EMS Frequently Asked Questions

Updated 6/13/2019

Rules governing the possession and use of dangerous drugs by emergency medical service organizations can now be found in Chapter 4729:5-14 of the Ohio Administrative Code. This chapter includes the following rules:

- 4729:5-14-01 Emergency medical services – definitions.
- 4729:5-14-02 Licensure.
- 4729:5-14-03 Security and control of dangerous drugs.
- 4729:5-14-04 Record keeping.

To assist EMS organizations in complying with all applicable rules, the Board has developed the following frequently asked questions document. If you need additional information, the most expedient way to have your questions answered will be to e-mail the Board office by visiting: http://www.pharmacy.ohio.gov/contact.aspx.

1. What does the term "controlled substance" mean?

"Controlled substance" as defined in section 3719.01(C) of the Ohio Revised Code means a drug, compound, mixture, preparation, or substance included in Schedule I, II, III, IV, or V.

2. What does the term "dangerous drug" mean?

"Dangerous drug," as defined in section 4729.01 of the Ohio Revised Code, means any drug or drug product whose commercial package bears a label containing the symbol "Rx only", the legend "Caution: Federal Law Prohibits Dispensing Without Prescription" or "Caution: Federal Law Restricts This Drug to Use By Or On The Order Of A Licensed Veterinarian", or any similar restrictive statement. This includes medical grade oxygen and IV solutions.

The definition of dangerous drug also includes any drug (including non-prescription) intended for administration by injection into the human body other than through a natural orifice of the human body.

3. What is a responsible person?

A "responsible person" as defined in rule 4729:5-2-01 of the Ohio Administrative Code is responsible for the compliance with all state and federal laws, regulations, and rules regulating the distribution of drugs. For an EMS organization, the responsible person must be an Ohio licensed physician (MD or DO) or a pharmacist.

As defined in rule 4729:5-14-03 of the Ohio Administrative Code: Overall supervision and control of dangerous drugs is the responsibility of the responsible person. The responsible person may delegate the day-to-day tasks to the emergency medical service (EMS) organization personnel who hold appropriate certification to access the dangerous drugs for which they are responsible.

4. What are the requirements for the storage of dangerous drugs?

Rule 4729:5-14-03 of the Ohio Administrative Code requires all dangerous drugs to be secured in a tamper-evident manner with access limited to EMS personnel based on certification status, except for the following if stored in a sealed (by the manufacturer), tamper-evident manner:

- Solutions labeled for irrigation use;
- Dextrose solutions;
- Saline solutions;
- Lactated ringers;
- Sterile water; and
- Naloxone hydrochloride.

NOTE: Rule 4729:5-14-01 of the Ohio Administrative Code defines tamper-evident as any of the following: a package, storage container or other physical barrier that 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.

All areas where dangerous drugs and devices are stored shall be dry, well-lit, 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.

5. Who can have access to controlled substances?

Only the following may have access to controlled substances maintained by the EMS organization:

(1) A paramedic or emergency medical technician-paramedic;

(2) An advanced emergency medical technician or emergency medical technician-intermediate; or

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

NOTE: Other EMS organization personnel may have access to controlled substances only under the direct supervision of the individuals listed above. Direct supervision means EMS organization personnel shall be physically present at the licensed location or within the immediate proximity of an EMS unit to deter and detect the diversion of dangerous drugs.

6. What EMS personnel may administer dangerous drugs?

Administration of dangerous drugs by EMS personnel is limited to the individual's scope of practice based upon certification level and either:

(1) The protocols established by the organization's medical director; or

(2) A verbal order by a prescriber received in-person or over an electronic communications device.

7. What should you do with medications that have expired?

Rule 4729:5-14-03 of the Ohio Administrative Code states that a drug that reaches its expiration date is considered adulterated and must be separated from active stock to prevent possible administration to patients.

Rule 4729:5-3-06 of the Ohio Administrative Code states that 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.

8. How do I dispose of non-controlled dangerous drugs?

A non-controlled dangerous drug that is expired may be returned to the supplier where the drug was obtained or may be disposed of in a manner that renders the drug unavailable and unusable as required by rule 4729:5-3-06 of the Ohio Administrative Code.

Rule 4729:5-14-04 of the Ohio Administrative Code requires all records of disposal or destruction of noncontrolled dangerous drugs to contain the name, strength, dosage form, and quantity of the dangerous drug disposed, the date of disposal, the method of disposal, and, if disposal is performed on-site, the positive identification of the EMS personnel who disposed of the drugs.

9. How do I dispose of controlled substance dangerous drugs?

Unless the EMS organization is registered with the United States Drug Enforcement Administration (DEA), any controlled substance that is expired shall be returned to the hospital acting as the EMS organization's responsible DEA registrant.

If the EMS organization is a DEA registrant, it may conduct controlled substance disposal in accordance with rule 4729:5-3-01 of the Administrative Code. Controlled substance disposal may only be conducted by the following persons:

(1) A paramedic or emergency medical technician-paramedic;

(2) An advanced emergency medical technician or emergency medical technician-intermediate; or

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

10. How do I dispose of partially used controlled substances (a.k.a. waste)?

Destruction of partially used controlled substances shall be conducted by two licensed/certified healthcare personnel, one of whom must be any of the following:

(1) A paramedic or emergency medical technician-paramedic;

(2) An advanced emergency medical technician or emergency medical technician-intermediate; or

(3) Licensed prescribers, nurses or pharmacists who are employed or affiliated with the EMS organization (this may include hospital staff serving as the responsible DEA registrant).

Rule 4729:5-14-04 of the Ohio Administrative Code requires all records of the disposal or destruction of non-controlled dangerous drugs to contain the name, strength, dosage form, and quantity of the dangerous drug disposed, the date of disposal, the method of disposal, and, if disposal is performed onsite, the positive identification of the EMS personnel (or affiliated prescribers, nurses or pharmacists) who disposed of the drugs.

11. What does the term "positive identification" mean?

As defined in rule 4729:5-14-01 of the Ohio Administrative Code:

"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 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. The printout must be maintained for three years and made available on request to those individuals authorized by law to review such records; or

(h) Other effective methods for identifying individuals that have been approved by the board.

NOTE: 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.

12. Do I need to document drug administration using positive identification?

No. Drug administration may be documented using either of the following methods:

(1) An electronic signature in a computerized recordkeeping system; or

(2) Any form of positive identification.

NOTE: An electronic signature may include any of the following:

- 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.

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.

IMPORTANT: See Q17 for updated information on the documentation of drug administration.

13. What should I do if drugs are discovered to be missing?

Any theft or significant loss of dangerous drugs must be reported immediately upon discovery. More information on theft or loss can be accessed here: www.pharmacy.ohio.gov/theft

14. What should you do if drugs appear to be damaged or tampered with?

Rule 4729:5-14-03 requires any dangerous drug showing evidence of damage or tampering to be removed from active stock and replaced immediately. The drug must be stored no longer than one year from the date of discovery of tampering or damage by the EMS organization and must be stored in a manner that prohibits access by unauthorized persons.

Note: Tampering with dangerous drugs is a criminal act, and must be reported to the Board of Pharmacy. If a dangerous drug is suspected of being tampered with, it is to be secured as evidence and held for Board of Pharmacy agents.

15. When an EMS vehicle is removed from any licensed facility for service or maintenance should all the drug stock be removed?

Yes. All dangerous drugs shall be removed from the vehicle and properly secured at the licensed facility.

16. What are the record retention requirements for drug accountability and security?

All records of receipt, 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.

All records must be uniformly maintained and readily retrievable. Rule 4729:5-14-01 of the Ohio Administrative Code 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.

Records from satellites may be stored at the headquarters if a prior written request is sent to the Board of Pharmacy and approved. The request must be submitted electronically. The request form can be found on the Board's terminal distributor licensing page: https://www.pharmacy.ohio.gov/Licensing/TDDD.aspx

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

17. What information must be included in my records?

Rule 4729:5-14-04 of the Ohio Administrative Code requires the following:

- **Records of receipt** shall contain a description of all dangerous drugs received, the kind and quantity of dangerous drugs received, the name and address of the persons from whom received, and the date of receipt.

- **Records of administration** can be documented in one of the following ways:

    1. Dangerous drugs 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:

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

-OR-

2. An EMS organization participating in an emergency scenario where drugs are administered from one EMS unit by personnel of another EMS unit, may document drug administration as follows:

    (1) Records of administering dangerous drugs shall be legible and shall contain the name of the EMS organization of the person who administered the drug, 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

    (2) The first name and last name of the EMS personnel from the EMS unit, which originally possessed the dangerous drugs administered, who will assume responsibility for documenting drug administration using either of the following methods:

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

NOTE: Option #2 for documenting drug administration was authorized via Board resolution adopted on June 3, 2019. A corresponding change to the record keeping rule is forthcoming.

- **Records of 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 EMS personnel who disposed of the drugs.

- **Records of the disposal of non-controlled dangerous drugs** shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed, the date of

disposal, the method of disposal, and, if disposal is performed on-site, the positive identification of the EMS personnel who disposed of the drugs.

- **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 EMS personnel who disposed of the drugs.

- **Records of transfer or sale** conducted in accordance with rule 4729:5-3-09 of the Administrative Code shall contain the name, strength, dosage form, national drug code, expiration date and quantity of the dangerous drug transferred or sold, the address of the location where the drugs were transferred or sold, and the date of transfer or sale.

18. What type of license does an EMS organization need to possess dangerous drugs?

Ohio Licensure: All EMS physical locations that possess dangerous drugs must obtain a license as a terminal distributor of dangerous drugs (TDDD) from the Board of Pharmacy and each satellite location that possesses dangerous drugs, whether stored in a squad vehicle or on the physical premises, must have a satellite TDDD license. The license issued will be a limited license that includes a drug list. The drug list will list the specific drugs (along with drug administration protocols) that an EMS organization may possess as approved by the organization's medical director.

DEA Registration: An EMS organization may, or may not, need a DEA registration. It depends on how the
EMS organization wants to obtain and possess controlled substances. An EMS organization must use **only ONE** of the methods below to obtain controlled substance stock. An EMS organization shall NOT use a combination of the two to obtain controlled substances.

- An EMS organization does NOT require a DEA registration if they obtain their controlled substances via a 1:1 exchange system with a hospital acting as its responsible DEA

registrant as discussed further in this document. **IMPORTANT:** You are not required to conduct an annual controlled substance inventory if you are using a 1:1 exchange system.

- An EMS organization will require a DEA registration if they want to purchase, store, and distribute controlled substances to their squads. Additional DEA registrations are required at each satellite location if controlled substances are stored as contingency stock to replenish squad drug supplies. Additional satellite locations do NOT need a DEA registration if controlled substances are only stored on a squad vehicle. **IMPORTANT:** You are required to conduct an annual controlled substance inventory if you are a DEA registrant. Inventories must be conducted in accordance with rule 4729:5-3-07.

19. If our EMS organization does not have a DEA registration, how do we get start up drug stock, utilizing a "1:1 drug exchange" system?

An EMS organization is required to have an agreement with one specific hospital acting as its responsible DEA registrant, commonly referred to as a "medical control pharmacy." An EMS organization must provide their specific responsible DEA registrant with a copy of the following documents: TDDD license with drug list and a copy of the organization's drug administration protocols signed by the medical director. The specific responsible DEA registrant's pharmacist will fill your initial drug order, or release a new drug box and keep copies of the above documents. You should be prepared to show your employee identification and any other information the hospital deems necessary for security and accountability.

20. What if the receiving hospital/facility will not do a 1:1 exchange?

If a receiving hospital will not do a 1:1 exchange, the EMS organization is to return to their specific responsible DEA registrant hospital with a properly completed run sheet to replace their used drug stock.

21. In a 1:1 exchange system, what if the patient refuses transportation after we have administered dangerous drugs?

If a patient refuses transport after drugs were used, the EMS organization is to return to their specific responsible DEA registrant hospital with a properly completed run sheet to replace their used drug stock.

22. In a 1:1 exchange system, what should we do with dangerous drug stocks that are expired or about to expire?

Soon to be outdated: Try to use these stocks before they go out of date, or have your specific responsible DEA registrant hospital replace your short-dated drug stock.

Individual outdates: Return them to your specific responsible DEA registrant hospital and have them replaced.

Outdates of items in boxes: Return to specific responsible DEA registrant hospital and have a new box issued.

23. My EMS organization has a DEA registration, can we still utilize a 1:1 drug exchange with a medical control pharmacy?

No. An EMS organization that is registered with the DEA is **NOT** eligible to use a 1:1 exchange system to drug exchange for controlled substances.

24. Can an EMS unit do a drug transfer or exchange with another EMS?

It depends on the circumstance.

No: If the EMS organization is utilizing 1:1 drug exchange with a hospital or if the EMS units are from different companies or governmental entities. A curbside exchange shall not occur under any circumstances.

Yes: If the EMS units are owned and operated by a single entity and the drug stock is under common EMS ownership. The exchange must be accompanied with proper documentation. Example: Acme EMS Squad#1 may perform a curbside exchange with Acme EMS Squad#2 with proper documentation of the transfer.

-OR-

EMS units are permitted to conduct "occasional sales" of the following drugs with EMS units from different companies or governmental entities in accordance rule 4729:5-3-09:

- Naloxone; or
- Any dangerous drugs if the drugs are in shortage. A drug that is in shortage means a drug on the United States Food and Drug Administration's drug shortage list.

NOTE: Occasional sales may occur even if no money changes hands.

25. In the event that two EMS units from different agencies both administer drugs to the same patient, who is required to complete a run sheet?

Both EMS units must complete a run sheet documenting their own administration of drugs. See Q17 for more information on document drug administration.

26. Does the hospital need a completed run sheet at the time of the 1:1 drug exchange?

It is strongly recommended that a completed run sheet be presented at the time of the 1:1 drug exchange. However, if this is not possible and the hospital permits it, the EMS can use an alternate drug report at the time of the exchange (i.e. drug box accountability form). The EMS must follow-up by sending a completed run sheet to the exchange hospital at some point and within a reasonable time period (i.e. end of shift). The hospital must then compare the drug use documented on the alternate drug report form to that on the completed run sheet. If there are discrepancies, the hospital must investigate and contact the Board of Pharmacy, and, if appropriate, the DEA, if it is determined that a theft or loss exists.

27. What does the term "posting up" mean?

As defined in rule 4729:5-14-01:

"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.

28. What does the term "posting up at a special event" mean?

"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.

Except for an emergency management assistance compact or an emergency declared by the governor, posting up at a special event requires notification to the Board.

This notification must be submitted electronically. The request form can be found on the Board's terminal distributor licensing page: https://www.pharmacy.ohio.gov/Licensing/TDDD.aspx

29. If there is a modification to my agency's drug list, am I required to notify the Board?

Yes. You are required to update your drug list and submit the entire list (not just the changes) electronically. Your drug list must be signed by the agency medical director and submitted electronically in .PDF format by visiting: www.pharmacy.ohio.gov/upload. A sample drug list can be found on the Board's terminal distributor licensing page: https://www.pharmacy.ohio.gov/Licensing/TDDD.aspx.

NOTE: If your drug list has not changed, you are not required to submit a new list upon renewal.

IMPORTANT: If uploading a new drug list, be advised that this will replace the current drug list on file. The list should include all drugs (not just updates) that may be purchased and possessed by the licensee.

30. If there is a modification to my agency's protocol or personnel list, am I required to notify the Board?

No. An agency should not submit any changes to their protocol or personnel list. However, such documentation should be updated and made available upon inspection by a Board of Pharmacy agent. A sample personnel list can be found on the Board's terminal distributor licensing page: https://www.pharmacy.ohio.gov/Licensing/TDDD.aspx.

NOTE: DO NOT submit your personnel list or protocols upon renewal, even if there was a change.

31. What do I need to submit to the Board in the event of a change of medical director/responsible person?

If the medical director is the new responsible person: The new medical director will have to submit a change of responsible person request using the state's eLicense system. For instructions on submitting a change or responsible person request, click here.

If the medical director is not the new responsible person: The organization must submit a current drug list signed by the new medical director. See Q29 for instructions on electronically submitting an EMS organization's drug list.

32. What is required if there is a change of location, addition of satellite location, change of category, name change or change of ownership?

Rule 4729:5-2-03 of the Administrative Code requires a change of location, change of category, name change or change of ownership requires a new application and fee.

The addition of a satellite location requires a new license application and the appropriate fee ($60.00 annual fee).