



**STATE OF
OHIO**
BOARD OF PHARMACY

Emergency Medical Services - Rules for Stakeholder Feedback

Date Issued: 3/4/2024

As part of its required 5-year rule review process, the Board proposes the rescission and replacement of all rules in Chapter 4729:5-14.

Please be advised that these proposed rules incorporate pending federal rule changes from the Drug Enforcement Administration. A copy of the proposed federal changes can also be found as an appendix to this document.

For information regarding the pending changes, visit:

<https://www.federalregister.gov/documents/2020/10/05/2020-21675/registering-emergency-medical-services-agencies-under-the-protecting-patient-access-to-emergency>

Comments on the proposed rules will be accepted until close of business on **Friday, April 12, 2024**. Please send all comments to the following email address:

RuleComments@pharmacy.ohio.gov.



Proposed OAC 4729:5-14:

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

(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 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) "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.

(G)

(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 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 drug enforcement 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 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) "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.

Rule 4729:5-14-02 | Licensure. (NEW)

(A) An EMS organization that possesses dangerous drugs shall apply for and maintain a license as a terminal distributor of dangerous drugs with an emergency medical services classification.

(1) The location that serves as the main station of the EMS organization will be deemed the headquarters. The headquarters shall be the location where records and drugs for distribution to satellite locations are maintained.

(2) Any satellite location associated with the headquarters of the EMS organization where dangerous drugs will be stored must be licensed as a terminal distributor of dangerous drugs.

(B) An application for licensure shall include all the following:

(1) A completed application;

(2) A copy of the organization's protocols signed by the program medical director;

(3) A list of the dangerous drugs, or drug list, that may be possessed and administered by EMS organization personnel, expressed in standard dose units, signed by the program medical director;

(4) A list of personnel employed, including volunteers, by the EMS organization who may access and administer dangerous drugs, which includes the name of each employee or volunteer, level of certification, certification number, and expiration date; and

(5) The fee for the appropriate category of licensure.

(C) Each location, headquarters and satellite, may only possess those dangerous drugs that are on the drug list submitted to the board pursuant to paragraph (B)(3) of this rule and only at locations licensed by the state board of pharmacy.

(1) A program medical director may modify the drugs that may be possessed and administered by EMS organization personnel by submitting a new drug list to the state board of pharmacy in a manner determined by the board.

(2) A modification to the drug list shall require an update to the EMS organization's protocols. Any updates or changes to the protocols shall only be submitted to the board upon request.

(D) If there is a change of the medical director of an EMS organization, the new medical director shall submit notification, in a manner determined by the board, no later than five business days following the change. Notification shall include a current drug list signed by the new medical director.

(E) Any change to the EMS organization's personnel list shall be updated within thirty days of a change of personnel. Any change of personnel shall only be submitted to the board upon request.

(F) An EMS organization shall maintain a current copy or have access to a current copy of the organization's signed protocols, personnel list, and drug list at each licensed location.

(G) In accordance with 21 CFR 1301.20 **[NOTE THIS PROPOSED RULE TEXT CAN BE FOUND ON PAGE 24 OF THIS DOCUMENT]** (XX/XX/XXXX), an EMS organization shall be either:

(1) Maintain a current registration with the United States drug enforcement administration; or

(2) If the EMS organization does not maintain a current registration with the United States drug enforcement administration, operate under the hospital registration where an emergency medical services organization is based.

Rule 4729:5-14-03 | Security and control of dangerous drugs.

(A) The security and control of dangerous drugs is the responsibility of the responsible person on the terminal distributor of dangerous drugs license. The responsible person may delegate the day-to-day tasks to EMS organization personnel who hold appropriate certification/licensure to access the dangerous drugs for which the personnel are responsible. A responsible person shall comply with the requirements set forth in agency 4729 of the Administrative Code.

(B) A licensed EMS organization shall provide effective controls and procedures to deter and detect the theft and diversion of dangerous drugs.

(C) All dangerous drugs must be secured with access limited to EMS personnel based on certification status, except for the following:

(1) Solutions labeled for irrigation use;

(2) Dextrose solutions;

(3) Saline solutions;

(4) Lactated ringers;

(5) Sterile water; and

(6) Naloxone hydrochloride or other overdose reversal drug as defined in rule 4729-8-01 of the Administrative Code.

(D) Only the following may have access to any controlled substances maintained by the EMS organization in accordance with the security requirements in paragraph (E) of this rule:

(1) A paramedic or emergency medical technician-paramedic certified in accordance with Chapter 4765. of the Revised Code;

(2) An advanced emergency medical technician or emergency medical technician-intermediate certified in accordance with Chapter 4765. of the Revised Code; and

(3) Licensed prescribers, nurses, or pharmacists who are employed or affiliated with the EMS organization.

(E) A licensed emergency medical services organization shall store controlled substances in a storage component that is identified as either:

(1) A securely locked, substantially constructed cabinet or safe that cannot be readily removed; or

(2) An automated dispensing machine as defined in 21 CFR 1300.01 (3/4/2024) that meets the following requirements:

(a) Is located at a secured location specified in 21 CFR 1301.80(a)(1) and (2) **[NOTE THIS PROPOSED RULE TEXT CAN BE FOUND ON PAGE 26 OF THIS DOCUMENT]** (X/XX/XXXX);

(b) Is installed and operated by the emergency medical services organization; and

(c) Is not used to directly dispense controlled substances to an ultimate user.

(F) All areas where dangerous drugs and devices are stored shall be dry, well-lighted, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling unless otherwise directed by the board. Refrigerators and freezers used for the storage of drugs and devices shall comply with the following:

(1) Maintain either of the following to ensure proper refrigeration and/or freezer temperatures are maintained:

(a) Temperature logs with, at a minimum, daily observations; or

(b) A temperature monitoring system capable of detecting and alerting staff of a temperature excursion.

(2) The terminal distributor shall develop and implement policies and procedures to respond to any out-of-range individual temperature readings or excursions to ensure the integrity of stored drugs.

(3) The terminal distributor shall develop and implement a policy that no food or beverage products are permitted to be stored in refrigerators or freezers used to store drugs.

(G) A dangerous drug that is stored improperly, expired, damaged, tampered, or otherwise adulterated shall be separated from active stock to prevent possible administration to patients. Adulterated drugs shall be stored no longer than one year from the date of adulteration or expiration by the EMS organization. Adulterated drugs shall be stored in a manner that prohibits access by unauthorized persons.

(H) A non-controlled dangerous drug that is expired or adulterated shall be disposed of in a manner that renders the drug unavailable and unusable.

(I) Unless the EMS organization is registered with the United States drug enforcement administration (DEA), any controlled substance that is expired or otherwise adulterated shall be returned to the hospital acting as the EMS organization's responsible DEA registrant.

(J) Except as provided in paragraph (K) of this rule, disposal of controlled substances shall be conducted in accordance with rule [4729:5-3-01](#) of the Administrative Code by individuals listed in paragraph (D) of this rule.

(K) The unused portion of a controlled substance resulting from administration to a patient from a licensee's stock or emergency supply may be destroyed using an on-site method. The on-site method does not have to meet the definition of non-retrievable in rule [4729:5-3-01](#) of the Administrative Code but must render the drug unavailable and unusable.

The destruction of partially used controlled substances shall be conducted by two licensed/certified healthcare personnel, one of whom shall meet the qualifications listed in paragraph (D) of this rule.

(L) If there is a recall of oxygen by the manufacturer, all portable oxygen tanks affected by the recall shall be handled in accordance with the manufacturer's recall instructions.

Rule 4729:5-14-04 | Record keeping.

(A) All EMS organizations shall keep a record of all dangerous drugs received, administered, sold, transferred, destroyed, or disposed.

(B) Records of receipt shall contain the name, strength, dosage form, and quantity of the dangerous drugs received, the name and address of the seller, the name and address of the recipient, and the date of receipt. An invoice from a drug distributor licensed in accordance with division 4729:6 of the Administrative Code containing the required information may be used to meet this requirement.

(C) All records of receipt, delivery, distribution, administration, selling, disposing, destroying, or using dangerous drugs shall be maintained for a period of three years at the place where the dangerous drugs are located.

Records from satellites may be stored at the EMS organization headquarters if prior approval, in a manner determined by the board, is obtained by the EMS organization.

(D) Records of administration shall be legible and shall contain the first and last name of the EMS personnel who administered the drug, name of the EMS organization, name and strength of the drug administered, date of administration, time of administration, amount of the dose administered, the name or other means of identifying the patient, such as medical record number or run number, and the identification of the individual administering the drug using either of the following methods:

- (1) An electronic signature in a computerized recordkeeping system; or
- (2) Any form of positive identification.

(E) Records of disposal of dangerous drugs from inventory, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed, the date of disposal, the method of disposal, and the identification of the EMS personnel that performed the disposal.

(F) Records for the disposal of controlled substance drugs shall be maintained in accordance with rule [4729:5-3-01](#) of the Administrative Code and, if disposal is performed on-site, the positive identification of the two EMS personnel who disposed of the drugs in accordance with rule 4729:5-14-03 of the Administrative Code.

Records for the disposal or destruction of the unused portion of a controlled substance resulting from administration to a patient from a licensee's stock or emergency supply shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed, the date disposed, the method of disposal, and the positive identification of the two EMS personnel who disposed of the drugs.

(G) All records maintained in accordance with this rule shall be uniformly maintained and readily retrievable.

(H) An EMS organization that holds a registration with the drug enforcement administration shall conduct an annual inventory of all controlled substances in accordance with rule 4729:5-3-07 of the Administrative Code.

(I) All records maintained pursuant to this rule may be electronically created and maintained, provided that the system that creates and maintains the electronic record does so in accordance with the following:

(1) Complies with the requirements of this rule;

(2) All paper records maintained electronically shall be scanned in full color via technology designed to capture all information in the paper record in one form and reproduce it in an electronic medium presentable and usable to an end user;

(3) Contains security features to prevent unauthorized access to the records; and

(4) Contains daily back-up functionality to protect against record loss.

(J) Records of oxygen transfilling shall include the manufacturer's lot number of the oxygen used for transfilling the portable oxygen tanks.

(K) An EMS organization shall comply with all recordkeeping requirements applicable to controlled substances in accordance 21 CFR 1304 (X/XX/XXXX), including 21 CFR 1304.27

[NOTE THIS PROPOSED RULE TEXT CAN BE FOUND ON PAGE 28 OF THIS DOCUMENT] (X/XX/XXXX).

Rule 4729:5-14-05 | Protocols and Verbal Orders for Drug Administration (NEW)

An emergency medical services professional with a certificate to practice and acting within their scope of practice may administer directly (but not prescribe) a dangerous drug, including controlled substances, outside the physical presence of a medical director or authorizing prescriber in accordance with the following:

(A) A protocol or standing order that is issued and adopted by one or more medical directors of the EMS organization; or

(B) A verbal order that is:

(1) Issued in accordance with a policy of the agency; and

(2) Provided by a medical director or an authorizing prescriber in response to a request by the emergency medical services professional with respect to a specific patient in any of the following circumstances:

(a) In the case of a mass casualty incident; or

(b) To ensure the proper care and treatment of a specific patient.

(C) An emergency medical services organization shall maintain, at each licensed location, a record of all verbal orders issued or adopted in accordance with this rule. Such orders shall be readily retrievable and maintained for three years from the date of authorization. A verbal order issued by a medical director and recorded by a emergency medical services organization shall contain the following information:

(1) Patient name;

(2) Date;

(3) Drug name and strength;

(4) Quantity administered;

(5) Name and positive identification of the authorizing medical director.

(D) An emergency medical service organization may administer an initial dose of buprenorphine, or another medication for opioid use disorder approved by the board, to a patient in accordance with a protocol approved by the organization's medical director. Such a protocol shall ensure that the EMS agency is able to provide a direct linkage to a program or prescriber who will continue the patient's therapy.

(E) A controlled substance administered in accordance with paragraph (D) of this rule is exempted from reporting to the drug database established in section 4729.75 of the Revised Code.

NOTES:

- Much of this text adopted directly from 1306.07 **[SEE PAGE 32 OF THIS DOCUMENT]**
- Paragraph (D) permits EMS personnel to administer an initial dose of buprenorphine treatment at the site of an overdose. For more information on such promising practices, visit: <https://opioidprinciples.jhsph.edu/reaching-people-where-they-are-using-ems-to-start-buprenorphine/>

Rule 4729:5-14-06 – Hospital Restocking of Dangerous Drugs to Emergency Medical Service Organizations (NEW)

(A) An emergency medical service organization may receive controlled substances from a hospital pharmacy licensed as a terminal distributor of dangerous drugs for purposes of restocking an emergency medical services vehicle following an emergency response if it complies with all of the following:

(1) The EMS organization operating the vehicle maintains the record of such receipt in accordance with 21 CFR 1304.27(b) **[NOTE THIS PROPOSED RULE TEXT CAN BE FOUND ON PAGE 28 OF THIS DOCUMENT]** (X/XX/XXXX).

(2) The hospital pharmacy maintains a record of such delivery to the agency in accordance with 21 CFR 1304.22(c) (2/27/2024);

(3) If the vehicle is primarily situated at a designated or satellite location of an emergency medical services organization, such location notifies the headquarters of the EMS organization within seventy-two hours of the vehicle receiving the controlled substances;

(4) The EMS organization and hospital pharmacy are appropriately licensed as terminal distributors of dangerous drugs in accordance with Chapter 4729. of the Revised Code; and

(5) The hospital pharmacy conducts documented annual licensure verifications to ensure each EMS organization is appropriately licensed in accordance with Chapter 4729. of the Revised Code. This provision does not apply if the EMS organization is a hospital-based agency.

(B) An EMS organization obtaining controlled substances in accordance with this rule shall not be required to complete a DEA Form 222 or its electronic equivalent.

(C) An EMS organization may receive dangerous drugs that are not controlled substances from a hospital pharmacy licensed as a terminal distributor of dangerous drugs for purposes of restocking an emergency medical services vehicle following an emergency response if it complies with all of the following:

(1) The EMS organization operating the vehicle maintains the record of such receipt in accordance with rule 4729:5-14-04 of the Administrative Code;

(2) The hospital pharmacy maintains a record of such delivery to the organization in accordance with rule 4729:5-9-02.3 of the Administrative Code;

(3) The EMS organization and hospital pharmacy are appropriately licensed as terminal distributors of dangerous drugs in accordance with Chapter 4729. of the Revised Code; and

(4) The hospital pharmacy conducts documented annual licensure verifications to ensure each EMS organization is appropriately licensed in accordance with Chapter 4729. of the Revised Code. This provision does not apply if the EMS organization is a hospital-based agency.

(D) The sale or transfer of controlled substances or dangerous drugs in accordance with this rule are exempt from the drug database reporting requirements of 4729:8 of the Administrative Code.

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 [4729.52](#) 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 [4729:5-3-09](#) 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 [4729.51](#) of the Revised Code in making the purchase.

(C) Before a terminal distributor of dangerous drugs may make ~~a~~ **any** sale of dangerous drugs pursuant to rule [4729:5-3-09](#) 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 **licensee's licensees** 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 [4729.541](#) of the Revised Code; ~~or~~

(3) The sale or distribution of dangerous drugs to an EMS organization from a hospital pharmacy licensed as a terminal distributor of dangerous drugs for purposes of restocking an emergency medical services vehicle in accordance with rule 4729:5-14-05 of the Administrative Code.

(E) A terminal distributor of dangerous drugs may make a sale of a dangerous drug to any of the exempted persons described in section [4729.541](#) of the Revised Code in accordance with rule [4729:5-3-09](#) 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 [4729.541](#) 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 4729:5-3-09 | Occasional sale and drug transfers. (AMEND)

(A) The term "occasional sale" as used in section [4729.51](#) of the Revised Code means a wholesale sale of a commercially manufactured dangerous drug to a person licensed in accordance with section [4729.52](#) of the Revised Code, terminal distributor of dangerous drugs, or any entity or person exempted from licensure as a terminal distributor of dangerous drugs by any of the following:

- (1) A pharmacy licensed as a terminal distributor of dangerous drugs;
- (2) A licensed terminal distributor of dangerous drugs that is not a pharmacy, but only as authorized in section [4729.51](#) of the Revised Code;
- (3) A local health department, as defined in paragraph (H) of this rule, licensed as a terminal distributor of dangerous drugs for the purpose of improving or promoting public health within the department's jurisdiction, but only for the sale of non-controlled dangerous drugs;~~or~~
- (4) A drug repository program pursuant to rule [4729:5-10-07](#) of the Administrative Code;~~;~~
or

(5) The sale or distribution of dangerous drugs to an EMS organization from a hospital pharmacy licensed as a terminal distributor of dangerous drugs for purposes of restocking an emergency medical services vehicle in accordance with rule 4729:5-14-05 of the Administrative Code.

(B) The dosage units of all dangerous drugs distributed by the pharmacy pursuant to this rule shall not exceed five per cent of the total dosage units dispensed by the pharmacy during the same calendar year.

(C) The limits set forth in this rule do not apply to the following:

- (1) A licensed terminal distributor of dangerous drugs as described in paragraph (A)(2) of this rule;
- (2) Pharmacies that are also licensed to conduct sales of dangerous drugs in accordance with section [4729.52](#) of the Revised Code; and
- (3) Drug repository programs pursuant to rule [4729:5-10-07](#) of the Administrative Code.

(D) The requirements of this rule do not apply to the transfer of dangerous drugs pursuant to paragraph (E) of this rule.

(E) A licensed terminal distributor of dangerous drugs having more than one licensed location may transfer or deliver dangerous drugs from one licensed location to another licensed location owned by that terminal distributor if the license issued for each location

is in effect at the time of the transfer or delivery. Such transfer or delivery includes either of the following:

(1) Intracompany sales, which includes any transaction or transfer between any division, subsidiary, parent, or affiliated or related company under the common ownership and control.

(2) The sale, purchase, or transfer of a drug or an offer to sell, purchase, or transfer **of** a drug among hospitals or other health care entities that are under common control. Common control means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise.

(F) Occasional sales by a licensed terminal distributor shall comply with the reporting requirements set forth in division 4729:8 of the Administrative Code.

(G) "Drug shortage," with respect to an occasional sale, means a drug on the United States food and drug administration's drug shortage list that is not commercially available regardless of the reason that the drug is not available, including the absence of a manufacturer for the drug or the lack of a readily available supply of the drug from a manufacturer or wholesaler.

(H) "Local health department" means a department operated by a board of health of a city or general health district or the authority having the duties of a board of health as described in section [3709.05](#) of the Revised Code.

PART 1300—DEFINITIONS

1. The authority citation for part 1300 continues to read as follows:

Authority: 21 U.S.C. 802, 821, 822, 829, 871(b), 951, 958(f).

2. Add § 1300.06 to read as follows:

§ 1300.06 Definitions relating to emergency medical services agencies.

(a) Any term not defined in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802).

(b) As used in parts 1301, 1304, 1306, and 1307 of this chapter, the following terms shall have the meanings specified:

(1) *Authorizing medical professional* means an emergency or other physician, or other medical professional (including an advanced practice registered nurse or physician assistant) –

(i) Who is registered under 21 U.S.C. 823;

(ii) Who is acting within the scope of the registration; and

(iii) Whose scope of practice under a State license or certification includes the ability to provide verbal orders.

(2) *Designated location* means a location designated by an emergency medical services agency under 21 U.S.C. 823(j)(5).

(3) *Emergency medical services* means emergency medical response and emergency mobile medical services provided outside of a fixed medical facility.

(4) *Emergency medical services agency* means an organization providing emergency medical services, including such an organization that –

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- (i) Is governmental (including fire-based and hospital-based agencies), non-governmental (including hospital-based agencies), private, or volunteer-based;
- (ii) Provides emergency medical services by ground, air, or otherwise; and
- (iii) Is authorized by the State in which the organization is providing such services to provide emergency medical care, including the administering of controlled substances, to members of the general public on an emergency basis.

(5) *Emergency medical services professional* means a health care professional (including a nurse, paramedic, or emergency medical technician) licensed or certified by the State in which the professional practices and credentialed by a medical director of the respective emergency medical services agency to provide emergency medical services within the scope of the professional's State license or certification.

(6) *Emergency medical services vehicle* means an ambulance, fire apparatus, supervisor truck, or other vehicle used by an emergency medical services agency for the purpose of providing or facilitating emergency medical care and transport or transporting controlled substances to and from the registered and designated locations.

(7) *Hospital-based* means, with respect to an emergency medical services agency, owned or operated by a hospital.

(8) *Medical director* means a physician who is registered under 21 U.S.C. 823(f) and provides medical oversight to an emergency medical services agency.

(9) *Medical oversight* means supervision of the provision of medical care by an emergency medical services agency.

(10) *Registered emergency services agency* means –

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(i) An emergency medical services agency that is registered under 21 U.S.C. 823(j);
or

(ii) A hospital-based emergency medical services agency that is covered by the registration of the hospital.

(11) *Registered location* means, for purposes of emergency medical services, a location that appears on a DEA certificate of registration issued to an emergency medical services agency, which shall be where the agency receives controlled substances from distributors.

(12) *Specific State authority* means a governmental agency or other such authority, including a regional oversight and coordinating body, that, pursuant to State law or regulation, develops clinical protocols regarding the delivery of emergency medical services in the geographic jurisdiction of such agency or authority within the State that may be adopted by medical directors.

(13) *Standing order* means a written medical protocol in which a medical director determines in advance the medical criteria that must be met before administering controlled substances to individuals in need of emergency medical services.

(14) *Stationhouse* means an enclosed structure that houses one or more emergency medical services agency vehicles within a State in which that emergency medical services agency is registered, and that is actively and primarily being used for emergency response by that emergency medical services agency.

(15) *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 controlled substance to

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individuals in need of emergency medical services outside the physical presence of the medical director or authorizing medical professional.

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

3. The authority citation for part 1301 is revised to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 956, 957, 958, 965.

4. In § 1301.12, add paragraph (b)(5) to read as follows:

§1301.12 Separate registrations for separate locations.

* * * * *

(b) * * *

(5) A designated location that is identified to the Administration by a registered emergency medical services agency at least 30 days prior to first delivering controlled substances to that unregistered location.

5. In § 1301.13:

- a. Revise paragraph (d);
- b. Redesignate rows (e)(1)(v) through (x) as rows (e)(1)(vi) through (xi); and
- c. Add new row (e)(1)(v).

The revision and addition read as follows:

§ 1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.

* * * * *

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(d) At the time a retail pharmacy, hospital/clinic, practitioner, emergency medical services agency or teaching institution is first registered, that business activity shall be assigned to one of twelve groups, which correspond to the months of the year. The expiration date of the registrations of all registrants within any group will be the last day of the month designated for that group. In assigning any of the above business activities to a group, the Administration may select a group the expiration date of which is not less than 28 months nor more than 39 months from the date such business activity was registered. After the initial registration period, the registration expires 36 months from the initial expiration date.

(e) * * *

(1) * * *

Business activity	Controlled substances	DEA Application forms	Application fee (\$)	Registration period (years)	Coincident activities allowed

(v) Emergency Medical Services Agency	Schedules II-V	New — 224 Renewal — 224a	731	3	

* * * * *

6. Add § 1301.20 under undesignated heading “Registration” to read as follows:

§ 1301.20 Registration for emergency medical services agencies.

(a) An emergency medical services agency shall be issued a registration under §1301.13 if the agency submits an application demonstrating it is authorized to conduct such activity under the laws of each State in which the agency practices,

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unless the Administration determines that the issuance of such a registration would be inconsistent with the requirements of 21 U.S.C. 823(j) or the public interest based on the factors listed in 21 U.S.C. 823(f).

(1) An agency has the option of requesting a single registration in each State where the agency administers controlled substances in lieu of a separate registration for each location of the agency within a State.

(2) If a hospital where an emergency medical services agency is based is registered under §1301.13, the agency may use the registration of the hospital to administer controlled substances in accordance with § 1306.07(e) of this chapter, without being separately registered as an emergency medical services agency.

(b) A registered emergency medical services agency may deliver controlled substances from a registered location of the agency to an unregistered location of the agency only if the agency designates the type of unregistered location as a stationhouse for such delivery; and notifies the Administration at least 30 days prior to the first delivery of controlled substances to the unregistered location. The delivery of controlled substances by a registered emergency medical services agency pursuant to this section shall not be treated as distribution. To notify the Administration, the emergency medical services agency must submit the name and physical address of the designated location online at www.DEAdiversion.usdoj.gov.

§§ 1301.78 and 1301.79 [Added and Reserved]

7. Add and reserve §§ 1301.78 and 1301.79 under undesignated heading “Security Requirements”;

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8. Add § 1301.80 under undesignated heading “Security Requirements” to read as follows:

§ 1301.80 Security controls for emergency medical services agencies.

(a) A registered emergency medical services agency may store controlled substances at any of the following secured locations:

(1) A registered location of the agency;

(2) A designated location of the agency 30 days following notification to DEA in accordance with § 1301.20;

(3) In an emergency medical services vehicle situated at a registered location or designated location of the agency; or

(4) In an emergency medical services vehicle used by the agency that is traveling from, or returning to, a registered location or designated location of the agency in the course of responding to an emergency, or otherwise actively in use by the agency.

(b) A registered emergency medical services agency may store controlled substances in a storage component that is identified as:

(1) A securely locked, substantially constructed cabinet or safe that cannot be readily removed; which is located at a secured location specified in § 1301.80(a)(1) through (4); or

(2) An automated dispensing machine as defined in § 1300.01; which is

(i) Located at a secured location specified in 1301.80(a)(1) and (2);

(ii) Installed and operated by the emergency medical services agency;

(iii) Not used to directly dispense controlled substances to an ultimate user; and is

(iv) In compliance with the requirements of State law.

PART 1304—RECORDS AND REPORTS OF REGISTRANTS

9. The authority citation for part 1304 is revised to read as follows:

Authority: 21 U.S.C. 821, 823(j), 827, 831, 871(b), 958(e)-(g), and 965, unless otherwise noted.

10. In § 1304.03, add paragraphs (i) and (j) to read as follows:

§ 1304.03 Persons required to keep records and file reports.

* * * * *

(i) For each emergency medical services professional employed by a registered emergency services agency, the registered agency must maintain in a readily retrievable manner those documents (as required by the State in which an emergency medical services professional practices), which describe the conditions and extent of the professional's authorization to dispense controlled substances, and must make such documents available for inspection and copying by authorized employees of the Administration. Examples of such documentation include protocols, practice guidelines, or practice agreements.

(j) A registered emergency medical services agency shall maintain records, as described in § 1304.27, of all controlled substances that are received, administered, or otherwise disposed of pursuant to the agency's registration.

11. In § 1304.04, revise paragraph (a) introductory text and add paragraphs (a)(4) and (5) to read as follows:

§ 1304.04 Maintenance of records and inventories.

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- (a) Except as provided in paragraphs (a)(1) and (2) of this section, every inventory and other record required to be kept under this part must be kept by the registrant, and be available for inspection and copying by authorized employees of the Administration, for at least 2 years from the date of such inventory or record.

* * * * *

- (4) Records shall include records of deliveries of controlled substances between all locations of the agency.

- (5) Records shall be maintained, whether electronically or otherwise, at each registered and designated location of the agency where the controlled substances involved are received, administered, or otherwise disposed of.

* * * * *

12. Add § 1304.27 to read as follows:

§ 1304.27 Additional recordkeeping requirements applicable to emergency medical services agencies.

- (a) Each emergency medical services agency registered pursuant to § 1301.20 of this chapter (including a hospital-based emergency medical services agency using a hospital registration under § 1301.20(a)(2) of this chapter) must maintain records for each dose of controlled substances administered or disposed of in the course of providing emergency medical services. The following information shall be included in each record:

- (1) Name of the substance;
- (2) Finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

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- (3) Date administered or disposed of;
- (4) Identification of the patient (consumer), if applicable;
- (5) Amount administered;
- (6) Initials of the person who administered the controlled substance;
- (7) Initials of the medical director or authorizing medical professional issuing the standing or verbal order;
- (8) Whether a standing or verbal order was issued and adopted;
- (9) Amount disposed of, if applicable;
- (10) Manner disposed of; and
- (11) Initials of person who disposed and witness to disposal.

(b) For each acquisition of a controlled substance from another registrant, or each distribution of a controlled substance to another registrant, each emergency medical services agency registered pursuant to §1301.20 of this chapter must maintain records with all of the following information:

- (1) For each acquisition of a controlled substance from another registrant:
 - (i) Name of the substance;
 - (ii) Finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);
 - (iii) Number of units or volume of finished form in each commercial container;
 - (iv) Number of commercial containers acquired (e.g., 100-tablet bottle or 3-milliliter vial);
 - (v) Date of the acquisition;

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(vi) Name, address, and registration number of the person from whom the substance was acquired; and

(vii) Name and title of the person acquiring the controlled substance.

(2) For each distribution of a controlled substance to another registrant:

(i) Name of the substance;

(ii) Finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

(iii) Number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

(iv) Number of commercial containers distributed;

(v) Date of the distribution;

(vi) Name, address, and registration number of the person to whom the substance was distributed; and

(vii) Name and title of the person in receipt of the distributed controlled substances.

(3) For each delivery of controlled substances between a designated location and a registered location:

(i) Name of the substance;

(ii) Finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

(iii) Number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

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- (iv) Number of units or volume of finished form in each commercial container and number of commercial containers delivered (e.g., 100-tablet bottle or 3-milliliter vial);
- (v) Date of the delivery;
- (vi) Name and address of the designated location to which the substance is delivered; and
- (vii) Name and title of the person in receipt of the controlled substances.

(4) For destruction of a controlled substance:

- (i) Name of the substance;
- (ii) Finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);
- (iii) Number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);
- (iv) Number of units or volume of finished form in each commercial container and number of commercial containers destroyed (e.g., 100-tablet bottle or 3-milliliter vial);
- (v) Date of the destruction;
- (vi) Manner of disposal of the substance, if applicable;
- (vii) Name, address, and registration number of the person to whom the substance was distributed, if applicable; and
- (viii) Name and title of the person destroying the controlled substance.

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(c) A designated location of an emergency medical services agency that receives controlled substances must notify the agency's registered location within 72 hours of receipt of the controlled substances, in the following circumstances:

- (1) An emergency medical services vehicle primarily situated at a designated location of the emergency medical services agency acquires controlled substances from a hospital while restocking following an emergency response;
- (2) The designated location of the emergency medical services agency receives controlled substances from another designated location of the same agency.

PART 1306—PRESCRIPTIONS

13. The authority citation for part 1306 is revised to read as follows:

Authority: 21 U.S.C. 821, 823(j), 829, 831, 871(b), unless otherwise noted.

14. Revise § 1306.01 to read as follows:

§ 1306.01 Scope of part 1306.

This part sets forth the process and procedures for dispensing, by way of prescribing and administering controlled substances to ultimate users. The purpose of such procedures is to provide safe and efficient methods for dispensing controlled substances while providing effective controls against diversion.

15. Amend § 1306.07 by adding paragraphs (e) and (f) to read as follows:

§ 1306.07 Administering or dispensing of narcotic drugs.

* * * * *

(e) An emergency medical services professional of a registered emergency medical services agency may administer directly (but not prescribe) controlled substances in schedules II-V outside the physical presence of a medical director or authorizing

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medical professional in the course of providing emergency medical services if the administration is authorized by law of the State in which it occurs; and is pursuant to:

- (1) A standing order that is issued and adopted by one or more medical directors of the agency, including any such order that may be developed by a specific State's authority; or
- (2) A verbal order that is:
 - (i) Issued in accordance with a policy of the agency; and
 - (ii) Provided by a medical director or an authorizing medical professional in response to a request by the emergency medical services professional with respect to a specific patient —
 - (A) In the case of a mass casualty incident; or
 - (B) To ensure the proper care and treatment of a specific patient.
- (f) An emergency medical services agency shall maintain, at a registered location of the agency, a record of the standing or verbal orders issued or adopted in accordance with § 1304.13 of this chapter.

PART 1307—MISCELLANEOUS

16. The authority citation for part 1307 is revised to read as follows:

Authority: 21 U.S.C. 821, 822(d), 823(j), 871(b), unless otherwise noted.

17. Add § 1307.14 under undesignated heading “Special Exceptions for Manufacture and Distribution of Controlled Substances” to read as follows:

§ 1307.14 Delivery of controlled substances to designated locations of emergency medical services agencies.

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(a) Notwithstanding the definition of registered location in § 1300.06 of this chapter, a registered emergency medical services agency may receive controlled substances from a hospital for purposes of restocking an emergency medical services vehicle following an emergency response, and without being subject to the requirements of § 1305.03 of this chapter, provided all of the following criteria are met:

- (1) The registered or designated location of the agency operating the vehicle maintains the record of such receipt in accordance with § 1304.27(b) of this chapter;
- (2) The hospital maintains a record of such delivery to the agency in accordance with § 1304.22(c) of this chapter; and
- (3) If the vehicle is primarily situated at a designated location of an emergency medical services agency, such location notifies the registered location of the agency within 72 hours of the vehicle receiving the controlled substances.

18. Add § 1307.15 under undesignated heading “Special Exceptions for Manufacture and Distribution of Controlled Substances” to read as follows:

§ 1307.15 Delivery of controlled substances in emergency situations.

(a) Hospitals and emergency medical services agencies’ registered locations, and designated locations may deliver controlled substances to each other, with written approval from the Special Agent in Charge of DEA for the area or DEA Headquarters, in the event of:

- (1) Shortages of such substances;
- (2) A public health emergency; or

(3) A mass casualty event.

Timothy J. Shea,

Acting Administrator.

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