**National Ambulance Service (NAS)**

**Policy**

# Management of Controlled Drugs including Morphine Sulphate and Midazolam

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| **Document reference number** | ***NASPO34*** | **Document developed by** | **Advanced Paramedic Framework Group** |
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**Table of Contents:**

## 1.0 POLICY STATEMENT

1.1 The National Ambulance Service (NAS) is committed to ensuring that Controlled Drugs (CDs) are managed safely and effectively, thus enhancing staff, patient and public safety. The Medical Advisory Group (MAG) endorses Morphine Sulphate as the opiate analgesic of choice. The NAS provides authorisation for individual practitioners to use controlled drugs.

## 2.0 PURPOSE

2.1 The purpose of this policy and procedure is to provide guidance on:

A. Requisitioning
B. Supply
C. Storage
D. Record keeping
E. Return
F. Disposal
G. Action in the event of loss

## 3.0 SCOPE

3.1 Applies to all staff members who are employed by the National Ambulance Service (NAS)

## 4.0 LEGISLATION/OTHER RELATED POLICIES

A. Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2008 (SI 512 of 2008)
B. The Misuse of Drugs (Amendment) Regulations 1993 (SI No. 342 of 1993)
C. Misuse of Drugs (Amendment) Regulations 1993 (SI 338 of 1993)
D. Misuse of Drugs Regulations 1988 (SI no. 328 of 1988)
E. Misuse of Drugs (Safe Custody) Regulations 1982 (SI no 321 of 1982)
F. Policy – AMBP005 – Medicines Management
G. Policy – HCRM005 – Incident/Near Miss Reporting Guideline
H. Procedure – AMBOE002 - Requisition of Controlled Drugs

## 5.0 GLOSSARY OF TERMS AND DEFINITIONS

5.1 Supervisor - Leading EMT (Paramedic/Advanced Paramedic)
5.2 Manager - Ambulance Officer
5.3 Morphine Sulphate is a Controlled Drug. For the purposes of administration by Practitioners within the NAS, it currently (subject to change) has two presentations:

A. Injection: 10 mg in 1ml
B. Oral Suspension (10mg in 5ml)

5.4 For the purposes of this Policy, a controlled drug (CD) is a drug named in Schedule 2 (CD2) or schedule 3 (CD3) of the regulations under the Misuse of Drugs Acts 1977, 1984 and 1988 (S.I. No. 328 of 1988), and any amendments, and also any drugs which it is considered necessary to control for risk management reasons. The Misuse of Drugs (Amendment) Regulations 1993 (S.I. No. 342 of 1993) includes Midazolam as a Schedule 4 Drug. Both Midazolam for injection and oral Midazolam are included in this policy.
5.5 The Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003), amended in 2005, i.e. (S.I. No. 510 of 2005), amended in 2008, i.e. (S.I. No. 512 of 2008) allows PHECC Registered Advanced Paramedics to administer Morphine Sulphate under the Seventh Schedule without direct reference to a medical practitioner.

## 6.0 ROLES AND RESPONSIBILITIES

6.1 The relevant Assistant National Director has overall statutory responsibility and accountability for the safe and secure handling of Controlled Drugs including Morphine Sulphate and Midazolam.
6.2 The Health Service Executive has responsibility and accountability for ensuring the provision of the appropriate resources required to implement this policy.
6.3 The Training and Development Department is responsible for the maintenance of this policy
6.4 Specific responsibilities also lie with a cross section of staff.
6.5 The policy specifies who is responsible for each activity.
6.6 For the purpose of this policy any reference to Advanced Paramedic refers to Registered Advanced Paramedics, registered with the Pre Hospital Emergency Care Council (PHECC).

## 7.0 PROCEDURE

### 7.1 Requisitioning, Supply and Storage of Morphine and Midazolam

7.1.1 Morphine and Midazolam stock will be held in a locked Controlled Drug (CD) Cabinet on each Ambulance Station.

7.1.2 The key to the Station CD cabinet will be held in a key safe. Access to the key safe will be by coded lock and will be limited to PHECC Registered Advanced Paramedics and designated Supervisors/Managers. The spare key for the CD cabinet will be held in a separate key safe located in or near to the Station Office.

7.1.3 The code to the key safe will be changed by the Training and Development Officer (TDO) on an annual basis or when it is felt that security has been compromised. All Station key safes will use the same code to facilitate movement of Advanced Paramedics between Stations.

7.1.4 It is the responsibility of the TDO to advise Advanced Paramedics of the confidential code.

7.1.5 When the level of Morphine and/or Midazolam held in the CD cabinet reaches the minimum stock level, as specified by each area, an Advanced Paramedic or Supervisor/Manager will complete the *Controlled Drug Requisition Book* (see Appendix II). An order will be placed with the agreed Pharmacy (see Appendix V - Procedure – AMBOE002 - Requisition of Controlled Drugs).

7.1.6 The *Controlled Drug Requisition Book* is a 3-part form in pads. Each form is number controlled. A Stock of pads is maintained in a secure safe under the control of the Training and Development Department. A register will be maintained by the Training and Development Department of all pads currently in use in the NAS, and to which Station they have been allocated to aid traceability.

7.1.7 The top copy will be retained by the Pharmacy Service. The second copy should be forwarded to the Training and Development Department by the receiving designated Supervisor/Manager and the third copy left in the pad. When the pad is complete, it will be forwarded to the Training and Development Department by an Advanced Paramedic, for safe storage for 8 years (Adult) or 25 years (Paediatric), from date of last collection.

7.1.8 The Training & Development Department will perform routine audits of all requisition and storage arrangements.

7.1.9 An NAS identity badge will be required as authorised identification when collecting Morphine and/or Midazolam from any Pharmacy. A list of approved designated Supervisors/Managers and their signatures will be provided to the relevant Pharmacies and updated as required.

7.1.10 The Morphine and/or Midazolam will be counted and checked by the relevant Pharmacy in the presence of the designated Supervisor/Manager

7.1.11 During transit from the Pharmacy to the Ambulance Station, the Morphine and/or Midazolam must be kept with the designated Supervisor/Manager until secured in the Station CD cabinet.

7.1.12 The items will be carried in a secure cabinet on their vehicle (where vehicular transport is required) and must not be left unguarded at any time until secured in the Station CD cabinet.

7.1.13 The designated Supervisor/Manager will place the Morphine and/or Midazolam in the Station CD cabinet. The order will be entered in the *Controlled Drug Station Record Book*, see Appendix III, and the stock balance will be amended to reflect new levels.

7.1.14 Stocks of the *Controlled Drug Station Record Book* will be maintained in the Training and Development Department. When the book is complete, it will be forwarded by the designated Supervisor/Manager to the Training and Development Department for safe storage for 8 years (Adult) or 25 years (Paediatric) from date of last entry.

## 7.2 Issuing of Morphine and Midazolam

7.2.1 At the commencement of each shift, the Advanced Paramedic will access the Station CD cabinet and obtain 2 ampoules of Morphine Sulphate for injection. The Advanced Paramedic will also obtain 2 ampoules of Midazolam, and the appropriate dosage of Oral Morphine and Midazolam (Buccal).

7.2.2 The withdrawal of Morphine and Midazolam will be recorded in the *Controlled Drug Station Record Book*. The *Controlled Drug Station Record Book* must be countersigned, to acknowledge the remaining running stock total.

7.2.3 If no witness is available, then the reason must be recorded in the *Controlled Drug Station Record Book* (e.g. solo responder only).

7.2.4 The Advanced Paramedic must check each ampoule (two of Morphine and two of Midazolam) to identify that each ampoule is correct and not a similar ampoule, which may have accidentally been placed in the box. The containers for Oral Morphine and Midazolam will also be checked and confirmed. If any discrepancy is found, this must be reported immediately.

7.2.5 At the end of the shift, the Morphine and Midazolam must be signed back in by the Advanced Paramedic who booked it out. The *Controlled Drug Station Record Book* must be amended to reflect the running stock total.

7.2.6 The *Controlled Drug Station Record Book* should be countersigned to acknowledge the amended running stock total.

7.2.7 If no witness is available then the reason must be recorded in the *Controlled Drug Station Record Book* (e.g. solo responder only).

7.2.8 Normally, Advanced Paramedics will draw Morphine and Midazolam stock from their base Station and at the end of their shift, will return any unused ampoules to the same stock. If there is a need to draw stock from another Station, then any unused stock at the end of shift must be returned to that Station's stock, and not back to their normal base Station's stock.

7.2.9 Ampoules must be placed back in their original packaging, or ampoule pouch at end of shift.

## 7.3 Storage on Vehicles

7.3.1 The Advanced Paramedic who booked the Morphine and Midazolam out of the Station CD cabinet is responsible for ensuring that it is stored in the vehicle security safe and that the access key to the vehicle storage safe is under their control throughout their operational shift.

7.3.2 The access key must be placed back in safe storage at end of shift.

7.3.3 The spare access key will be retained centrally in secure storage by the relevant designated Manager.

## 7.4 Recording usage of Morphine and Midazolam

7.4.1 Morphine Sulphate and Midazolam will only be administered as per the PHECC Clinical Practice Guidelines. Their use will be recorded on the Patient Care Report Form (PCR) following standard working practice.

7.4.2 The following details will be included:

A. Staff PIN number
B. Issuing Station
C. Incident number
D. Date
E. Amount administered
F. Amount disposed witnessed

7.4.3 The usage of Morphine and Midazolam should be recorded on:

G. PCR
H. Controlled Drug Station Record Book

7.4.4 The usage of Morphine and Midazolam will be audited by the Training & Development Department.

7.4.5 An anonymised photocopy of the PCR will be sent in a sealed envelope to the Training & Development Department, as per Divisional protocols.

7.4.6 The electronic / paper version of the Patient Care Report Form and the copy of the Controlled Drug Station Record Book will form the long term record of Morphine and Midazolam usage by the NAS.

7.4.7 If oral Morphine is used, then once the seal is broken on the container, it must be returned at the end of shift and placed back into the Station CD cabinet. It must not be used again after completion of shift.

7.4.8 The Supervisor must be notified of the usage. The designated Supervisor/Manager will complete the *Controlled Drug Return Stock to Pharmacy Book* (see Appendix IV)

7.4.9 The Pharmacist will acknowledge the receipt of the returned drug by signing the *Controlled Drug Return Stock to Pharmacy Book*. The designated Supervisor/Manager should sign to acknowledge this transaction.

## 7.5 Disposal of Unused / Damaged Ampoules

7.5.1 In the event that any ampoules are not completely used, then the remaining aliquot must be disposed of in a sharps disposal container on arrival in the Emergency Dept.

7.5.2 Disposal of unused aliquots must be recorded in the *Controlled Drug Station Record Book* at the end of shift.

7.5.3 If any ampoules are damaged and require disposal, then any aliquot must be disposed of in a sharps disposal container and the *Controlled Drug Station Record Book* must be completed, giving details on how the ampoule was damaged and confirmation of disposal. The *Controlled Drug Station Record Book* must be witnessed to confirm disposal.

7.5.4 The Training and Development Department must be notified by phone and in writing, of the circumstances of the breakage. The written confirmation must be countersigned by any witness.

## 7.6 Out of Date Stock

7.6.1 It is the responsibility of Advanced Paramedics to monitor the Morphine and Midazolam stock so as to reduce the likelihood of stock exceeding it's expiry date.

7.6.2 Where an Advanced Paramedic identifies that stock is out of date, then the box must be clearly marked "out of date, do not use".

7.6.3 Out of date stock will remain stored in the Station's CD safe.

7.6.4 A designated Supervisor/Manager will return the out of date stock to the issuing Pharmacy for safe destruction (see Appendix IV *Controlled Drug Return Stock to Pharmacy Book*).

7.6.5 The designated Supervisor/Manager will record return of the out of date drug in the *Controlled Drug Station Record Book* in red ink.

## 7.7 Action in the event of loss of Morphine and/or Midazolam from Vehicle Stock

7.7.1 In the event that an Advanced Paramedic loses any stock of Morphine and/or Midazolam from the vehicle, this should be reported immediately to Ambulance Control.

7.7.2 Ambulance Control must advise An Garda Siochana and the relevant Officer, as per Divisional protocol.

7.7.3 The Manager will liaise with the Advanced Paramedic and conduct a preliminary investigation. The Manager or a nominated NAS Representative must be present during any Garda interview.

7.7.4 An Incident/Near Miss Report Form must be completed at the earliest opportunity. The form must be completed prior to ending the shift in which the incident occurs.

7.7.5 If the Advanced Paramedic is unable to complete the Incident/Near Miss Report Form, the Advanced Paramedic should make this known to the Manager immediately.

7.7.6 The Manager must advise the Training and Development Department.

## 7.8 Action in the event of loss of Morphine and / or Midazolam from Station Stock

7.8.1 It is the responsibility of Advanced Paramedics to monitor the Station stock levels during each shift.

7.8.2 When an Advanced Paramedic withdraws Morphine and/or Midazolam, the witness must confirm the remaining stock. For opened boxes, the Advanced Paramedic must check each ampoule within the opened box, to identify that each ampoule is the correct one and not a similar ampoule, which may have accidentally been placed in the box.

7.8.3 If there is a discrepancy between the running stock total and the remaining stock or on the content of the stock, the Supervisor or Manager (time dependent) must be informed. The Supervisor or Manager will carry out an initial investigation to confirm the discrepancy within 2 working days.

7.8.4 In the event of a discrepancy, the Manager will notify the Training and Development Officer immediately.

7.8.5 If the discrepancy is confirmed and the cause cannot be determined, the Manager must inform An Garda Siochana and initiate a full investigation immediately.

## 7.9 Controlled Drug Records

7.9.1 The following NAS documentation will be used to administrate the Controlled Drugs, including Morphine Sulphate Policy:

*A. Controlled Drug Requisition Book*
One copy on each Ambulance Station

*B. Controlled Drug Station Record Book*
One copy for each Station Controlled Drug cabinet

*C. Register of Controlled Drug Station Record Book issue*
Held by the Training and Development Department

*D. Register of Controlled Drug Requisition Book issue*
Held by the Training and Development Department

*E. Controlled Drug Return Stock to Pharmacy Book*
One copy for each Station Controlled Drug cabinet

*F. Register of Controlled Drug Return Stock to Pharmacy Book*
Held by the Training and Development Department

7.9.2 In cases of any written error when using the above documents, the error should be scored through with a single line and the error initialled. Correction fluid must not be used.

7.9.3 Any grade of NAS operational staff may provide a countersignature.

## 7.10 Adverse Event Reporting

7.10.1 If an untoward incident occurs through the use of Morphine or Midazolam, this must be reported using the NAS Policy – AMBP005 – Medicines Management, Section 7.11 Reporting Adverse Events following Administration of Medicines.

## 7.11 Misconduct

7.11.1 If found guilty of serious misconduct with regards to the handling of controlled drugs following an internal investigation, staff may be subject to criminal proceedings, internal disciplinary action and reported to the Pre Hospital Emergency Care Council's Fitness to Practice Committee.

## 8.0 IMPLEMENTATION PLAN

8.1 This Policy will be circulated electronically to all Managers, all Supervisors and Staff

8.2 This Policy will be given electronically to each staff member where possible and must be confirmed in writing by each AP, and may also be placed in hardcopy in the Policy Manual in each Ambulance Station and Ambulance Control for ease of retrieval and reference

8.3 Each designated Supervisor/Manager who is responsible for updating the Policy and Procedures Manuals will return the Confirmation Form to Ambulance Headquarters.

## 9.0 REVISION AND AUDIT

9.1 This Policy will remain under constant review and may be subject to change to facilitate any changes/developments in service requirements, procedures and/or legislation

9.2 The Training and Development Dept. will monitor compliance with this Policy on a quarterly basis at minimum in relation to the management of controlled drugs within the Ambulance Service and any deviation will be reported to the Chief Ambulance Officer or designate for remedial action.

9.3 The NAS Training and Development Department is responsible for carrying out an internal audit of this policy.

9.4 The safe storage and handling of controlled drugs will be subject to annual audit by An Garda Siochana.

9.5 It is the responsibility of the NAS Training and Development Dept. to arrange the storage audit with An Garda Siochana.

9.6 It is the responsibility of the Training and Development Department to arrange the external audit.

**Revision History:**

(This captures any changes that are made to a SOP when it has been revised. This may be placed at the back or close to the front of the document according to local preference.)

| No | Revision No | Date | Section Amended | Approved by |
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## 10.0 REFERENCES

- PHECC Advanced Clinical Practice Guidelines, (Current Version) incorporating Medications Formulary (copy supplied to each Pharmacy Dept.)
- Group Authority Licence
- Regulatory Impact Assessment – Fourth Report of the Shipman Inquiry
- A Guide to Good Practice in the Management of Controlled Drugs in Primary Care (England), Third Edition December 2009

- The Safer Management of Controlled Drugs, Quality Care Commission Annual Report 2008

## 11.0 APPENDICES

- Appendix I - Policy – Acknowledgement Form
- Appendix II - Controlled Drug Requisition Book
- Appendix III - Controlled Drug Station Record Book
- Appendix IV – Controlled Drug Returned Stock to Pharmacy Book
- Appendix V – Procedure – AMBOE002 – Requisition of Controlled Drugs

**Document Control No. 1 (to be attached to Master Copy)**

**NAS**

**Reviewer:** The purpose of this statement is to ensure that a Policy, Procedure, Protocol or Guideline (PPPG) proposed for implementation in the HSE is circulated to a peer reviewer (internal or external), in advance of approval of the PPPG. You are asked to sign this form to confirm to the committee developing this Policy or Procedure or Protocol or Guideline that you have reviewed and agreed the content and recommend the approval of the following Policy, Procedure, Protocol or Guideline:

**Title of Policy, Procedure, Protocol or Guideline:**

**NAS**

I acknowledge the following:

- I have been provided with a copy of the Policy, Procedure, Protocol or Guideline described above.
- I have read Policy, Procedure, Protocol or Guideline document.
- I agree with the Policy, Procedure, Protocol or Guideline and recommend its approval by the committee developing the PPPG.

| _____ | _____ | _____ |
|---|---|---|
| Name | Signature (Block Capitals) | Date |

**Please return this completed form to:**

**Name:** **Niamh Murphy**
**Contact Details:** **Corporate Office**
**National Ambulance Service**
**Rivers Building**
**Tallaght Cross**
**Dublin 24**
**email niamhf.murphy1@hse.ie**

**Document Control No. 2 (to be attached to Master Copy)**

## Key Stakeholders Review of Policy, Procedure, Protocol or Guidance Reviewer Statement

**Reviewer:** The purpose of this statement is to ensure that a Policy, Procedure, Protocol or Guideline (PPPG) proposed for implementation in the HSE is circulated to Managers of Employees who have a stake in the PPPG, in advance of approval of the PPPG. You are asked to sign this form to confirm to the committee developing this Policy or Procedure or Protocol or Guideline that you have seen and agree to the following Policy, Procedure, Protocol or Guideline:

**Title of Policy, Procedure, Protocol or Guideline:**

**NAS**

I acknowledge the following:

- I have been provided with a copy of the Policy, Procedure, Protocol or Guideline described above.
- I have read Policy, Procedure, Protocol or Guideline document.
- I agree with the Policy, Procedure, Protocol or Guideline and recommend its approval by the committee developing the PPPG.

| _____ | _____ | _____ |
|---|---|---|
| Name | Signature (Block Capitals) | Date |

**Please return this completed form to:**

**Name:** **Niamh Murphy**
**Contact Details:** **Corporate Office**
**National Ambulance Service**
**Rivers Building**
**Tallaght Cross**
**Dublin 24**
**email niamhf.murphy1@hse.ie**

**Document Control No. 3 Signature Sheet:**
*(to be attached to Master Copy)*

## Policy, Procedure, Protocol or Guideline:

**NAS**

*I have read, understand and agree to adhere to the attached Policy, Procedure, Protocol or Guideline:*

| Print Name | Signature | Area of Work | Date |
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