National Association of State EMS Officials (NASEMSO)
Comments to Proposed DEA Rules – Docket No. DEA–377
Protecting Patient Access to Emergency Medications Act of 2017

The National Association of State Emergency Medical Services Officials (NASEMSO) is a non-profit organization composed of members from the 56 state and territorial emergency medical services (EMS) offices. These state officials are responsible for providing oversight to the emergency medical services in their respective states or territories, including one or more of the following: licensing of EMS clinicians (emergency medical responders, emergency medical technicians, advanced EMTs and paramedics) licensing of ambulance services, providing medical oversight, overseeing EMS data collection, providing grant support and ensuring the public has access to high quality prehospital emergency medical care. NASEMSO submits the following comments in the interest of ensuring the public is protected while having access to safe, efficient and effective emergency care.

RE: Federal Register/ Vol. 85. No. 193/ Monday, October 5, 2020, Pages 62634-62651

DEA Registration - Crossing State Lines

Under the Act and the proposed 21 CFR §1301.20, EMS agencies would be permitted to choose the option of a single registration in each state where the EMS agency administers controlled substances. The EMS agency would be required to obtain a DEA registration for the registered location at which the EMS agency would receive controlled substances from distributors. EMS agencies would then be permitted to designate specific unregistered locations where controlled substances would be delivered and stored, provided the EMS agency provides notice of the name and physical address of the designated location to the DEA at least thirty (30) days prior to the first delivery of controlled substances to the designated location by the EMS agency. Unless an objection is raised by the DEA, an unregistered location automatically becomes a designated location of the EMS agency 30 days after notification of the designated location is made to the DEA.

COMMENT: Many EMS agencies located near state borders respond to EMS calls in neighboring states. Would this prevent an EMS agency from administering a controlled substance when responding to an EMS call in a neighboring state if their registration is only with the state where they are based (physically registered)?

Security Controls for EMS

§1301.80 proposes two (2) options for storage of controlled substances:

1. A securely locked, substantially constructed cabinet or safe that cannot be readily removed. This storage component must be located at a secured location.
2. In an automated dispensing system, provided the following conditions are met:
    a. The ADS machine is located at an EMS agency registered location or designated location.
    b. The EMS agency cannot permit any entity other than the registered EMS agency install and operate the ADS machine.
    c. The ADS machine cannot be used to directly dispense controlled substances to an ultimate user.
    d. The EMS agency must operate the ADS machine in compliance with state law
    e. Access to the ADS machine must be limited to employees of the EMS agency in order to account for and monitor dissemination of controlled substances

COMMENT: This does not address how controlled substances are to be stored in the emergency vehicle, but rather at the station/base. *Are there security requirements for controlled medications while in the vehicle?*

Recordkeeping for Administration and Disposal

The proposed § 1304.27(a) specifies recordkeeping requirements, some of which are as follows:

Administration and Disposal

(1) Name of the substance;
(2) Finished form of the substance (e.g., 10mg tablet or 10mg concentration per fluid ounce or milliliter);
(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 or adopted;
(9) Amount disposed of, if applicable;
(10) Manner disposed of; and
(11) Initials of person who disposed and witness to disposal.

COMMENT: It would be extremely burdensome for the medical director to initial EVERY patient care record where a controlled substance was delivered. In real time the medical director would not be available to "initial" each run sheet. *Can this requirement be met by standing approvals in the electronic patient care report (EPCR) or other "deemed" approvals for EMS clinicians following approved standing orders from the medical director?*

COMMENT: in some areas, controlled medications are disposed of ("wasted") at the hospital in collaboration with hospital staff and record keeping is maintained by the hospital. Rural and semi-rural EMS systems commonly only have one EMS clinician on a given call whose license allows for administering controlled substances and may have few advanced life support (ALS) providers available in general to waste a controlled medication at an EMS agency's registered or designated location. *Would § 1304.27(a) allow the practice of wasting controlled medications in collaboration with the hospital staff? If so, would the record-keeping of the medication disposal by the hospital staff meet the proposed requirements?*

Recordkeeping for Destruction of a Controlled Substance

§ 1304.27(a) (4) For destruction of a controlled substance

(i) Name of the substance
(ii) Finished form of the substance (e.g. 10 mg tablet or 10 mg concentration per fluid ounce or milliliter);
(iii) 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);
(iv) Date of the destruction;

(v) Manner of disposal of the substance, if applicable;
(vi) Name, address, and registration number of the person to whom the substance was distributed, if applicable; and
(vii) Name and title of the person destroying the controlled substance.

COMMENT: *How does disposal differ from destruction? What is an acceptable means of destruction? Disposal?*

Medical Director Standing Orders

The Act and proposed § 1306.07 allow for standing orders to administer controlled medications. The language is explained in the Federal Register notice, in relevant part, as "only the medical director *of an EMS agency* is given the authority to issue and adopt a standing order."

§ 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 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.

COMMENT: Several states have statewide prehospital clinical protocols under which all EMS clinicians in the state must practice. These protocols are regularly revised and approved by a committee or board composed of EMS physicians. There is concern that the language allowing "one or more medical directors of the agency" and "only the medical director *of an EMS agency* is given the authority to issue and adopt a standing order" may allow the agency medical director to usurp the state's authorized guidelines.

Restocking – Exception or Standard Practice?

The DEA's proposed § 1307.14(a) codifies the allowance for restocking for non-hospital-based EMS agencies. Following an emergency response where controlled substances were administered, EMS personnel may not have enough time to return to their stationhouse to

restock their EMS vehicle with controlled substances. Depending on the circumstances, the stationhouse may be a considerable distance from the hospital where the EMS personnel brought a patient, or the volume of emergencies may be so great that the ambulance does not have time to return to the stationhouse. Rural EMS systems in the United States may face transport distances of 20 to 100 miles to the nearest hospital. Thus, the Act allows non hospital-based EMS agencies to receive controlled substances from a hospital for the purpose of restocking an EMS vehicle following an emergency response. 21 U.S.C. 823(j)(8). DEA's proposed § 1307.14(a) codifies this allowance in DEA regulations.

§ 1307.14 (a) would allow a non-hospital-based EMS vehicle to receive controlled substances from a hospital following an emergency response provided

(1) The registered or designated location of the agency operating the vehicle maintains the record of such receipt in accordance with…
(2) The hospital maintains a record of such delivery to the agency in accordance with…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.

COMMENT: In some areas, the hospitals supply the majority of medications to EMS services, sometimes at no cost. In these situations, EMS agencies participate in a drug kit exchange program with local hospitals where the hospital stocks a drug kit and then exchanges used kits with EMS units, following state Board of Pharmacy regulations, for a fresh, stocked kit. *Would restocking of controlled medications by hospitals be limited to the above-noted exceptions only (distance from station house, high volume, rural EMS) and not be allowed as a standard practice? Would EMS agencies have to obtain their controlled medications from a distributor instead of the hospital?*