



Guidance and Procedures for
Purchase, Storage and
Use of Drugs Policy

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Ratified by:	Board of Directors
Date ratified:	September 26 th 2016
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Name of responsible Committee/Individual:	Board of Directors
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1. Introduction

The majority of this policy and procedure refers directly to the storage, administration and destruction of morphine sulphate injection for intravenous (IV), intramuscular (IM) or subcutaneous (SC) administration. This will be referred to as "morphine for injection".

Where it needs to refer specifically to: diazepam IV or rectal (PR) administration, morphine sulphate for oral administration, ketamine for IV administration or midazolam for IV administration that distinction will be made clear. These will be referred to as "diazepam", "oral morphine", "ketamine" and "midazolam" respectively.

The term "controlled drug" as used in this policy applies to the following drugs under their respective Schedules of the Misuse of Drugs Act 1985:

- ✚ Morphine sulphate injection – Schedule 2 (Class A)
- ✚ Ketamine – Schedule 2 (Class C)
- ✚ Midazolam – Schedule 3
- ✚ Diazepam (and thus diazemuls) – Schedule 4
- ✚ Morphine sulphate oral solution (10mg/ 5ml) (Oromorph) – Schedule 5

Morphine and Ketamine are Controlled Drugs under schedule 2 of the Misuse of Drugs Act 1985, and are therefore subject to full controlled drug requirements relating to prescriptions, safe custody and the requirement to keep and register records. Within All Wales Ambulance Services Limited, midazolam will also be treated as though it is a Schedule 2 drug.

Midazolam, Diazepam IV and PR, and morphine sulphate oral solution, by virtue of their respective places in Schedule 3, 4 & 5 respectively of the Misuse of Drugs Act 1985 are not subject to the same record keeping regulations as ketamine and morphine sulphate injection.

Further guidance on the storage and administration of diazepam and morphine sulphate oral solution is contained within OP 002 – Procedure covering the issue & use of drugs by AWAS Staff (POMs).

All Wales Ambulance Services Limited (AWAS) allows the administration of morphine sulphate, morphine sulphate oral solution, diazepam for intravenous use and diazepam for rectal use to a patient by all registered paramedics who are employed by or contracted by AWAS.

AWAS will only authorise certain paramedics/doctors employed by or contracted by AWAS to carry and administer ketamine and midazolam to patients. The names of these paramedics/doctors will be recorded in the master PGD for each drug held by the Company.

The carriage and administration of the controlled drugs covered by this policy is in accordance with the relevant group authorities issued under The Misuse of Drugs Regulations 2001 (as amended).

A registered paramedic is defined as a person whose name appears in the relevant part of the Register maintained by the Registrar of the Health and Care Professions Council under the rules of Part III of the Health Professions Order 2001.

Medical practitioners registered with the General Medical Council (GMC) who are employees of or sub-contractors of AWAS, are also permitted, subject to the Medical Directors discretion, to have access to AWAS controlled drugs. Such doctors will abide by this policy in terms of the storage, signing in/out whilst on duty only, and the destruction of unused amounts of controlled drugs.

With respect to the indications, contraindications and doses they are expected to work within their own scope of practice and professional judgement, and the advice of the GMC contained in *Good practice in prescribing medicines – guidance for doctors* (GMC; Sept 2008).

AWAS registered paramedics must only draw controlled drugs for the duration of their shift period. Under no circumstances are these drugs to be retained whilst staff are off duty.

- ✚ Any controlled drug drawn from a controlled drug safe must be signed out in the Controlled Drug Register for that safe. Those drugs must then be signed back into that same safe, and the Controlled Drug Register reconciled. Any controlled drug administered to a patient is to be recorded in accordance with Section 14.7
- ✚ If a paramedic, having administered a controlled drug to a patient, needs to hand that patient over to another paramedic; Then the second paramedic must use their own controlled drugs to continue the treatment of the patient. Any unused controlled drugs in the possession of the first paramedic must be destroyed in accordance with Section 14.4, they are never to be handed to the second paramedic. Both paramedics are responsible for ensuring that each other knows exactly what dose of any controlled drug has actually been administered up to the point of handover.
- ✚ Guidance with regard to whom and at what dose morphine sulphate, morphine sulphate oral solution, diazepam for intravenous use and diazepam for rectal use may be administered is provided by The Joint Royal Colleges Ambulance Liaison Committee (JRCALC) in their National Clinical Guidelines for use in UK Ambulance Services. This guidance has been wholly adopted by the AWAS.
- ✚ Guidance with regard to whom and at what dose ketamine and midazolam may be administered is found within the relevant PGD for these two drugs. (Master copies of these two PGDs are held by the Medical Director, and copies will be held by every paramedic who has been authorised by AWAS to carry and administer ketamine and midazolam).

The Misuse of Drugs Regulations 2001 defines those persons who are authorised to supply and possess controlled drugs while acting in their professional capacities, and describes the conditions under which these activities may be carried out. In these regulations

consideration must be given to such activities as import, export, production, supply, possession, prescribing, audit and record keeping relevant to that particular drug.

The safe and secure handling of morphine sulphate within the Company requires appropriate policies, procedures and quality assurance systems to be in place so that it is handled safely and securely, in accordance with legislative requirements and established best practice. This policy must be read in conjunction with the AWAS Risk Management Framework.

The Accountable Officer, as required by the Department of Health in their guidance on the governance arrangements for controlled drugs, will be the Chief Executive Officer of All Wales Ambulance Services Limited.

The Responsible Manager, as outlined in the Security standards and guidance for the management and control of controlled drugs in the ambulance Sector (2012), will be the Operations Manager.

The person appointed by the Accountable Officer for the witnessing of the destruction of controlled drugs is the Health & Safety Officer. In addition, members of the Dyfed Powys Police Controlled Drugs Liaison Team will assist as required with controlled drugs destruction. (See also Appendix 2).

2. Scope

This policy and procedure refers to all personnel legally authorised to possess and administer those controlled drugs used by AWAS. It relates to the daily operational management of all controlled drugs:

- ✚ Morphine sulphate injection
- ✚ Ketamine
- ✚ Midazolam
- ✚ Diazepam (and thus diazemuls)
- ✚ Morphine sulphate oral solution

This policy and procedure does not cover the use of any controlled drug used by Voluntary Aid Society staff, i.e., St. John Ambulance, British Red Cross, BASICS or private organisations subcontracted by AWAS. It does cover registered paramedics employed by other UK Ambulance Services working on behalf of the AWAS under pre-planned or mutual aid arrangements.

This policy and procedure gives clear guidance on the record keeping, security and destruction of controlled drugs used by AWAS. For these areas it draws on the following guidelines or legislation:

Legislation:

- ✚ Health Act 2006
- ✚ Misuse of Drugs Act 1971
- ✚ The Controlled Drugs (Supervision of Management and Use) Regulations 2006 (SI 2006 No. 3148)
- ✚ The Misuse of Drugs (Amendment No. 2) (England, Wales and Scotland) Regulations 2012 (SI 2012 No. 973)
- ✚ The Misuse of Drugs (Safe Custody) Regulations 1973 (SI 1973 No. 798)
- ✚ The Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007
- ✚ The Misuse of Drugs Regulations 2001 (SI 2001 No. 3998)
- ✚ The Misuse of Drugs Regulations 2001: Group Authority for National Health Service (NHS) Ambulance Paramedics and Employing NHS Ambulance Trusts, July 2008

NHS Codes of Practice / other guidance:

- ✚ Confidentiality, NHS Code of Practice, Department of Health, November 2003
- ✚ Records Management, NHS Code of Practice (Part 1), Department of Health, May 2006
- ✚ Records Management, NHS Code of Practice (Part 2), Department of Health, January 2009
- ✚ Security standards and guidance for the management and control of controlled drugs in the ambulance sector 2012

3. Objectives: Policy and Procedure for the Ordering, Storage, Use and Destruction of Controlled Drugs within AWAS:

- ✚ Defines which controlled drugs that the Company uses.
- ✚ Gives guidance to staff on their responsibilities in relation to all aspects of controlled drugs.
- ✚ Gives specific guidance on the actions to take if any controlled drug is lost / stolen or misplaced.
- ✚ Details the method by which unused controlled drugs are to be disposed of.
- ✚ Details the procedure to be applied for destroying all out of date controlled drugs.

4. Responsibilities:

All staff who are involved in the ordering, storage, carriage, use and administration of controlled drugs held by the Company are under an explicit legal obligation to report any discrepancies, no matter how minor, as soon as possible to either an Operations Manager (OM), Duty Station Officer (DSO), or other appropriate person, in order that the matter can be quickly and thoroughly investigated. In addition all discrepancies must be recorded.

IN ADDITION

If ANY drug in the possession of any person by virtue of their authority to store, carry or administer that drug is stolen or otherwise lost, the loss shall be reported by that person as soon as possible to Operations Manager and then to the local police station.

The Accountable Officer (The Medical Director), must also be informed of any thefts or loss as soon as is possible.

4.1 Specific Responsibilities:

The specific responsibilities for specific grades of staff are detailed below:

4.1.1 Registered Paramedics:

Registered paramedics are accountable at all times for controlled drugs in their possession. They are responsible for recording the withdrawal, movement, administration, and disposal of controlled drugs, in their possession in the Controlled Drugs Register, and for ensuring that the running total is kept up-to-date and accurate. (For the greater majority of paramedics this will only be for morphine sulphate, but for authorised paramedics also means ketamine, midazolam and all other drugs kept and used by AWAS).

Where a controlled drug has been administered to a patient, it is the responsibility of the paramedic to ensure that the details are also accurately documented on the Patient Report Form (PRF).

Thus the main responsibilities of individual paramedics, no matter what their rank / grade under AWAS in relation to controlled drugs are as follows:

- ✚ The safe and legal handling of any controlled drug that is in their possession as a result of their duties.
- ✚ Recording the amounts of morphine sulphate, ketamine, midazolam and all other drugs issued from or returned to stock in the relevant Controlled Drugs Register.
- ✚ Receiving, checking, recording and storage of stock as appropriate.
- ✚ Recording accurately in the patient's clinical record the amount of drug administered, and any amount destroyed / wasted.
- ✚ Returning unused units to stock following shift completion and amending all balances accordingly.
- ✚ Reporting adverse incidents involving controlled drugs, as soon as is possible to AWAS management.

4.1.2 Ambulance Operations Managers:

Only the Operations Manager, can order controlled drugs.

The responsibilities of individual OMs in relation to morphine sulphate are as follows:

- ✚ Ordering morphine sulphate from pharmacy.
- ✚ Regular auditing of station and authorised individuals record keeping.
- ✚ Checking and reconciling controlled drugs stocks and register accuracy, at least quarterly.
- ✚ Ensuring that any adverse incidents involving morphine sulphate are reported appropriately.
- ✚ Changing the keypad code for the controlled drugs safe every third payday from the previous change. The change is then to be notified by e-mail to the Paramedics/Doctors and Chief Executive.
- ✚ Ensuring that Duty Station Officers and Station Administration Staff who are not registered paramedics understand their role in assisting the OM to ensure this policy is adhered to by all members of staff.

4.1.3 Assistant Director of Operations:

The safe storage and maintenance of records / registers for controlled drugs within the Sector for which they are responsible will be audited, unannounced, on an annual basis by the Medical Director, or a person delegated under their authority to carry out the audit.

4.1.4 Duty Station Officer:

The Duty Station Officer, in addition to other duties specified above, if they are registered paramedics (section 4.1.1 & 4.1.2), are to assist the OM in ensuring that Daily Audit Checks (Or whenever drugs are deployed to work) are carried out and that the general security of controlled drugs and observance of this policy is carried out by all grades of staff.

4.1.5 Accountable Officer:

The Accountable Officer is responsible for the safe management and use of controlled drugs within the Company

5. Storage of Controlled Drugs on AWAS premises:

5.1 The law requires that there must be suitable and sufficient provision for safe and secure storage of controlled drugs on all AWAS premises.

5.2 Currently the only controlled drugs to be stored in a "controlled drug" safe on stations are morphine sulphate for IV, IM or SC use, ketamine for IV use and midazolam for IV use.

5.3 Diazepam IV & PR, and morphine sulphate oral solution will be stored and issued via the paramedic drug packs and thus subject to – Procedure covering the issue & use of drugs by AWAS Staff (POMs).

5.3 Logistics HQ will have a controlled drugs safe accessible by a key and an electronic keypad which has been sited on the advice of the AWAS Health & Safety Department.

5.4 The controlled drugs safe must only be opened by persons authorised by AWAS for legal reasons and the safe keeping of key codes is essential.

5.5 Currently the only persons allowed access to the controlled drugs safe are;

- ✚ Any person authorised by the Medical Director
- ✚ Registered Paramedics
- ✚ Duty Station Officers
- ✚ Ambulance Operations Managers – and those persons they have authorised to do

5.6 The access number for the Controlled Drugs Safe will be changed as follows:

- ✚ The safe entry code is displayed **inside** the safe on the door.
- ✚ For one week prior to any change a notice is displayed **inside** the safe providing the new entry code & date of change.
- ✚ The code is to be changed at least once in any three month period.
- ✚ The code is to be changed if any "incident" occurs involving the CD safe, or other drugs lockers on the premises.
- ✚ The code is to be changed if any member of the Company is dismissed from AWAS.
- ✚ Relief Paramedics and other Paramedics visiting the Complex will need to contact the Operations Manager/s for the number.

6. The Carriage of Morphine Sulphate in the possession of Registered Paramedics once signed out from a controlled drugs safe:

6.1 The law requires that there is acceptable provision for safe and secure storage of morphine sulphate on all vehicles in which controlled drugs are carried.

6.2 Morphine sulphate will only be carried in the receptacle detailed by AWAS. Currently this is a drugs box with an ampoule holder provided individually to each registered paramedic by AWAS.

6.3 Morphine sulphate must not be placed / carried in any other holder / carriage device without the written permission of the Operations Manager.





6.4 Any controlled drug will only be prepared for use once its clinical need has been established. It must not be carried "pre-prepared" in any form.

6.5 If at any time the security of any controlled drug has been or could be compromised, the appropriate manager must be advised as soon as possible.

7. System for ordering and recording the storage and usage of morphine sulphate for injection in AWAS (General Information):

7.1 There is an absolute requirement in law that each unit of morphine sulphate for injection purchased by AWAS must be accounted for from the point of ordering to the point of administration to a patient, or disposal either as unused or as out of date.

7.2 The main documents that AWAS will use to track the ordering, issue and usage of morphine sulphate will be:

-  All Wales Ambulance Service Patient Report Form (LA4)
-  All Wales Ambulance Service Controlled Drugs Order Book
-  All Wales Ambulance Service Controlled Drugs Register
-  All Wales Ambulance Service Out of Date Controlled Drugs Register

7.3 The All Wales Ambulance Service Controlled Drugs Order Book is a pre-printed order book. This is the only form on which an order for morphine sulphate will be accepted at either the main office, or at the pharmacy which supplies AWAS with its drugs.

8. Witnessing Signatures in Controlled Drugs Registers:

8.1 When controlled drugs are signed out of a controlled drugs safe by paramedics, every effort must be made to obtain a witness to sign in the "Witnessed by ... column of the Controlled Drug Register.

8.2 On some occasions it is understandable and therefore acceptable that single staff members may not be able to obtain a witness signature for the withdrawal or return of controlled drugs. However the member of staff should endeavour to obtain a witness signature at the earliest opportunity

8.3 It is acceptable for any member of staff such as Duty Station Officers, Emergency Medical Technicians and administration staff to witness to the withdrawal or return of controlled drugs and sign in the appropriate place in the register. They are merely witnessing the signature of the paramedic withdrawing or returning the drugs, and confirming the quantities in the CD Safe and the Register tally and are correct.

8.4 Any member of staff who falsifies an entry / signature in any Controlled Drugs paperwork / stationery or book, will be subject to investigation under AWAS Disciplinary Procedure and may also be reported to the Police. If that member of staff is a paramedic, they will also be reported to the Health and Care Professions Council.

9. Detailed guidance for requisitioning and receiving morphine sulphate into station stocks and usage:

9.1 Requisition and Ordering of Drugs –Pharmacy:

9.1.1 The Operations Manager, The Chief Executive Manager and the Medical Officer, in consultation with the supplying pharmacy, will be responsible for maintaining an ongoing review of the supply arrangements to ensure that they meet AWAS needs and comply with current legislation. The Operations Manager will ensure that a register of all Logistics staff authorised to order, maintain, issue or transport morphine is produced and updated when necessary.

9.1.2 The Operations Manager shall set a minimum / maximum stock level for morphine sulphate that can be regularly monitored. When stock reaches the agreed replenishment level, an order will be prepared for the supplying pharmacy.

9.1.3 All supplies of controlled drugs will be ordered from the supplying pharmacy by The Operations Manager, or their designated deputy. The drugs will be ordered by means of an "Order for Controlled Drugs Record Book". This book will be maintained and stored at the head office. Used or completed books should be stored for a period of two years from the date of the last entry.

9.1.4 When completing the order book, the name of the drug preparation, strength and quantity should be entered in the appropriate boxes. The Operations Manager or the designated deputy should check that the details are correct.

9.1.5 The order book will then be taken to the Medical Director for the order to be and taken to the supplying pharmacy.

9.1.6 When issuing the drugs, a designated person at the supplying pharmacy will sign the appropriate serial numbered sheet (on line stating "Supplied by"). The designated member of AWAS Staff will then receive the drugs and confirm this by signing the appropriate serial numbered sheet (on line stating "Accepted for delivery"). The top (white copy) of the serial numbered sheet should be removed from the book and handed to the designated person at the hospital pharmacy. The second copy of the sheet (pink copy) should be left in the book. The drugs should then be secured in the lockable cabinet on the LAS delivery vehicle and returned to the Storage and Distribution Centre.

9.1.7 When the drugs are delivered, the Operations Manager, or their designated deputy, shall check that the drugs delivered conform with the serial numbered sheet on the Order book. Account should be taken of any reduction in provision made by the Pharmacy. If the order has been correctly supplied, the sheet should be signed (on line stating "Received by"). If there are any discrepancies in the order supply, the Operations or their designated deputy should immediately investigate the situation.

9.1.8 Controlled drugs must only be ordered as outlined in this procedure. In particular, no member of staff is to replenish stocks from any other source.

9.2 Storage and Record Keeping:

9.2.1 When an order has been delivered to the head office, it should immediately be placed in the lockable storage cupboard by the Operations Manager or their designated deputy. The stock book held in the cupboard should be completed. The date, quantity of drug, serial number and expiry date should be recorded in the appropriate boxes. The stock level of the drug held should also be updated in the appropriate box. The Operations Manager or their designated deputy should witness that this action has been correctly carried out. The register should be retained for a period of two years from the date of the last entry

10. Audit:

10.1 A regular audit of controlled drugs held shall be carried out in the head office. The Controlled Drugs Register should be checked against the stock held and any necessary reconciliation should be made. The Controlled Drugs Audit Check record should be completed on each occasion. This requires the date and time and the signature of the designated person checking to be entered. The quantity of drugs in the safe and the quantity recorded in the „Controlled Drugs Register“ should also be entered. The Controlled Drugs Audit Check record should be kept for a period of two years from the last date of entry.

10.2 If there are any discrepancies discovered, the Operations Manager or their designated deputy should investigate the situation immediately and suspend any further withdrawals of stock until the matter has been resolved. The Chief Executive should also be advised of the situation.

10.3 When a stock audit is carried out, a line should be drawn under the last entry in the book. The date and findings of the audit should be recorded, and initialled by the auditor. A line should then be drawn under the audit entry for normal stock transactions to be resumed.

11.1 As with any drug administered to a patient, the drug code, name, amount administered, number of doses, route, time and by whom administered must be recorded on patient clinical record (PRF).

11.2 In the case of morphine for injection, ketamine and midazolam the controlled drugs register on the station from which it was drawn must be reconciled as soon as possible. The PRF number must also be recorded.

11.3 Any unused amounts of controlled drugs that were prepared for administration, but not actually given to a patient must be squirted onto a piece of tissue which is then placed into a sharps bin (all other "sharps" will be disposed of in the normal manner into the sharps bin as well).

11.4 The dosage actually administered to the patient (in mg), and the amount (in mg) that has been destroyed must both be recorded on the PRF. The amount administered will be documented in the "Fluid and Drug Administration" section of the PRF and the amount that has been destroyed recorded in the "Notes" area of the PRF. Wherever possible, witness signatures are to be obtained.

11.5 On return to station the CD register must be completed ASAP and the amounts administered / destroyed recorded in the relevant section of the CD Register.

11.6 On return to the Ambulance Station the paramedic will where possible find another member of staff to ensure that the CD Register entries for that usage / wastage is witnessed and completed properly. If no such person is available then the CD Register is to be completed in the normal manner as far as possible. The PRF will then be placed in a RED Envelope and placed in either the Black Box or a separate but secure location so that the OM can check the PRF against the CD Register at the earliest opportunity.

11.7 Any member of staff who falsifies an entry / signature in any Controlled Drugs paperwork / stationery or book, will be subject to investigation under AWAS Disciplinary Procedure and may also be reported to the Police. If that member of staff is a paramedic, they will also be reported to the Health and Care Professions Council.

12. Incident Reporting and Near Misses:

12.1 Serious incidents must be verbally reported immediately, either directly to the Health & Safety Department, or via Control.

12.2 Any adverse reaction to a drug administered by a member of staff, or any untoward event/ near miss that occurs as a result of drug administration is to be reported as soon as possible using the Incident Reporting form and following Health and Safety Incident Reporting Procedure.

12.3 For Incidents classified as "High risk", a root cause analysis will be undertaken by the appointed investigating officer.

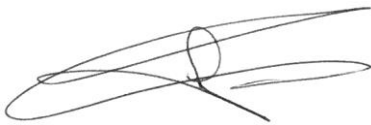
12.4 Managers and Investigating Officers will feed back to individuals the lessons learned and monitor progress against action plans drawn up.

Version Control Sheet.

Appendix 1.

Version	Date	Author	Summary of changes
1.1	01.10.2016	G Llewellyn	

Signed on behalf of All Wales Ambulance Services Limited:



Name: Gareth Llewellyn (CEO)

Date: 01/10/2016