South Central Ambulance Service
NHS Foundation Trust

CONTROLLED DRUG POLICY

South Central Ambulance Service NHS Foundation Trust
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DOCUMENT INFORMATION

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1. Introduction

1.1. Trust The Controlled Drugs (Supervision of Management and Use) Regulations 2006 was introduced as part of the Government's response to the Shipman Inquiry's Fourth report in 2004.

1.2. These regulations aim to strengthen the governance arrangements for the use and management of controlled drugs (CDs). CDs are therefore subject to several legislative controls due to the potential for them to be abused, misused, or diverted, causing possible harm

1.3. Following a Department of Health and Social Care review of the regulations in 2015, Controlled Drug Licensing of NHS organisations commenced.

1.4. The Home Office advice in 2020 was that a Trust is required to hold a license in order to possess and supply stocks of controlled drugs to its stations and employees, including the supply and distribution process within the Trust.

1.5. A Controlled Drug License (CDL) under Regulation 5 of the Misuse of Drugs Regulations 2001 is required to allow the Trust to possess and supply (to employees) CDs from Schedules 2 to 5 and to supply CDs from Schedule 5. CDs cannot be supplied to another individual, except for the purpose of intent of administration for the immediate necessary treatment of sick or injured persons

1.6. CDs are an essential part of the ambulance services. The South Central Ambulance Service (SCAS) (hereafter, "the Trust") is required to comply with the statutory requirements and guidance with respect to the management of CDs, including ordering, receiving, storing, supplying, administering, and recording.

1.7. Registered Paramedics are authorized by the Home Office to supply or offer to supply diazepam and/or morphine sulphate injection (to a maximum strength of 20mg inclusive of all parenteral routes of administration) and/or morphine sulphate oral for the purpose of intent of administration for the immediate necessary treatment of sick or injured persons

1.8. Registered Paramedics may also possess ketamine and midazolam and schedule 4 and 5 drugs permitted under the Misuse of Drugs regulations and its amendments when administering or supplying medicines in accordance with a patient group direction (PGD)

1.9. Registered nurses may carry morphine sulphate (oral and injection), ketamine and midazolam and the schedule 4 and 5 CDs permitted under the Misuse of Drugs Regulations and its amendments when administering or supplying medicines in accordance with a PGD

1.10. CDs are an essential part of the emergency services. The South Central Ambulance Service (SCAS) (hereafter, "the Trust") is required to comply with the statutory requirements and guidance with respect to the management of CDs including receiving, storing, supplying, administering, and recording.

2. Scope

2.1. This policy applies to all individuals employed by the Trust including those that work under contract for services and those supplied to work by a third-party including volunteers, agency staff and students engaged by SCAS.

2.2. This policy does **not** apply to any subcontracted organization whom as part of their contract with South Central Ambulance Service is required to take responsibility for management of their own medicines e.g., Voluntary Aid Society staff, such as St. John Ambulance, British Red Cross, or private organisations subcontracted by the SCAS.

2.3. This policy has been developed as a separate section of CSPP5 Medicines Management Policy, to acknowledge the importance of managing CDs safely and securely, to give greater clarity to CD management and to expedite staff access to information relevant to CD management.

3. Equality Statement

3.1. The Trust is committed to promoting positive measures that eliminate all forms of unlawful or unfair discrimination on the grounds of age, marriage and civil partnership, disability, race, gender, religion/belief, sexual orientation, gender reassignment and pregnancy/maternity or any other basis not justified by law or relevant to the requirements of the post. The Trust will therefore take every possible step to ensure that this procedure is applied fairly to all employees regardless of the afore mentioned protected characteristics, whether full or part time or employed under a permanent or a fixed term contract or any other irrelevant factor.

3.2. By committing to a policy encouraging equality of opportunity and diversity, the Trust values differences between members of the community and within its existing workforce, and actively seeks to benefit from their differing skills, knowledge, and experiences in order to provide an exemplary healthcare service. The Trust is committed to promoting equality and diversity best practice both within the workforce and in any other area where it has influence.

3.3. Where there are barriers to understanding; for example, an employee has difficulty in reading or writing, or where English is not their first language, additional support will be put in place wherever necessary to ensure that the process to be followed is understood and that the employee is not disadvantaged at any stage in the procedure. Further information on the support available can be sought from the HR Department.

4. Aim

4.1. This policy aims to ensure that all staff are clear on the standards that are expected of them in relation to the handling and storage of CDs.

4.2. That patient's, staff and the public are not put at risk as a result of the incorrect handling of CD medicines

4.3. All legislation is adhered to with respect to CDs

4.4. Risks associated with the incorrect handling and storage of CDs are reduced to a minimum

4.5. To provide robust systems for procuring, storing, supplying, transporting, prescribing, administering, recording and disposal of CDs safely.

5. Roles and Responsibilities

5.1. Trust Board: will receive the annual report from the Medicines Optimisation and Governance Group to enable the monitoring of compliance with this policy. Has responsibility and accountability for ensuring the provision of appropriate resources required to implement this policy.

5.2. Chief Executive Officer (CEO): has overall statutory responsibility for the safe and secure handling of medicines. The CEO has delegated this responsibility to the Director of Patient Care. They are responsible for notifying the Care Quality Commission (CQC) of any changes to the appointment of the Controlled Drug Accountable Officer (CDAO), so that the national register is maintained.

5.3. Director of Patient Care: the nominated CDAO for CDs and takes organisational responsibility for CDs. Accountable for the delegation of CD responsibilities to a member of staff with the appropriate level of skills and knowledge.

5.4. Controlled drugs Accountable Officer (CDAO): must ensure that the organisation has appropriate arrangements in place for securing the safe management and use of CDs. This includes:

5.4.1. Appropriate monitoring and auditing of the management and use of CDs
5.4.2. Appropriate investigation and analysis of CD incidents
5.4.3. Providing quarterly reports to the CD Local Intelligent Network (CDLIN) network regarding incidents within the organisation.
5.4.4. Obtain and implement intelligence from the local CDLINs

- The controlled drugs accountable officer for South Central Ambulance NHS Trust is the Director of Patient Care & Services Tranformation/Chief Nurse
- Controlled drug incidents or concerns must be raised with the Director of Patient Care & Services Tranformation/Chief Nurse and the Head of Pharmacy.

5.4.5. Any concerns or issues with controlled drugs must be raised with the Accountable Officer. The CDAO is accountable for all the systems for the safe management of CDs, including standard operating procedures covering each of the activities concerned with CDs.

5.4.6. The CDAO will regularly review incident reports for controlled drugs and will identify trends and issues. Where appropriate these will be reported to the Controlled Drugs Local Intelligence Network (CD LIN).

5.4.7. The CDAO will conduct a yearly review of compliance to these guidelines.

5.4.8. The CDAO may appoint authorised witnesses for the destruction of controlled drugs. The 2001 regulations prevent the CDAO from being an authorised person directly. Persons authorised by the CDAO are usually senior members of staff who are not involved in the day-to-day management of controlled drugs.

5.5. Chief Operating Officer (COO): ensure all operational staff are aware of and accountable for compliance with the Controlled Drug Policy and associated Standard Operating Procedures (SOPs)

5.6. Head of Operations and Clinical Operations Managers

5.6.1. Make all registered clinical staff within the Area aware of and accountable for compliance with the CD Policy and associated SOPs

5.6.2. Accountable for all medicines, including security) held within the Area and for making sure clinic

5.7. Head of Pharmacy

5.7.1. Oversee the management of medicines in accordance with this policy and associated SOPs

5.7.2. Ensure all staff within the scope of the policy are aware of and accountable for compliance with the policy and associated SOPs

5.7.3. Support the CDAO in all matters relating to CDs

5.7.4. Oversee the completion of CD annual CD audits and actively seek to

share learning, identify audit trends, and address concerns.

5.8. Medication Safety Officer (MSO): will act under the direction of the Head of Pharmacy and support local and national medication incident reporting and learning.

5.9. Medicines Optimisation and Governance Group: will interpret law, regulations, introduce new drugs, and develop policy to guide the management of all medicines within the Trust. The group also provides assurance to the Trust regarding the governance of CDs. The group does not deal with supply of drugs or operationalisation of policy

5.10. Health, Safety and Security Officer: responsible for security management matters within the Trust

5.11. Registered Clinical Staff

5.11.1. Complete all prescription documentation and administer medicines in accordance with the appropriate SOPs and Administration Policy.

5.11.2. Comply with the safe storage, custody, and disposal of CDs in accordance with the Misuse of Drugs Act and the relevant SOPs

5.11.3. Communicate changes in patient treatment plans to patients, carers, allied health professionals and other medical staff as appropriate

5.11.4. Provide a specimen signature to the Pharmacy Team for authorization from the handling of CDs

5.11.5. In the absence of the team leader will be accountable for all CDs (including security) held within the area and for making sure that staff adhere to the Policy and SOPs.

5.11.6. Accountable for the implementation and the monitoring of CDs in accordance with the Trust SOP

5.12. Team Leaders

5.12.1. Ensure all staff within their team are aware of, accountable for compliance and adherence with the CD Policy.

5.12.2. Ensure that all staff within their team have read, understood and are accountable for their actions in relation to Trust CD SOPs

5.12.3. Undertake checks of CD storage in accordance with the audit schedule

5.12.4. Ensure a registered member of staff within the team is available to receive and securely store CD orders at stations.

5.13. Pharmacy Staff: will support the management and supply, and colleagues in the supply and management of CDs and monitor compliance with the policy and associated SOPs.

5.14. Prescribers: will accurately completely all prescription documentation and comply with the Misuse of Drugs regulations, Prescribing Policy, relevant professional guidance, and the appropriate SOPs. Non-medical prescribers will also adhere to the Non-Medical Prescriber Policy.

5.15. Logistics staff: will adhere to all relevant SOPs in relation to the transport of CDs.

5.16. All staff: all staff involved in the ordering, receiving, storage, carriage, use and administration of CDs held by the Trust are under obligation to:

5.16.1. Report any discrepancy or loss, no matter how minor, in accordance with the Incident Reporting Policy.

5.16.2. Responsible for understanding the policy and attending relevant training and update sessions

5.16.3. Carry out all activities in compliance to appropriate legislations, policies, and SOPs.

5.16.4. Raise any concerns regarding excessive or unusual use of CDs through incident reporting and where appropriate notify their manager and/or the Head of Pharmacy.

5.16.5. Notify the Head of Pharmacy and the CDAO where serious breaches occur

6. Definitions

6.1. Controlled Drugs Accountable Officer (CDAO): An appointee required by the Controlled Drugs (Supervision and management of Use) Regulations 2006 who is accountable for the safe and effective use of and management of controlled drugs within the Trust.

6.2. Controlled Drugs (CDs): Medicines are defined as Controlled under The Misuse of Drugs Regulations 2001 (and subsequent amendments). The named CDs are divided into five schedules each specifying the requirements governing such activities as import, export, production, supply, possession, prescribing, and record keeping which apply to them. CDs defined in this policy are those substances contained within Schedules 2, 3, 4 and 5 of the Misuse of Drugs Act 1971. The Trust has additional security measures in place to include other substances that are open to abuse, are high risk medicines or 'controlled' for other reasons.

6.3. Local Intelligence Network: NHS England manages "Local Intelligence Networks" which is part of their legal duty to enable the sharing of information and intelligence about the use of CDs in the health and social care sector in their area.

6.4. Controlled Stationery – any stationery used in the order, supply, distribution or return of Controlled Drugs. This includes

- CD requisition books
- CD record Registers
- CD Transport Register
- CD audit books
- Local CD documents including consignment notebooks
- Secure storage e.g., Numbered Tamper Evident Drug (TED) bags
- Numbered seals for TED bags

7. Controlled Drugs – Potential for Misuse

7.1. All CDs have the potential for misuse, with the emergency care setting being particularly vulnerable due to individuals seeking supplied of CDs from clinicians, who will usually be unfamiliar with the patient and limited/no access to their medical records.

7.2. Preventing misuse of CDs is pivotal. Patients who are identified as contacting the Trust frequently and/or repeatedly for the supply and/or administration of CDs should be reported to the CDAO, and a warning message should be indicated in the patient's medical record so that other clinicians are alerted for the potential for misuse.

7.3. Patients with known or suspected CD dependency/misuse problems must not be supplied, prescribed, or administered CDs, expect where there is a genuine clinical need.

7.4. If a clinician has any doubts about prescribing, supplying, or administering CDs to a patient they should consider the use of an alternative medicine or seek the advice of a senior colleague before prescribing, supplying, or administering the CD.

7.5. Misuse of CDs could occur within Trust staff, consequently endangering the lives of patients and colleagues, and tainting the reputation of the Trust. There is also the risk of a registered clinician being 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 Head of Pharmacy, CDAO or through the Trust Whistleblowing Policy

7.6. Early detection and support for staff with potential substance misuse related problem is essential. Staff should also be encouraged to seek assistance voluntarily.

8. Controlled Drug Stationery

8.1. All Controlled Drug stationery should be stored securely and access to it should be restricted. Specifications for Controlled Drug cupboards are documented in the Safe and Secure Handling of Medicines Policy.

8.2. CD stationery is subject to similar security controls as CDs in order to ensure there is a clear audit trail from receipt of CD stationery items to the use and return of CD stationery. This aims to prevent the misuse of CD stationery and to adhere to standards set by the CQC, Home Office and GPhC.

8.3. As per the Misuse of Drugs Regulations 2001 all Trust CD record books/registers must be bound books with numbered pages.

8.4. The station and date period to which the register or record book relates must be clearly indicated on the front cover. This cover should also include the book number being replaced and nook number that will replace the current book.

8.5. CD stationery should be requisitioned using the CD order book in the same manner as CDs. See SOP MEDCD005.

8.6. Any loss or theft of CD stationery must be reported to the Head of Pharmacy and the CDAO and the Trust incident reporting process should be followed.

8.7. The Pharmacy Team will keep a record of all Controlled stationery issued detailing

8.7.1. Date on which the supply was made
8.7.2. The station to which the stationery was supplied

8.7.3. The name and ESR number of the person ordering the stationery
8.7.4. The type and quantity of stationery issued
8.7.5. Serial number of the stationery
8.7.6. Signature of the person making the supply

8.8. Only one CD requisition/order book per safe should normally be in use.

8.9. When a new CD register is started the balances of CDs in stock should be transferred into the new book promptly by staff. This should be witnessed, signed, and dated by another member of clinical staff.

8.10. Completed CD stationery must be retained by the site of use for a **2-year period** from the date of the last entry and must be available for inspection if required. If the stationery contains any record of destruction, it must be retained for an **8-year period.**

8.11. Controlled Drug Registers

8.11.1. Each site of storage, including Trust vehicles, should only have one CD register at any time. Any additional registers must be discussed with and authorised by the Head of Pharmacy.
8.11.2. Registers must be bound (not loose leaf)
8.11.3. CD registers must have a separate page for each strength and formulation of drug. These details must be clearly recorded at the top of each page.
8.11.4. Each page is sequentially numbered: pages must not be removed
8.11.5. Entries should be made in chronological order and must be indelible
8.11.6. When starting a new book or page the current balance must be checked and transferred from the previous page to the top of the new page. The balance transfer must be witnessed by a second registered healthcare professional and must be countersigned
8.11.7. All entries should be signed by a registered healthcare professional and should be witnessed by a second registered healthcare professional. At least one of the registered practitioners must be a substantive member of SCAS staff.
8.11.8. Each time an entry is made the balance of the stock must be physically checked against the register balance. Any discrepancies must be reported as per the Trust Incident Reporting system
8.11.9. If a mistake is made it should be bracketed in such a way that the original entry is still clearly legible. This should be signed, dated, and

Requirements for CD Register stock entries

- Date stock was received
- Formulation of drug received
- Quantity received in dose units
- Serial number of the CD order
- Updated running balance
- Name and signature of person making the entry
- Name and signature of person witnessing the entry
- Entries are written in indelible ink

witnessed by a second registered healthcare professional. The witness should also sign the correction

9. Controlled Drug Security

9.1. For full specification of CD cupboards, CD safes and CD rooms including security requirements refer to the Safe and Secure Handling of Medicines Policy.

9.2. Stock CDs remain the property of the Trust at all times, however all registered clinicians have a professional responsibility to be accountable for the CDs in their possession, on vehicle or in Trust premises.

9.3. Access to CD safes on vehicles is restricted to authorised Trust registered professionals. The only persons allowed access to controlled drugs safes are;

- Any person authorised by the Medical Director
- Registered Paramedics, Pharmacists and Nurses
- Heads of Operations
- Clinical Team Leaders
- Logistics Support Unit personnel authorised by the Logistics Manager

9.4. The registered professional on duty and assigned to the vehicle will have overall responsibility to ensure that CDs are stored, administered, recorded, and handled securely in accordance with Trust policies and SOPs.

9.5. The CDAO may authorise named non-registered staff to carry an individually issued coded ID card that will open the CD safe. A register of these authorized staff will be held in the Medicines Unit.

9.6. Registered staff must not share their authorised ID card with any other member of staff. Non-registered or non-authorised staff must not use an authorised ID card to access CDs with the exception of authorisation by the CDAO as in 9.5

9.7. Controlled Drugs must not be transferred between stations without authorisation from the Head of Pharmacy.

9.8. Controlled Drugs must not be transferred between vehicles.

10. Controlled Drug Storage

10.1. For full storage requirements of CDs in stations, Trust premises and vehicles refer to the Safe and Secure Handling of Medicines Policy.

10.2. Amendments to existing storage areas must not be actioned without authorisation from the Head of Pharmacy.

10.3. New storage areas must be authorised by the Head of Pharmacy.

10.4. For registered professionals in possession of a personal ambulance vehicle see section 18 of this policy.

11. Ordering and Receipt of Controlled Drugs

11.1. Ordering and receipt of CDs by Pharmacy will be carried out in accordance with SOP MEDCD002

11.2. Ordering and receipt of CDs from Pharmacy will be carried out in accordance with SOP MEDCD005

11.3. Ordering and receipt of CDs by Trust vehicles will be carried out in accordance with SOP MEDCD007

11.4. In all cases maintenance of records for CDs will be in accordance with the Trust SOPs and will be consistent with the Misuse of Drugs Regulations 2001.

11.5. Stock levels for stations and vehicles will be determined by the Head of Pharmacy and the Medicines Manager. These levels will be reviewed at a minimum on an annual basis.

12. Supply and/or Administration of Controlled Drugs

12.1. The supply of CDs from Pharmacy will be carried out in accordance with SOP MEDCD004.

12.2. The administration and/or supply of CDs to patients will be carried out in accordance with the Trust Pre-Pack Policy and/or the Trust Administration Policy and SOP MECD011.

12.3. CDs may only be administered by Trust employed registered professionals. Administration must be witnessed by a second employed registered professional wherever feasible.

12.4. For registered professionals working “solo” if possible, the used CD container should be retained and a witness signature obtained wherever possible from a registered professional, either from the attending ambulance crew, a GP, or a registered clinician at the receiving hospital. This witnesses the administering registered professional’s signature and record book balance entry only.

12.5. The CD Register and Patient Clinical Record must be completed on each occasion a schedule 2 or 2 CD are administered.

12.6. Patients own prescribed CDs remain the property of the patient. All patients own drugs should be returned to the patient or relative and advised of appropriate disposal if no longer required. For illicit substances refer to section 23 of this document.

13. Prescribing of Controlled Drugs

13.1. It is not lawful for a doctor or a non-medical prescriber to issue a prescription for a schedule 2 or schedule 3 controlled drug, or for a pharmacist to dispense it, unless it complies with the following requirements in accordance with the Misuse of Drugs Regulations (2001) and associated regulations. In addition to these specific

requirements for CDs, the general prescription requirements as per the Human Medicines Regulations 2012 must also be met.

13.2. The requirements apply to both handwritten and electronic prescriptions

Schedule 2 and 3 CD Prescription Requirements:

- Signature – of the prescriber in indelible ink
- Date – the date on which the prescription was issued. Prescriptions are valid for 28 days
- Prescriber address – this must be in the UK
- Name and address of patient – "no fixed abode" is acceptable. The use of PO Boxes is not
- Drug name
- Drug dose - specify the dose to be taken. For 'when required' medicines a minimum interval for administration should be specified, and a maximum total quantity to be administered in 24 hours.
- Formulation - the prescription must specify the formulation of the preparation (e.g., capsules, tablets, injection), even where only one formulation exists
- Strength - the prescription must specify the strength of the preparation, except where the preparation is only available in one strength. Where a prescription requests multiple strengths of a formulation, each strength should be prescribed separately
- Quantity - specify the total quantity to be supplied **in words and figures** e.g., '*supply 280 (two hundred and eighty) mg*', or '*supply 60 (sixty) capsules*. The quantity should not exceed 30 days' supply.

13.3. Prescriptions written incorrectly will be returned to the prescriber to be re-written. This will result in a delay to the supply of medication.

13.4. If any amendments need to be made, these must also be subsequently signed off by the prescriber.

13.5. The use of sticky patient-ID labels (addressograph labels) should be avoided unless they are tamper-evident. If used, the prescriber should sign the sticky label, ideally so that the signature runs across the label and onto the prescription form. This is as an extra safeguard to ensure sticky labels are not tampered with or covered with another label.

13.6. Further information on prescribing can be found in the 'Prescription Writing' guidance section at the front of the British National Formulary (www.bnf.org)

13.7. Patients known to be addicted to controlled drugs should still be prescribed appropriate treatment, but care must be taken as they may require higher doses of opiates and may have taken extra illicit doses

14. Controlled Drugs in Clinical Trials

14.1. In the event that the Trust participates in a clinical trial involving use of controlled drugs, the management of those drugs must comply with the Misuse of Drugs Regulations, as well as local policies and procedures governing trials medication, clinical trials legislation and MHRA guidance on clinical trials.

15. Unused or Wasted Controlled Drugs

15.1. Where an ampoule or vial is broken or opened and not all the dose is administered the unused medicine must be soaked up in a paper towel and placed in the clinical waste container.

15.2. Any broken ampoules or sharp objects should be disposed of in the yellow sharps bin.

15.3. A record of unused CDs must be made in the CD register/record book and witnessed in the usual way.

15.4. All broken ampoules or vials must be reported on the in line with the Trust Incident Reporting Policy.

16. Expired Controlled Drugs

16.1. CDs may only be destroyed in accordance with SOP MEDCD001

16.2. CDs may only be destroyed by persons formally nominated by the Accountable Officer. All broken ampoules or vials must be reported on the in line with the Trust Incident Reporting Policy.

16.3. The destruction of CDs must be witnessed by a second person and a record made in the CD record book/register in accordance with SOP MEDCD001.

16.4. CDs awaiting destruction should be stored according to the legal requirements detailed in the Safe and Secure Handling of Medicines Policy and separated from other CDs in the cupboard.

16.5. Record of destruction of CDs will be kept for 7 years

17. Vehicle Servicing or Repair

17.1. Where repair/servicing is undertaken on Trust premises CDs may remain on the vehicle and are in the possession of the Trust.

17.2. When a vehicle is to be taken to a third party or off-site for repair or servicing CDs should be managed in accordance with SOP MEDCD009

18. Record Keeping

18.1. A separate CD register must be kept for each of the premises of an organisation

where CDs in schedule 2 are stored, in line with regulation 20 of the 2001 Regulations.

18.2. Controlled drugs registers must be kept for 2 years from the date of the last entry in line with Regulation 23 of the 2001 Regulations

18.3. All entries made in the CD record book/register must be:

18.3.1. Made legibly in indelible black ink
18.3.2. Appear consecutively in date order
18.3.3. Be legible and made at the time of transaction
18.3.4. Quantities record as number of tablets/ampoules (not as number of containers or boxes)
18.3.5. Each unit of issue for administration is signed out on a separate line in the register

18.4. No cancellation, obliteration or alteration of an entry will be made, and any corrections shall be made only by way of marginal note. The error should be bracketed, the error signed and dated in the margin or at the bottom of the page. Under no circumstances should an attempt be made to remove or delete the error e.g., by use of Tippex® or other correction fluid.

18.5. The CD Record Book will be completed by the registered professional and witnessed by a colleague:

18.5.1. Once a week (stock check)
18.5.2. With every administration of a CD
18.5.3. At every reordering/restocking
18.5.4. On the transfer of the vehicle to another registered professional (stock check)

CD Stock Checks

- These must be carried out at least every 7 days; in some areas local policy may require more frequent checking.
- The check must be carried out by two registered healthcare professionals, one of whom should normally be the Responsible Manager in charge of that shift and a permanent member of SCAS staff.
- Where possible, the staff undertaking this check should be rotated periodically.
- The check must be based on the register record, not purely on the contents of the cabinet.

19. Personal Issue of Controlled Drugs

19.1. In specific circumstances staff may be authorised by the Head of Pharmacy and their Line Manager to withdraw Controlled Drugs into personal possession

19.2. Persons authorised to be in personal possession of a Controlled drug will be named on a register held by the SCAS Pharmacy Team

19.3. A registered healthcare professional may carry CDs that have been signed out to their personal possession, meaning that they are personally responsible for the storage, security, handling, and management of that drug.

19.4. The keys of the vehicle and CD storage container must be kept in a secure location.

19.5. Once signed out of the CD register for the storage location the drug must be stored in a suitable storage container authorised by the Head of Pharmacy

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

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

19.8. Registered professionals who are away from work for any period of 72 hours or more (e.g., sickness, annual leave) should store CDs with the CD record book/register in a CD cabinet at a designated Ambulance Station.

19.8.1. CDs must be stored together
19.8.2. The CD stock will be checked by a registered professional delegated responsibility by the Head of Operations or Clinical Operations Manager, who will witness the CD record book/register on handover to and from the ambulance station.
19.8.3. The CDs remain in possession of the Trust
19.8.4. Arrangements will be made for the collection of the CDs from the registered professionals home address where necessary

20. End of Service

20.1. When a registered professional leaves the service the SCAS Medicines Team must be notified scasmedicines@scas.nhs.uk. This will be done through an emailed monthly report as part of the Leavers process.

20.2. For registered professionals in possession of a personal ambulance vehicle, where there is no registered professional taking over the vehicle the remaining CDs must be returned to an ambulance station

20.3. Line managers must ensure that any access to drugs, including CDs, is revoked. This includes collecting the ID badge. ID cards will be informed as part of the leavers process and the card decommissioned.

21. Controlled Drug Losses

21.1. Any incidents involving or relating to the loss or theft of CDs must be reported via the Trust incident reporting system. This includes CD stationery and safe keys.

21.2. The incident reference number must be recorded in the CD record book/register to cross reference the incident report with the entry.

21.3. The Medicines Optimisation and Governance Group will monitor incidents reports and review unusual patterns of administration, loss, or other events.

21.4. The Trust will share CD discrepancies with the CDLIN to enable benchmarking and learning from incidents.

What to do if it is suspected that CDs are missing

- Investigate to determine whether the CDs are really missing:
  - Check CD supplies received have been entered onto the correct page?
  - Have all doses administered been entered into the register, and onto the correct page?
  - Have all CD stock items been put away into the CD cupboard correctly, and into the right place?
  - Is the arithmetic correct for all running balances?
- Report to the Responsible Manager of the ambulance station, and to SCAS Head of Pharmacy
- Complete a DATIX form – ensure that CDAO is included.
- Jointly determine the need for further action
- Consider informing the police
- If the reason for the discrepancy is determined, the Responsible Manager in charge must make an entry in the register showing the reason for the entry, the cause of the discrepancy, and the corrected balance. This entry must be witnessed by a registered healthcare professional.
- The check must be recorded in the register on a separate line for each entry checked.

22. Thames Valley Police & Hampshire Constabulary

22.1. The Controlled Drugs Liaison Officers (CDLO) of the Thames Valley Police and Hampshire Constabulary will support the Accountable Officer and the Chair of the Medicines Optimisation and Governance Group in ensuring compliance with legislation and investigating discrepancies, loss, and theft.

22.2. The CDLOs may also conduct visits, both announced and unannounced, to SCAS premises to ensure that the legislation in respect of CDs is being adhered to. Where such visits take place, a formal report will be given to the SCAS, and the Accountable Officer Chair of the Medicines Optimisation and Governance Group will compile an Action Plan. Both the report and the Action Plan will be submitted formally to the next available Patient Safety Group meeting and detailed within the next scheduled quarterly report to the Controlled Drugs Local Intelligence Network Meeting.

22.3. The police may ultimately prosecute an individual or organisation where they consider that the regulations have not been complied with.

23. Station Closures

22.1. The Head of Pharmacy and Medicines Team should be notified of all planned and unplanned station closures

22.2. During a short-term station closure CDs will be removed and temporarily stored by the Medicines Unit

22.3. During a long-term or permanent station closure the stock will be removed and returned, along with the CD register and order book, to the Medicines Unit. Stock will be returned and re-used if possible, or will be destroyed appropriately if necessary following approved SOPs

22.4. The Responsible Manager, should, with another registered healthcare professional carry out a full stock check, confirming that all stock balances are accurate.

22.5. The SOP MEDCD012 must be followed during the event of a station closure.

22.6. When the ambulance station re-opens the reverse processes will occur.

22.7. If a station moves location, a decision must be made as to whether the CD stock and stationery must also be transferred. This decision will be made in conjunction with the Head of Pharmacy.

24. Illicit Substances

23.1. It is not acceptable for patients to use or abuse illicit drugs or solvents while in the care of the Trust.

23.2. The patient's healthcare is paramount and should be the first priority for responding crews. Staff are not expected to search patients, or their homes, for illicit substances, whether use is suspected or not.

23.3. If a quantity of illicit drugs is present in a public setting there is a duty of care to the public to report this to the police.

23.4. Any illicit substances that are removed from patient possession should under no circumstances be returned to the patient as this constitutes a supply.

23.5. In the event of police co-responding to a scene they are best placed to manage any quantity of illicit drug found on scene.

23.6. In the event a patient is conveyed to hospital in possession of any illicit substances, a registered healthcare professional at the receiving unit should be notified to their presence. The receiving unit should have their own policies for the management of illicit substances.

25. Audit and Stock Check

25.1. All CD stock checks will be carried out as described in SOP MEDCD010

25.2. CDs will be stock checked and reconciled by each site/station at least once a week, or more frequently when requested by the CDAO.

25.3. Vehicle stock will be checked at each change of shift and witnessed

25.4. Where a vehicle is off the road for a period of 24 hours or more (and will be in possession of the CD), a delegated registered nurse or paramedic will undertake a daily stock check

25.5. Personal vehicle stock will be checked at least once a week, or more frequently when requested by the CDAO.

25.6. CD stock checks and audits will be reported to the Medicines Optimisation and Governance Group.

26. Training

26.1. All registered clinical staff will receive CD training as part of Trust induction and refresher training periodically.

26.2. All other staff involved in the management or handling of CDs will receive relevant training at induction and refresher training annually

26.3. All staff will read and sign the relevant SOPs when joining the Trust and when the SOPs are updated

26.4. Any additional training on CDs will be agreed by the Trust's Workforce Board.

27. Equality and Diversity

27.1. An initial screen equality and diversity impact assessment has been carried out on this policy and, as per appendix 3 is available on request.

28. Monitoring

The effectiveness of this policy will be monitored in the following way.

Standard/ process / issue	Monitoring and audit			
	Method	By	Committee	Frequency
a. Controlled Drug stock and administration errors will be reviewed	All errors reported on the Datix system will be documented	Lead Pharmacist	Medicines Optimisation and Governance Group	Quarterly
b. The weekly stock checks for each ambulance station will be recorded.	A spreadsheet will be maintained of all weekly stock checks declared to the CDAO.	Medicines Manager	Medicines Optimisation and Governance Group	6 monthly
c. The Trust will self-audit annually against the CQC self-assessment tool	Self-audit against the CQC primary care self-assessment tool	Lead Pharmacist	Medicines Optimisation and Governance Group	Annually

29. Consultation and Review

29.1. A consultation exercise on the policy will be carried out with the stakeholders every 3 years, or less if there are any relevant changes to legislation or best practice.

30. Implementation (including raising awareness)

30.1. The policy will be implemented and communicated to managers and staff within the Trust via weekly newsletter, Staff Matters. Emails will also be sent to senior managers and area managers asking them to bring the existence of the policy to their staff.

31. References

- Care Quality Commission (2019) Controlled Drugs Governance Self-Assessment Tools
- UK Public General Acts The Misuse of Drugs Act (1971)
- UK Statutory Instruments The Misuse of Drugs Regulations (2001)
- UK Statutory Instruments The Misuse of Drugs (Safe Custody) Regulations (1973)
- UK Public General Acts The Health Act (2009)
- UK Statutory Instruments The Human Medicines Regulations (2012)
- UK Statutory Instruments The Controlled Drugs (Supervision of Management and Use) Regulations 2013
- UK Statutory Instruments The Human Medicines (Amendment) Regulations, Statutory Instrument No. 199 (2018)
- UK Statutory Instruments Misuse of Drugs (Amendment No.2) (England, Wales and Scotland) Regulations Statutory Instrument No. 973. (2012)
- UK Statutory Instruments 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, Controlled Drugs Safe Use and Management (April 2016)
- Security standards and guidance for the management and control of controlled drugs in the ambulance sector. Version 3 NHS Protect (March 2017)
- UK Statutory Instruments Controlled Waste (England and Wales) Regulations (2012)
- Confidentiality, NHS Code of Practice, Department of Health, (November 2003)
- Records Management, NHS Code of Practice (Part 2), NHSX, January (2021)
- Professional guidance on the safe and secure handling of medicines, Royal Pharmaceutical Society (December 2018)

32. Associated Documentation

32.1. There are also the following documents associated with this policy:

- Adverse Incident Reporting and Investigation Policy
- Medicines Administration Policy
- Medicines Management Policy
- Prescription Management and Security Policy
- Patient Group Direction Policy
- Safe and Secure Handling of Medicines Policy
- SOP MEDCD001 Destruction of Controlled Drugs
- SOP MEDCD002 Ordering and Receipt of CDs by Pharmacy
- SOP MEDCD003 Emergency procedures in transport of CDs
- SOP MEDCD004 Ordering CDs from Pharmacy
- SOP MEDCD005 Issue of CDs by Pharmacy
- SOP MEDCD006 Delivery and Receipt of CDs from Pharmacy
- SOP MEDCD007 Management of CDs at Resource Centres
- SOP MEDCD008 Order and Receipt of CDs by vehicles
- SOP MEDCD009 Controlled Drug storage for vehicles off road

- SOP MEDCD010 Controlled Drug stock check process
- SOP MEDCD011 Administration of Controlled Drugs
- SOP MEDCD013 Personal Issue and Possession of Controlled Drugs

33. Appendix 1: Controlled Drug Safe Specification

Emergency vehicles

- The Salto Lock safes will be fitted in the rear or side of the vehicle either directly to the floor or in an unmarked cupboard.
- The safe will be bolted to the side, floor or in a cupboard with the minimum of two M8 8.8 bolts, which **can only** be accessed from within the safe.
- The use of M8 8 lock nuts will be used if accessible or if not then *Versa nuts* will be employed.
- All fixings will be through the metal structure of the vehicle, cupboard walling or flooring
- Should lock nuts be utilised these will terminate within the safe if possible.
- Access to the CD Safes can only be accessed via the staffs ID Cards and authorised staff only

The exact positioning is agreed with the vehicle convertor at the specification meeting prior to build.

All SRV'S have tinted windows which ensures that safes will not be visible from the outside of the vehicle. There is also an interface fitted to the vehicle to allow the vehicles engine to keep running and lock the vehicle, should anyone try to move the vehicle the engine will automatically shut down.

(1) The property of a bolt is identified by two numbers separated by a decimal point. The first number equals 1/100th of the minimum tensile strength. the second is a number that is 10 times the ratio of the yield point in relation to the tensile strength. Multiplying the two numbers gives 1/10 of the minimum yield point (example: 8.8> Re = Rp0.2 = 640MPa). The property class of a standard nut is identified by one number. This number corresponds to 1/100 of the minimum tensile strength of a bolt of the same property class.

Versa nuts have a pull-out resistance as below:
Versa nut fitted into 0.76mm steel would withhold 5.4KN.
All fixing will have a form of thread locking devise, and a washer to spread the loads.

34. Appendix 2: Review Table

34.1. This policy is regularly reviewed and updated with information in line with relevant national guidance and legislation. A full "Review Table of contents" is available on request.

35. Appendix 3: Responsibility

35.1. The responsibility for this policy is shared between various Policy Groups, Lead Directors/Officers, Working Groups and Committee members.

35.2. A full list of responsible parties can be made available on request.

36. Appendix 4: Equality Impact Assessment – Screening

36.1. An initial screening equality impact assessment has been carried out and has identified that the policy does not have an adverse or detrimental impact on any of the proscribed equality groups as the policy is designed to protect all staff who carry out work for or on behalf of the Trust.

36.2. The screening element of the initial "Equality Impact Assessment" is available on request.

37. Appendix 5: Equality Impact Assessment Form – Section Two – Full assessment

37.1. Due to the outcome of the initial screening equality impact assessment, it has not been necessary to carry out a full equality impact assessment.

38. Appendix 6: Ratification

Policy Title: Controlled Drugs Policy

Author's Name and Job Title: Victoria Bray, Consultant Pharmacist

Review Deadline: 26/09/22

Consultation From – To (dates): 05/09/22 – 26/09/22

Comments Received? (Y/N): Y

All Comments Incorporated? (Y/N): Y

If No, please list comments not included along with reasons:

Equality Impact Assessment completed (date): 20/08/22

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Name of Accountable Group: Clinical Review Group

Date of Submission for Ratification: 04/08/22

Template Policy Used (Y/N): Y

All Sections Completed (Y/N): Y

Monitoring Section Completed (Y/N): Y

Date of Ratification: 01/09/22

Date Policy is Active: 01/11/22

Date Next Review Due: 01/07/24

Signature of Accountable Group Chair (or Deputy):

Name of Accountable Group Chair (or Deputy): John Black, Medical Director