



## Controlled Drugs Possession using Body Worn Pouches Standard Operating Procedure

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South East Coast Ambulance Service **NHS**  
NHS Foundation Trust



## Scope

- 1.1. South East Coast Ambulance (SECAmb) NHS Foundation Trust is committed to providing high quality patient care and the safe and secure management of medicines.
- 1.2. This procedure describes the use of personal issue body-worn controlled drug (CD) pouches for the possession of the controlled drugs (CDs) Morphine Sulphate, Midazolam and Diazepam (Diazemul) ampoules.
- 1.3. The document will provide a single point of reference which describes the method by which staff authorised and legally entitled to possess CDs **must** adhere to.
- 1.4. This procedure is applicable to all clinicians in the Trust, with the exception of Critical Care Paramedics (CCPs) who hold all CDs & extended CD formulary in locked pelicase, and sets out the scope of clinical practice to which clinicians must adhere.
- 1.5. Only SECAmb authorised Healthcare Professionals Registered with the HCPC can be in direct possession of stock CDs in the course of their duties.
- 1.6. Non-registered staff cannot possess stock CDs unless this is authorised by SECAmb as part of their duties in line with the Trust CD policy (e.g. Logistics staff transporting stock CDs).

## 2 Procedure

### 2.1. The Controlled Drug pouch:

#### 2.1.1. Overview:

- 2.1.1.1. The CD pouch is a belt-worn product comprising a wipe clean outer case and an inner plastic ampoule holder (see Appendix A – images 1, 2 and 3).
- 2.1.1.2. The pouch is designed to be worn on the belt and should only be worn in this way. Staff are advised to wear the pouch on a part of the belt which is most comfortable for them, but which prevents inadvertent opening of the pouch in order to avoid the dropping or loss of ampoules.

#### 2.1.2. Issuing and Returning pouches:

- 2.1.2.1. CD pouches are issued locally by Operating Unit Managers (OUMs), via their team structures. Non-operational Paramedics will receive their CD pouches from their Head of Department. These are currently ordered via the uniform ordering form.
- 2.1.2.2. When the Paramedic receives it, they must put their personnel number on the lid and base of the pouch.



- 2.3. The pouches are personal issue, but remain the property of the Trust.
- 2.1.2.4. Staff leaving the Trust must return their pouch along with other uniform items. Spare pouches should be retained within the OU/department and used to replace soiled/damaged pouches or to issue to new staff.
- 2.1.2.5. Staff must not use their SECAmb CD pouch in other employment, and should follow the medicines arrangements in each of their contracted roles.
- 2.1.2.6. The CD pouch product selected for use by the Trust has been approved by our Infection Prevention & Control (IPC) Team. The pouch can be cleaned using Clinell wipes, but in the event of heavy soiling, the pouch should be discarded appropriately as clinical waste.
- 2.1.2.7. If the pouch becomes heavily soiled with the medicines in situ, you MUST discard/waste all CDs within the pouch according to Trust approved processes (see Disposal of Controlled Drugs SOP). Once the medicines have been discarded, place the soiled pouch in a clinical waste bag and discard appropriately. You should attempt to source a replacement pouch and sign out further CDs as necessary.

## 2.2. **The medicines to be carried in the pouch:**

- 2.2.1. Only the following medicines may be carried in the CD pouch:

### **Paramedics:**

- Morphine Sulphate (two vials)
- Diazepam Solution (two vials)

### **Practitioner Paramedics (PP)**

- Midazolam (only 1 vial in a 2<sup>nd</sup> pouch)

- 2.2.2. The pouch must only be used for carrying CDs, and not be used for other items (for example, you must not keep gloves in the pouch).
- 2.2.3. The ampoule holder inside the pouch has slots for 5 vials. A maximum of 4 vials are permitted to be carried in the CD pouch. One slot must always remain empty (see Appendix A – image 4).
- 2.2.4. To increase safety have the empty slot in the middle with two morphine one side and two Diazepam the other to maintain separation.

## 2.3. **Wearing of the CD Pouch:**

- 2.3.1. The CD pouch should be worn on the belt of the uniform trousers (see Appendix A – image 5).



The pouch must not be worn on utility belts as these are often removed and left in vehicles. This would lead to CDs not being in direct possession of the Paramedic.

2.3.3. CD pouches should not be worn when not in uniform. This applies mainly to Response Capable Managers (RCMs), and reminds staff that the process for possessing CDs is associated with planned periods of duty only.

## 2.4. **Process for withdrawing and replacing CDs using CD Pouch:**

2.4.1. The approved process for withdrawing and replacing CDs is broadly unchanged, and the following guidance outlines the differences when using the CD pouch.

2.4.2. The same approach to safe-custody **MUST** be applied when dealing with CDs at all times. The change to using CD pouches does not change any other aspect of medicines management/governance.

2.4.3. Any damage or loss of the CD pouch will need reported using the Datix DIF1 form.

2.4.4. Any loss of the CD pouch and CD content will need to be escalated to the duty Operational Team Leader (OTL) and OUM.

2.4.5. The Chief Pharmacist and Controlled Drug Accountable Officer (CDAO) will also need to be informed.

## 2.5. **Withdrawing CDs and placing into pouch**

2.5.1. Withdraw your CDs in the usual way. Transfer each vial immediately into the pouch – either by holding the pouch in your hand, or in situ on your belt. Once all CDs are withdrawn, securely close the pouch and place on belt (if holding).

2.5.2. Do not put CDs down during this process to do anything else. CDs should be immediately placed into the pouch and then on your belt.

## 2.6. **Use of Pelicases (or equivalent CD case) in the Trust:**

2.6.1. Paramedic Practitioners also carry Peli cases. This does not alter the use of body worn CD Pouches. Paramedic Practitioners are not to put midazolam in their pelicase.

## 2.7. **Medicines management and governance relating to the CD pouch:**

### 2.7.1. Safe Handling of Medicines:

2.7.1.1. The Trust has a corporate responsibility to design systems to promote the safe handling of medicines. The personal issue body worn CD pouch was intended to support this as an improvement over the previous system.



2. The body worn CD pouch must only contain the indicated medicines, and great care must be taken to select the correct medicine for administration. Currently, staff must be vigilant to errors and check/witness vials prior to preparation and administration.
  - 2.7.1.3. Staff should consider developing a consistent approach to placing vials in the pouch (i.e. always put morphine on the left and diazepam on the right) and they **MUST** always carefully check the vial selected for correct drug administration, and this should be witnessed wherever possible.
  - 2.7.1.4. Staff must not deviate from the use of CD pouches\*.
  - 2.7.2. Breakages:
    - 2.7.2.1. One of the main benefits of the body worn CD pouches is to reduce breakages. Refer to the Disposal of Controlled Drugs SOP on how to record and dispose of CD breakages.
    - 2.7.2.2. Any breakages need reporting via a Datix DIF-1 form.
- 2.8. **Security Arrangements:**
  - 2.8.1. Body worn CD belt pouches are used extensively in EMS systems across the UK and the rest of the world.
  - 2.8.2. The pouches do not draw attention to their purpose, and therefore are not felt to increase risk of theft or reduction in personal security.
  - 2.8.3. Staff are advised that in the event of attempted theft, they **MUST NOT** try to protect their CDs and should give them up to the assailant without question. Staff are not legally responsible for loss of CDs in the event of loss through crime.
  - 2.8.4. In the rare event of an incident such as this, the Police must be notified immediately (to report both the crime and the loss of the CDs), and local security procedures must be followed (supported by an immediate response from a Bronze Manager). The Medicines Governance Team will lead on the response to the incident, liaising with the necessary agencies after the event (i.e. Police, controlled drugs local intelligence network (CD LIN)).
- 2.9. **Response Capable Managers (RCMs):**
  - 2.9.1. RCMs **MUST** follow the same procedures as their operational colleagues.
  - 2.9.2. Where an RCM is not a registered HCP, they must not possess CDs.
  - 2.9.3. RCMs are not authorised to store CDs in their cars or homes, and must sign out and return CDs **ON THE DAY** for planned periods of duty.



Where a planned period of duty includes on-call from home, CDs cannot be taken home and therefore must be returned to stock prior to heading home.

- 2.9.5. It is accepted that in certain circumstances, RCMs may be required to possess more than the maximum permitted number of CD vials (for example, dealing with a road traffic collision (RTC) involving a service vehicle where the paramedic is taken to hospital and cannot take their CDs back to base).
- 2.9.6. In these circumstances, the CD pouch from that member of staff should be placed on the RCMs belt, along with their own CDs and returned to stock.

### 3 Definitions

- 3.1. Datix is the Trust's incident management system.
- 3.2. DIF1 is the form used as part of the Datix reporting process.

### 4 Responsibilities

- 4.1. The **Chief Executive Officer (CEO)** is accountable for Medicines use and governance in the Trust
- 4.2. The **Chief Medical Officer** through delegation by the CEO, has overall responsibility for medicines governance system design and overall assurance. The Chief Medical Officer has responsibility for the implementation, review, and thus revision where required, of this procedure.
- 4.3. The **Chief Pharmacist** is the professional medicines governance lead for the Trust and is responsible for producing robust systems and processes which comply fully with legislation, national guidance, and regulatory requirements to ensure the safe and effective management and use of medicines throughout the Trust. The Chief Pharmacist supports the Chief Medical Officer and Executive Director of Operations providing pharmaceutical professional advice with regards to all medicines related policies, procedures and practices.
- 4.4. 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 his/her staff to account for any deviations from this policy and is responsible for the operational compliance of this procedure.
- 4.5. The **Executive Director of Operations, Chief Medical Officer and Chief Pharmacist** are responsible for escalating unresolved concerns to the Medicines Governance Group (MGG).





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

- 4.7. The **Associate Directors of Operations, Operational Units 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.
- 4.8. The **Executive Director of Nursing and Quality** has responsibility for matters relating to regulatory compliance, risk management, health and safety relating to this procedure.
- 4.9. **Controlled Drug Accountable Officer** is also the **Chief Medical Officer** and is responsible for the safe management and use of Controlled Drugs within the Trust along with co-operating and sharing information relating to concerns about the Trust's use and management under the Controlled Drug (Supervision of Management and Use) Regulations 2013. These responsibilities include keeping records of the investigation of concerns and acting where appropriate.
- 4.10. 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).
- 4.11. The **Medicines Governance Group (MGG)** is responsible, for providing strategic direction for the implementation of medicines management and practice within the Trust. The primary objective of MGG is to ensure appropriate clinical and cost-effective use of medicines, promoting the highest standards of medicines management and safe practice throughout the Trust, by ensuring that senior managers are aware of issues relating to the use of medicines within the organisation as part of the overall clinical and corporate governance structure.
- 4.12. The role of The **Non-Medical Prescribing (NMP) Group** is to provide overarching multidisciplinary leadership for non-medical prescribing (NMP) within the Trust. In doing so, it manages the process of Trust approval to train as a non-medical prescriber and to prescribe, taking account of service redesigns and improved patient access to medicines. The NMP Group aims to strengthen and monitor the governance issues associated with non-medical prescribing, to determine potential and support existing non-medical prescribers, advise the MGG on matters relating to non-medical prescribing and will report exceptions relating to non-medical prescribing to the MGG.
- 4.13. The **Medical Gas Subgroup** provides assurance to MGG that medical gases are effectively monitored and managed within the Trust.





The **Patient Group Direction (PGD) Approval and Working Group** provides assurance to MGG and ensures the development, review, updates and implementation of PGDs are in line with legislation and national good practice.

- 4.15. The **Medicines Governance Team (MGT)** are responsible for ensuring the safe and efficient procurement of medicines, including controlled drugs to ensure the quality of the product, safe dispensing/packing into medicines pouches through to safe disposal of pharmaceutical waste. The MGT will support the Chief Pharmacists with drug shortages, drug alerts and relevant information relating to medicines is communicated in a timely manner.
- 4.16. **All staff** are responsible for their own professional practice. All staff involved in the prescribing, supply, dispensing, handling, storage, administration and disposal of medicines, including controlled drugs, must receive appropriate training and assessment of competence before commencing their roles. All staff who handle medicines are personally accountable for complying with this policy and relevant standard operation procedures, for reporting any concerns and for the safe handling of all medicines.

## **5 Audit and Review (evaluating effectiveness)**

- 5.1. The use of body worn CD pouches, and associated benefits (i.e. reduced breakages) will be audited as part of the standard medicines governance reporting processes.
- 5.2. This document will be reviewed on behalf of the Medicines Governance Group to ensure it is meeting its aims and objectives.
- 5.3. The procedure will be reviewed every three years or sooner if new legislation, codes of practice or national standards are introduced.
- 5.4. All procedures have their effectiveness audited by the responsible Management Group at regular intervals, and initially six months after a new policy is approved and disseminated.
- 5.5. 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).
- 5.6. 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.
- 5.7. All changes made to this procedure will go through the governance route for development and approval as set out in the Policy on Policies



- 6.1. Controlled Drugs Policy
- 6.2. Administration of Controlled Drugs
- 6.3. Controlled Drugs Possession Using Body Worn Pouches
- 6.4. Changing Security Codes for Medicines Storage
- 6.5. Controlled Drug Stock Checks and Reconciliation
- 6.6. Disposal of Controlled Drugs
- 6.7. Security Management Policy
- 6.8. Record Keeping and Controlled Drug Register Entries
- 6.9. Use of the Omnicell Emergency Access Barcode
- 6.10. Emergency access to medicines in the event of Omnicell Failure or Malfunction

## **7 Financial Checkpoint**

- 7.1. **This document has been confirmed by Finance to have no unbudgeted financial implications.**

## **8 Equality Analysis**

- 8.1. 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.
- 8.2. 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.



Images of the pouch;

Image 1 – closed pouch



Image 2 - open pouch



Image 3 - inner ampoule holder





Image 4 – open pouch, open amouple holder with view of vial slots



Image 5 - belt mounting

