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EMS FREQUENTLY ASKED QUESTIONS

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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 are the security requirements for the storage of dangerous drugs?

As defined in rule 4729-33-03 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.

The "responsible person" as defined in rule 4729-5-11 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, the responsible person must be an Ohio licensed physician (MD or DO) or a pharmacist.

All dangerous drugs and hypodermics must be secured in a tamper-evident setting with access limited to EMS personnel based on their certification status. All licensees shall provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs. All dangerous drugs must be maintained in a clean and temperature-controlled environment.

An Example of a Common Security & Storage Practice: A drug box, cabinet, drawer, etc. that contains prescription drugs which is secured with a tamper-evident numbered seal tab system or a lock system. EMS organizations using a seal tab system must also maintain a complete and

accurate tamper-evident log book for each box, cabinet, drawer, etc. to document access and drug accountability.

4. Who can have access to controlled substances?

Only emergency medical technician-paramedics, emergency medical technician-intermediates, registered nurses, physicians, and pharmacists who are associated with that EMS organization may have access to any controlled substances maintained by the EMS organization. Other persons employed by the EMS organization may have access to controlled substances only under the direct and immediate supervision of an emergency medical technician-paramedic, an emergency medical technician-intermediate, a registered nurse, or a physician in emergency situations.

5. What EMS personnel may administer dangerous drugs?

Administration of dangerous drugs by EMS personnel is limited to the scope of practice as defined by the law (Ohio Revised Code) and by rules (Ohio Administrative Code) adopted by the Board of Emergency Medical Services, for the individual's certification level and protocols (within scope of practice) as established by the medical director. Please see section 4765.16 of the Ohio Revised Code and rules 4765-15-04, 4765-16-04, and 4765-17-03 of the Ohio Administrative Code for scope of practice information.

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

As defined in rule 4729-33-03 of the Ohio Administrative Code: Any dangerous drug that reaches its expiration date is considered adulterated and must be separated from the active stock to prevent possible administration to patients. Any non-controlled dangerous drug that is outdated may be returned to the supplier where the drug was obtained or may be disposed of in the proper manner. Any controlled substance that is outdated may be returned to the supplier where the drug was obtained. Destruction of outdated controlled substances may be done with prior written permission from the Board of Pharmacy office *(See question #19).*

To obtain permission to destroy controlled substances, visit: www.pharmacy.ohio.gov/csdispose

7. How should you dispose of partially used controlled substances (a.k.a. waste)?

As defined in rule 4729-33-03(J) of the Ohio Administrative Code: Destruction of partially used controlled substances can be accomplished, with the appropriate documentation, by two licensed health care personnel, one of which must have at least an emergency medical technician-intermediate level of training. An Example of Wasting: The paramedic who administered the controlled substance has an E.R. nurse witness the disposal of the drug waste, and then both document the destruction on a record with positive identification.

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

As defined in rule 4729-5-01(N) of the Ohio Administrative Code: "Positive identification" means a method of identifying an individual who prescribes, administers, or dispenses a dangerous drug. Positive identification includes a manual signature on a hard copy record or report, a biometric method, or a private personal identifier such as a password with an additional secure

means of identification such as, a bar code reader, a magnetic card reader, a proximity badge reader, a Board of Pharmacy approved system of randomly generated personal questions, or other effective method approved by the Board of Pharmacy.

Note: Positive identification must be attached to a run sheet, or other drug record, only by the specific individual that personally administered the drug. Another person cannot attach positive identification to drug administrations that they did not personally administer.

Examples of common positive identification practices:

- Handwritten run reports, with the wet-ink signature (i.e., not electronic) of the EMS personnel that administered a dangerous drug.
- Computerized run reports with a Board of Pharmacy approved electronic positive ID system.
- Computerized run reports that are printed out, and signed in wet ink by the EMS personnel who administered a dangerous drug.

More information on positive identification for EMS and how to obtain approval of a positive ID system can be accessed here: www.pharmacy.ohio.gov/emsID

9. What should you do if drugs are discovered to be missing?

As defined in rule 4729-33-03(K) of the Ohio Administrative Code: Any theft or significant loss of dangerous drugs must be reported immediately upon discovery, by telephone (immediately after theft is suspected), to the Board of Pharmacy, local law enforcement and, if controlled substances are involved, to the Drug Enforcement Administration. A report must be filed with the Board of Pharmacy of any loss or theft of the vehicle, storage cabinets, or drug boxes containing dangerous drugs used by the EMS organization within 30 days of discovery. The DEA requires that losses and thefts of controlled substances must only be submitted electronically via their DEA 106 Form and only by the registrant.

More information on theft or loss can be accessed here: www.pharmacy.ohio.gov/theft

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

As defined in rule 4729-33-03(L) of the Ohio Administrative Code: Any dangerous drug showing evidence of damage or tampering shall be removed from stock and replaced immediately.

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 the Board of Pharmacy.

11. 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.

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

As defined in rule 4729-33-04 of the Ohio Administrative Code:

All emergency medical service (EMS) organizations are required to keep complete and accurate records for at least three years of receipt, use, administration, destruction, and waste of dangerous drugs. These records must be readily available for inspection by Board of Pharmacy agents or inspectors as per section 3719.27 of the Ohio Revised Code and rule 4729-5-29 of the Ohio Administrative Code.

Records from satellites may be stored at the headquarters if a prior written request is sent to the Board of Pharmacy and approved. A letter requesting storage of records at the headquarters must be sent to the Board of Pharmacy office by verifiable delivery. The Board of Pharmacy will notify the organization of the board's approval or denial of the request within sixty days. The request may be submitted electronically by visiting: www.pharmacy.ohio.gov/emsrecord

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 that may have any of that lot number shall be dealt with according to the manufacturer's recommendations; but, in all such cases, such portable oxygen tanks must be purged and then refilled.

A readily retrievable record of controlled substances shall be kept containing documentation of administration, use, or waste of the controlled substances. Such records shall contain at least the following information:

- The name, strength, and quantity of the controlled substance administered, used, or wasted;
- The date of administration, use, or waste;
- The name or other means of identifying the patient, such as medical record number or run number;
- The signature and identification number of the individual administering the controlled substance;
- In the case of waste, the signatures and identification numbers of both individuals involved in wasting the controlled substance.

Also, if a computerized record keeping system is being utilized to document any drug transactions, including but not limited to the receipt, use, administration, destruction, and wastage, then the system must have "positive identification", pursuant to paragraph (N) of rule 4729-5-01 of the Administrative Code, of the individual responsible for the drug transaction and be approved by the Board of Pharmacy (*See question #8)*.

13. What are the security requirements for the storage of intravenous (IV) solutions?

Intravenous solutions are dangerous drugs (prescription drugs). They must be stored and secured with a tamper-evident seal or locked with keys that are only accessible to authorized licensed EMS personnel.

14. What are the security requirements for the storage of irrigation solutions?

Irrigation screw-top containers are tamper-evident when sealed by the manufacturer prior to the distribution and sale and therefore do not need to be stored within a separate secured or locked area. Also, the container must be labeled "Irrigation only." Note that the irrigation solution must be destroyed after the seal is broken on the screw-top container.

15. What type of licenses does an EMS organization need to possess dangerous drugs?

Ohio Licensure: All EMS physical locations that possess dangerous drugs must obtain a Terminal Distributor of Dangerous Drugs license 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 Terminal Distributor of Dangerous Drug license. The license issued will be a limited license that includes a Drug Addendum. The Drug Addendum will list the specific drugs (along with emergency drug protocols) that an EMS organization may possess as approved by their medical director and the Board of Pharmacy.

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.

- 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.

16. 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 "medical control pharmacy." An EMS organization must provide their specific responsible DEA registrant with a copy of the following documents: Board of Pharmacy Terminal Distributor of Dangerous Drug License with Drug Addendum, and Board of Pharmacy approved and medical director authorized and signed EMS drug protocols. 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.

PLEASE NOTE: *A 1:1 drug exchange is only permissible with a hospital. The Ohio Revised Code and the Board's Administrative Code (ORC 3727.01/OAC 4729-17-01) defines hospital as an institution classified as a hospital under section 3701.07 of the Revised Code in which are*

provided to inpatients diagnostic, medical, surgical, obstetrical, psychiatric, or rehabilitation care for a continuous period longer than twenty-four hours or a hospital operated by a health maintenance organization.

Hospital does not include a facility licensed under Chapter 3721. of the Revised Code, a health care facility operated by the department of mental health and addiction services or the department of developmental disabilities, a health maintenance organization that does not operate a hospital, the office of any private licensed health care professional, whether organized for individual or group practice, or a clinic that provides ambulatory patient services and where patients are not regularly admitted as inpatients.

17. 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.

18. 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.

19. 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. *Also, see question #6.*

20. 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.

21. While on a call for service, can an EMS unit do a drug transfer or exchange with another EMS unit (a.k.a. curbside exchange)?

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.

22. 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 with positive identification.

23. 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 as long as the drug use is documented with positive identification (i.e. drug box accountability form). The EMS must follow-up by sending a completed run sheet with positive identification 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.

24. Are we required to have positive identification on the run sheet at the time we complete a 1:1 drug exchange with the hospital?

No, positive identification must be applied to the run sheets within a reasonable period of time. Positive identification does not need to be applied to the run sheet immediately upon administering a medication or to complete a 1:1 exchange.

Note: The hospital is responsible for establishing policies and procedures to ensure the security and accountability of the drugs and the exchange.

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

As defined in rules 4729-33-01 and 4729-33-05: "Posting up" means locating an EMS unit containing dangerous drugs at a location other than the location licensed by the Board of Pharmacy. "Posting up" must be a temporary, short-term location of the EMS unit for less than 24 hours where the EMS unit is under constant supervision of the EMS personnel on duty (i.e. local school sporting event, coverage of a station pursuant to a written mutual aid agreement).

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

As defined in rules 4729-33-01 and 4729-33-05 of the Ohio Administrative Code: "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 pursuant to a formal agreement with the sponsors of the special event. A "special event" means an event requiring EMS coverage for more than twenty-four hours such as a county fair or weekend festival. To do this requires written notification to, and approval from, the Board of Pharmacy. The notification must include the

name and location of the event, dates of the event, and name and telephone number of the contact person of the EMS unit.

This notification may be submitted electronically: www.pharmacy.ohio.gov/postingup

27. 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 in .PDF format and can be uploaded by visiting: www.pharmacy.ohio.gov/limited

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

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

No. Rule 4729-33-02 no longer requires an agency to 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.

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

29. What do I need to submit to the Board in the event of a change of medical director?

The new medical director will have to submit a notarized letter to the Board office within 5 business days of the change. In that letter, the medical director shall indicate whether or not they approve of the existing protocol and drug list.

With that letter, the medical director is also required to submit a change of responsible person form. This form can be accessed under the TDDD forms section: http://www.pharmacy.ohio.gov/Licensing/TDDD.aspx

NOTE: While not required, it is recommended that the medical director submit a new drug list (even if the same list) with their signature.

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

A change of location, addition of satellite location, change of category, name change or change of ownership requires a new application and fee. This is required within 30 days of any of these changes.