16 DEPARTMENT OF PUBLIC SAFETY

163 EMERGENCY MEDICAL SERVICES BOARD (MAINE EMS)

CHAPTER 6: DRUGS AND MEDICATIONS

SECTION 1. DEFINITIONS

1. **"Administer" or "Administration"** means the direct application of a Non-Controlled Substance or a Controlled Substance to the body of a patient.
2. **"Authorizing Medical Professional"** means:
   A. A State of Maine licensed physician authorized by a hospital to provide contemporaneous direction of an Emergency Medical Services Person using telecommunications or in-person contact; or
   B. A State of Maine licensed Advanced Practice Registered Nurse or Physician Associate, authorized by a hospital to provide contemporaneous direction of an Emergency Medical Services Person using telecommunications or in-person contact.
3. **"Controlled Substance"** means a drug or other substance, or immediate precursor, included in Schedule I, II, III, IV, or V of part B of the Controlled Substances Act. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986.
4. **"Designated Location"** means a location designated by a Service to the U.S. Drug Enforcement Administration as a location for the delivery of Controlled Substances.
5. **"Distribute"** means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term 'distributor' means a person who so delivers a controlled substance or a listed chemical.
6. **"Mean Kinetic Temperature"** means the single calculated temperature that represents the cumulative thermal stress experienced by a controlled or non-controlled substance during a specified period and is equivalent to the temperature at which the same amount of chemical degradation would occur as that resulting from the actual varying temperatures experienced over that period.
7. **"Non-Controlled Substance"** means a substance that is not a controlled substance as defined within this chapter, and:
   A. Is used by Maine EMS-licensed services and Emergency Medical Services Person(s) in the delivery of emergency medical treatment, consistent with a Maine Emergency Medical Services Protocol; and
   B. Is listed as approved within a Maine Emergency Medical Services Protocol approved by the Medical Direction and Practices Board and filed with the Emergency Medical Services' Board; and
   C. Is a drug that is approved by the U.S. Food and Drug Administration.
8. **"On Call"** means that the Emergency Medical Services Person(s) are ready and available to respond, but may not be responding to an emergency at that precise moment.

9. **"Service"** means an Ambulance Service or a Non-Transporting Service, as defined within Chapter 2 of these Rules.
10. **"Shortage"** means an event where the supply of a Non-Controlled Substance or Controlled Substance is disrupted. A Shortage is not an event in which the service experiences a disruption in supply due to a mistake in inventory management.
11. **"Unit Dose"** means a single, pre-packaged, and labeled dose of medication intended for one patient at a specific Administration time.

SECTION 2. NON-CONTROLLED SUBSTANCES

1. Authorization
   A. An Emergency Medical Services Person is authorized to Administer Non-Controlled Substances to a patient, according to applicable protocol(s) and/or verbal order(s) issued by an Authorizing Medical Professional, that pertains to their level of licensure. The Emergency Medical Services Person must record any Administration of a Non-Controlled Substance on the Patient Care Report for that patient.
   B. A Service is authorized to obtain, possess, store, and furnish Non-Controlled Substances for the purpose of enabling an Emergency Medical Services Person to provide emergency medical treatment to patients.
2. Supply
   A. A Service must ensure that a sufficient quantity of Non-Controlled Substances is available on every request for service so that a patient can receive emergency medical treatment for the duration of that call, at the highest level of licensure of responding personnel to that call, up to the level or permit of the service.
   B. In the event of a Shortage of a Non-Controlled Substance, a Service is not required to ensure the availability of that specific Non-Controlled Substance. A Service must supply any alternative required by a shortage protocol authorized by the Medical Direction and Practices Board and filed with the Emergency Medical Services' Board.
3. Storage
   A. A Service must store all Non-Controlled Substances according to the U.S. Food and Drug Administration label, including but not limited to:
      (1) Permitted temperature range;
      (2) Allowed excursion(s); and
      (3) Mean Kinetic Temperature.
   B. A Service must store all Non-Controlled Substances, when not actively being used or attended, in an area that limits access to those individuals who are charged in the course of their participation with the Service, with the stocking, use, inventory, or ordering of those Non-Controlled Substances.
   C. A Service must store all Non-Controlled Substances in their Unit Dose packaging as dispensed to the service, and/or labeled by the distributor from which the non-controlled substances are received.
   D. A service must store all Non-Controlled Substances in a manner that prevents:
      (1) Contamination of the Non-Controlled Substance or its package with blood or other bodily fluids;

(2) Contamination of the Non-Controlled Substance or its package with dirt or debris; or
(3) Cross-contamination of the Non-Controlled Substance between patients.

E. The location(s) in the ambulance and/or in a building where Non-Controlled Substances are stored by a Service are subject to inspection by the Office of Emergency Medical Services. A service must allow an inspection by the Office of Maine Emergency Medical Services, and refusal to allow an inspection is subject to disciplinary action against the Service's license. Inspections shall be conducted during normal business hours.

4. Recordkeeping
   A. A single, legible log for each storage location documenting every Non-Controlled Substance must be kept by the Service. This log must contain the following information:
      (1) The location of the Non-Controlled Substance;
      (2) The description and unit-dose quantity of Non-Controlled Substance;
      (3) The expiration date of the Non-Controlled Substance;
      (4) The unique digital or physical signature of the person making an entry into the log;
      (5) The printed name of the person making an entry into the log;
      (6) If applicable, the Maine EMS License Number of the person making an entry into the log.
   B. A Non-Controlled Substance must be checked by the Service, and an entry made in its log, no less than monthly.

SECTION 3. CONTROLLED SUBSTANCES

1. Authorization for Procuring, Possessing, Furnishing, and Administering Controlled Substances
   A. A Service with valid licensure or permit from the Board, at the Paramedic level, is authorized to procure, possess, store, and furnish Controlled Substances in schedules II through V established pursuant to the Controlled Substances Act, 21 U.S.C. § 801, et seq.
   B. A Service with valid licensure or permit at the Paramedic level is authorized to furnish a Controlled Substance to an Emergency Medical Services Person associated with that service for the purpose of providing Emergency Medical Treatment to a patient, or while the Emergency Medical Services Person is On Call. The Service must ensure that the Administering Emergency Medical Services Person records any Administration of a Controlled Substance on the Patient Care Report for that patient.
   C. An Emergency Medical Services Person may administer a Controlled Substance to a patient during a request for service, for the purpose of providing Emergency Medical Treatment to that patient. Such Administration must be in accordance with any protocol approved by the Medical Direction and Practices Board and filed with the Emergency Medical Services' Board, or by verbal order from an Authorizing Medical Professional. The Emergency

Medical Services Person must record any Administration of a Controlled Substance on the Patient Care Report for that patient.

2. Supply
   A. A Service licensed at or permitted to the Paramedic-level must ensure that a sufficient quantity of Controlled Substances is available on every request for service so that a patient can receive Emergency Medical Treatment for the duration of that call.
   B. In the event of a Shortage of a Controlled Substance, a Service is not required to ensure the availability of that specific Controlled Substance. A Service must supply any alternative required by a shortage protocol authorized by the Medical Direction and Practices Board and filed with the Emergency Medical Services' Board.
3. Storage
   A. A Service must store all Controlled Substances according to the U.S. Food and Drug Administration label, including but not limited to:
      (1) Permitted temperature range;
      (2) Allowed excursion(s); and
      (3) Mean Kinetic Temperature.
   B. A Service must store all Controlled Substances in a manner that prevents:
      (1) Contamination of the Controlled Substance or its package with blood or other bodily fluids;
      (2) Contamination of the Controlled Substance or its package with dirt or debris; or
      (3) Cross-contamination of the Controlled Substance between patients.
   C. The location(s) in the ambulance and/or in a building where Non-Controlled Substances are stored by a Service are subject to inspection by the Office of Emergency Medical Services. A service must allow an inspection by the Office of Maine Emergency Medical Services, and refusal to allow an inspection is subject to disciplinary action against the Service's license. Inspections shall be conducted during normal business hours.
4. Recordkeeping
   A. A Service must report its U.S. Drug Enforcement Administration registration number to Maine EMS as part of its service licensure or licensure renewal process.
   B. A Service must report to Maine EMS the registered location of the Service, and any Designated Location of the Service, as part of its service licensure or licensure renewal process.
   C. A Service must report any change in its U.S. Drug Enforcement Administration registration or any change in the Designated Location(s) of the Service, to Maine EMS in writing, within ten (10) business days.
   D. A Service must report to Maine EMS, any suspension, revocation, surrender, or denial of renewal taken against its U.S. Drug Enforcement Administration registration, in writing, within ten (10) business days.
5. Registration with the U.S. Drug Enforcement Administration

A. A Service that registers with the U.S. Drug Enforcement Administration must maintain a valid registration to remain licensed or permitted to the Paramedic level. A failure to maintain registration with the U.S. Drug Enforcement Administration while licensed or permitted to the Paramedic level is grounds for disciplinary action against a Service.

AUTHORITY: 32 M.R.S. § 84.1, 32 M.R.S. § 86.1, 32 M.R.S.§86-A, 32 M.R.S. § 87.

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April 30, 1985 - Sec. 1, 2.846.222, 6.332, 9.313, 8.3216 and 9.11
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