TITLE
CONTROLLED DRUGS AND SUBSTANCES

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NOTE: The first appearance of terms in bold in the body of this document (except titles) are defined terms – please refer to the Definitions section.

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OBJECTIVES

- To outline the responsibilities for Designated Administrator and Medical Directors: ordering, transporting, storing, providing, and documenting controlled substances that are used by Alberta Health Services (AHS) Emergency Medical Services (EMS).

- To outline the responsibilities for Paramedics when; processing, transporting, administering, documenting and destroying controlled substances that are used by AHS EMS.

- To outline the responsibilities for EMS health care professionals when monitoring, administering and documenting Nitrous Oxide when used by AHS EMS (direct delivery and contracted service providers).

- To ensure the requirements for High-Alert Medications, Accreditation Canada and Nitrous Oxide are met.

- To outline compliance requirements.

PRINCIPLES

- AHS EMS (direct delivery and contracted service providers) is committed to the standards dictated by federal legislation the Controlled Drugs and Substances Act (S.C 1996, c.19), and affiliated regulations, Accreditation Canada (AC) standards and integrating High-Alert Medication requirements into EMS practice.
• This policy is supported by the EMS Managing Medications, Solutions and Medical Supplies Procedure (the procedure). The details of how to implement the policy elements are outlined within the procedure.

APPLICABILITY

Compliance with this document is required by all Alberta Health Services employees, members of the medical and midwifery staffs, students, volunteers, and other persons acting on behalf of Alberta Health Services (including contracted service providers as necessary).

ELEMENTS

1. Designated Administrator and Medical Director’s Responsibilities
   1.1 Storage and Security
      a) The designated administrator and medical director will take the necessary steps in accordance with the procedure and with measures implemented by the Zone Executive Leadership (ZEL) to ensure the security of Controlled Substances.
      b) Security will be ensured when storing Controlled Substances within EMS facilities including stations, in paramedic’s possession, and within EMS vehicles.
      c) Only authorized employees will have access to controlled substances.
   1.2 Loss or Theft
      a) The designated administrator or medical director will ensure that all activity involving Controlled Substances is documented in a Controlled Substances Registry.
      b) All incidences of loss or theft will be reported to the local law enforcement agency immediately, and in writing to Health Canada within 10 days of discovery.
      c) In addition to contacting the local law enforcement agency; the designated administrator or designate will submit a loss or theft report to Health Canada called the, Loss of Theft Report From for Controlled Substances and Precursors as identified in the Managing Medications, Solutions and Medical Supplies.
   1.3 Ordering
      a) The designated administrator or medical director will order Controlled Substances from a licensed pharmacy in Alberta and will return unserviceable controlled substances for destruction to the originating pharmacy.
2. Paramedic’s Responsibilities

2.1 Storage and Security
a) Paramedic’s will take the necessary steps in accordance with the procedure and the measures that have been implemented by the Executive Director ZEL to ensure the security of Controlled Substances while in paramedics possession, in storage at EMS facilities including stations and during transport within EMS vehicles.

2.2 Obtaining Controlled Substances
a) The paramedic will obtain Controlled Substances from the designated administrator or medical director.

2.3 Administration
a) The paramedic will administer Controlled Substances in accordance with AHS EMS Medical Control Protocols (MCP’s) or in accordance with case-specific directions by a medical director or physician.

b) The paramedic will document administration and wastage of Controlled Substances within the Patient Care Record.

2.4 Controlled Substance Registry
a) The paramedic will record the following associated with Controlled Substances using the Controlled Substance Registry:

   • dates and times of administration, of wastage, of replacement and return
   • names of the patient, the person who witnessed wastage and the person who administered the medication
   • quantities obtained, returned, disposed of through breakage or wastage and administered.

2.5 Loss or Theft
a) The paramedic will report immediately to designated administrator or designate (this may be a supervisor or team lead) or medical director when they become aware of any loss or theft of controlled substances in their possession, from within the ambulance, the EMS facility including station, EMS vehicle or aircraft.

b) The paramedic will submit a report to the AHS Reporting and Learning System for Patient Safety (RLS) RLS Report for direct delivery services. Contracted service providers are to submit an EMS Risk Management Form. RLS reports will be submitted in accordance to the AHS Reporting
of Clinical Adverse Events, Close Calls and Hazards Policy. Where possible the following will be provided in the report:

- description of occurrence; how the loss or theft was identified
- type of loss or theft (break and entry, pilferage, loss unexplained, armed robbery, grab theft, loss in transit, other)
- time of occurrence
- place of occurrence
- location of occurrence
- substance involved
- total dose or approximate
- number of vials
- EMS health care professionals or staff license numbers and signatures
- designated administrator’s signature

2.6 Unserviceable Controlled Substances

a) The paramedic will dispose of unserviceable Controlled Substances by returning these substances to the designated administrator or medical director.

3. Health Care Professional’s Responsibilities

3.1 Roles

a) EMS health care professionals identified for this policy and associated procedure are Paramedics, Emergency Medical Technicians (EMT) and Emergency Medical Responders (EMR).

3.2 Responsibility

a) EMS health care professionals can:

- Provide a dual signature for medication administration and wastage and within the Controlled Substance Registry
- Possess, transport, administer within their scope of practice; Nitrous Oxide and High-Alert Medications
3.3 Restrictions
   a) Emergency Medical Technicians (EMT) and Emergency Medical Responders (EMR) cannot be in possession and transportation of medications listed in the Controlled Drugs and Substances Act (S.C 1996, c.19).

4. High-Alert Medications
   4.1 High-Alert Medications and EMS
   a) High-Alert Medications can cause significant patient harm when used in error and therefore require specific risk reduction strategies. Risk reduction strategies are identified but not limited to ones outlined in the procedure.
   b) The designated administrator will take the necessary steps in accordance with the procedure and measures that have been implemented by the ZEL to ensure:
      - EMS high-alert medications have risk reduction strategies
      - EMS high-alert medications have compliance measures
   c) EMS will abide by the AHS Management of High Alert Medication Policy and the AHS Management of High Alert Medication Procedure.

5. Nitrous Oxide
   5.1 Federal Legislation
   a) Nitrous Oxide is not a Controlled Substance as per Controlled Drugs and Substances Act (S.C 1996, c.19). However; EMS will be monitoring the Controlled Substance Registry and administration.
   b) Nitrous Oxide falls under federal legislation the Canadian Environmental Protection Act, 1999 - Schedule 1 (Sections 56, 68, 71, 77, 79, 90, 91, 93 to 96 and 199) -- LIST OF TOXIC SUBSTANCES. 76. Nitrous Oxide, which has the molecular formula N2O.

   5.2 Controlled Substances Registry
   a) The EMS health care professional will record usage of Nitrous Oxide in the Controlled Substance Registry.

   5.3 Administration
   a) The EMS health care professional will document the administration of Nitrous Oxide on the Patient Care Record.
6. Compliance

6.1 Substance and Registry Reconciliation
   a) Designated administrators or medical directors will ensure that all required information is documented in the EMS Controlled Substance Registry and that the information reconciles.

6.2 Conducting Audits
   a) Designated administrators or medical directors will conduct and document routine audits, on a minimum annual basis to ensure the following:
      - Controlled Substance management meets the requirements set out by the Controlled Drugs and Substances Act (S.C 1996, c.19).
      - Controlled Substance management meets Accreditation Canada EMS Standards and the AC Required Operational Standards.

DEFINITIONS

Breakage means a drug product containing a controlled substance that has been unintentionally broken.

Controlled Drugs and Substances Act means a drug specifically named in the federal legislation Controlled Drugs and Substances Act, and associated regulations (Narcotic Control Regulation, Benzodiazepines and Other Targeted Substances Regulation), and Alberta EMS section 56 exemptions.

Controlled Substances means a drug identified in the Controlled Drugs and Substances Act and associated regulations as controlled or a scheduled drug. The activity and distribution is tightly controlled because its abuse potential or risk. AHS EMS controlled drugs list in accordance with the AHS EMS Medical Control Protocols are: FentaNYL, Ketamine, LORazepam, Midazolam, and Morphine.

Controlled Substances Registry means a registry that is required by Controlled Drugs and Substances Act documenting all activity involving a controlled substance within the EMS service. This activity will be recorded in a Controlled Substance Registry. The registry is designed to record movement of all quantities of controlled substance from the time it is acquired by the EMS system to the time of its use or disposition. Each EMS station or EMS vehicle where Designated Administrators, Medical Directors or Paramedics involved with controlled drugs and substances will maintain a registry. The controlled substance registry documentation and tracking will be comprised from various sources such as PCRs Pyxis, Vehicle Equipment Check System database and paper methods.

Designated Administrator means a person in the zone or service who is in a managerial position and is ultimately responsible for ordering, transporting, storing, and providing controlled substances for an ambulance operator licensed under the Alberta Emergency Health Services Act and the Emergency Health Services (interim) Regulation.
Health care professional means an individual who is a member of a regulated health discipline, as defined by the Health Disciplines Act or the Health Professions Act, and who practises within scope or role.

High-Alert Medications means medications that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error are clearly more devastating to patients. Therefore require specific risk reduction strategies. High Alert Medications are identified by the Institute for Safe Medication Practices and supported by Accreditation Canada and AHS High Alert Medication requirements. The AHS High Alert Medication list that are identified the AHS EMS Medical Control Protocols and the Critical Care MCPs are listed on the AHS EMS web site.

Medical Director means a person, as defined in the Alberta Emergency Medical Technicians Regulation, who is a physician designated to provide medical control to paramedics, and is in a managerial position with the ultimate responsibility for ordering, transporting, storing and providing controlled substances for an organization that provides emergency medical services in Alberta.

Medication means any substance or mixture of substances manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings and restoring, correcting or modifying organic functions in human beings.

Paramedic means a person who is registered and entitled under the Alberta Health Disciplines Act and Emergency Medical Technicians Regulation to practice as an Emergency Medical Technologist-Paramedic in the Province of Alberta and to administer controlled substances as part of the practice of paramedicine and is actively on duty.

Unserviceable controlled substance means a drug product containing a controlled substance that is expired, contaminated, damaged or any residual controlled substance remaining in a multi dose vial.

Wastage means residual amounts in an administration device (syringe) that needs to be disposed.
REFERENCES

- Alberta Health Services Resources:
  - AHS EMS: Provincial Medical Control Protocols
  - EMS Risk Management Form: AHS Risk Management Form
- Non-Alberta Health Services Documents:
  - Accreditation Canada. (January 29, 2013). Qmentum Program, Emergency Medical Services
  - Accreditation Canada. (January 29, 2013). Qmentum Program, Medication Management Standards
  - Government of Alberta: Emergency Health Services Act Overview
  - Government of Alberta: Emergency Health Services (Interim) Regulation
  - Government of Alberta: Emergency Health Services Act
  - Government of Alberta: Emergency Medical Technicians Regulation
  - Government of Alberta: Licensing and Ambulance Maintenance Regulation
  - Government of Alberta: Staff, Vehicle and Equipment Regulation
  - Canadian Environmental Protection Act, 1999 – S.C. 1999, c. 33 (SCHEDULE 1 : List of Toxic Substances) (for Nitrous Oxide)
  - Health Canada: Controlled Drugs and Substances Act (S.C 1996, c.19)
  - Health Canada: Section 56 Class Exemption For Paramedics in Alberta
  - Health Canada: Section 56 Class Exemption For Designated Administrators of Ambulance Operators in Alberta
  - Health Canada: Section 56 Class Exemption For Medical Directors in Alberta
  - Health Canada: Benzodiazepines and other Targeted Substances Regulation (SOR/2000-217)
  - Health Canada: Narcotic Control Regulations (Current to March 18, 2013)
    - Material Safety Data Sheet (Version 12): Nitrous Oxide