NHS
South Western
Ambulance Service
NHS Foundation Trust

Controlled Drug Policy

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Title of originator/author:	Sue Oakley, Pharmaceutical Advisor and Accountable Officer for Controlled Drugs
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Trust Policy Foreword

South Western Ambulance Service NHS Foundation Trust (SWASFT) has a number of specific corporate responsibilities and obligations relating to patient safety and staff wellbeing. All Trust policies need to appropriately include these.

Health and Safety - SWASFT will, so far as is reasonably practicable, act in accordance with the Health and Safety at Work Act 1974, the Management of Health and Safety at Work Regulations 1999 and associated legislation and approved codes of practice. It will provide and maintain, so far as is reasonable, a working environment for employees which is safe, without risks to health, with adequate facilities and arrangements for health at work. SWASFT employees are expected to observe Trust policy and support the maintenance of a safe and healthy workplace.

Risk Management - SWASFT will maintain good risk management arrangements by all managers and staff by encouraging the active identification of risks, and eliminating those risks or reducing them to the lowest level that is reasonably practicable through appropriate control mechanisms. This is to ensure harm, damage and potential losses are avoided or minimised, and the continuing provision of high quality services to patients, stakeholders, employees and the public. SWASFT employees are expected to support the identification of risk by reporting adverse incidents or near misses through the Trust web-based incident reporting system.

Equality Act 2010 and the Public Sector Equality Duty - SWASFT will act in accordance with the Equality Act 2010, which bans unfair treatment and helps achieve equal opportunities in the workplace. The Equality Duty has three aims, requiring public bodies to have due regard to: eliminating unlawful discrimination, harassment, victimisation and any other conduct prohibited by the Act; advancing equality of opportunity between people who share a protected characteristic and people who do not share it; and fostering good relations between people who share a protected characteristic and people who do not share it. SWASFT employees are expected to observe Trust policy and the maintenance of a fair and equitable workplace.

NHS Constitution - SWASFT will adhere to the principles within the NHS Constitution including: the rights to which patients, public and staff are entitled; the pledges which the NHS is committed to uphold; and the duties which public, patients and staff owe to one another to ensure the NHS operates fairly and effectively. SWASFT employees are expected to understand and uphold the duties set out in the Constitution.

Code of Conduct and Conflict of Interest Policy - The Trust Code of Conduct for Staff and its Conflict of Interest and Anti-Bribery policies set out the expectations of the Trust in respect of staff behaviour. SWASFT employees are expected to observe the principles of the Code of Conduct and these policies by declaring any gifts received or potential conflicts of interest in a timely manner, and upholding the Trust zero-tolerance to bribery.

Information Governance - SWASFT recognises that its records and information must managed, handled and protected in accordance with the requirements of the Data Protection Act 1998 and other legislation, not only to serve its business needs, but also to support the provision of highest quality patient care and ensure individual's rights in respect of their personal data are observed. SWASFT employees are expected to respect their contact with personal or sensitive information and protect it in line with Trust policy.

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1. Purpose

1.1 Introduction

1.1.1 The Controlled Drug Policy (The Policy) is a sub section of the Medicines Governance Policy. It draws together all the information relevant to the management of controlled drugs by individuals employed by the South West Ambulance Service NHS Foundation Trust (The Trust). It was developed as a separate section of the Trust's Medicines Governance Policy to acknowledge the importance of managing controlled drugs safely and securely, to give greater clarity to controlled drug management and to expedite staff access to information relevant to controlled drug management.

1.1.2 The Controlled Drug Policy must be read in conjunction with the Trust's Medicines Governance Policy.

1.1.3 The following documents have been used in the preparation of this policy:

- The Human Medicines Regulations 2012
- The Misuse of Drugs Act 1971
- The Misuse of Drugs Regulations 2001
- The Misuse of Drugs (Safe Custody) Regulations 1973
- Misuse of Drugs and Misuse of Drugs (Safe Custody) (amendment) Regulations 2007
- Misuse of Drugs (Supply to Addicts) Regulations 1997
- Misuse of Drugs Act 1971 (Ketamine etc.) (Amendment) Order 2014.
- The Health Act 2006
- The Controlled Drugs (Supervision of Management and Use) Regulations 2013
- The Misuse of Drugs Regulations 2001 : Group Authority for National Health Service (NHS) Ambulance Paramedics and Employing NHS Ambulance Trusts
- The Human Medicines (Amendment) Regulations 2018, Statutory Instrument No. 199
- Misuse of Drugs (Amendment No.2) (England, Wales and Scotland) Regulations 2012**.** Statutory Instrument No. 973.
- Misuse of Drugs (Amendment No. 2) (England, Wales and Scotland) Regulations 2015 (S.I. 2015/891)
- National Institute for Health and Care Excellence, NICE Guideline 46, April 2016, Controlled Drugs Safe Use and Management.
- The Joint Royal Colleges Ambulance Liaison Committee (JRCALC) Clinical Practice Guidelines 2016
- Security standards and guidance for the management and control of controlled drugs in the ambulance sector. Version 3 (March 2017) NHS Protect
- Controlled Waste (England and Wales) Regulations 2012.

1.1.4 The legislative and good practice criteria and standards contained in these documents have been applied to the management of controlled drugs in the Trust.

1.2 Controlled Drug Legislation

1.2.1 The Misuse of Drugs Act 1971 and its associated Regulations control the availability of drugs that are considered sufficiently 'dangerous or otherwise harmful', with the potential for diversion or misuse. Drugs controlled under the Misuse of Drugs Act 1971 are divided into three classes; A, B and C. The Class of drug establishes the maximum penalties which can be imposed in criminal law on persons convicted of any of the offences under the Act.

1.2.2 The 2001 Regulations divide controlled drugs (CD) into five Schedules, which dictate the degree to which each drug is regulated and these influence the use of the drug in clinical practice. The Schedule in which a CD is placed depends upon its medicinal or therapeutic benefit, balanced against its harm when misused. Schedule 1 CD are subject to the highest level of control, whereas Schedule 5 CD are subject to a much lower level of control. Schedule 4 has two parts:

- Part 1 includes the benzodiazepines except temazepam, ketamine and midazolam;
- Part 2 Includes most of the anabolic and androgenic steroids such as testosterone together with clenbuterol (adrenoreceptor stimulant) and growth hormones.

1.2.3 The Misuse of Drugs Regulations 2001 governs the legitimate clinical use of CD. The CD listed on the Trust Formulary are indicated in Table 1. Those marked with an asterisk are not stock items but can be prescribed by medical prescribers working in the Urgent Care Service (UCS).

Table 1 - Controlled Drugs:

Drug	Preparation	Class	Schedule
Codeine phosphate	15mg and 30mg* tablets	B	5
Diamorphine	10mg*, 30mg* and 100mg* injection	A	2
Diazepam	Injection (Diazemuls) Tablets Rectal tubes	C	4(1)
Fentanyl preparations patches*		A	2
Ketamine	10mg injection	B	2
Morphine sulphate	10mg in 1ml injection	A	2
Midazolam	10mg in 2ml injection (UCS only) and 1mg in 1ml	C	3
Oral morphine solution	10mg in 5ml solution	A	5
Oxycodone tablets, capsules, injection and oral solution. *	5mg, 10mg, 20mg, 40mg, 60mg,80mg,120mg MR tablets 10mg and 50mg/ml injection 1mg and 10mg/ml oral solution 5mg, 10mg and 20mg capsules	A	2

1.2.4 In 2001 an independent public inquiry, the Shipman Inquiry, was set up to examine the issues arising from the case of Dr Harold Shipman. The Inquiry's Fourth Report focused on the methods used by Shipman to divert large quantities of controlled drugs for his own purposes, and considered how he was able to do so for so long without detection. The Fourth Report concluded that there were serious shortcomings in the systems for regulating CD.

1.2.5 In response, the Government proposed a series of measures, the Controlled Drugs (Supervision of Management and Use) Regulations 2006. These were revoked and replaced by updated legislation in April 2013 by the Controlled Drugs (Supervision of Management and Use) Regulations 2013. The 2013 Regulations include provision for:

- The appointment of accountable officers in healthcare organisations described as 'controlled drug designated bodies';
- Formal, on-site inspections of providers of health and social care by various bodies;
- The sharing of information, including a legal duty of collaboration among all 'responsible bodies'. The NHS Commissioning Board (NHSCB) must determine what are to be the local intelligence network areas for England, and must nominate or appoint a fit, proper and suitably experienced person to be its accountable officer in respect of each local intelligence network area, and an accountable officer of the NHSCB may be the accountable officer in respect of one or more than one local intelligence network area.

1.2.6 The Trust is a controlled drug designated body and has an accountable officer. The Accountable Officer is the Pharmaceutical Advisor.

1.2.7 The Chief Executive is responsible for ensuring that the Trust complies with the Controlled Drugs (Supervision of Management and Use) Regulations 2013.

1.3 Controlled Drug Licensing

1.3.1 Controlled Drug Licensing of NHS organisations commenced in 2015 following a Department of Health review of the Regulations. Whilst limited licensing exemptions apply, the Home Office advice in 2017 was that the Trust is required to hold a licence in order to possess and supply stocks of controlled drugs to its stations and employees. The Home Office view, based on the opinion of their own legal advisors, is that licensing is required for supply because the distribution process within the Trust involves a transfer of ownership and responsibility.

1.3.2 In March 2017 the Trust was issued with a Controlled Drug Licence (CDL) under Regulation 5 of the Misuse of Drugs Regulations 2001. This licence allows the Trust to possess and supply (to employees) CD on Schedules 2 to 5 and to supply (to employees) CD on Schedule 5.

1.3.3 Under the terms of the CDL, CD cannot be supplied to patients, they may only be administered. Similarly, the Trust can only supply another legal entity with a stock of CD if that legal entity has a valid CDL which allows them to possess the CD.

1.3.4 14 sites are named in the CDL to enable storage and distribution within the Trust. The Home Office may decide to undertake a compliance visit at any of these sites. The decision to visit is made using a risk-based approach. The Trust was visited before a licence was granted and a follow up visit is usually made in the following year. Further visits may take place between 3 to 5 years later.

1.3.5 Enhanced Disclosure and Barring Service (DBS) checks are mandatory for all individuals named on the licence application.

1.3.6 The CDL must be renewed annually. The application must be placed 4 weeks in advance of its expiry. Failure to apply for a new CDL before the existing licence expires risks a new application fee being levied instead of a renewal fee.

1.3.7 The Chief Executive is the Licensee and his duties include:

- Ensuring that activities concerned with CD are restricted to those authorised by the CDL.
- Ensuring that the Trust's activities with and handling of CD are fully compliant with current legislation including CD security, storage and record-keeping.
- Notifying Home Office and Police of any theft or loss of CD using the proforma on the Home Office website.
- Keeping the original CDL safe and available for inspection as required.
- Completing an Annual Statistical Return when required to do so by 31st January.
- Obtaining export/import licences for any shipments to or from the UK that need licensing.

1.4 Mandatory Requisitions

1.4.1 Mandatory requisitions are required to obtain stocks of CD where there is a transfer of ownership and responsibility. The requirements surrounding the mandatory requisition form are set out in regulations 14(2) and 14(4) of the Misuse of Drugs Regulations 2001.

1.4.2 Home Office acknowledge that some operationally obstructive consequences have been identified within the ambulance sector specifically around the internal requisitioning of CD using mandatory requisition forms within the same legal entity. However, while there is a specific requisition requirement set out in Regulation 14(6) in relation to nurses requisitioning internal supply of CD to hospital wards and theatres there is not a similar authorisation for paramedics to write a requisition for CD for their station.

1.4.3 Home Office believe that whilst the mandatory requisition form must be completed, the person responsible for the supply of medicines at an organisation providing ambulance services does not need to then send the mandatory requisition form to the NHS Business Service Authority. As such, the external auditing process within an NHS Ambulance Trust is the same as it was before the 2015 amendments. This is set out in Regulation 14(5B).

1.4.4 In light of the above, there is a Home Office view that the requirement to complete a mandatory requisition form by paramedics each time drugs are requisitioned from the same NHS ambulance trust is superfluous and excessively operationally burdensome and, as such, a regime akin to that in Regulation 14(6) should apply to such internal requisition. The Trust uses L4 forms for this purpose.

1.4.5 NHS Ambulance Trusts still remain responsible for ensuring they remain compliant with the 2001 regulations and Home Office have, therefore, decided that a regulatory amendment may be necessary. This may be a lengthy process since the normal pre-regulation amendment requirements would be necessary and Home Office would be required to consult. However it has been decided that this is the only option to ensure that the correct and legal approach is adopted nationwide.

1.4.6 In the interim, the Trust will use the internally determined standard requisition form (L4) across the whole of the Organisation when a mandatory form would be required internally and use a legally required mandatory requisition form when obtaining stock controlled drugs from external suppliers.

2. Scope

2.1 This Policy covers systems and processes for using and managing controlled drugs safely in the Trust. It aims to improve working practices to comply with legislation and have robust governance arrangements. It also aims to reduce the safety risks associated with controlled drugs.

2.2 The policy applies to all staff, clinicians, and volunteers, employed by, or working on behalf of the Trust.

2.3 This policy does not give clinical guidance on the use of controlled drugs. This can be found in the clinical guidance, produced by the Joint Royal Colleges Ambulance Liaison Committee, Clinical Notices and Clinical Guidelines issued by the Trust.

2.4 The Policy does not remove the professional obligation on every clinician to understand and comply with the legislation in respect of their own professional practice. Clinicians must comply with the most current legislation even when the Policy has not been updated to reflect the change.

3. Accountability and Responsibility

3.1 The Board

3.1.1 The Board are ultimately responsible for ensuring that the Trust complies with all applicable CD legislation, regulations, national and regional guidance.

3.2 Chief Executive

3.2.1 The Chief Executive is the Home Office CDL Responsible Person. He is responsible for ensuring that the Trust complies with the terms of the CDL. He also

takes overall responsibility for the Trust's compliance with legislation and this Policy but delegates the task of ensuring compliance to the Executive Medical Director.

3.2.2 The Chief Executive is responsible for ensuring that the Care Quality Commission are notified of any changes to the appointment of the Accountable Officer for Controlled Drugs so that the central national register of Accountable Officers can be updated.

3.3 Executive Medical Director

3.3.1 The Executive Medical Director has been nominated by the Board to have executive responsibility for ensuring full compliance with legislation, this Policy and the Trust's CDL. The Executive Medical Director is responsible for the clinical use of all controlled drugs by Trust employees and also has responsibility for the management of controlled drugs in the Trust's Central Store.

3.4 Executive Director of Nursing and Quality

3.4.1 The Executive Director of Nursing and Quality has organisational responsibility for quality. The specific responsibilities of the role are detailed in the Medicines Governance Policy.

3.5 Pharmaceutical Advisor/ Accountable Officer for CD

3.5.1 The Pharmaceutical Advisor is the Trust's nominated Accountable Officer for CD and has a statutory responsibility for the safe and secure management of Trust CD.

3.5.2 The Accountable Officer is responsible for:

- Ensuring appropriate arrangements for monitoring and auditing the management and use of controlled drugs;
- Ensuring that the Trust has up to date medicines governance instructions in relation to the management and use of controlled drugs, which cover best practice relating to the prescribing, supply and administration of CD;
- Investigating concerns and incidents related to CD;
- Ensuring that relevant individuals involved in prescribing, supplying, administering or disposing of CD receive adequate training and are kept up to date;
- Collaborating with other responsible bodies to share information.

3.5.3 The Accountable Officer must not, or must only exceptionally, prescribe, supply, administer or dispose of controlled drugs as part of their duties as an employee or officer of the Trust.

3.5.4 The Accountable Officer can delegate tasks to named individuals but cannot delegate responsibility.

3.6 Medical Director, Primary Care (Deputy Accountable Officer for CD)

3.6.1 The Medical Director, Primary Care is designated as the Deputy Accountable Officer. The post holder is also responsible for providing sufficient operational support to enable the full implementation and monitoring of this Policy.

3.7 Clinical Director

3.7.1 The Clinical Director, as the lead Paramedic within the Trust, is responsible for working with the Pharmaceutical Advisor to ensure that all policy and guidance is practical for frontline operations.

3.8 Director of Operations

3.8.1 The Director of Operations is responsible for providing sufficient operational support to enable the full implementation of this Policy and for the provision of monthly assurance in the Short Station Review data.

3.9 Head of Education

3.9.1 The Head of Education and Professional Development is responsible for ensuring that all employees receive education, information and training which fully reflects the evolving evidence base and the requirements of this Policy. The post holder is responsible for supporting the Accountable Officer and ensuring that all employees receive training in CD Management commensurate with their role.

3.10 Clinical Development Managers and Officers

3.10.1 The Clinical Development Managers and Officers are responsible for supporting the Pharmaceutical Advisor in the reviewing CD occurrences and incidents.

3.11 Operations Officers/Operations Support Manager (Urgent Care)

3.11.1 Operations Officers/Operations Support Manager (Urgent Care) are responsible for supporting the Director of Operations with the practical implementation of this Policy and for collating the monthly assurance data from their base station/s and treatment centres.

3.12 Trust Employees

3.12.1 All Trust employees are responsible for ensuring that they follow this policy and associated Medicines Governance Instructions (MGI) at all times and ensure that their practice complies with all applicable CD legislation.

3.12.2 All Trust employees have a duty and responsibility, within the restrictions of their role, to ensure that CD are managed safely and securely in accordance with this Policy and its associated MGI. Any member of staff who suspects that this Policy is not being implemented correctly has a duty to report their concerns to the Accountable Officer for CD.

3.13 Committee and Group Structure

3.13.1 The Committee and Group structure is detailed in Section 17 - Monitoring.

3.14 Local Intelligence Networks

3.14.1 The Accountable Officer for CD appointed by NHS England is responsible for leading the local intelligence networks in the South West. The Local Intelligence Network (LIN) includes all local NHS and independent healthcare accountable officers, along with regulatory bodies and agencies (eg. Care Quality Commission, police, military). The task of the LIN is to share information about the use, management and any concerns relating to CD.

3.14.2 The LIN can investigate individuals who give cause for concern and, where necessary, establish an incident panel to investigate serious concerns.

3.14.3 The NHS England Accountable Officer is the Chair of the CD LIN meeting. The Trust's Accountable Officer attends the CD LIN meetings as requested by the NHS England Accountable Officer.

3.14.4 The Accountable Officer will share information on controlled drug concerns with other Accountable Officers using the framework of the 'Joint Memorandum of Understanding for Sharing and Managing Information/Intelligence within and between the CD LINs in South West'. In this way information will be managed securely and appropriately.

4. Practice Framework

4.1 Professional Duty of Care

4.1.1 Healthcare professionals in legal possession of a CD have a professional duty of care to take all reasonable steps to maintain the safe custody of that CD at all times.

4.1.2 Healthcare professionals who do not demonstrate this professional duty of care will be reported to their Professional Regulatory Body.

4.1.3 Criminal activity will be reported to the Police and/or NHS Security Management Service / NHS Counter Fraud Service.

4.1.4 Individuals who intentionally breach this Policy will be managed under the Trust's disciplinary policy.

4.2 Medicines Governance Instructions (MGI)

4.2.1 A MGI defines in writing what should be done, when, where and by whom.

4.2.2 The Trust has MGI for activities connected with the management and use of CD which interpret the context of this Policy and present it as practical guidance. The MGI defines the roles and responsibilities of each individual or staff grade in relation to the activity specified.

4.2.3 The MGI for CD are available to all Trust staff on the intranet in the MGI Manual.

4.2.4 All MGI for CD management will be developed in consultation with operational staff and must be approved by the Accountable Officer for CD and the Trust's Medicines Governance Group.

4.2.5 MGI must reflect any advice issued by NHS England or NHS Improvement relevant to the operation described.

4.2.6 All staff must read and understand the MGI for CD that apply to their role. It is the responsibility of every individual to ensure compliance with the MGI governing the management and security of CD in their area of operation.

4.3 Education and Training

4.3.1 The Accountable Officer, the Deputy Accountable Officer, the Head of Education and the Heads of Operations will ensure that individuals involved in any aspect of CD management receive training to carry out their responsibilities.

4.3.2 The training will include the provision of information on MGI for CD.

4.3.3 Induction for new staff involved in CD management and use will include material on the need for secure storage, possession and the legal status of all CD.

4.3.4 All staff will be trained to ensure they have the relevant knowledge and skills to undertake the tasks required of them to manage CD safely.

4.3.5 Healthcare professionals who work with CD will demonstrate reflective learning relating to their use of CD in their continuing professional development portfolio.

5. Guidance on the Safer Management and Use of Controlled Drugs

5.1 Naloxone Storage in Clinical Areas

5.1.1 Naloxone must be immediately available where morphine sulphate 10mg in 1ml injection and other opiate based drugs are used in all clinical areas. On a mobile unit the naloxone must be stored in a Trust drug bag, doctor's bag or crash box. It must not be stored in the morphine pouch. Naloxone must be immediately available at the patient's side when opiates are administered. An incident report must be submitted for all actual or near miss incidents linked to an opioid administration overdose by a Trust clinician.

5.2 Reducing Dosing Errors with Opioid Medicines

5.2.1 Opioid medicines are invaluable in the treatment of acute and chronic pain, but there are risks if clinicians who prescribe, supply or administer opioid drugs have insufficient knowledge of the dosage and the requirements of the individual patient concerned. The nature of urgent and emergency care increases this risk, as practitioners do not usually have access to the patient's notes and will have to rely on the information that they are given by the patient or their carer(s).

5.2.2 Opioid drugs include:

- Buphrenorphine

- Codeine
- Diamorphine
- Dipipanone
- Fentanyl
- Hydromorphone
- Meptazinol
- Methadone
- Morphine
- Oxycodone
- Papaveretum
- Pethidine
- Tramadol

5.2.3 Particular care must be taken to determine the correct formulation that the patient has been taking. Clinicians prescribing, supplying or administering opioid drugs should be alert to similarities in packaging that could lead to confusion between a formulation with a prolonged action (i.e. MR tablets generally used with a regular twice daily dose) and an immediate release dosage form (i.e. capsules more commonly used for breakthrough pain). Oxycodone formulations are often confused, leading to the patient receiving an excessive dose of the opioid.

5.2.4 The patient response to opioid drugs can vary widely and is partly dependent on previous doses received. Particular care must be taken when checking the safety of increased doses.

5.2.5 When prescribing, supplying or administering an opioid drug, clinicians must confirm and record in the Patient Clinical Record (PCR), the details of any recent opioid dose, including the type of formulation and frequency of administration. Any other non-opioid analgesic medicines prescribed for the patient should be recorded. This information may be obtained, for example, by discussion with the patient and /or their representative (although not in the case of treatment for addiction), contacting the prescriber or through available medical records. The source of this information must be recorded in the patient's notes.

5.2.6 Ambulance clinicians must ensure that opioid dosages are checked against relevant national guidance, local guidelines or Trust Patient Group Direction (PGD) prior to administration or supply.

5.2.7 Prescribers must ensure that where a dose increase is intended, that the calculated dose is safe for the patient (e.g. for oral morphine or oxycodone in adult patients, not normally more than 50% higher than the previous dose). The prescriber must record the check in the patient's notes.

5.2.8 Clinicians must ensure that they are familiar with the following characteristics of an opioid drug before they prescribe it for a patient:

- Usual starting dose
- Frequency of administration
- Standard dosing increments
- Symptoms of overdose
- Common side-effects

5.3 Midazolam

5.3.1 To reduce the risk that a patient may be overdosed with midazolam injection when used for conscious sedation, the presentation of high strength midazolam as 5mg/ml (10mg in 2ml ampoules), which exceeds the dose required for most patients, will not be stocked except in the Urgent Care (UC) Service in Dorset for GP use and in Specialist Paramedic Urgent and Emergency Care cells where it will be reserved for use in palliative care.

5.3.2 There is a risk when high strength ampoules are stocked in other areas that the entire contents are administered to the patient when only a fraction of this dose is required. Consequently, only the 1mg in 1ml ampoules will be stocked where clinicians use midazolam for conscious sedation. The two strengths must never be stocked in the same location.

5.3.3 All clinicians involved directly, or participating in, sedation techniques must have the necessary knowledge, skills and competences required to ensure the safety of the patient. Registered paramedics and registered nurses must be assessed as competent in the use of the relevant midazolam PGD.

5.3.4 Doctors working with the air ambulances or working as British Association for Immediate Care (BASIC) doctors must be able to evidence their competence to use this drug and have administered midazolam at least once in the last two years. They must provide this evidence every two years to the Executive Medical Director.

5.3.5 Stocks of flumazenil must be available where midazolam is used for conscious sedation and the use of the flumazenil must be reported on the Trust's incident reporting system. Use must be regularly audited as a marker of excessive dosing of midazolam.

5.3.6 All sedation with midazolam performed by Trust clinicians must be carried out in accordance with Trust Guidelines. An incident report must be submitted for all actual or near miss incidents linked to the use of midazolam. The responsibility for the Trust guidance is assigned to the Executive Medical Director.

5.4 Prescribing, Supply or Administration for Personal Use or for Family Members

5.4.1 Other than in emergencies, no clinician may prescribe, supply or administer a CD to or for themselves or anyone with whom they have a close personal or emotional relationship. In an emergency situation, if this is unavoidable, the clinician must record the event on the Trust's incident reporting system and inform the Accountable Officer for CD.

5.4.2 If any staff member suspects that such an incident has occurred but not been reported, they must alert the Accountable Officer.

5.5 Drug Driving

5.5.1 Staff who drive Trust vehicles and who take CD available from a pharmacy or prescribed by their doctor should be aware of new legislation giving the police powers to test and arrest drivers suspected of driving after taking certain CD in

excess of specified levels. The new law also provides a medical defence if you are taking medicine in accordance with instructions from a healthcare professional or an accompanying leaflet, provided that you are not impaired.

5.5.3 If staff drive Trust vehicles and take prescription medicine, they are advised to keep evidence of this with them in case they are stopped by the police or involved in an accident.

5.6 Preventing Misuse

5.6.1 All CD have the potential for misuse. The urgent and emergency care settings can be particularly vulnerable to abuse by individuals seeking supplies of CD as the clinician will usually be unfamiliar with the patient and unable to access their medical records.

5.6.2 It is important to prevent the misuse of urgent and emergency care services to obtain supplies of CD.

5.6.3 Patients who are identified as contacting Trust services frequently to request CD must be reported to the Accountable Officer for CD and a special message or flag file created to warn other clinicians of the potential for misuse.

5.6.4 Patients with known or suspected CD dependency problems must not be supplied, prescribed or administered CD, (See also 'Prescribing for Drug Treatment Service Users or Drug Misusers') except when there is a genuine need for ambulance clinicians, BASICS Doctors or doctors flying with the air ambulance to administer a drug for sedation, pain relief or seizure control.

5.6.5 If a clinician has any doubts about prescribing, supplying or administering CD to a patient, they should consider the use of an alternative medicine or seek the advice of a doctor or senior colleague before administering the CD or making a supply. The practitioner should document their concerns and any advice they received from a doctor or senior colleague.

5.6.6 Misuse of CD is not restricted to patients. Misuse of CD by Trust staff may endanger the lives of patients and colleagues, compromise the quality of care given to patients, tarnish the reputation of the Trust and cause a clinician to be removed from their professional register. All staff must be vigilant to the potential for misuse by staff members and report any concerns, in confidence, to the Accountable Officer for CD or through the Trust's Whistle Blowing Policy.

5.6.7 The Trust has an agreed Alcohol and Drugs at Work policy to effectively manage it's responsibilities as an employer. The Policy aims to provide a framework to facilitate the early detection and support for staff with a potential substance misuse related problem, encouraging staff to seek assistance voluntarily and giving guidance on how such matters should be dealt with.

5.7 Intelligence Gathering

5.7.1 The Accountable Officer for CD has a duty to gather and share intelligence on CD occurrences.

5.7.2 Individual incidents may not seem important when viewed in isolation but may assume greater significance when considered together with other reports.

5.7.3 All departments must inform the Accountable Officer when CD are involved in incidents, complaints or HR issues. This includes investigations into the prescribing or administration of CD, audits of CD use or disciplinary procedures. A report must be submitted in confidence which gives the date of the occurrence, a brief overview of events, location, names of individual members of staff/controlled drug involved.

6. Procurement of Controlled Drugs for use by Trust Clinicians

6.1 Requisitioning Controlled Drugs from a Supplier

6.1.1 The CDL enables the Trust to possess controlled drugs on Schedules 2 to 5 and supply them to employees of the Trust for the purpose of administration for the immediate necessary treatment of sick or injured persons. This means that the Trust can order, stock and supply drugs to paramedics and other healthcare professionals employed by the Trust including doctors.

6.1.2 A supplier providing controlled drugs to the Trust must have a CDL which allows them to supply CD and they must check that the Trust alos has a CDL before making the supply. The Procurement Team will ensure that any supplier supplying CD to the Trust possesses a licence to supply CD.

6.1.3 Controlled Drugs on Schedules 2 and 3 must be requisitioned on a Mandatory Requisition Form from the Trust's suppliers. The mandatory requisition, in writing, signed by the Trust's Executive Medical Director, or a named Medical Director authorised by the Executive Medical Director, must be received by the Supplier before any CD can be released and delivered to the Trust. The Supplier must be provided with a specimen signature of any doctor authorised to order CD on behalf of the Trust BEFORE the doctor signs a mandatory requisition. If the Supplier operates an electronic mandatory requisition this may be used but the L4 form must be approved by the Executive Medical Director and the order placed by an authorised person using the approved log in.

6.1.4 The Central Store, Exeter will maintain a list of authorised doctors who may write mandatory requistions to order CD for the Trust.

6.1.5 All mandatory requisitions placed with the Trust's suppliers for CD are made by the Central Store at Exeter so that the Trust has oversight of all CD requisitioning.

6.1.6 Clinicians working in UCS may not request or obtain CD from another provider.

6.1.7 CD must be delivered by the Supplier to the Central Store, Exeter and the delivery must be checked in the Store against the original requisition. However, by prior agreement with the Accountable Officer for Controlled Drugs, the CD ordered from the Specials Manufacturer may be delivered direct to the nominated airbase or ambulance station. Direct delivery is useful when the product has a short shelf-life. If the CD are not delivered to the Central Store, an Operations Officer must confirm the safe receipt of the CD with Central Store within 12 hours of receipt. The original invoice must be sent to the Central Store at the earliest opportunity and checked

against the requisition. A copy of the invoice must be retained by the airbase or ambulance station.

6.1.8 Any discrepancies between the requisition and the goods received, unless accompanied by an explanatory note from the Supplier, must be reported immediately to the Supplier's Operations Manager. If the situation remains unresolved the discrepancy must be reported to the Executive Medical Director or his nominated deputy who will manage the incident according to the Trust's Medicines Governance Instructions.

6.1.9 All invoices for CD from the Trust's Suppliers will be retained for seven years by the Central Store for VAT purposes. Internal L4 forms must be retained for 2 years for CD purposes.

6.2 Distribution of Controlled Drugs to Frontline staff

6.2.1 Controlled drugs obtained for use by Trust clinicians must be distributed from the Central Store or the receiving ambulance station to the clinicians who will administer them. This movement of controlled drugs is facilitated using L4 forms which act as internal requisition forms. Together with entries in unit CD registers, the L4 forms create an audit trail for the CD:

- L4M The form used to distribute morphine sulphate 10mg injection
- L4Mi The form used to distribute midazolam injection
- L4K The form used to distribute ketamine injection
- L4DOC The form used to distribute CD to doctors working on air ambulances.
- L4BASICS The form used to distribute CD to BASICS clinicians employed by the Trust.

6.2.2 Only staff authorised to requisition CD may complete these forms. Their names and specimen signatures will be registered with Central Store, Exeter.

6.2.3 Normally, the person receiving or collecting CD orders should not be the same person who placed the requisition, except on smaller stations where this may be unavoidable. BASICS doctors should place orders via the Medical Director, Primary Care or the Executive Medical Director. This increases the transparency of the process and reduces the opportunity for diversion of stock by one individual.

6.2.4 To request CD distribution between Trust locations, the location making a request must complete and submit the appropriate L4 form to the location that will provide the CD.

6.2.5 The L4 form must be authorised and signed by an Operations Officer (OO), Medical Director or, in exceptional cases a registered paramedic authorised by an Operations Manager (OM), before the CD request is submitted. L4Doc forms must be signed by an authorised doctor and L4Mi forms for UCS must be signed by the Operations Support Manager (OSM). OM are responsible for authorising individuals in their area to requisition CD on a form L4 and will ensure that a specimen signature for each person authorised to request morphine is received by the location providing the morphine before any request is submitted. The OM is

responsible for ensuring that any changes to the list of authorised staff are notified to the location holding the authorisation.

6.2.6 All locations are required to provide data on CD supplied to other locations each month in the Short Station Review data.

Morphine Sulphate 10mg Injection

6.2.7 Morphine sulphate 10mg injection is a Schedule 2 drug (CD POM).

6.2.8 Registered paramedics are authorised by the Misuse of Drugs Regulations 2001: Group Authority for National Health Service (NHS) Ambulance Paramedics and Employing NHS Ambulance Trusts, to possess and administer morphine sulphate 10mg injection.

6.2.9 Registered nurses are authorised to possess morphine sulphate 10mg injection (morphine) by the amendments to the Misuse of Drugs Regulations 2001 contained in Misuse of Drugs (Amendment No.2) (England, Wales and Scotland) Regulations 2012**.** Statutory Instrument No. 973. Registered nurses require a PGD to authorise the administration of morphine.

6.2.10 Doctors and pharmacists are authorised to possess all CD on Schedules 2 to 5.

6.2.11 Morphine is distributed to all employees legally authorised to possess and administer it from the Trust Central Store in Exeter and via strategically placed sites named in the Trust's CDL.

6.2.12 To requisition morphine sulphate 10mg injection a receiving location must complete and submit an L4M to the supplying location that will provide the morphine.

6.2.13 Individual employees are authorised by the Accountable Officer to sign out up to five ampoules of morphine from Trust Stock into their personal possession. The supply is made only for the purpose of administration for the immediate necessary treatment of sick or injured persons. If the morphine is not required during the employee's shift it must be returned to Trust Stock. The following employees may sign out a supply of Trust morphine:

- Registered paramedics
- Registered nurses who have been assessed by an OO as competent to administer morphine in accordance with the Trust's PGD for morphine sulphate 10mg injection
- Registered nurse independent prescribers who have completed the Medicines and Healthcare products Regulatory Agency learning module available at http://www.mhra.gov.uk/ConferencesLearningCentre/LearningCentre/Medicineslearningmodules/Opioidslearningmodule/index.htm and who have demonstrated to their line manager that they understand the Trust's Medicines Management (Controlled Drug) Policy and associated SOPs.
- Doctors employed by the Trust in Urgent or Emergency Care roles. This morphine may not be supplied by the doctor, to a patient, for

future use or left in a patient's home for another healthcare professional to administer.

6.2.19 The NHS Group Authority allows a registered NHS paramedic to supply morphine sulphate injection (up to a strength of 20mg), diazepam or oral morphine in their possession to any person lawfully allowed to be in possession of the drug, including a doctor or nurse, for the immediate, necessary treatment of sick or injured persons.

6.2.20 When a registered paramedic or registered nurse has a time critical handover of a patient to whom he/she has already administered a dose of morphine they may not supply any remaining part of a dose of morphine to the receiving clinician unless the clinician is a doctor who does not have his/her own supply of morphine and the care of the patient would be compromised. They must retain and destroy any morphine remaining from the supply which they have signed out of Trust Stock and the receiving clinician must administer the morphine from their own personal issue.

Ketamine Injection

6.2.21 Ketamine is a Schedule 2 controlled drug subject to the same level of control as morphine sulphate 10mg injection.

6.2.22 Registered paramedics and registered nurses who have been assessed as competent to use a Trust ketamine PGD can possess ketamine and sign out a supply for use during a shift.

6.2.23 Ketamine is requested using an L4K form and is stocked as either a pre-filled syringe containing 10mg in 1ml or as a 10mg vial. Only the 10mg strength of ketamine is stocked to reduce the risk of administration errors. Prefilled syringes are unlicensed products and cannot be authorised for use under a PGD. They cannot be signed out for use during a shift by staff who require a PGD to authorise administration.

Midazolam Injection

6.2.24 Midazolam injection is a Schedule 3 CD (CD No Register POM).

6.2.25 Doctors and pharmacists may possess midazolam.

6.2.26 Registered paramedics and registered nurses who have been assessed as competent to use a Trust midazolam PGD can possess midazolam and sign out a supply for use during a shift.

6.2.26 Two presentations of midazolam are stocked by the Trust: midazolam 1mg in 1ml injection and midazolam 10mg in 2ml injection. Midazolam 10mg in 2ml is obtained for use by doctors and Specialist Paramedics Urgent and Emergency Care (SPUEC) for use in the provision of end of life care only. Midazolam 1mg in 1ml injection is obtained for use as a sedative. Under no circumstances may the two presentations be stocked at the same location.

6.2.27 Requisitions for midazolam must be made on an L4Mi.

6.2.28 Medical practitioners working in UCS will be provided with access to a supply of midazolam 10mg in 2ml injection to use in end of life care only. This midazolam may not be supplied by the doctor, to a patient, for future use or left in a patient's home for another healthcare professional to administer.

Other Schedule 2 CD (Diamorphine, Fentanyl)

6.2.29 Medical practitioners and pharmacists can possess all CD on Schedule 2 to 5.

6.2.30 Medical practitioners employed by the Trust may possess these CD which are obtained and supplied exclusively for their use.

6.2.31 Diamorphine and Fentanyl are Schedule 2 CD (CD POM) which cannot be possessed by the Trust's registered paramedics or registered nurses.

6.2.31 Requests for these CD must be made on an L4Doc.

Lower Schedule Controlled Drugs

6.2.32 CD on Schedules 3 to 5 (except injectable forms of midazolam) are requested using the standard trust process for non-controlled drugs but in all other respects they are managed as Schedule 2 CD with CD register entry and secure storage.

6.2.33 Doctors, registered nurses and pharmacists may possess CD on Schedules 3 to 5. The NHS Group Authority allows a registered NHS paramedic to possess diazepam preparations and oral morphine. They may supply these CD when they are in their possession to any person lawfully allowed to be in possession of the drug, including a doctor or nurse, for the immediate, necessary treatment of sick or injured persons.

6.2.34 Buccal midazolam, diazepam emulsion for injection, diazepam rectal tubes and oral morphine may be signed out at the start of each shift by a registered paramedic or registered nurse contained in a sealed Trust drug bag which has been allocated a unique asset number. The registered paramedic or registered nurse must sign out the uniquely numbered bag and accept responsibility for the security of the lower schedule CD during the shift.

6.2.35 Access to lower schedule CD is restricted to registered clinicians and separate storage provided on station.

6.3 Controlled Drug Access for Out-of-Hours (OOH)

6.3.1 Doctors working on mobile units in UCS OOHs services will have access to up to 5 ampoules of morphine and up to 5 ampoules of midazolam 10mg in 2ml injection. This must be signed out of Trust Stock and onto the vehicle by the GP at the start of the shift.

6.3.2 In addition, the NHS Group Authority allows registered paramedics to supply morphine sulphate 10mg injection to persons who may lawfully have the drug in their possession provided that it is for administration for the immediate treatment of sick and injured persons. Similarly, registered nurses are also able to supply morphine sulphate 10mg injection to persons who may lawfully have the drug in their possession.

6.3.3 Because the supply to doctors is made to allow the immediate treatment of sick or injured persons, and because of the restrictions of the CDL and the legal requirements for labelling of medicinal products, UCS doctors may not leave a supply of ampoules of morphine sulphate 10mg injection or midazolam 10mg in 2ml injection in a patient's home for a carer or another healthcare professional to administer at a later point in time.

6.4 Controlled Drug Access for British Association of Immediate Care (Schemes) (BASICS)

6.4.1 BASICS carry their own personal supply of CD but those employed by the Trust may be supplied directly by the Trust. It is recommended that BASICS carrying privately obtained stock, carry the Trust formulary drugs in the same presentations to reduce the risk of administration errors on scene.

6.4.2 Where BASICS carry their own stock the clinician will adhere to the SW BASICS CD Policy.

6.4.3 CD obtained by BASICS from the Trust will be managed in accordance with this Policy as they remain at all times the property of the Trust.

6.4.4 BASICS employed by the Trust who wish to carry a supply of Trust CD must complete the L4BASICS and submit it for authorisation. The signed and authorised request will be forwarded to the Central Store which will make arrangements for the supply to be made available to the BASIC clinician. The signed and authorised L4BASICS form will be retained by Central Store.

6.4.5 If the BASICS clinician wishes to collect the CD from a local location this can be arranged. If the CD is stocked by the location an entry must be made in the location's CD Register to record the supply to the BASICS clinician which includes the number on the L4BASICS form on which it was originally ordered. The Stores Team Leader will share a copy of the signed and authorised L4BASICS with the location to authorise local clinicians to make the supply. The copy must be retained at the location for two years. If the CD cannot be possessed by non-medical staff, it must be delivered in a sealed container and stored in this container securely until it is collected. The BASICS doctor must sign and fax back the L7b to acknowledge receipt.

6.4.6 If a doctor administers his privately purchased supply of CD to a patient of the Trust he/she may claim reimbursement from the Trust. Only claims approved by the Trust's Executive Medical Director will be paid by the Trust.

6.4.7 To claim reimbursement the doctor must submit a copy of the original receipt for the purchase of the CD together with the call numbers of the patients treated and the dates of administration to the Executive Medical Director, Trust Headquarters, Exeter.

6.4.8 The administration details must be verified with the SWASFT patient clinical record to verify that the drugs were administered as stated.

6.4.9 The Executive Medical Director must see evidence that the doctor has been allocated a PIN number and issued with a supply of private CD prescriber's prescription forms FP10CDF before approving payment.

6.4.10 All invoices passed to the Finance Department for payment must be countersigned and approved by the Executive Medical Director, SWASFT.

6.5 Controlled Drug Access for Staff Responders

6.5.1 Staff Responding Officers who are allocated a Trust lease car with a CD safe approved by the Clinical Director or Executive Medical Director, fixed to the vehicle, may apply to carry CD. No other staff responders are eligible to apply. The Staff Responding Officer must be authorised in writing by the Clinical Director or the Executive Medical Director to carry personal issue CD in their cars when acting as a responder.

6.5.2 Staff Responding Officers can only be authorised to be supplied with a CD if they are legally authorised to possess and administer that drug.

6.5.3 Application forms to carry CD are available from the Clinical Director.

6.5.4 Paramedic and Nurse responding officers and staff responders who are not allocated a Trust lease car with a CD safe fixed to the vehicle, may still apply to carry CD on Schedules 4 and 5 in a sealed Trust drug bag.

6.5.5 Staff Responding Officers must complete the application form and return it to the Clinical Director. If approved, the standard letter of authorisation will be returned, and copied to the manager/director's personal file. An authorisation will be valid for a period of three years after which it must be reviewed. Responding officers/staff responders will be expected to demonstrate that they have continued to maintain their competence by responding regularly before an authorisation is issued.

7. Transport of Controlled Drugs

7.1 Internal Transportation of Controlled Drugs

7.1.1 As far as reasonably practicable, all stages of the collection, delivery and receipt of CD must be witnessed and supervised by two members of Trust staff.

7.1.2 Legislation allows anyone to transport controlled drugs and take them to someone who may legally possess them provided that the courier has the approval of the person receiving the CD.

7.1.3 All CD must be transported securely. Registered clinicians may sign out a supply of CD they may possess into their personal controlled drug register (CDR) for transportation. In all other instances a Trust Transportation Form (L7b) must be used. The CD will be signed out of one location and into the safe-keeping of the courier. The person accepting the drug for delivery must check the L7b form with the person dispatching the CD and only sign the form if they are satisfied that all details are correct. The quantity of CD that may be signed out must not exceed the total quantity requisitioned.

7.1.4 Anyone releasing CD to a clinician or courier must never rely just on a uniform, a signature or familiarity with staff, as this could enable a member of staff who has left or been suspended from the Trust, and has had their ID card taken from them, to still collect CD. The person collecting CD must be in uniform and present a Trust ID card with photographic ID before the CD is handed over.

7.1.5 When the CD are received at their destination, the L7b transport form or personal CDR must be checked with the person receiving the CD to ensure that all the CD dispatched have been delivered, and the transportation form must be signed by the Trust clinician receiving the CD at their destination.

7.1.6 The transportation form must be signed and faxed to the issuing unit as soon as the order is checked. The completed form must be returned to the issuing unit at the first opportunity.

7.1.7 Within the Trust all Schedule 2 and 3 CD (diamorphine 10mg injection, fentanyl injection, morphine sulphate 10mg injection, ketamine 10mg in 1ml injection, midazolam 1mg in 1ml injection and midazolam 10mg in 2ml injection) must be transported within a locked safe secured to the vehicle's chassis or a locked doctor's bag. The CD must be kept out of view during transportation. It is the responsibility of the person requisitioning and authorising the collection of the CD to ensure that the vehicle has a suitable safe.

7.1.8 The CD will be transported directly and not left in an unattended vehicle at any time during the journey, unless tasked to an emergency call, when the vehicle must be locked.

7.1.9 Medicine deliveries which contain lower schedule CD must never be left unattended in an unsecured location if a courier is unable to find a staff member on station who is authorised to receive them.

7.1.10 Arrangements for receipt of deliveries of CD on Schedule 2 and 3 CD should be made in advance of transportation. All deliveries of Schedule 2 and 3 CD must be signed for and witnessed by an employee authorised to possess them. If the staff on the unit are deployed operationally when the courier arrives, the courier must telephone the Logistics Helpdesk and arrange for an OO to attend and take receipt of the CD.

7.1.11 Lower Schedule CD deliveries may be left in an agreed secure location, which must be authorised by the OM following a documented risk assessment. Where this is the case, the CD should be checked and signed into the station controlled drug cupboard (safe) at some point during the shift by two members of staff one of whom must be a registered nurse, registered paramedic or a doctor.

7.1.12 The transportation form must be signed and faxed to the issuing unit as soon as the order is checked. The completed form must be returned to the issuing unit at the first opportunity.

7.2 Transporting Controlled Drugs Prescribed for a Patient

7.2.1 CD taken with a patient on admission into hospital are individually dispensed for a named patient and therefore considered to be in the patient's possession. They

should not be stored in a Trust safe and therefore not recorded in any Trust CD Register. The same applies to CD that are part of discharge medication or to CD prescribed and supplied to patients in Patient Controlled Analgesic (PCA) devices.

7.2.2 Care should be taken when transporting patient medication in a 'Green Bag' as clinicians may not recognise a CD. Any patient medication must be given to a registered nurse, doctor or pharmacist in the hospital on arrival. If the patient dies in transit medicines must not be left in the mortuary.

7.2.3 Diversion of patient's own medication is theft.

8. Secure Storage

8.1 Legislation

8.1.1 Schedule 2 CD are subject to safe custody requirements and so must be stored in a locked receptacle meeting the requirements of the legislation which can only be opened by a person who may lawfully possess them.

8.1.2 The legislation exempts all other controlled drugs stocked by the Trust from the safe custody requirement but the Trust requires all CD, regardless of schedule, to be stored securely. This is not a legal requirement.

8.2 Controlled Drug Cupboards and Safes

8.2.1 The Trust aspires to achieve the minimum standards described by NHS Protect for the security of CD in ambulance services.

8.2.2 All Schedule 2 CD, including morphine sulphate 10mg injection, will be stored securely in CD cupboard or safe approved by the Trust's Accountable Officer except when carried in a morphine pouch on the belt of a Trust clinician as 'personal issue'.

8.2.3 CD cupboards must be made of metal with tamperproof hinges, and fixed to the floor or solid wall with rag bolts that are not accessible from outside the cabinet.

8.2.4 Nothing other than a CD may be stored in a CD cupboard. Nothing must be written or posted on the outside of the safe to indicate that CD are stored inside.

8.2.5 Access to CD cupboards will be provided by a combination code keypad which has a code change every three months or a proximity reader and key operated lock.

8.2.6 Access to areas where CD are stored must be controlled. All CD cupboards on ambulance stations and airbases used to store Schedule 2 and 3 CD must be situated in an area where the access is controlled either by a proximity reader that can record the identity of the person entering the room, by an alarm system or by a keypad lock.

8.2.7 CD cupboards in UCS local treatment centres are frequently situated in areas shared with other providers 'in hours'. Although this precludes the use of proximity readers to control access to the area, UCS Managers should work closely with the

provider's Local Security Management Specialist to ensure that the CD are secure and to prevent unauthorised access when the cupboard is unattended.

8.2.8 All safes at Trust locations used to store CD should be protected by closed circuit television which will provide 24 hour recorded surveillance of access to the CD. If CCTV is not currently installed at any location it will be considered at any future refurbishment as a priority. The position of the camera must be tested to ensure that there is a clear view of CD access.

8.2.9 Faulty or damaged CD cupboards/safes must be reported immediately to the Area Administrator. The security of the CD must be maintained and alternative arrangements for secure storage must be made and used until any repair has been carried out. The Accountable Officer should be contacted for advice on suitable alternative arrangements.

8.2.10 It is permissible for someone who is authorised to possess a CD to provide access to an individual who is not authorised to possess the CD, where access is required to audit CD or perform housekeeping functions, e.g an UCS Doctor opening a morphine safe to enable an UCS receptionist to complete a stock check. The authorised clinician must open the cupboard and retains responsibility for supervising the activity of the person provided with access; actual keys, access cards or codes must not be shared with anyone not authorised to possess a CD under any circumstances.

8.2.11 Override keys for all keypad locks will be kept securely by the OM or OSM (UCS).

8.2.12 BASICS doctors may carry controlled drugs in a locked doctor's bag.

8.3 Storage of Lower Schedule Controlled Drugs

8.3.1 Codeine Phosphate 15mg tablets and Diazepam 2mg tablets provided for use by Specialist Paramedics and Nurses Urgent and Emergency Care must be stored in a cupboard on their base station which can only be accessed by these clinicians.

8.3.2 Diazepam emulsion for injection, rectal diazepam and oral morphine provided for use by registered paramedics and registered nurses should be stored in a cupboard that can only be accessed by these clinicians. Non-clinicians may be permitted access to perform specific functions including auditing or replenishing a paramedic drug bag but the registered clinician facilitating access retains responsibility for the CD. Drug bags containing these CD must be sealed when not in use. Only a registered paramedic, registered nurse, doctor or pharmacist may sign out a sealed paramedic drug bag containing CD.

8.3.3 In UCS lower schedule CD (Schedule 4 and 5) must be stored securely in a locked medicines cupboard or sealed crash bag. Access is restricted to staff authorised to possess them. However, other grades of staff may be permitted access in order to perform specific stock reconciliation or routine management tasks if supervised by an individual authorised to possess the CD.

8.3.4 Schedule 4 and 5 CD supplied to Staff Responding Officers must be stored in a uniquely numbered sealed drug bag that has been assigned to this individual.

8.4 Controlled Drug Storage in Trust Stores

8.4.1 Trust stores holding bulk stocks of CD should be alarmed buildings with restricted access to the activation mechanism. Access to the CD will be controlled and monitored by CCTV.

8.5 Responding to an Activated Alarm or a CCTV Access Control Observation

8.5.1 When an alarm on an area where CD are stored is activated accidentally it must be immediately deactivated and the incident logged in the unit log book. It must be reactivated without delay to preserve the security of the CD.

8.5.2 If an alarm is activated by forced entry, the stock must be checked to determine what is missing. If any CD are missing the Medicines Governance Instructions for investigating discrepancies must be followed and the Accountable Officer for CD must be informed.

8.5.3 If the alarm is activated when the building is unstaffed the response will be a police response.

8.5.4 If when an alarm is activated, theft is suspected the Police must be informed unless they are already present. Evidence must not be disturbed and the area must be secured to prevent further access and contamination of a potential crime scene. At the earliest opportunity, by agreement with the senior investigating police officer, the CD must be removed to a secure location.

8.5.5 Until the police allow the CD to be moved, an OO must ensure that the area is secure and that the CD cannot be removed.

8.5.6 If any unusual activity is noted on a CCTV recording, the recording must be saved and the tape or disc must be labelled with the date, name of station or other location and the time that the recording was made. The labelled tape or disc must be stored in a locked drawer in the office of the OM. The incident must be reported to the Accountable Officer.

8.6 Storage of Personal Issue Morphine Sulphate 10mg

8.6.1 Personal issue morphine sulphate 10mg injection must be stored in a Trust morphine pouch which must be worn on the clinician's belt, or secured within a flight/responding suit or motorbike safe at all times whilst on duty. The pouch should be positioned between two belt loops to prevent its accidental loss from a belt when this is undone.

8.6.2 Personal issue morphine sulphate 10mg injection must not be carried in a fleece, jacket or trouser pocket.

8.6.3 Under no circumstances should staff place themselves in danger by attempting to prevent the theft of personal issue morphine or other CD. If threatened staff must hand over the CD but try to remember any key features of the thief's appearance or the direction in which they left the scene to inform the Police.

8.6.4 Morphine syringe labels must be carried in the morphine pouch but no other ampoules of medicine.

8.6.5 Personally issued morphine sulphate 10mg injection ampoules must be returned to the safe from which they were drawn in the event that a registered nurse or registered paramedic is taken ill whilst on duty and does not return to the ambulance station (e.g. hospital admission or going straight to their home address). The registered nurse or registered paramedic is responsible for entrusting their morphine sulphate 10mg injection to another member of staff authorised to possess the morphine. If no one is immediately available, they must ask an OO, or other trust employee authorised to possess morphine, to attend and return the morphine to trust stock. An audit trail must be maintained in the clinicians' personal morphine books.

8.7 Controlled Drug Storage on Vehicles

8.7.1 Stock of Schedule 2 and 3 CD must be stored on vehicles in a CD cupboard approved by the Accountable Officer or a locked doctor's bag when it is distributed around the Trust. The CD cupboard must be fixed to a secure vehicle mounting point (metal structure of the vehicle) on the vehicle chassis with bolts which can only be accessed from within the safe.

8.7.2 Schedule 2 and 3 CD supplied to UCS GPs for administration to sick and injured patients must be stored in a trust pouch worn by the GP or locked vehicle safe secured to the vehicle chassis.

8.7.3 Schedule 2 and 3 CD supplied to Staff Responding Officers for administration to sick or injured patients must be stored in a locked doctor's bag or a locked vehicle safe approved by the Accountable Officer, and secured to the vehicle chassis.

8.7.4 Schedule 2 and 3 CD supplied to trust employees who are members of BASICS for administration to sick or injured patients, must be stored in a locked doctor's bag or in a locked vehicle safe approved by the Accountable Officer or the Deputy Accountable Officer, and secured to the vehicle chassis.

8.7.5 Schedule 2 and 3 CD must be stored on aircraft in a controlled drug cupboard approved by the pilot and by the Accountable Officer which is secured to the airframe.

8.7.6 Lower Schedule CD must be stored in a uniquely numbered and sealed Trust drug bag registered on the Trust Drug Bag Register.

8.7.7 All CD must be removed from vehicles or aircraft and returned to an ambulance station, airbase or UCS treatment centre with CD storage if:

- A vehicle or aircraft is taken out of service or is permanently decommissioned.
- A vehicle or aircraft's CD safe has failed.
- Non-Trust personnel are working on a vehicle or the vehicle is unattended.
- A vehicle or aircraft is not operational, is parked off a Trust site and will be unattended (this particularly applies to manager/officer cars, e.g. where the person is on annual leave and the vehicle is at a home address).

- A vehicle or aircraft breaks down or is involved in an accident and has to be recovered.
- A vehicle or aircraft is involved in an untoward incident, i.e. a road traffic collision, and taken directly to a repair facility or police compound for evidential review.

8.7.8 Staff Responding Officers must carry their morphine sulphate 10mg stocks within a Trust morphine pouch when it is not secured within a vehicle safe.

8.7.9 Trust vehicles containing lower schedule CD in uniquely numbered and sealed Trust drug bags should be locked, alarmed and immobilised when not occupied or when left unattended (i.e. out of sight of the crew) at the scene, hospital or treatment centre.

8.7.10 Paramedic drug bags must not be left unsecured on unlocked vehicles.

8.7.11 Vehicle medicines cupboard keys should not be joined or bound to the main ambulance vehicle ignition key. This prevents the medicines cupboard key accidentally going to a garage or maintenance facility attached to the vehicle ignition key, or being left in the ignition should 'run lock' fail or should it not be utilised by a crew who leave a vehicle unattended.

8.7.12 Vehicles used to carry CD, that have security features such as locks or 'run lock' that are defective or non-operational should be reported and repaired as soon as possible. These vehicles should be taken 'off the road' and not used operationally.

8.7.13 Un-liveried lease, BASICS Clinician or Staff Responding Officer cars that are parked at non-Trust premises overnight, such as at a staff member's home address, potentially carry more risks. Cars should have the magnetic blue light removed so as not to draw attention to the fact that there may be CD and other valuable Trust property inside the vehicle. Any lease or officer car, liveried or un-liveried, should be locked, alarmed, and ideally garaged, and should not have an excessive number of CD stored, just the minimum stock required for operational response requirements overnight. CD safes or locked doctors' bags must not be visible from the outside of the vehicle.

9. Managing Controlled Drug Stationery

9.1 Standards

9.1.1 This section provides Trust Policy on the minimum security standards and good practice guidance for the security, use and management of controlled drug stationery. CD stationery includes CD Registers, record books and CD Requisition forms.

9.1.2 CD stationery must be subject to the same rigorous security controls as CD themselves, in order to prevent the illicit use of forms and the manipulation, falsification or destruction of records with the aim of obtaining CD for improper use. An important aspect of this is to ensure that there is a clear audit trail from receipt of CD stationery items to the use of and return of completed stationery.

9.1.3 All Trust CD record books/registers must be bound books with numbered pages. The premises, the vehicle, the aircraft or the individual to which the register or record book relates must be clearly indicated on the front cover. It must be clear which CD are recorded in the register and the name, form and strength of CD being recorded must be clearly written at the top of each page.

9.1.4 The records for Schedule 2 drugs are the only CD records that the Trust must legally keep. The Trust maintains one organisational record for a Schedule 2 CD as required by the Misuse of Drugs Regulations 2001, but the entries are made in individual store, station, airbase, treatment centre, paramedic/nurse and vehicle record books. Each month these record books must be reconciled.

9.2 Control of Stationery

9.2.1 CD Record Books, CD Requisition Books and other CD stationery are issued from the Trust Headquarters to all trust locations. The Central Store will keep a record of all CD stationery issued to all Trust locations. Trust locations receiving CD stationery will complete a receipt form and return it to the Central Store to confirm that they have received the stationery and to record the number (s) of the record book(s) or documents received. See also:

- CD1 – Controlled Drug Book – Station – Order form
- CD1A – Issuing of Controlled Drug Record Books - Station
- CD2 – Controlled Drug Book – Personal – Order form
- CD2A – Issuing of Controlled Drugs Record Books to Registered SWASFT Personnel
- CD3 – Controlled Drug Books – Doctor Books – Order Form
- CD3A – Issuing of Controlled Drug Books to Doctors

9.2.2 L4BASICS forms will be distributed by the Medical Director, Primary Care who will ensure that a record of forms issued to individual clinicians is maintained.

9.2.3 Requisitions for CD stationery must be completed by OO and nominated members of urgent care staff approved by OM or OSM and witnessed by a second member of staff at the ordering station or treatment centre. A copy of the requisition must be retained by both the ordering station or treatment centre and the Trust Central Store.

9.2.4 Every employee authorised to be supplied with Trust stock CD on Schedule 2, including morphine sulphate 10mg injection, must have their own personal CDR. It is the responsibility of the employee to ensure that their personal CDR is audited and signed by their line manager or a senior manager in the Trust at least once every three months.

9.2.5 Personal Morphine Record Books are issued from individual ambulance stations and airbases to individual registered paramedics or registered nurses. The Registered nurse or registered paramedic must requisition a new Personal

Morphine Record Book from an OO and must exchange their old Morphine Record Book for their new book. If the new book replaced a lost book this must be recorded by the OO. A copy of the requisition must be retained by both the registered nurse/paramedic and the ambulance station or airbase. Personal morphine books must not be taken home unless the staff member is a Staff Responding Officer.

9.2.6 Doctors' personal controlled drug record books must be requested from the Executive Medical Director using the same process used for requisitioning personal morphine record books.

9.2.7 During transfer from one location to another, CD stationery should be secured in the same way as CD stocks. Blank CD books or forms must not be sent through the post; however if this is unavoidable, additional security measures should be put in place in case the package is intercepted. For example, the books and packs of forms should be sealed in a way that is tamper-evident.

9.2.8 As a matter of good practice, all controlled stationery should be serial numbered and the numbers recorded. Where stationery goes missing during transfer, the serial numbers can be noted, which will enable staff to detect attempts to use stolen forms or books to obtain CD illicitly. The use of serial numbers can also assist in detecting fraudulently produced CD stationery.

9.2.9 CD stationery orders should be received, checked and signed for by an OO on station, and should never be left unattended in an unsecured location. Similar security precautions should be taken as with delivery of CD in instances where no staff members are present to receive an order.

9.2.10 CD record books should be kept close to but not inside the CD safe to which they relate. They must never leave the premises unless they are in an UCS treatment centre and become obsolete or have been completed.

9.2.11 Checks to verify the identity of staff collecting CD stationery and authorised signatories will be implemented as those described in relation to the collection, delivery and receipt of CD stock.

9.2.12 The CD Record Book must be kept at the premises to which it relates or on the person of the registered nurse or registered paramedic. When the registered nurse or registered paramedic is not operational their Personal Morphine Record Book must be locked in their personal locker on the station or airbase. It must be available for inspection at any time. It will be used solely for recording controlled drug use and must not be used for any other purpose.

9.2.13 UCS vehicle or aircraft record books must be returned to the treatment centre or airbase when the vehicle or aircraft is not operational. UCS record books and registers may not be left on an unattended vehicle.

9.2.14 If the premises to which record books relate are decommissioned, all record books, current or archived, must be returned to Trust Headquarters for storage

9.3 Destruction

9.3.1 In the case where CD stationery has been updated or amended in some way, all unused and obsolete items should still be treated as secure stationery. All items should be collected and disposed of with the same considerations as apply to completed CD stationery.

9.3.2 Completed CDR and CD Requisition Books must be stored in a locked drawer or cupboard at the station, airbase or store to which they relate or where the employee is based. They should be clearly marked to indicate that they are no longer to be used, and any remaining lines should be struck through. Completed UCS treatment centre CDR must be returned to the OSM for storage at St Leonards.

9.3.3 Obsolete CD Record Books, Personal Morphine Record Books and CD Requisition Books must be destroyed at the station, airbase or store to which they relate. While awaiting destruction, they should be clearly marked to indicate that they are no longer to be used. Obsolete treatment centre or OOH vehicle CD stationery must be destroyed at St Leonards.

9.3.4 Completed or obsolete aircraft CD record books must be returned to the airbase for storage or destruction as appropriate.

9.3.5 CD records must be retained by the Trust for two years from the date of the last entry.

9.3.6 Where old CD stationery awaiting destruction contains details of administration to patients, e.g. in the CD Record Book, this must be treated as confidential waste.

9.4 Loss of Controlled Stationery

9.4.1 Personal CDR contain the clinician's personal legal record of CD use. Employees are responsible for the security of their personal CD book/register.

9.4.2 Employees must report the loss of a personal CD book/register to their line manager and the Accountable Officer as soon as the loss is discovered. An incident report must also be completed.

9.4.3 The loss of all other CD Record Books must be reported to the OM and the Accountable Officer as soon as the loss is discovered.

10. **Record Keeping**

10.1 General Principles

10.1.1 Except in exceptional circumstances, two members of staff should check all stock received, administered or removed, and both individuals should sign the entry in the record book. When a second person is not available to conduct the check, the entry in the record book must be annotated to explain the circumstances that prevented a second check.

10.1.2 When first taking over accountability for a stock of CD the clinician must ensure that the stock levels are correct by conducting a physical check of the stock. This applies to all units which carry CD.

10.1.3 When making entries in the CD record book, a separate section of the book must be used for each class of drug and a separate page must be used for each strength and form of that drug.

10.1.4 The administration of all Trust CD will be recorded on a Trust Patient Care Record (PCR) which is retained by the Trust.

10.2 Stock Levels and Running Balances

10.2.1 Running balances must be recorded to ensure that irregularities are identified as quickly as possible.

10.2.2 The running balance of drugs remaining should be calculated and recorded after each transaction and balances should be checked with physical stock. Consideration must be given to any stock that may be issued to staff on operational duty.

10.2.3 Under no circumstances must an entry be counter-signed without this check of physical stock. Anyone signing to agree a balance without checking the actual stock may be held responsible for any CD that is later found to be missing.

10.2.4 It must be possible to identify an audit trail for the CD from entries in the register/record book. It must be clear that stock removed is either replaced at the end of the shift or use is identified by an entry associated with an incident number.

10.2.5 The running balance and stock level must be verified by a daily audit process.

10.2.6 Tamper-evident seals on packs of CD should be left intact when they are received from the supplier to speed up and simplify balance checks.

10.2.7 Stock levels of all CD must be kept to the minimum compatible with operational requirements. The stock level must be regularly reviewed to prevent excessive stock accumulating.

10.2.8 The optimum stock level for each storage location must be agreed with the OM for that area. The stock level must be recorded and be known to all staff responsible for ordering stock at that location. The OM will maintain a record of approved optimum stock levels for all locations in their area.

10.2.9 Doctors will agree airbase stock levels with the Executive Medical Director.

10.3 Discrepancies with Running Balances

10.3.1 If a discrepancy is discovered, the first action must be for the person discovering the discrepancy to check for obvious omissions, extra entries or arithmetical errors. The stock of CD must be checked and all CD recorded as being present physically witnessed by the person performing the reconciliation.

10.3.2 If these checks do not reveal the source of the discrepancy, an OO (or if not immediately available, another clinician) must perform a second check.

10.3.3 If the discrepancy remains unresolved, the OM or OSM must be informed and an incident report submitted. BASICS clinicians must inform the Executive Medical Director or the Medical Director, Primary Care.

10.3.4 The OM, OSM or Medical Director, Primary Care must instigate a formal investigation and decide if the discrepancy suggests that CD may have been lost, stolen or otherwise diverted. If there is any suggestion of criminal activity or if the safety of the public may be put at risk, the discrepancy must be reported to the Police.

10.3.5 The OM, OSM or Medical Director, Primary Care must inform the Accountable Officer as soon as possible of any concerns in relation to discrepancies in stock levels of CD.

10.3.6 All incidents reported to the Police must be reported as soon as possible to the Accountable Officer or Deputy Accountable Officer.

10.3.7 If the actions taken resolve the discrepancy and the source of the error is found, a note must be made in the CD record book or register correcting the discrepancy in the balance.

10.3.8 Tippex or other correction fluids must not be used in CD registers or record books.

10.3.9 A record must be kept by all parties of their actions taken when a discrepancy arises.

10.4 Accidental Damage/Breakage of CD Ampoules

10.4.1 Accidental damage or breakage of CD ampoules must be recorded in the relevant record book or register and the entry countersigned by a witness.

10.4.2 All breakages must be reported on the Trust's incident reporting system. The report must state the name of the clinician, the CD (form, strength and quantity) and the events leading to the breakage or damage.

10.4.3 All breakages will be reported in the Short Station Review and other CD audit data collected by the Accountable Officer.

10.4.4 The Accountable Officer will use the incident reports to develop a database that can be used to identify any common causative factors. The data will be used in benchmarking exercises with other ambulance trusts.

10.5 Requisitioning CD

10.5.1 The Misuse of Drugs Regulations 2001 require requisition forms to include the purpose for which the drug supplied is required (Regulation 14(2)). In the case of the Trust, this will always be for administration to patients in the context of emergency or urgent care. This requirement may be satisfied by way of a statement printed on the proforma requisition form, rather than written by hand for each individual order.

10.5.2 All requisitions should include the following information (the information in bold is legally required to be obtained by the supplier under the Misuse of Drugs Regulations 2001):

- Date of order
- **Name and address of the Trust**
- Name of Supplier
- **Name of the CD, formulation and strength**
- **Quantity**
- **Purpose for which the drug supplied is required**
- **Name (legible), profession, signature and either HPC, NMC or General Medical Council PIN of person placing the order**
- Name (legible) and signature of the person supplying the order.

10.5.3 The CD requisition form is controlled stationery and must be kept securely stored at all times with access restricted to authorised staff only.

10.5.4 The CD requisition form should not be amended or corrected in any way. If a mistake is made, the word 'VOID' should be written across the spoiled form and a new one made out.

10.6 Receipt Records

10.6.1 When CD are obtained the following information must be recorded in the CD record book:

- Date supply obtained
- Name and address of supplier and invoice number where applicable
- Name of drug (form, strength, quantity)
- Name of person making the entry
- Countersigned by a witness

10.6.2 Requisitions and orders for CD must be preserved for a minimum of two years. This may be in the original paper form or in computerised form.

10.7 Records of Supply/Administration

10.7.1 When CD are supplied or administered to patients or supplied to practitioners (in response to requisitions), the following information must be recorded in the CD record book:

- Date supplied/administered
- Name of drug (form, strength, quantity)
- Name and address of person, station, store, airbase or treatment centre supplied
- Detail of person administering/supplying to patient and situation (prescribing/PGD)
- Quantity, form and strength in which supplied

10.8 Records of Destruction

10.8.1 All CD requiring destruction, including those issued to BASICS clinicians, must be returned to either the Central Store or North Bristol Operations Centre (NBOC), locations. These locations have a T28 Exemption allowing CD to be denatured prior to destruction in the presence of an Authorised Witness or a Destruction Witness.

10.8.2 A record must be kept in the CD record book belonging to the BASICS clinician, ambulance station, airbase or treatment centre returning the drug for destruction which details:

- Date returned
- Quantity, form and strength of controlled drugs returned
- Name/signature of person making entry
- Countersignature of witness
- Nature of return (e.g 'expired stock returned for destruction')

11. Administration

11.1 Staff authorised to prescribe/administer CD

11.1.1 Oral morphine sulphate preparations up to 10mg/5ml are controlled by The Misuse of Drugs Act 1971 and The Misuse of Drugs Regulations 2001 but are legally exempt from all restrictions under the regulations concerning administration. However, within the Trust, the administration of this drug is restricted and it is only administered:

- from stock by registered paramedics and registered nurses;
- by independent prescribers;
- or by registered nurses or registered paramedics following the written instructions of an independent prescriber.

11.1.2 All CD listed in Schedules 2 to 5 may be prescribed under the legislation by doctors, nurse and pharmacist independent prescribers (IP) within their competence (except that nurse and pharmacist IPs may not prescribe cocaine, diamorphine and dipipanone for the treatment of addiction). However, the Trust requires IPs to prescribe only those CD listed on a Trust formulary. The IP may administer the CD prescribed or direct another person to administer the CD.

11.1.3 Registered nurses or registered paramedics may administer to a patient, in accordance with the written Patient Specific Directions (PSD) of an independent prescriber, any drug specified in Schedule 2, 3, 4 or 5 provided that they are competent to do so. This includes medication left for a patient in a 'Just in Case' box.

11.1.4 Registered nurses and registered paramedics may administer patient's own drugs, including CD prescribed for patients and left in the patient's home in a 'Just in Case' box, or medicines in the patient's possession that have been prescribed by an independent prescriber and obtained for the patient, on prescription, from a community pharmacy. However, they must be able to demonstrate that they have undertaken professional development and training to achieve the competence required to administer these drugs safely. If the clinician is administering patient's own drugs they must check the identity of individual dose units carefully and ensure

that the medicines are within their expiry date before administering the CD to the patient.

11.1.5 Advanced technicians may administer a patient's own buccal or intranasal midazolam in accordance with a PSD written by an IP. However, they must be able to demonstrate that they have undertaken professional development and training to achieve the competence required to administer these drugs safely. If the Advanced Technician is administering patient's own drugs they must check the identity of individual dose units carefully and ensure that the medicines are within their expiry date before administering the CD to the patient.

11.1.6 Verbal Orders (Verbal Directions for Care) may not legally be given for Schedule 2 and 3 CD. The administration of a Schedule 2 or 3 CD authorised by a verbal order will be considered a disciplinary matter.

11.1.7 Only employees who can evidence the successful completion of authorised training in the use of the syringe driver used on the aircraft may administer CD via a syringe driver.

11.1.8 Registered nurses or registered paramedics may supply or administer (as defined in the document) CD to a patient, in accordance with the written authorisation of a PGD following the successful completion of a competence assessment. (See 11.4)

11.2 Administering a Dose of Morphine in Excess of 20mg

11.2.1 The NHS Group Authority for ambulance paramedics allows them to administer diazepam injection, morphine sulphate 10mg injection and morphine sulphate oral solution for the immediate necessary treatment of sick or injured persons.

11.2.2 The NHS Group Authority limits the total dose of morphine sulphate, administered by any route to a patient during a single episode of care by a registered paramedic to 20mg.

11.2.3 Registered nurses, who are not independent prescribers, may administer a total dose of 20mg of morphine sulphate in accordance with the PGD for morphine sulphate 10mg injection.

11.2.4 The Trust acknowledges that in some cases doses in excess of 20mg of morphine may be required to manage a patient's pain.

11.2.5 If the attending registered nurse or registered paramedic feels that it is in the patient's best interest to administer a total dose of morphine sulphate greater than 20mg and the patient is aged 18 years and over, a second registered paramedic or registered nurse may administer up to 20mg of morphine sulphate in addition to the 20mg administered by the first clinician.

11.2.6 The two clinicians must agree that a further dose is appropriate and may contact a Doctor or the Senior Clinical Advisor On-call for advice before making a decision.

11.2.7 The following restrictions apply:

- An initial dose of 20mg must have been administered via the IV, IO or oral route and the patient's response recorded. Where administered, the increased time for maximal effect of oral morphine must be taken into consideration.
- A second dose is not authorised by the Trust if the initial 20mg dose of morphine was administered by the IM route.
- 20mg dose is the maximum second dose and the actual dose administered must be titrated to response.
- The second dose must be administered via the IV or IO routes. Further doses of IM or oral morphine are not permissible.
- There must be a clear rationale for further morphine being required e.g. entrapment RTC, long journey time to hospital.
- Both clinicians have considered any advice received and after reassessing the patient agree that it is necessary to increase the dose of morphine sulphate 10mg injection.
- The total maximum dose administered must not exceed 40mg.

11.2.8 The clinicians administering the morphine are professionally accountable for the decision to administer the additional dose of morphine, even if advice is received from a Doctor or other clinician, as it is not possible to give or receive a verbal direction for care (verbal order) for morphine sulphate 10mg injection.

11.2.9 If the decision is made to administer additional morphine the following must be recorded on the PCR:

- Any advice received from a Doctor or the Senior Clinical Advisor On-call
- The rationale for the increased dose

11.2.10 Both clinicians must sign the entry in the patient clinical record and both clinicians must make an entry in their personal morphine record book recording the administration which is then countersigned by their colleague.

11.3 Patient Specific Directions (PSD)

11.3.1 A patient specific direction (PSD) is a written instruction from an IP for a medicine including the dose, route and frequency or appliance to be supplied or administered to a named patient. These can be instructions written in the patient's notes, or a drug chart for the administration of a medicine or a course of medicine. The treatment and administration should be documented and auditable. Where a PSD exists, there is no need for a Patient Group Direction (PGD) but the IP's directions must clear and must be followed exactly.

11.3.2 Trust clinicians most commonly encounter PSD for patients receiving end of life care or for patients who suffer from frequent seizures, e.g. buccal midazolam.

11.3.3 The PSD must identify the individual patient and must be reviewed regularly as with any prescription of medicine (at least annually). The Trust provides a PSD template for prescribers which can be found on the intranet. Trust clinicians are encouraged to share this template with a patient's GP or carers for the GP to complete. Where a PSD template has been developed for local use it is advisable to have this approved by the Trust to ensure accountability and communications issues are addressed. Crews attending the patient can be alerted to the existence of the PSD using special messages.

11.3.4 PSD do not limit those who can supply or administer the medicine but Trust Policy only permits registered nurses, registered paramedic and advanced technicians to administer in accordance with a PSD, The ambulance clinician administering the medication is accountable for their actions and should be aware of the relevant sections of Trust Policy and specific Clinical Guidelines concerning the administration of medicines.

11.3.5 Trust clinicians considering the administration of a medicine in accordance with a PSD must check that the medicines are fit for purpose (within their expiry date, have been stored correctly and show no signs of deterioration, eg discolouration, precipitation) before they administer them.

11.3.6 The clinician administering medicines in accordance with a PSD must follow the prescriber's instructions exactly.

11.3.7 Trust clinicians administering any medicine in accordance with a PSD must ensure that they are familiar with the following characteristics of the medicine before they administer it to a patient:

- Usual starting dose
- Frequency of administration
- Standard dosing increments
- Symptoms of overdose
- Common side-effects

11.3.8 Trust clinicians may not administer controlled drugs from a patient's own supply via a syringe driver.

11.3.9 The Trust's Clinical Guideline for the Administration of Patient's own Buccal or intranasal Midazolam should be followed when buccal or intranasal midazolam is administered.

11.4 Patient Group Directions (PGDs)

11.4.1 The supply and administration of CD in accordance with a PGD is restricted to those individual professional groups and CD named in the legislation.

12. **Prescribing**

12.1 General Guidance

12.1.1 Within the Trust, CD may be prescribed by medical or non-medical prescribers within the constraints of current legislation, the Trust Formulary and their own competency.

12.1.2 In the UCS, when a CD is prescribed, then subsequently administered or supplied from stock, the prescription must be recorded on the patient's clinical record for purposes of reconciliation.

12.2 Prescriptions for Controlled Drugs

12.2.1 All prescriptions for Schedule 2 and 3 drugs should include the patient's NHS number where possible.

12.2.2 The profession of the person who writes the prescription and their professional registration number must be added to the prescription to assist with any future audit.

12.2.3 Any space on the prescription form that has not been written on should be blanked off, e.g. by drawing a line through it to reduce the opportunity for fraud.

12.2.4 All UCS CD prescriptions must be recorded on the patient's clinical record and correctly coded in the prescription section not entered as free text.

12.2.5 Prescriptions for CD must satisfy the very specific requirements for writing prescriptions for CD detailed in the Misuse of Drugs Act (1971) and subsequent amendments to the associated Regulations. Those CD which are also prescription only medicines must also comply with the requirements of the Human Medicines Regulations 2012.

12.2.6 It is a legal requirement under the Human Medicines Regulations 2012 that all prescriptions for Prescription Only Medicines (POMs) contain such particulars to indicate whether the appropriate practitioner is a doctor, independent nurse prescriber, etc

12.2.7 A prescription for Schedule 2 and 3 CD must contain the following details, written so as to be indelible e.g. written by hand, typed or computer-generated:

- The patient's full name, address and where appropriate, age;
- The name and form of the drug, even if only one form exists;
- The strength of the preparation, where appropriate;
- The dose to be taken (this must be specific i.e. 10mg to be injected IM every six hours);
- The total quantity of the preparation, or the number of dose units, to be supplied in both words and figures;

12.2.8 It is an offence for a prescriber to issue an incomplete prescription and a pharmacist is not permitted to dispense prescriptions for CD, unless all the above information is detailed on the prescription. Failure to comply with the regulations concerning the writing of prescriptions will result in inconvenience to patients and delay in supplying the necessary medicine. Practitioners are reminded that it is particularly important in the Out-of-Hours situation to ensure that the prescription is correctly written to prevent unnecessary delays in patient's treatment.

12.3 Facsimile Transmission of Controlled Drug Prescriptions

12.3.1 A 'fax' of a prescription does not fall within the definition of a legally valid prescription because it is not written in indelible ink, and has not been signed by an appropriate practitioner. A fax can confirm that at the time of receipt a valid, signed prescription is in existence.

12.3.2 Under no circumstances can CD listed in Schedule 2 or 3 (this includes temazepam) of the Misuse of Drugs Regulations (2001) be dispensed against a fax, therefore, prescribers must not send a fax for a CD on Schedule 2 or 3.

12.4 Benzodiazepine Prescribing

12.4.1 It is now established that the benzodiazepine group of drugs can rapidly cause dependence and that the resulting psychological and physical withdrawal syndrome may be severe and protracted. UCS Prescribers must not prescribe benzodiazepines to treat short-term 'mild' anxiety.

12.4.2 To ensure that no new cases of dependency are created by ambulance clinicians, Trust policy on prescribing benzodiazepines is as follows:

- Benzodiazepines may only be prescribed routinely by doctors working in the UCS for the relief of muscle spasm in back pain or torticollis, to manage restlessness in palliative care or for the relief of seizures. The maximum quantity to be supplied or prescribed is 18 x 2mg tablets of diazepam;
- Benzodiazepines should not be prescribed for sleeplessness;
- Lorazepam, which may cause a particularly severe withdrawal syndrome, should not be prescribed except for palliative care patients.(Note - Lorazepam may be prescribed as an anti-emetic for patients with uncontrolled nausea and vomiting induced by chemotherapy) or for rapid tranquillisation.

12.5 Prescribing Midazolam Injection 10mg in 2ml

12.5.1 Midazolam 10mg in 2ml may only be prescribed to provide palliative care.

12.5.2 Prescribers prescribing midazolam 1mg in 1ml for conscious sedation must be familiar with the Trust Policy on reducing the risk of overdose with midazolam injection in adults (See Section 5.3).

12.6 Prescribing for Registered Drug Service Users or Drug Misusers

12.6.1 A person is regarded as being addicted to a drug if, and only if, he/she has as a result of repeated administration become so dependent on a drug that he/she has an overpowering desire for the administration of it to be continued.

12.6.2 Patients who are registered drug users will receive treatment with opiates and/or opiate substitutes from local community or hospital based drug services or their GP. These medicines will be dispensed by a community pharmacist. Non-registered users may be obtaining opiates and opiate substitutes from their own illegal supplier.

12.6.3 Requests from registered addicts for Methadone, Subutex (Buprenorphine) or any other substance prescribed by the addictions team should be refused if the service user (registered addict) has failed to manage their medication supply. Methadone has a prolonged half-life of between 15 to 60 hours. Withdrawal symptoms appear slowly and not usually until 24 to 48hrs after the last dose. One of the objectives of treatment is to encourage service users to take responsibility for their own care and reduce the chaos in their lives.

12.6.4 Sometimes a service user may find that they do not have a prescription for their treatment because of failures in the prescription process which are beyond their control. Provided that the community pharmacist responsible for delivering usual care, (or their locum pharmacist), contacts the UCS to request a prescription on behalf of a client, and explains the circumstances of the request, the prescriber may issue a prescription for the minimum numbers of days of treatment. However, the prescriber must advise the service user's local Drug and Alcohol Treatment Service that a prescription has been issued and note any prescribing in the daily log so that the Lead GP is aware.

12.6.5 Unless the service user's medical condition dictates otherwise, the prescriber must provide a prescription that follows the schedule of the original prescriber.

12.6.6 It is important to remember that withdrawal symptoms, although unpleasant, are not fatal, whereas overdose with, for example, methadone, can be fatal.

12.6.7 No trust prescriber may authorise the supply of cocaine, diamorphine and dipipanone or their salts, to an addicted person.

12.6.8 Dihydrocodeine must not be prescribed as a substitute for substances used in the treatment of addiction.

13. Disposal and Destruction of CD

13.1 Guidance

13.1.1 CD must always be rendered irretrievable prior to onward safe disposal.

13.1.2 All CD disposal or destruction must be witnessed. If another member of staff is not immediately available to witness the destruction, a carer, other professional (police, fire, nurse, etc) may act as a witness or the destruction should be delayed until the return to base or a receiving hospital. If the witness is not a member of staff, their signature must be annotated with a printed name and contact details.

13.1.3 Suitable methods of rendering CD irretrievable are:

- Soaking up unused morphine sulphate 10mg or other injection with a paper towel.
- Use of integral absorbent pad in a sharps box.
- Using a commercially available 'DOOP' (Disposal Of Outdated Pharmaceuticals) product.

13.1.4 All disposal and destruction must be recorded and records retained.

13.2 Patients' Own Drugs

13.2.1 Patients' own CD must not be received for destruction unless there is a risk to the patient or the public if the CD is not removed. If removed they must be taken to the nearest community pharmacy for disposal.

13.2.2 Patients should be instructed to return unwanted medication to their community pharmacist who will accept patients' own CD for destruction.

13.2.3 Substances received from patients that are suspected to be illicit must not be destroyed under any circumstances. They must be managed as detailed in Section 16.

13.3 Destruction of Expired Stock

13.3.1 Stock within one month of its expiry date must be reported to the Central Store or the Operations Support Manager (UCS) so that it can be relocated and used before it expires.

13.3.2 If stock expires in use, it must be placed in a sealed bag and clearly marked 'Expired stock awaiting destruction'. It must remain in secure storage and recorded in the CD register or morphine book.

13.3.3 The Accountable Officer authorises individuals to destroy expired CD stock in accordance with an amendment to the Misuse of Drugs Regulations 2001 (August 2007).

13.3.4 Authorised witnesses may witness the destruction of all CD. They must have a current clear DBS check a professional Code of Ethics.

13.3.5 Destruction Witnesses may witness the destruction of all CD except Schedule 2 CD.

13.3.6 Any person authorised to witness destruction must have received appropriate training and be accountable for this activity directly to the Accountable Officer.

13.3.7 A list of individuals authorised to witness the destruction of expired stock will be maintained at sites holding a T28 Exemption from the Environment Agency.

13.3.8 If stock expires in use then the Central Store or NBOC which hold a current T28 Exemption must be notified to arrange destruction by an Authorised Witness or a Destruction Witness.

13.4 Destruction of Part Used Ampoules or Syringes

13.4.1 It is the responsibility of the clinician who administers a CD to a patient to ensure that any CD remaining in an ampoule or syringe, after an episode of care, is rendered irretrievable and destroyed.

13.4.2 The process of rendering the CD irretrievable and the drug's subsequent destruction must be witnessed by a colleague, who will countersign the individual's personal CD record book accordingly. If this is not possible the destruction must be reported to an OO who must note an entry recording the disposal/destruction in the clinician's personal morphine book (registered paramedics and registered nurses) or CD record Book, UCS.

13.4.3 When a registered paramedic or registered nurse has a time critical handover of a patient to whom he/she has already administered morphine sulphate 10mg

injection, they must retain and destroy any morphine remaining from their own personal supply. The receiving paramedic must administer the morphine from their personal supply.

14. Private Providers

14.1 The Trust employs private providers of ambulance services to perform patient transport services. The contract for these services specifies that the private provider does not carry CD.

14.2 Where a service provider is contracted to provide a service requiring them to use CD, the Accountable Officer must approve the Organisation's Controlled Drug Policy and associated SOPs before the provider can be engaged.

14.3 Private providers will be encouraged to engage with their Clinical Commissioning Group Pharmacy Team so that they can provide assurances of safe CD management.

15. Illicit Drugs

15.1 This section of the Policy is intended to guide Trust staff in the management of substances suspected to be illicit drugs found in the possession of, or dropped by a patient while on Trust property or being treated by Trust staff.

15.2 If a clinician discovers substances that they believe to be illicit drugs, they must inform the police immediately and request that the substance is removed. If it is necessary to transport the patient immediately, then the clinician must arrange for the police to meet them at the receiving hospital and place the substance in a sealed bag. The substance may not be stored on Trust property under any circumstances.

15.3 The discovery should be recorded in the call log on the Clinical Hub (recorded line) or in an appropriate local log book/patient record. The entry should be countersigned preferably by a witness if possible.

15.4 An incident form must be completed, identifying where the substance was found what action has been taken.

16. Incident Reporting

16.1 All incidents involving CD must be reported using the Trust's Incident Reporting system. They must be reported by the individual concerned or the person identifying the incident. Where the incident is reported to a member of staff from outside of the Trust it is the responsibility of the person receiving the report to complete the incident report.

17. Investigating Concerns

17.1 Concerns may arise from routine monitoring and inspection, or concerns may be raised by individuals.

17.2 The Accountable Officer will ensure that there are robust systems in place to enable concerns involving CD to be raised, logged, and where appropriate to initiate investigations.

17.3 The Accountable Officer may request an investigation by the NHS Counter Fraud and Security Management Service (CFSMS) Division of the NHS Business Service Authority solely or jointly with another responsible body.

17.4 The Local Counter Fraud Specialist (LCFS) and Local Security Management Specialist (LSMS), as the nominated advocates for the NHS CFSMS, would be responsible for conducting such an investigation on behalf of the NHS CFSMS.

18. Monitoring

18.1 Committees and Groups

18.1.1 The Accountable Officer is responsible for monitoring and auditing the management and use of CD.

18.1.2 The Accountable Officer reports directly to the Chief Executive.

18.1.3 The Medicines Governance Group will receive a monthly Accountable Officer's Report which will include:

- The results of any audits or inspection visits associated with controlled drugs use in the previous month
- Any CD occurrences reported in the previous month.
- Any new CD legislation or amendments to current controlled drug legislation which may impact on Trust operations.
- Any Safer Practice Notices, Alerts or Rapid Response Reports relevant to CD use in the Trust.

18.1.6 The Medicines Governance Group will use any learning derived from the Accountable Officer's Report to improve the management of CD within the Trust.

18.1.7 The minutes of the Trust's Medicines Governance Group are received by the Trust Clinical Effectiveness Group.

18.1.8 The Accountable Officer ensures that CD occurrences are reported on the National CD Reporting website.

18.1.9 The Accountable Officer attends and participates in the work of the CD LIN meetings in the South West to represent the Trust and share intelligence and learning.

18.2 Controlled Drug Inspections

18.2.1 The Accountable Officer has the responsibility to authorise individuals to enter and inspect premises in relation to the use and management of CD.

18.2.2 Any premises in the Trust with a CD safe may be inspected.

18.2.3 The Accountable Officer will receive a report of all inspection visits and will include these reports on the agenda of the Trust's Medicines Governance Group.

18.2.4 The Trust will periodically commission independent audit of CD management to ensure compliance with this policy.

18.3 Monthly Station Review

18.3.1 All locations where a stock of CD is available for use by Trust employees must provide CD use data for the previous calendar month to the Accountable Officer. The data collection point will be 23:59 hours on the first day of every month. All data must be reported to the Accountable Officer by the 7th day of the month.

18.3.2 The data collected for each CD will be the opening balance (the closing balance of the previous month), quantity received, quantity administered, quantity returned for destruction and the closing balance. The audit period will be the calendar month preceding the audit date.

18.3.3 OM/OSM is responsible for ensuring 100% compliance with this Audit.

18.3.4 The OM/OSM must submit a written explanation which details the reasons for any area being reported as non-compliant, to the Medicines Governance Group within 7 days of the request.

18.4 Patient Clinical Records

18.4.1 When monitoring clinical records, supervisory staff must be vigilant and ensure that individual clinicians adhere to recommended best practice when administering, prescribing or supplying CD.

18.4.2 CD record book entries relating to patient administration should be randomly checked by Managers against the corresponding patient clinical records to ensure accuracy and consistency in the details recorded.

18.5 Midazolam

18.5.1 The use of flumazenil will be audited annually by the operational manager of any clinical area of the Trust where midazolam is used to provide sedation.

18.6 Human Resources (HR)

18.6.1 The Trust ID card and uniform is of particular relevance to CD security, as it is part of the process that allows for CD ordering or collection. The Trust allows registered paramedics and registered nurses, including staff responding officers, to obtain a supply of CD from any station within the Trust, not just their normal place of work. It is the responsibility of the individual staff member to ensure that their ID card is properly used and secured. The Trust exit policy must ensure that Trust ID cards and uniforms are returned when staff leave the Trust or are suspended.

18.6.2 Records of those staff members with legitimate access to CD should be regularly reviewed by HR to reconcile them with information on starters and leavers. This

should be closely coordinated between managers, procurement and the HR department. Ideally, the CD proximity reader and staff responder authorisation lists should be updated every three months based on this information.

18.6.3 In the event of a staff member with swipecard access being investigated or leaving the organisation abruptly due to suspension or other disciplinary action, authorisation lists should be updated immediately and the proximity reader obtained from the individual involved. As part of the Trust's exit policy, line managers should ensure they document the return of any proximity readers, staff ID and uniform.

18.6.4 HR must have a process in place to allow for the 'quick time' cancellation and withdrawal of CD access at any time if a member of staff is suspended for an issue related to CD. This may include not only withdrawal of proximity readers but also changing numerical codes for station CD safe access as well as revising the authorised signatories list.

Staff Responding Officer (Registered Nurse or Registered Paramedic) Application to Carry Controlled Drugs

I would like to apply to carry the following controlled drugs (Delete as appropriate):

- Morphine sulphate 10mg injection (2 ampoules)
- Morphine sulphate 10mg in 5ml oral solution (1 vial)
- Diazepam emulsion for injection 10mg in 2ml (2 ampoules)
- Diazepam rectal tubes 2.5mg (2 tubes)
- Diazepam rectal tubes 5mg (2 tubes)

I have read, understood and agree to comply with the Trust's Controlled Drug Policy and acknowledge that these CD are the property of the Trust. I accept full responsibility for their safety and security while they are in my possession.

Applicants Full Name:_____

Professional Registration PIN :_____

Applicants Signature:_____

Date of Application:_____/_____/_____

Appendix B

Controlled Drug Internal Transportation Form:

Delivery of Schedule 2,3,4 & 5 (Misuse of Drugs Act 2001)
Medicines Form

Address of location releasing CD for transportation:

Name of Clinician/Stores Team Leader

_____

Clinician/Stores Team Leader Signature _____ Date ___/___/_____

List of Medicines accepted for delivery: (Name of drug, quantity, form, strength)

_____

_____

_____

_____

_____

Signature of Authorised Person Accepting Delivery _____ Date ___/___/_____

Received and checked at _____

By (Signed by Authorised Person Accepting Receipt) _____ Date ___/___/_____

Appendix C

Version Control Sheet

Version	Date	Author	Summary of Changes
2	Feb 2013	Sue Oakley	Complete revision.
3	Feb 2014	Sue Oakley	Correction to index, removal of Accountable Officer Authorisation and reclassification of ketamine from Class C to Class B, 6.3.21 insert 'issue'. Change of title – Field Operations Manager to Operations Support Manager Addition of doctor only drugs and removal of all references to administration slips. Updating PGDs currently used by Trust Updating supply to reflect county morphine stores and Centralised supply Change of role from Procurement Assistant to Stores Team Leader
4	June 2015	Sue Oakley	Revision to include changes to legislation and organisational structure.
5	March 2018	Sue Oakley	Revision to include new CDL and position on Mandatory Requisitions. Use of sealed drug bags and restricted access to LSCDs.