South East Coast Ambulance Service NHS
NHS Foundation Trust

Controlled Drugs (CD) Policy

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1 Statement of Aims and Objectives

This policy outlines the principles and responsibilities with respect to the safe, secure and effective use of controlled drugs in South East Coast Ambulance Service NHS Foundation Trust (SECAmb). It describes the practice required in all aspects of use of controlled drugs in order to ensure compliance with legislation, best practice guidance and to minimise risks associated with these medicines. If any of the principles or standards in this policy are not met, a risk assessment should be undertaken.

1.1. Introduction

1.1.1. SECAmb is committed to continue to improve and align its policies and procedures for the management of medicines including controlled drugs, to ensure that good practice is consistently applied across SECAmb and that all staff are aware of their responsibilities.

1.1.2. The Misuse of Drugs Regulations 2001 defines those persons who are authorised to supply and possess controlled drugs while acting in their professional capacities, and describes the conditions under which these activities may be carried out. In these regulations consideration must be given to such activities as supply, possession, prescribing, audit and record keeping relevant to that particular drug.

1.1.3. The safe and secure handling of controlled drugs within SECAmb requires standard operating procedures (e.g., for ordering, storing, administering, recording, transporting and destruction of CDs) and quality assurance systems to be in place so that controlled drugs are handled safely and securely, in accordance with legislative requirements and established best practice.

1.1.4. SECAmb only authorises certain registered healthcare professionals (e.g., registered paramedics, registered nurses) employed by SECAmb to carry and administer controlled drugs.

1.1.5. Controlled drugs are classified in terms of different schedules (schedules 1 to 5 depending on therapeutic usefulness and misuse potential) and by Home Office classification into classes A, B & C (see appendix A for further details)

1.1.6. The controlled drugs used within SECAmb are:

- Morphine sulphate injection (Schedule 2)
- Ketamine injection (Schedule 2)
- Midazolam injection (Schedule 3)
- Diazepam emulsion for injection (e.g. diazemuls) – (Schedule 4 part 1)
- Diazepam rectal tubes (Schedule 4 part 1)

1.1.7. Other controlled drugs can only be added to the SECAmb drug formulary by following the application process outlined in the Medicines Policy. These controlled drugs need to comply with the standards set in this policy.

1.1.8. SECAmb manages all controlled drugs under the control levels required of Scheduled 2 controlled drugs. This is irrespective of which controlled drugs schedule they are all under. This is to ensure increased control around controlled drugs activities within SECAmb. The only exception to this is Diazepam rectal tubes (Schedule 4 part 1).

1.2. Aims

1.2.1. To ensure that SECAmb complies with all relevant legislation around the storage, supply, disposal / destruction and use of controlled drugs (CDs).

1.2.2. To ensure that SECAmb has governance arrangements in place for controlled drugs.

1.2.3. To ensure that all SECAmb staff involved with controlled drugs are aware of the standards and procedures regarding CDs and that they understand their responsibilities in the safe management and use of CDs.

1.3. Scope

1.3.1. This policy describes the principles and rules governing controlled drugs and specifically covers the additional control measures for the management of controlled drugs (i.e. those drugs subject to controlled drug legislation due to their potential for misuse). It applies to all staff, clinicians, and volunteers, employed by, or working on behalf of SECAmb.

1.3.2. 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 and clinical management plans for some CDs developed by SECAmb.

1.3.3. This Policy does not remove the professional obligation for every clinician to understand and comply with the legislation in respect of their own professional practice.

2.1. Government Arrangements

The Controlled Drugs (Supervision of Management and Use) Regulations 2006 set out additional controlled drugs measures to strengthen governance arrangements for the management of controlled drugs (CDs). This regulation was replaced in April 2013 by the Controlled Drugs (Supervision of Management and Use) Regulations 2013. The 2006 and 2013 Regulations include provision for designated bodies appointing controlled drugs accountable officers (CDAOs) (section 2.1.1) and places a legal duty on local agencies to share intelligence on CD issues (section 2.1.2 LINs).

2.1.1. Controlled Drugs Accountable Officer (CDAO)

2.1.1.1. SECAmb as a designated body must appoint a Controlled Drugs Accountable Officer (CDAO) who is responsible for overseeing governance arrangements for management of CDs within SECAmb. The SECAmb CDAO is the Executive Medical Director who is also a member of the Board.

2.1.1.2. The SECAmb CDAO must be registered with the Care Quality Commission (CQC). CQC must be informed when a SECAmb CDAO is removed and a new CDAO appointed.

2.1.1.3. The CDAO must ensure that all concerns about incidents that involved or may have involved improper management or use of CDs by a healthcare professional (or other staff, responsible individual or medical practitioner working on behalf of the trust) are properly recorded. This task may be delegated to an appropriate member of staff by the CDAO.

2.1.1.4. The register of concerns must be subject to appropriate measures to maintain confidentiality and to limit access to the CDAO (and his/her staff) and others who need access for the purposes of ensuring the safe management and use of CDs.

2.1.1.5. Prior to the 2013 regulations, there was a requirement for the register of concerns to include the following at a minimum, and this is still considered good practice:

- date the concern was reported to the CDAO
- date(s) on which the relevant incident(s) took place
- details regarding the nature of the concern
- details of individual(s) related to the concern
- name and details of the person or body who raised the concern
- details of any action taken by the designated body
- whether the information has been/should be shared with the CD Local Intelligence Networks (CDLIN) and/or disclosed to another responsible body, and associated details

2.1.1.6. See also Responsibilities section – CDAO

2.1.2. **CD Local Intelligence Networks (CD LINs)**

2.1.2.1. Local agencies are required to share information and intelligence about the use of CDs in the health and social care sector. This information is shared through CD Local Intelligence Networks (CD LINs). SECAmb CDAO attends the relevant LINs meetings.

2.1.2.2. The CDAO may be required to submit an occurrence report on a quarterly basis (or more frequently if appropriate) to the CDAO at NHS England leading the CD LIN. The occurrence report should contain details of any concerns that the ambulance trust has regarding its management or use of CDs; or confirmation that it has no concerns to report regarding its management and use of CDs.

2.1.2.3. The CDAO should attend the CD LIN meetings or nominate an appropriate named member of staff, such as the Pharmacist or Trust Lead on Security as Accredited Security Management Specialist (ASMS), to attend on his/her behalf, in order to share information on CD related activity and incidents with other organisations who may be affected or have additional information.

2.1.3. **Controlled Drugs Home Office Licence**

2.1.3.1. SECAmb, in line with other ambulance trusts, is required to obtain a Controlled Drugs Licence from the Home Office to be allowed to obtain and hold stock controlled drugs, distribute these to identified ambulance stations and individual employees (e.g., registered paramedics).

2.1.3.2. The Controlled Drugs Licence includes a defined list of all CDs that SECAmb are permitted to hold.

2.1.3.3. The Controlled Drugs Licence needs to be renewed on a regular basis (as specified on the licence) or if there are any changes before the renewal date e.g. a new CD added to the SECAmb formulary or a new location where stock CDs will be kept.

2.1.4. **Standard Operating Procedures (SOPs)**

2.1.4.1. SECAmb will ensure that that SOPs are in place relating to all aspects of controlled drugs safe use and management.

2.1.4.2. SECAmb must ensure that there is a full audit trail in place for CDs from ordering to use or disposal.

2.2. **Clinical Guidance and Patient Group Directions (PGDs)**

2.2.1. Clinical management plans should be in place for all controlled drugs, regardless of schedule.

2.2.2. Clinical guidelines (e.g. JRCALC) are not a legal authorisation that allows ambulance staff to administer the CDs listed in the clinical practice guidelines to patients.

2.2.3. For all controlled drugs (except Morphine and Diazepam emulsion for injection where Paramedics have an exemption – see section 2.3.2), Patient Group Directions (PGDs) should be in place to provide a legal framework for administration by Paramedics.

2.2.4. Registered Nurses (if not prescribers) need a PGD for administration of all CDs in SECAmb.

2.3. **Authority to possess and administer controlled drugs**

2.3.1. Only SECAmb authorised registered healthcare professionals can be in possession of stock CDs in the course of their duties. Non-registered staff cannot possess stock CDs unless this is authorised by SECAmb as part of their duties e.g. Logistics staff transporting stock CDs.

2.3.2. Registered Paramedics have a 'group authority' to possess and administer the CDs: Morphine injection at a strength not exceeding 20mg/ml (Schedule 2) and Diazepam – all forms (Schedule 4). Registered Paramedics are also authorised to possess and administer Morphine Oral solution 10mg in 5ml (Schedule 5).

2.3.3. Critical Care Paramedics may also possess and administer Ketamine injection (Schedule 2), Midazolam (Schedule 3) and the Schedule 4 and 5 CDs permitted under the Misuse of Drugs Regulations and its amendments provided they are authorised to administer under a SECAmb Patient Group Direction (PGD) i.e. they are individually named and have been signed off as competent in accordance with the associated PGD.

2.3.4. Registered Nurses have authority to possess morphine if they have been authorised to administer Morphine under a SECAmb Patient Group Direction (PGD).

2.3.5. Medical Doctors and Pharmacists have general authority to possess, supply and procure all Controlled Drugs in the course of their duties except those in Schedule 1 (see Appendix A).

2.3.6. Patients' own CDs are the property of the individual named patient but may be transported with the patient and therefore be in the possession of SECAmb staff in certain circumstances (see section 10 Transporting Controlled Drugs prescribed for a patient).

2.4. **Ordering Controlled Drugs**

2.4.1. Controlled drugs can only be ordered from the SECAmb approved wholesaler and delivered directly to Central Main Stores (see Medicines Policy section 2.5 Procurement and acquisition of medicines).

2.4.2. Purchase orders raised for controlled drugs (or any medicines) must be authorised and approved according to SECAmb procedures.

2.5. Storage of Controlled Drugs

2.5.1. Storage of CDs in ambulance premises

2.5.1.1. Ambulance premises are subject to security risks which can have a significant impact on operations and business continuity. These risks include:

- burglary
- theft of drugs, equipment and vehicles
- criminal damage to property
- vandalism
- antisocial behaviour on premises
- violence against staff
- lone worker risks
- single responder risks
- theft of staff property
- unauthorised actions by disgruntled staff or staff facing disciplinary action
- unauthorised access by members of the public who could tamper with CDs

2.5.1.2. risks to patients as a result of individuals impersonating paramedics Suitable physical security measures that address identified risks and are supported by a strong pro-security culture among staff provide further protection for CDs.

2.5.1.3. For new build and refurbishment projects, the Chief Pharmacist or Medicines Governance Team and the Trust lead on Security (ASMS) must be included as part of the project team to ensure that all security risks are identified and addressed in the new plans. The pharmacist understands the law and best practice around the safe and secure management of CDs and the ASMS will have data on security incidents that can inform the design and aid in the selection and use of physical security measures. The local police design out crime officer (DOCO) or crime prevention design adviser (CPDA) must also be consulted in conjunction with the police Controlled Drugs Liaison Officer (CDLO) on any new build or major refurbishment projects. The DOCO or CPDA will be able to provide a Crime Impact Assessment for the local area of the ambulance building and the CDLO will be able to provide input into planning the location of storage facilities for CDs.

2.5.1.4. Further general advice on landscaping, building security, perimeter security and CCTV is available in *Security Standards and Guidance for the Management and Control of Controlled Drugs in the Ambulance Sector, Version 3 (March 2017)*

2.5.2. Controlled Drugs Cupboards

2.5.2.1. All CDs will be stored securely in CD cupboards approved by the SECAmb Controlled Drugs Accountable Officer (CDAO) except when carried in a CD pouch on the person of an authorised registered Paramedic (section 2.4.2).

2.5.2.2. 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 cupboard.

2.5.2.3. As ambulance premises do not have a 24-hour staff presence, the CD cupboards must be tested and certificated to the SOLD SECURE standard silver rating. The CD cupboard must be installed in accordance with SOLD SECURE specifications and wherever possible to the silver grade.

2.5.2.4. Only CDs may be stored in a CD cupboard. Nothing must be written or posted on the outside of the CD cupboard to indicate that CDs are stored inside.

2.5.2.5. CD cupboards must be locked when not in use. The lock must not be common to any other lock in the ambulance station (see also section 2.5.3 Controlled drugs cupboard keys).

2.5.2.6. Access to areas where CDs are stored must be controlled. All CD cupboards within SECAmb must be situated in rooms where the access is restricted to authorised staff.

2.5.2.7. Faulty or damaged CD cupboards must be reported immediately. The security of the CDs must be maintained and alternative arrangements for secure storage must be made and used until any repair has been carried out. The Controlled Drugs Accountable Officer should be contacted for advice on suitable alternative arrangements.

2.5.2.8. CD cupboards should be stored within a lockable room. It is recommended that numeric key pads are avoided for the lockable room where CDs are stored, because codes can be easily observed, written by staff on door frames, or not changed on a regular basis, compromising security. They also do not provide a means of auditing movement into an area. If numeric key pads are used, the codes must be changed every three months unless following a risk assessment there is a need to change immediately. In addition, key pads should be monitored for signs of wear and replaced as worn keys can indicate the access code. SECAmb will be moving towards having swipe card access to all medicines rooms in the future and this will be overseen by SECAmb's Security Manager.

2.5.2.9. It is recommended that the room where CDs are kept does not have windows as this provides a potential means of access. If this is unavoidable, the window should be a non-opening light, with laminated

glass certified to BSEN356:2000 Performance Specification P5a (minimum) or a fixed security grille installed from the inside. Any such grille should be tested and certificated to LPS1175 SR2 or similar.

2.5.2.10. 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 CDs (e.g. CD reconciliation by pharmacy) or perform housekeeping functions. The authorised clinician must open the cupboard and retains responsibility for supervising the activity of the person provided with access; actual keys or access codes must not be shared with anyone not authorised to possess a CD under any circumstances.

2.5.2.11. In circumstances where an ambulance station closes (including temporary closure e.g. for refurbishment), the contents of the CD cupboard and the CD register must be removed and transferred as appropriate. The Chief Pharmacist and CDAO should be contacted for advice.

2.5.3. **Controlled Drugs Cupboard Keys**

2.5.3.1. The following precautions must be taken to securely manage CD keys:

- All CD keys must be signed for on initial issue.
- A SOP must be established for the distribution of CD keys which includes an audit trail that shows how keys are managed and used.
- As part of the system to manage CD keys, a regular inventory must be undertaken of the keys in possession of individuals/departments.
- The frequency of this inventory must be determined by a local risk assessment.
- There must be strict controls around the access to, and use of, master keys which open all the locks of a particular set.
- In the event that a master key is used to provide access, its use must be supervised.
- The number of staff with key holding responsibility for master keys must be strictly limited to a small number of authorised staff.

2.5.3.2. CD keys must be kept securely (e.g. in a key press with a code) in a secure location (locked room within a supervised area) and on sealed, numbered rings with no other means of identification. CD keys must not be marked or labelled with the terms ‘Morphine’, ‘Drugs’, ‘CDs’ or ‘Medicines’.

2.5.3.3. There should be spare keys available which are stored securely with restricted access and accounted for in the same ways as the keys in use.

2.5.3.4. Registered staff with access to CD keys should be advised that they are not to duplicate CD keys and are made aware of the ambulance trust’s process for reporting lost or missing keys. If CD keys are lost or missing,

extra precautions should be taken to ensure that a secure environment is maintained.

2.5.3.5. If the CD keys cannot be found then the OUM or OTL should be notified immediately. A procedure should be in place to ensure that the security of CD stocks is preserved as soon as practicable. The contents of the CD cupboard are checked against the CD record book to identify any discrepancies or anomalies.

2.5.3.6. Once efforts to retrieve the missing key are exhausted and the keys still cannot be found, then the CDAO should be informed as soon as practicable and, depending on circumstances, the police should be contacted.

2.5.3.7. Any actions or decisions taken should be proportionate and risk assessed against the circumstances of the potential loss. This should be recorded on the Trust's incident reporting system (DATIX). In high-risk situations, CDs should be removed from the CD cupboard pending changing of the locks or the CD cupboard itself.

2.5.4. **Controlled Drugs Pouches**

2.5.4.1. Controlled drug ampoules (morphine and diazepam emulsion) may be withdrawn at the start of a shift by authorised registered Paramedics and stored within body worn controlled drugs (CD) pouches for the duration of shift. All unused ampoules are returned at the end of the shift (see also section 2.5 Record keeping)

2.5.4.2. The Paramedic is responsible and accountable for the safe storage of the controlled drugs within the CD pouch and must be in direct possession of the CD pouch containing CDs at all times (see SOP Controlled Drugs Possession Using Body Worn Pouches).

2.5.5. **Controlled Drugs Peli Cases**

2.5.5.1. Extended controlled drugs formulary CDs i.e. Midazolam and Ketamine may be withdrawn at the start of a shift by authorised Critical Care Paramedics (CCPs) and stored within locked peli cases for the duration of the shift. All unused ampoules are returned at the end of the shift (see also section 2.5 Record keeping).

2.5.5.2. The Critical Care Paramedic is responsible and accountable for the safe storage of the controlled drugs within the peli case at all times.

2.5.5.3. The locked peli case should be placed in a locked medicines cupboard in a Double Crew Ambulance (DCA) vehicle or locked in the boot of a Single Response Vehicle (SRV).

2.5.6. **Logistics Vehicles**

2.5.6.1. When being transferred between Trust locations, CDs should be in a secure, locked CD safe that meets the specification given in section

2.5.6.3 below. The vehicle should not bear any visible indication of the fact that it is carrying CDs. If a CD order is unable to be delivered, it should not be left on the vehicle and should be signed back into the CD safe at the medicines store (or equivalent) on return. Where this is not possible, the Chief Pharmacist or CDAO should be contacted for advice.

2.5.6.2. Medicine deliveries which contain CDs should never be left unattended in an unsecured location if a logistics driver is unable to find a staff member on station who is authorised to receive them. Ideally, all deliveries should be signed for and witnessed by an appropriate member of Trust staff. However if this is not possible, the delivery will be returned to stores and an alternative time arranged

2.5.6.3. The CD safe should be tested and certificated to the SOLD SECURE standard silver rating. To achieve the adequate protection, all brackets and fixtures supplied with the safe should be utilised in accordance with the manufacturer's instructions. CD safes should 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.

2.5.7. **Mass Casualty Vehicles (HART vehicles)**

2.5.7.1. The governance around CDs stored in HART vehicles is the responsibility of SECAmb and should conform with SECAmb CD standards. The exception to this is that CDs are stored in HART vehicles overnight. There should be a local standard operating procedure in place for: Safe and Secure Storage of Medicines including Controlled Drugs within Mass Casualty Vehicles.

2.6. **Record Keeping**

2.6.1. **CD Stationery**

2.6.1.1. CD stationery (e.g. CD registers, CD requisitions) used within SECAmb should be subject to the same rigorous security controls as CDs themselves. This is to ensure a clear audit trail from receipt of CDs to their use or destruction. It is also to prevent illicit use or any manipulation, falsification or destruction of CD records.

2.6.1.2. CD registers should only be accessible to staff authorised to possess CDs as well as managers and delegated staff responsible for CD stock checks and audits. CD stationery that are in use should not be stored in the same locked cupboard as controlled drugs.

2.6.1.3. The requisition, use, movement and disposal of CDs should be recorded in the CD register that pertains to a particular operational site (e.g., ambulance station). A separate CD register should be used for each type of CD even if the CDs are stored in the same CD cupboard.

2.6.1.4. Any SECAmb staff who falsify an entry or signature in any CD paperwork/stationery/register or try to circumvent the electronic system

(e.g., Ominicell) will be subject to investigation under the SECAmb Disciplinary Policy and Procedure and may also be reported to the police. Registered healthcare professionals may also be reported to their respective regulatory body.

2.6.2. **Paper Controlled Drugs Register**

2.6.2.1. The controlled drugs register (paper) must:

- Be bound
- Have separate sections for each CD
- Have the name, form and strength of the drug specified at the top of each page
- Appear in chronological order
- Be made on the day of the transaction
- Be indelible (any errors should NOT be crossed through, must be left visible and the correction made should be signed and dated in the margin, or linked to a footnote at the bottom of the page)
- Have a record of who the controlled drug has been supplied to and when returned back to stock

2.6.2.2. The CD register must be kept on the premises to which it relates and be available for inspection at any time.

2.6.2.3. The CD register should ideally not be stored in the CD cupboard but should be stored securely close by e.g. in a locked filing cabinet.

2.6.2.4. The CD register must not be used for any other purpose and should be kept for a minimum of two years after the date of the last entry.

2.6.3. **Electronic Controlled Drugs Register (i.e., within Omnicell)**

2.6.3.1. A computerised CD register may also be used provided it records the same details as a paper CD register and that the software has safeguards to ensure the author of each entry is identifiable (e.g., biometrical scanner such as finger print); entries cannot be altered at a later date, a log of all data entered is kept and can be recalled for audit purposes.

2.6.3.2. These computer CD records must be preserved and it must not be possible to alter the data at a later date.

2.6.3.3. Legislation requires that entries in an electronic Controlled Drugs register must be:

- Attributable
- Capable of being audited
- Compliant with best practice.

2.6.3.4. An electronic Controlled Drugs register must also be accessible from the premises and capable of being printed.

2.6.3.5. Access control systems should be in place to minimise the risk of unauthorised or unnecessary access to the data. Adequate backups must be made of computerised registers. Arrangements should be made so that inspectors can examine computerised registers during a visit with minimum disruption to the dispensing process.

2.6.3.6. In the event of a power failure of the Omnicell, refer to the Omnicell Power Failure SOP.

2.6.4. **Records of Controlled Drugs Received into Stock**

2.6.4.1. For CDs received into stock, the following details must be recorded in the CD register:

- Date and time of entry
- Name and address of the supplier (e.g. Wholesaler or Central Main Store)
- Quantity received
- Name, form and strength of the CD received
- Batch number
- Name, signature & HPC PIN (if appropriate) of person receiving the CD
- Name & signature of witness
- Running total

2.6.4.2. For CDs received into stock, the following details must be recorded in the CD register:

- Date and time of entry
- Name and address of the supplier (e.g. Wholesaler or Central Main Store)
- Quantity received
- Name, form and strength of the CD received
- Batch number
- Name, signature & HPC PIN (if appropriate) of person receiving the CD
- Name & signature of witness
- Running total

2.6.5. **Records of Controlled Drugs Supplied**

2.6.5.1. For CDs supplied from Central Main Store to operational locations, the following details must be recorded in the CD register:

- Date supplied
- Name of location supplied to
- Quantity supplied
- Name, form and strength of the CD supplied
- Requisition number
- Name & signature of person booking out the CD
- Name & signature of witness
- Running total

2.6.6. **Records of CDs withdrawn and returned (for shifts)**

2.6.6.1. Registered healthcare professionals (e.g., paramedics) should only draw controlled drugs for the duration of their shift period and are responsible and accountable for returning all unused CDs at the end of their shift period. Under no circumstances should CDs be retained whilst being off duty

2.6.6.2. Any controlled drug withdrawn from the CD cupboard/Omnicell must be signed out in the CD Register for that CD cupboard or electronically from Omnicell sites. CDs should always be signed back into that same CD cupboard, the Controlled Drug Register reconciled or into the same Omnicell updating the electronic CD register where possible (see SOP on Record Keeping and Controlled Drug Entries).

2.6.6.3. The registered healthcare professional who withdrew the individual drug/s will be responsible for placing these back into the CD cupboard and signing the CD register. CDs that have been used should be accounted for back at the operational location (e.g., ambulance station) and an entry made in the CD register.

2.6.6.4. When controlled drugs are withdrawn or returned to a controlled drugs cupboard by paramedics, a witness should also sign in the Controlled Drugs Register. SECAmb has allowed that in exceptional circumstances, where no witnesses are available (e.g. twilight hours) it is accepted that single responders should annotate the witness section as “single response vehicle (SRV) no witness available (NWA)” The same principles apply to Omnicell sites. See risk register entry: 373.

2.6.6.5. OTLs will monitor, through reconciliation checks, all entries of “NWA” and will report all instances where witnesses should have been available using the online incident reporting system.

2.6.6.6. Controlled drugs must not be transferred between practitioners for any reason including to continue patient care.

2.7. Administration of controlled drugs to patients

2.7.1. As with any medicine administered to a patient, the details of the controlled drug administered must be recorded in the Patient Clinical Record (PCR).

2.7.2. This process should be witnessed and this recorded by the witness wherever possible (see also section 2.8 and relevant SOPs).

2.7.3. On return to the operational location e.g. ambulance station, the CD register must be completed as soon as possible including the amounts administered / destroyed recorded in the relevant section of the CD Register. This should be witnessed wherever possible. (see section 2.8).

2.7.4. If a dose of a Controlled Drug is prepared for administration to a patient but not required or if part of a dose is administered, the remaining CD should be discharged into a DOOP (Disposal of Old Pharmaceuticals) container which has a denaturing pad/gel at the bottom. The amount disposed of should be recorded in the Patient Clinical Record and this witnessed wherever possible. A record must also be made in the CD register and witnessed in the usual way.

2.7.5. Under no circumstances should a partially used syringe of a CD be handed to another crew or other practitioner taking over care of the patient, because the originally attending healthcare professional will not be able to account for any further amount administered or disposed of. This will also prevent any opportunities for diversion.

2.7.6. If a patient has their own supply of controlled drugs at home e.g. “just in case” CDs (usually sub-cutaneous injections) or has a syringe driver set up, a registered healthcare professional may administer these in certain circumstances:

- There is a valid Patient Specific Direction (PSD) in place from a prescriber.
- The healthcare professional is working within their scope of practice and has used their clinical judgement to assess whether to administer the CD
- There are clear records made of the CD administration (in patient’s records in the home in addition to the PCR)
- The process of administering “just in case” or syringe driver medicines is covered by a SOP.

2.8. **Role of the Witness in CD processes**

2.8.1. The witness signing the CD register at operational locations e.g. ambulance stations, does not need to be a registered healthcare professional e.g. can be an ambulance technician.

2.8.2. The witness should be aware of their responsibilities and understand what they are checking and signing.

2.8.3. For administration of CDs to a patient by a solo responder, a witness is still required. This witness does not need to be SECAmb staff. It can be staff from other organisations or family members/carers.

2.8.4. For CD administration to patients, the witness should sign the Patient Clinical Record (PCR).

2.8.5. Solo responders administering CDs to patients should use their professional judgement regarding whether there is a suitable witness available (e.g. witnesses who are intoxicated or distressed may not be suitable).

2.8.6. In these cases, the reason why there is no suitable witness should be recorded on the Patient Clinical Record (PCR).

2.9. **Disposal/Destruction of Controlled Drugs**

2.9.1. **Authorised Witness**

2.9.1.1. Those persons authorised by the CDAO to act as witnesses for CD destruction (described in the Misuse of Drugs Regulations 2001 as 'authorised persons') should be directly accountable to a director of the Trust and should not be involved in the routine supply or administration of CDs.

2.9.1.2. The authorised witness should have appropriate training and follow SECAmb SOP on destruction of controlled drugs.

2.9.1.3. The authorised witness should be subject to a professional code of ethics and/or Criminal Records Bureau checks.

2.9.1.4. The Police Controlled Drugs Liaison Officer (CDLO) amongst others can be an authorised witness for the destruction of CDs, although this is not normally part of the CDLO's routine role.

2.9.2. **Disposal of broken ampoules**

2.9.2.1. If an ampoule containing controlled drugs is broken, the ampoule and remaining medicine should be placed in a DOOP container and an incident form completed. A record should be made in the CD Register about the incident and should also be reported using the online incident reporting system.

2.9.2.2. If a box or boxes of ampoules are received broken or found to be broken on opening, these must be quarantined for investigation and destruction.

2.9.3. **Destruction of expired stock controlled drugs**

2.9.3.1. Disposal of expired stock controlled drugs must be carried out in accordance with the SECAmb SOP for destruction of controlled drugs and must be witnessed by a SECAmb authorised witness (written authorisation provided by the SECAmb Controlled Drugs Accountable Officer and their name listed on the SECAmb Controlled Drugs Home Office licence) or by a Controlled Drugs Liaison Officer (CDLO) with appropriate Home Office Authorisation (see also section 2.9.1).

2.9.3.2. A record of the destruction must be made in the CD register including both signatures (person destroying and witness).

2.9.3.3. Expired CDs awaiting destruction should be stored in the same manner as 'in date' CDs but kept separate from other CDs in the CD cupboard and clearly marked (e.g. 'EXPIRED NOT FOR USE') to minimise the risk of inadvertent use. They should never be used for training purposes.

2.9.3.4. Records of controlled drug destruction must be maintained for seven years.

2.10. **Transporting Controlled Drugs Prescribed for a Patient**

2.10.1. CDs 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 brought back to base and therefore not recorded in any SECAmb CD register. The same applies to CDs that are part of discharge medication (See Medicines Policy).

2.10.2. Care should be taken when transporting patient medication in a 'Green Bag' if the patient dies before reaching the hospital. The patient may be prescribed CDs, which the ambulance clinician does not recognise. Consequently, any patient medication must be given to a registered nurse, doctor or pharmacist in the hospital and not accompany the patient to the mortuary.

2.10.3. If a patient has been transferred to hospital and the medicines have been left in the ambulance in error, the medicines should be conveyed to the hospital as soon as possible and be re-united with the patient (see Medicines Policy).

2.10.4. If a patient has been transferred to the mortuary and medicines have been left in the ambulance in error, these should be taken to a local community pharmacy for destruction or to a local police station (e.g. if out of hours or there is the potential for the death to be part of a Coroner's inquest).

2.10.5. When patient's own medicines (including controlled drugs) have been taken to the community pharmacy or local police station, this should always be documented in the Patient Clinical Record (PCR).

2.10.6. SECAmb employees must not retain CDs belonging to patients in their personal locker.

2.11. Discrepancies, loss or theft of controlled drugs

2.11.1. All staff who are involved in the ordering, storage, carriage, use, administration of and disposal of controlled drugs held by the SECAmb are under legal obligation to report any discrepancies, no matter how minor, as soon as possible to either an Operational Unit Manager (OUM), or other appropriate person, in order that the matter can be quickly and thoroughly investigated.

2.11.2. In addition, all discrepancies must be recorded and reported via the SECAmb incident system and the Chief Pharmacist and CDAO informed.

2.11.3. If ANY drug in the possession of any person by virtue of their authority to store, carry or administer that drug is stolen or otherwise lost, the loss must be reported by that person as soon as possible to an Operational Unit Manager (OUM) as well as reporting this to the local police and a crime number obtained. That person must complete an incident report (including recording the crime number). The Chief Pharmacist should be informed.

2.11.4. The CD Accountable Officer (Executive Medical Director) must be informed of any CD thefts, CDs unaccounted for or loss of CDs as soon as possible. For CDs which remain unaccounted for, for more than 24 hours, the Police Controlled Drugs Liaison Officer (CDLO) must be informed by the CDAO or Chief Pharmacist

2.12. Illicit Drugs

2.12.1. The following process should be followed to manage substances suspected to be illicit drugs (i.e. Schedule 1 Controlled Drugs e.g. cannabis) found in the possession of, or dropped by a patient while on SECAmb property (e.g. SECAmb ambulance) or being treated by SECAmb staff.

2.12.2. 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 or vehicles under any other circumstances.

2.12.3. The discovery should be recorded in an appropriate local log book/patient record. The entry should be signed and the event witnessed if possible.

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

2.13. **Action in the event of assault on crews**

2.13.1. In the event that any member of staff is threatened by a member of the public with a view to them retaining the controlled drugs (or any other drugs), the member of staff MUST OFFER NO RESISTANCE.

2.13.2. The member of staff must immediately report the loss to the local police. The Operational Unit Manager (OUM), Duty Operations Manager or Duty Silver must also be informed and an incident form completed.

2.14. **Naloxone Storage in Clinical Areas**

2.14.1. Naloxone must be immediately available where opiate medicines (e.g. morphine) are used in all clinical areas. On a mobile unit, the naloxone must be stored in a Paramedic drug bag or crash box. It must not be stored in the CD pouch.

2.14.2. Naloxone must be immediately available at the patient's side when opiates are administered.

2.14.3. An incident report must be submitted for all actual or near miss incidents linked to an opioid overdose.

2.15. **Controlled Drugs Stock Checks and Reconciliations**

2.15.1. **CD Stock and Reconciliation Checks in Operational Locations**

2.15.1.1. The stock balance of Controlled Drugs should be checked daily, including maintaining a running balance and this recorded, by the staff members who have responsibilities for ensuring this takes place during withdrawal and returning of CDs on operational shifts.

2.15.1.2. Once a week, all sections of the CD Registers should be checked (reconciled) to ensure the balance recorded in the CD Register corresponds with the actual balance in the CD cabinet. Omnicell sites undertake this check by printing the electronic CD Register.

2.15.2. **CD Reconciliation Checks by Pharmacy**

2.15.2.1. The security of Controlled Drugs should be checked, by pharmacy staff, with audit and reconciliation, at least every six months and when overall responsibility for drugs changes (e.g. change of appointments) within all sites and the Central Main Store (due to this not being managed by pharmacy).

2.15.3. **CD Reconciliation Checks by CDLCD Reconciliation Checks by CDLO**

2.15.3.1. The Police Controlled Drugs Liaison Officer (CDLO) may carry out unannounced spot checks of CD reconciliation.

2.15.3.2. The CDLO will produce a standard report from an unannounced visit for the CDAO and Chief Pharmacist.

2.16. **Training**

The following training is available for the management of controlled drugs:

- All registered clinical staff will receive CD training as part of their induction.
- In addition, there is an expectation that staff will be trained locally as SOPs are issued and updated.

3 Definitions/Glossary

Administration	To give a medicine either by introduction into the body e.g. orally, by injection or by external application e.g. impregnated dressing
CDs	See Controlled Drugs
CDLO	Controlled Drug Liaison Officers. CDLOs are members of the police force.
Community Pharmacy	A retail pharmacy – a private provider delivering some NHS services, e.g. dispensing of FP10 prescriptions.
Controlled Drugs (CDs)	Drugs that are controlled under Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001.
Controlled Drugs Accountable Officer (CDAO)	Member of staff responsible for the governance of controlled drugs within the Trust
Controlled Drugs (CD) Cupboard	A lockable cupboard specifically used only for the safe storage of CDs which meets all regulatory specifications

'Green medicines bag'	A re-sealable green bag which can be used by ambulance staff to collect patients' medicines (enabling them to be kept together) when the patient is transferred to hospital as well as when patients are discharged from hospital. Patient's name must be written on this green medicines bag.
Home Office Group Authority	Persons who are covered by an applicable Home Office licence group authority can possess and supply Controlled Drugs in accordance with the terms of the group authority (e.g. there is currently a group authority covering paramedics that allows them to possess and supply certain Controlled Drugs)
Home Office Licence	This is a licence issued by the Home Office. Organisations or persons who have an applicable Home Office licence can possess and supply Controlled Drugs in accordance with the terms of the licence
HMR	Human Medicines Regulation
Joint Royal Colleges Ambulance Liaison Committee (JRCALC) Clinical Guidelines	These are established clinical practice guidelines which include medicines commonly used by ambulance services.
JRCALC	See Joint Royal Colleges Ambulance Liaison Committee (JRCALC) Clinical Guidelines.
Medicine	Medicinal Products as defined by the Medicines Act 1968 i.e. a substance administered by mouth, applied to or introduced into the body for the purpose of treating or preventing disease, diagnosing disease or ascertaining the existence, degree or extent of a physiological condition, contraception, inducing anaesthesia, or otherwise

	preventing or interfering with the normal operation of a physiological function.
Operational Team Leaders (OTLs)	OTLs are registered paramedics with responsibilities for the safe and secure storage, handling and management of medicines including controlled drugs within operational locations (e.g., ambulance stations).
OTLs	See Operational Team Leaders
Registered Paramedic	A person whose name appears on the Paramedic Register maintained by the Health and Care Professions Council.
Parenteral medicines	Medicines which are administered by injecting directly into the body, bypassing the skin and mucous membranes. The common parenteral routes are intramuscular (IM), subcutaneous (SC) and intravenous (IV).
Patient Specific Direction (PSD)	A written instruction from an appropriate prescriber for medicines to be supplied or administered to a named patient. This includes instructions on patients' prescription charts.
PSD	See Patient Specific Direction.
Receipt of medicines	The formal activities undertaken when medicines are received by SECAmb from any external source, or transferred from one location to another within SECAmb.
Registered doctor	A person whose name appears on the List of Registered Medical Practitioners maintained by the General Medical Council.
Registered nurse	A person whose name appears on the Register maintained by the Nursing and Midwifery Council as a registered nurse.

Standard Operating Procedures (SOP)	A document that describes in detail, step-by-step, how a task should be carried out. It also describes the responsibilities, including audits, necessary to safely manage and accountably manage any set processes. It is a working document detailing current agreed working practices

4 Responsibilities

4.1. The **Chief Executive Officer (CEO)** has overall responsibility for medicines use and governance in SECAmb.

4.2. The **Executive Director of Finance** through delegation by the CEO, has overall responsibility for Security of Estates. Their security and estates staff provide professional advice to the Chief Pharmacist, Executive Medical Director and Executive Director of Operations for the safe and secure handling of medicine in SECAmb.

4.3. The **Executive Director of Operations**, through delegation by the CEO, has overall responsibility for the implementation, operation and local assurance of this policy. The Executive Director of Operations has overall responsibility for holding their staff to account for any deviations from this policy.

4.4. The **Executive Director of Operations** delegates local responsibilities and accountability for this procedure to the Regional Operations Managers, Operational Unit Managers, Operational Managers, Specialist Managers and where relevant the Head of Fleet and Logistics.

4.5. The **Regional Operations Managers**, **Operational Units Managers**, **Hazardous Area Response Team Operations Managers**, **Operational Managers**, **Specialist Managers** and where relevant the **Head of Fleet and Logistics** delegate their local responsibility and accountability for this policy to their staff including the Operational Team Leaders (OTLs), Logistics Manager, and others.

4.6. The **Executive Medical Director** through delegation by the CEO, has overall responsibility for medicines governance system design and overall assurance.

4.7. The **Executive Medical Director** is the board member with responsibilities for Medicines Optimisation and Controlled Drugs.

4.8. The **Executive Medical Director** is the **Controlled Drugs Accountable Officer (CDAO)** and is responsible for governance of controlled drugs (CDs) within SECAmb (see CDAO below).

4.9. The **Chief Pharmacist** supports the **Executive Medical Director** and Executive Director of Operations providing pharmaceutical professional advice with regards to all medicines related policies, procedures and practices

4.10. The **Chief Pharmacist** delegates local responsibility for Medicines Management practices to their staff

4.11. The **Executive Director of Operations**, **Executive Medical Director** and **Chief Pharmacist** are responsible for escalating unresolved concerns to the Medicines Governance Group.

4.12. **The Medicines Safety Officer (MSO)** is also the Chief Pharmacist. The MSO supports local medication error reporting and learning. The MSO acts as the main contact for NHS England and Medicines and Healthcare Products Regulatory Agency (MHRA).

4.13. **The Trust Lead on Security (ASMS):**

4.13.1. Is responsible for supporting the Medicines Governance team and working with the **Chief Pharmacist** to consider risk mitigation, providing guidance and recommendations for the security of CDs.

4.13.2. Joint working with the **Chief Pharmacist** on audits and quality assurance for the governance and security of CDs.

4.13.3. Supporting as a Trust liaison point to the Police Services for significant incidents that pose a risk to the security of CDs.

4.14. **The CDAO (Controlled Drugs Accountable Officer):**

4.14.1. The CDAO is responsible for all aspects of the safe and secure management of CDs in his or her organisation. This includes ensuring that storage arrangements for CDs meet legal requirements and recommended security standards.

4.14.2. The CDAO must ensure that adequate and up-to-date SOPs are in place which specify roles, responsibilities and procedures to be followed for all aspects of the CD journey.

4.14.3. The CDAO must ensure that systems are in place for monitoring and auditing of the management systems themselves and investigation of concerns and incidents related to CDs.

4.14.4. The CDAO must ensure that arrangements are established for the proper sharing of information with responsible bodies and participation in the CD Local Intelligence Network (CDLIN) on behalf of the trust.

4.14.5. The CDAO has statutory responsibility for ensuring that appropriate arrangements are put in place and operated at the trust for the management of access to CDs, in order to comply with misuse of drugs legislation. The CDAO must ensure that a SOP is in place covering who has access to CDs.

4.14.6. The CDAO is required to establish and operate, or ensure that the trust establishes and operates, appropriate arrangements for securing the safe destruction and disposal of CDs which comply with relevant statutory requirements. There should be a SOP which specifies the details of who is authorised to undertake CD destruction and how this should be carried out within the organisation. The CDAO is also responsible for authorising individuals to witness CD destruction; however the CDAO themself is not authorised to take part or act as a witness to the process.

4.15. **Operational Unit Managers (OUMs)**

4.15.1. OUMs are accountable for ensuring that Trust policies and SOPs are implemented correctly and consistently within their area of work and locality. This may be delegated to OTLs as appropriate.

4.15.2. The OUMs with overall responsibility for key holding and access to CDs in their area should ensure that arrangements are in place to only enable access to CDs by appropriate registered health care professionals.

4.16. **Operational Team Leaders (OTLs)**

4.16.1. OTLs are responsible for ensuring that CD stock checks and audits are carried out with the correct frequency; and that reports of discrepancies or incidents are investigated and escalated properly. OTLs who are not legally authorised to possess CDs will need to conduct CD tasks in conjunction with someone authorised to do so.

4.17. **Registered paramedics and Registered Nurses**

4.17.1. Registered healthcare professionals are accountable at all times for CDs in their possession. They are responsible for recording the withdrawal, movement, administration, and disposal of all CDs in their possession in the CD Record Book, and for ensuring that the running total is kept up-to-date and accurate. Where a CD has been administered to a patient, it is the responsibility of the healthcare professional to ensure that the details are also documented on the Patient Clinical Record (PCR).

4.17.2. All registered healthcare professionals are accountable for the disposal of unused amounts of CDs following administration to a patient and of broken or damaged ampoules in their possession.

4.18. **All Staff**

4.18.1. All staff involved in the use and/or management of CDs are obliged to report any discrepancies or concerns to an appropriate on-duty manager as soon as practicable and before completion of their shift so that these can be investigated in a timely manner. Any discrepancies or untoward incidents should be reported using the local reporting procedure.

5 Monitoring Compliance

5.1. Competence, monitoring and audit in relation to this policy will be aligned to the associated procedure.

6 Policy Review

6.1. This policy will be reviewed every three years or sooner if new legislation, codes of practice or national standards are introduced

7 Audit and Review (evaluating effectiveness)

7.1. This policy is the first of its kind at SECAmb. Its effective implementation must be seen in relation to all CD activity and CD incident reporting. It will be monitored through Medicines Governance Group.

7.2. All policies have their effectiveness audited by the responsible Management Group at regular intervals, and initially six months after a new policy is approved and disseminated.

7.3. Effectiveness will be reviewed using the tools set out in the Trust's Policy and Procedure for the Development and Management of Trust Policies and Procedures (also known as the Policy on Policies).

7.4. This document will be reviewed in its entirety every three years or sooner if new legislation, codes of practice or national standards are introduced, or if feedback from employees indicates that the policy is not working effectively.

7.5. All changes made to this policy will go through the governance route for development and approval as set out in the Policy on Policies.

8 References

8.1. National Institute for Health and Care Excellence (NICE). Controlled drugs: safe use and management. 12 April 2016.*Link* (Accessed: 26 Mar 2018)

8.2. Security standards and guidance for the management and control of controlled drugs in the ambulance sector, Version 3, March 2017, NHS

Protect.

8.3. Association of Ambulance Chief Executives (2016). UK Ambulance Services Clinical Practice Guidelines 2016 (Joint Royal Colleges Ambulance Liaison Committee (JRCALC) Clinical Guidelines). *Link*. (Accessed: 26 Mar 2018)

8.4. Royal Pharmaceutical Society. Professional Standards for Hospital Pharmacy Services. For Providers of pharmacy services in or to acute hospital, mental health, private, community service, prison, hospice and ambulance settings. Version 3. December 2017. *Link* (Accessed: 26 Mar 2018)

8.5. Royal Pharmaceutical Society. Safe and Secure Handling of Medicines (currently being updated) (Royal Pharmaceutical Society of Great Britain, The Safe and Secure Handling of Medicines: A Team Approach, March 2005, *Link,* Accessed: 26 Mar 2018)

8.6. The Controlled Drugs (Supervision of Management and Use) Regulations 2013. *Link*. (Accessed: 26 Mar 2018).

8.7. The Human Medicines Regulations 2012. *Link*. (Accessed: 26 Mar 2018).

8.8. The Misuse of Drugs Regulation 2001. *Link*. (Accessed: 26 Mar 2018).

8.9. Guidance on the destruction of controlled drugs: New role for Accountable Officers – Authorising people to witness the destruction of controlled drugs, Department of Health, December 2007

8.10. Medicines, Ethics and Practice (MEP), Royal Pharmaceutical Society of Great Britain, July 2017.

8.11. Drug Penalties, https://www.gov.uk/penalties-drug-possession-dealing (accessed 26 Mar 2018)

9 Equality Analysis

9.1. The Trust believes in fairness and equality, and values diversity in its role as both a provider of services and as an employer. The Trust aims to provide accessible services that respect the needs of each individual and exclude no-one. It is committed to comply with the Human Rights Act and to meeting the Equality Act 2010, which identifies the following nine protected characteristics: Age, Disability, Race, Religion and Belief, Gender Reassignment, Sexual Orientation, Sex, Marriage and Civil Partnership and Pregnancy and Maternity.

9.2. Compliance with the Public Sector Equality Duty: If a contractor carries out functions of a public nature then for the duration of the contract, the contractor or supplier would itself be considered a public authority and

have the duty to comply with the equalities duties when carrying out those functions.

Appendix A:

Schedules and Classes of Controlled Drugs (CDs)

a) CD Schedules

The Misuse of Drugs Regulations 2001 as amended classify Controlled Drugs into five Schedules according to the different levels of control attributed to each based on their therapeutic usefulness and misuse potential:

Schedule 1 (CD Lic POM)
Most Schedule 1 drugs have no therapeutic use and a licence is generally required for their production, possession or supply. Examples include hallucinogenic drugs (e.g.'LSD'), ecstasy-type substances, raw opium and cannabis.

Schedule 2 (CD POM)
Schedule 2 includes opiates (e.g. diamorphine, morphine, methadone, oxycodone, pethidine), major stimulants (e.g. amfetamines) and ketamine.

Schedule 3 (CD No Register POM)
Schedule 3 Controlled Drugs include minor stimulants and other drugs (such as buprenorphine, temazepam, tramadol, midazolam and phenobarbital) that are less likely to be misused (and less harmful if misused) than those in Schedule 2.

Schedule 4 (CD Benz POM and CD Anab POM)
Schedule 4 is split into two parts:

- Part I (CD Benz POM) – contains most of the benzodiazepines (such as diazepam), non-benzodiazepine hypnotics (such as zopiclone), and Sativex (a cannabinoid oromucosal mouth spray)

- Part II (CD Anab POM) – contains most of the anabolic and androgenic steroids, together with clenbuterol
(an adrenoceptor stimulant) and growth hormones.

Schedule 5 (CD INV P and CD INV POM)
Schedule 5 contains preparations of certain Controlled Drugs (such as codeine, pholcodine and morphine) that are exempt from full control when present in medicinal products of specifically low strengths.

b) Classes of Controlled Drugs

The Home Office classifies controlled drugs into different classes A, B and C. The maximum penalties for drug possession, supply (dealing) and production depend on what type or 'class' the drug is. Class A drugs have the highest penalties associated with possession and supply, followed by Class B and then Class C.

Class A: Crack cocaine, cocaine, ecstasy (MDMA), heroin, LSD, magic mushrooms, methadone, methamphetamine (crystal meth)

Class B: Amphetamines, barbiturates, cannabis, codeine, ketamine, methylphenidate (Ritalin), synthetic cannabinoids, synthetic cathinones (eg mephedrone, methoxetamine)

Class C: Anabolic steroids, benzodiazepines (diazepam), gamma hydroxybutyrate (GHB), gamma-butyrolactone (GBL), piperazines (BZP), khat