> of the Revised Code.
- (8) Prescription information transcribed from an order received by telephone, facsimile, or recording device.
- (9) Any changes or annotations made to a prescription.
- (B) All records maintained in accordance with this rule shall be uniformly maintained for a period of three years.
- (C) Record keeping systems shall provide immediate retrieval via digital display and hard copy printout or other mutually agreeable transfer medium of information for all prescriptions dispensed within the previous twelve months and shall provide, in a manner that is readily retrievable, information on all prescriptions dispensed beyond the previous twelve months but within the previous three years. This information shall include, at a minimum, the following data:
- (1) The original prescription number;
- (2) Date of issuance of the original prescription order by the prescriber;

- (3) Full name of the patient for whom the drug is intended; or, if the patient is an animal, the last name of the owner, name of animal (if applicable), and species of the animal or animals;
- (4) Residential address, including the physical street address and telephone number of the patient or owner;
- (5) Full name and address of the prescriber, including the physical address of the prescriber's practice location;
- (6) The prescriber's credential (MD, DDS, DVM, etc.), if indicated on the prescription;
- (7) Directions for use;
- (8) The brand name, if any, or the generic name and the name of the manufacturer or distributor or national drug code of the drug or device dispensed;
- (9) The strength, dosage form, and quantity of the drug or device dispensed;
- (10) The prescriber's federal drug enforcement administration number, if applicable;
- (11) The positive identification of the persons performing specific actions pursuant to paragraph (A) of this rule;
- (12) The total number of refills authorized by the prescriber;
- (13) The date of dispensing;
- (14) The refill history of the prescription, including all of the following:
- (a) The prescription number;
- (b) The brand name, if any, or the generic name and the name of the manufacturer or distributor or national drug code of the drug or device dispensed;
- (c) The date(s) of dispensing; and
- (d) The quantity dispensed.
- (D) Except as provided in paragraphs (N) and (O) of this rule, a pharmacy that utilizes a computerized system to dispense dangerous drugs that is unable to shall electronically document positive identification in accordance with paragraph (A) of this rule. If a pharmacy does not use a computerized system to dispense dangerous drugs or has obtained a waiver pursuant to paragraph (N) of this rule, the pharmacy shall be required to maintain hard copy documentation. Hard copy documentation shall be provided by each registered or licensed individual who makes use of such system by one of the following methods:

- (1) A hard copy printout of each day's prescription data.
- (a) The printout shall include, at a minimum, the following data:
- (i) Date of dispensing;
- (ii) Prescription number;
- (iii) Patient name;
- (iv) Name, strength, and quantity of drug dispensed;
- (v) Identification of the pharmacist or pharmacy personnel responsible for any activity described in paragraph (A) of this rule;
- (vi) Identification of the pharmacy; and
- (vii) Identification of controlled substances.
- (b) The printout must be verified, dated, and signed by each individual responsible for any activity described in paragraph (A) of this rule. The printout must be verified and manually signed by the individual within a reasonable timeframe to ensure the accuracy of the record.
- (c) If the printout is prepared at a location other than where the drug was dispensed, the printout must be provided to the licensed location within three business days of the date on which the drugs were dispensed. Such printouts must be verified and signed by each individual responsible for any activity described in paragraph (A) of this rule within twenty-four hours of the date the printout is received by the individual.
- (d) The printout must be readily retrievable and maintained in chronological order in a separate file at the licensed location where the drug was dispensed for a period of three years from the date of dispensing.
- (e) The signed printout may be stored electronically in accordance with paragraph (E) of this rule.
- (2) A tamper evident log book.
- (a) Each individual pharmacist involved in dispensing drugs must enter into a tamper evident log book the following data for each prescription dispensed:
- (i) Date of dispensing;
- (ii) Prescription number;
- (iii) Patient name;

- (iv) Name, strength, and quantity of drug dispensed;
- (v) Identification of the pharmacist and pharmacy personnel responsible for any activity described in paragraph (A) of this rule;
- (vi) Identification of controlled substances.
- (b) Each individual responsible for any activity described in paragraph (A) of this rule shall review this information at the end of each day, or at the end of the individual's shift, and must either:
- (i) Manually sign a statement in the log book attesting to the fact that the prescription information entered into the computer that day and recorded in the log book has been reviewed by the individual and is correct as shown; or
- (ii) Manually initial each entry of the log book to indicate that the prescription information entered into the computer that day and recorded in the log book has been reviewed by the individual and is correct as shown.
- (c) The log book must be readily retrievable and maintained at the licensed location where the drug was dispensed for a period of three years from the date of dispensing.
- (E) A signed printout that is maintained in accordance with paragraph (D) of this rule may be electronically created and maintained, provided the system creates and maintains the printout in accordance with the following:
- (1) All information in the printout shall be scanned in full color (i.e., retains color information and/or color graphics in the document) via technology designed to capture information in one form and reproduce it in an electronic medium presentable and usable to an end user;
- (2) A record or image once created shall be unalterable but may be annotated as necessary so long as the original record or image is still available for review and the individual that made the annotation is noted;
- (3) Contains security features to prevent unauthorized access to the records;
- (4) Contains daily back-up functionality to protect against record loss.
- (F) In addition to the immediate retrieval and production of prescription information required by paragraph (C) of this rule, an outpatient pharmacy that utilizes a computerized record keeping system shall comply with the following:
- (1) Make readily retrievable the following information:

- (a) An electronic record in a character-delimited or fixed-width ASCII text file or other mutually acceptable format that contains any requested data fields the pharmacy is responsible for maintaining pursuant to all federal and state laws, rules and regulations; and
- (b) A hard copy printout sorted by any requested data fields that the pharmacy is responsible for maintaining pursuant to all federal and state laws, rules, and regulations.
- (2) Make readily available upon request by an individual authorized by law to access such records any of the following:
- (a) A printout; or
- (b) An electronic record and a definition file describing the file layout and column width, if applicable.
- (3) All computerized record keeping systems shall be able to capture records edited by authorized personnel and maintain an audit trail.
- (G) In the event that a pharmacy utilizes a computerized record keeping system that experiences an outage, the pharmacy must have an auxiliary procedure which will be used for documentation of refills of prescription orders.
- (1) This auxiliary procedure must ensure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data is recorded and retained.

# (2) This auxiliary procedure may utilize hardcopy records and manual signatures to capture positive identification.

- (3) Nothing in this paragraph shall preclude a pharmacist from dispensing a refill if, in the exercise of the pharmacist's professional judgement, failure to dispense or sell the drug to the patient could result in harm to the health of the patient.
- (H) Prescriptions entered into a computer system that are not dispensed shall meet all of the following requirements:
- (1) The complete prescription information must be entered in the computer system;
- (2) The information must appear in the patient's profile;
- (3) There is positive identification of the person who is responsible for entering the prescription information into the system and the pharmacist responsible for verifying the prescription information in accordance with paragraph (A) of this rule;

- (4) The prescription must be assigned a prescription number; and
- (5) The original prescription is filed according to rule 4729:5-5-03 of the Administrative Code.
- (I) Records shall be maintained for three years and made readily retrievable for all immunizations administered in accordance with section <u>4729.41</u> of the Revised Code and rules <u>4729:1-3-02</u> and <u>4729:2-3-03</u> of the Administrative Code and shall include the following information:
- (1) Full name and address of the patient;
- (2) Patient's date of birth or age;
- (3) Patient's applicable allergy information;
- (4) Date of administration;
- (5) Name, strength, and dose of the immunization administered;
- (6) Lot number and expiration date of the immunization;
- (7) Route of administration;
- (8) Location of the injection site;
- (9) Positive identification of the administering pharmacist or the administering pharmacy intern<u>or pharmacy technician</u> and supervising pharmacist;
- (10) Identification of the patient, parent, or legal guardian of the patient who gives informed consent to administer the immunization.
- (J) Immunization records may be electronically created and maintained if done so in accordance with the standards set forth in paragraph (E) of this rule.
- (K) A pharmacist may document the pharmacist's own administration of an immunization or an immunization administered by a pharmacy intern the pharmacist is personally supervising on a prescription form, which may be assigned a number for record keeping purposes.
- (L) Records shall be maintained for three years and made readily retrievable for all dangerous drugs administered in accordance with section <u>4729.45</u> of the Revised Code and rule <u>4729:1-3-03</u> of the Administrative Code and shall include the following information:
- (1) Full name and address of the patient;
- (2) Patient's date of birth or age;

- (3) Patient's applicable allergy information;
- (4) Date of administration;
- (5) Name, strength, and dose of the drug administered;
- (6) Lot number and expiration date of the drug;
- (7) Route of administration;
- (8) Location of the injection site;
- (9) Documentation of test results required prior to the administration of an opioid antagonist in accordance with rule 4729:1-3-03 of the Administrative Code;
- (10) Required physician notification pursuant to rule 4729:1-3-03 of the Administrative Code;
- (11) Positive identification of the administering pharmacist; and
- (12) Identification of the person who provides permission to administer the dangerous drug pursuant to rule <u>4729:1-3-03</u> of the Administrative Code.
- (M) Dangerous drug administration records may be electronically created and maintained if done so in accordance with the standards set forth in paragraph (E) of this rule.
- (N) A waiver of the requirement for electronic positive identification in paragraph (D) of this rule may be granted by the board upon written request of a pharmacy.
- (1) The request shall include all information, as specified by the board, to determine if it is in the public interest to waive the electronic positive identification requirement. The board reserves the right to request additional information from the pharmacy and conduct an inspection of the pharmacy pursuant to rule 4729:5-3-03 of the Administrative Code prior to rendering its decision.
- (a) The pharmacy must demonstrate that the requirement of electronic positive identification would impose an undue economic hardship and that the proposed system of recording positive identification is sufficient to ensure safety to the public and to patients given the pharmacy's prescription volume and staffing.
- (2) If the board approves a waiver, the pharmacy shall retain the waiver until there is a change of ownership or the pharmacy acquires a new computerized system to dispense dangerous drugs or there is a significant increase in the pharmacy's prescription volume, unless otherwise determined by the board.

- (2) If the board approves a waiver it shall remain in effect until the pharmacy acquires a new computerized system to dispense dangerous drugs or there is a significant increase in the pharmacy's prescription volume, unless otherwise determined by the board.
- (3) A pharmacy that is denied a waiver by the board will be provided with a written explanation of the denial.
- (4) In determining whether to grant the waiver, the board shall consider, at a minimum, all of the following:
- (a) Whether the requirement to implement electronic positive identification will be cost prohibitive so as to impact the continued viability of the business;
- (b) The average number of dangerous drugs dispensed at the pharmacy to determine the reliability of a non-electronic method of positive identification;
- (c) The results of an inspection authorized in accordance with rule 4729:5-3-03 of the Administrative Code; and
- (d) A review of past disciplinary actions taken against the pharmacy, or against an individual while employed by the licensee, that are based, in whole or in part, on drug security, record keeping violations, errors in dispensing, and/or any other disciplinary actions deemed relevant to the board's analysis.
- (O) A pharmacy that utilizes a computerized system to dispense dangerous drugs may use hardcopy records and manual signatures to capture positive identification for any of the following:
- (1) Compounding and the dispensation of compounded drugs; and
- (2) Ancillary services as defined in rule 4729:5-5-02.1 of the Administrative Code.

**Proposed Rationale:** The Board received one external comment from Nationwide Children's Hospital supporting the amendments to the proposed rules. There is one update in a new proposed paragraph (N)(2) that clarifies the waiver is valid until the pharmacy adopts a new computer system or experiences a significant increase in prescription volume. The previous version of this rule made the waiver expire upon a change of ownership. However, a change of ownership does not necessarily indicate the waiver issued by the Board should no longer be valid. Therefore, staff a recommending a change to paragraph (N)(2) that would invalidate a waiver if the pharmacy experiences an significant increase prescription volume rather than a change of ownership.

## Rule 4729:5-14-01 | Emergency Medical Services - Definitions. (AMEND)

- (A) "Business day" means any day other than Saturday, Sunday, or a holiday recognized by the state of Ohio in which the offices of the board of pharmacy are not open for business.
- (B) "Certificate to practice" means the level to which an individual is trained and licensed as defined in sections 4765.01, 4765.011 and 4765.30 of the Revised Code and rule 4765-1-01 of the Administrative Code.
- (B) "Certificate to practice" means the certificate to practice as an emergency medical responder, emergency medical technician, advanced emergency medical technician, or paramedic issued by the division of emergency medical services within the department of public safety pursuant to section 4765.30 of the Revised Code and Chapter 4765-8 of the Administrative Code.
- (C) "Direct supervision" or "personal supervision" means EMS organization personnel shall be physically present at the licensed location or within the immediate proximity of an EMS unit.
- (D) "Electronic signature" means any of the following attached to or associated with an electronic drug administration record by EMS organization personnel to authenticate the drug administration record:
- (1) A private, unique personal identifier and secure passcode consisting of a combination of letters, numbers, and symbols that is adapted or executed by an individual as that individual's electronic signature.
- (2) An electronic image of an individual's handwritten signature that is captured following drug administration and is created by using a writing apparatus (i.e. stylus). The signature shall be legible and include the person's first name, last name, and credentials.
- (3) Any other method approved by the board.
- (E) "Emergency medical service organization," "EMS organization," or "emergency medical services agency" has the same meaning as in section 4765.01 of the Revised Code.
- (F) "Medical director" means a physician to whom an EMS organization has designated, pursuant to section 4765.42 of the Revised Code, to perform the duties of medical director including establishing medical protocols that must be followed in the delivery of emergency medical services.

The program medical director shall be registered with the United States drug enforcement administration pursuant to 21 U.S.C. 823 (12/7/2023).

(G) "Mutual aid" means a formal written agreement between two or more EMS organizations to assist in emergency medical coverage in the other's usual area of coverage, including having access to dangerous drugs during the emergency.

(H)

- (1) "Positive identification" means a method of identifying EMS personnel that does not rely solely on the use of a private personal identifier such as a password, but must also include a secure means of identification such as the following:
- (a) A manual signature on a hard copy record;
- (b) A magnetic card reader;
- (c) A bar code reader;
- (d) A biometric method;
- (e) A proximity badge reader;
- (f) A board-approved system of randomly generated personal questions;
- (g) A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who prescribed, administered, or dispensed the dangerous drug; or
- (h) Other effective methods for identifying individuals that have been approved by the board.
- (2) A method relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier, such as a password, for entry into a secure mechanical or electronic system.
- (H) "Program medical director" or "medical director" means a physician who is involved in the practice or supervision of emergency medicine in a hospital or prehospital setting in accordance with Chapter 4765. of the Revised Code and who advises the accredited institution or approved institution regarding the courses taught within an EMS training program or EMS continuing education program as set forth in section 4765.16 of the Revised Code and Chapter 4765-7 of the Administrative Code.

The program medical director shall be registered with the United States drugenforcement administration pursuant to 21 U.S.C. 823 (12/7/2023).

- (I) "Posting up" means locating an EMS unit containing dangerous drugs at a location other than a location licensed by the board of pharmacy for less than twenty-four hours and where the EMS unit is under the direct supervision of the EMS personnel on duty.
- (J) "Posting up at a special event" means locating an EMS unit containing dangerous drugs at a location other than a location licensed by the board of pharmacy for more than twenty-four consecutive hours pursuant to a formal agreement with the sponsors of the event and where the EMS unit is under the direct supervision of the EMS personnel on duty.
- (1) Posting up at a special event requires notification to the board. Notification shall be provided prior to the special event in a manner determined by the board.
- (2) The requirements of this paragraph do not apply in the event of an emergency management assistance compact or an emergency declared by the governor.
- (K) "Protocol" or "standing order" means a definitive set of written treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized and signed by the EMS organization's medical director. A protocol may be used only by licensed or certified EMS personnel, in accordance with the individual's scope of practice, when providing limited medical services to individuals in an emergency.
- (K) "Protocol" or "standing order" means a definitive set of written treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized and signed by the EMS organization's medical director. A protocol may be used only by licensed or certified EMS personnel or individuals licensed in accordance with Chapter 4723. of the Revised Code, in accordance with the individual's scope of practice, when providing limited medical services to individuals in an emergency.
- (L) "Readily retrievable" means that records maintained in accordance with this chapter shall be kept in such a manner that they can be separated out from all other records and, upon request, produced for review no later than three business days to an agent, officer, or inspector of the board.
- (M) "Responsible person" has the same meaning as defined in rule 4729:5-2-01 of the Administrative Code and is responsible for the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs, and maintaining all drug records otherwise required.

- (N) "Satellite" means a location licensed by the state board of pharmacy as a terminal distributor of dangerous drugs that is separate from the licensed headquarters of the EMS organization.
- (O) "Scope of practice" has the same meaning as defined in section 4765.35 of the Revised Code and rule 4765-12-04 of the Administrative Code for an emergency medical responder or first responder, section 4765.37 of the Revised Code, and rule 4765-15-04 of the Administrative Code for an emergency medical technician or emergency medical technician-basic; section 4765.38 of the Revised Code and rule 4765-16-04 of the Administrative Code for an advanced emergency medical technician or emergency medical technician-intermediate; and section 4765.39 of the Revised Code and rule 4765-17-03 of the Administrative Code for a paramedic or emergency medical technician-paramedic.
- (P) "Tamper-evident" means a package, storage container or other physical barrier is sealed or secured in such a way that access to the drugs stored within is not possible without leaving visible proof that such access has been attempted or made.
- (P) "Tamper-evident" means a storage container or other physical barrier is sealed or secured in such a way that access to the drugs stored within is not possible without leaving visible proof that such access has been attempted or made.
- (Q) "Verbal order" means an oral directive that is given through any method of communication including by radio or telephone, directly to an emergency medical services professional, to contemporaneously administer a dangerous drug, including a controlled substance, to individuals in need of emergency medical services outside the physical presence of the medical director or authorizing medical professional.

**Proposed Rationale:** The Board received one external comment from the Ohio Department of Public Safety, Division of EMS:

"These proposed rules introduce a new term, 'program medical director,' which is not used in Chapter 4765 and may create confusion."

This is a term used in the proposed DEA regulations. However, with those regulations not final, Board staff propose to revert to the previous version of medical director (see paragraph F and the deletion of paragraph H) that exists in current rule. The only addition to paragraph (F) is the requirement that the medical director have a registration with the United States Drug Enforcement Administration.