

CONTROLLED DRUGS

(Medicines Management Reference MO4)

Policy

CONTENTS

1.0	INTRODUCTION	3
2.0	DEFINITIONS	3
3.0	ROLES and RESPONSIBILITIES	3
4.0	PROCESS DESCRIPTION	4
5.0	TRAINING/COMPETENCE REQUIREMENTS	5
6.0	MONITORING COMPLIANCE AND EFFECTIVENESS	6
7.0	COUNTER FRAUD	7
8.0	REFERENCES	7
9.0	DOCUMENT CONTROL	8
	APPENDIX A: CONTROLLED DRUGS SCHEDULE	9

For the avoidance of any doubt, please note that the Standard Operating Procedures listed below are available on the Staff Intranet under [Operational Services > Medicines > Controlled Drugs](#) and are not attached to this document.

Standard Operating Procedures

- SOP1 – Requisitioning Controlled Drugs
- SOP2 – Receipt of Controlled Drugs
- SOP3 – Storage of Controlled Drugs
- SOP4 – Key-holding and access to Controlled Drugs
- SOP5 – Record-keeping of Controlled Drugs
- SOP6 – Management of Controlled Drugs that are the patient's property
- SOP7 – Disposal/Destruction of Controlled Drugs on wards
- SOP8 – Prescribing Controlled Drugs for inpatients / discharge patients / outpatients
- SOP9 – Administration of Controlled Drugs
- SOP10 – Controlled Drugs stationery
- SOP11 – Access to Controlled Drugs Out of Hours
- SOP12 – Controlled Drugs checks by ward staff
- SOP13 – Controlled Drugs checks by pharmacy staff
- SOP14 – Discrepancies / diversion of Controlled Drugs
- SOP15 – Dealing with illegal Controlled Drugs / substances
- SOP16 – Monitoring the prescribing of Controlled Drugs
- SOP17 – Handling of Controlled Drugs in the community

1.0 INTRODUCTION

- 1.1 Controlled drugs (CD) are subject to special legislative controls because there is a potential for them to be abused or diverted causing possible harm. The new strengthened governance arrangements for Controlled drugs and legislative changes that flow from the Government response to the fourth report of the Shipman inquiry impose significant new responsibilities on healthcare organisations.
- 1.2 Strengthened controls need to be implemented in a way that supports professionals and encourages good practice around the management and use of these important medicines when clinically required by patients.
- 1.3 The purpose of this policy is to promote the safe, secure and effective use of Controlled drugs and to set out the Somerset Partnership NHS Foundation Trust's policy on the management and governance of Controlled drugs in accordance with statutory requirements
- 1.4 The policy applies to all areas where Controlled drugs are used and to all staff who handle Controlled drugs.

2.0 DEFINITIONS

- 2.1 Controlled drugs are those defined in the current Misuse of Drugs Regulations 2001 (as amended) (MDR). The MDR classify the drugs in five schedules according to the different levels of control required.
- 2.2 The levels of control required are summarised in **Appendix A: Controlled Drugs Schedule**.

The Trust requires the following additional control measures to be in place even though they are not a legal requirement:

- Morphine sulfate oral solution 10mg in 5ml (schedule 5) stock must be requisitioned in the controlled drug order book.
- The receipt of stock and administration of all formulations of buprenorphine (schedule 3) must be recorded in the controlled drug record book.

3.0 ROLES and RESPONSIBILITIES

- 3.1 The **Chief Executive** is ultimately responsible for ensuring the Trust complies with legal requirements and national recommendations for medicines management.
- 3.2 The **Trust Board** has a responsibility to ensure training and competency assessment is available to all relevant staff.
- 3.3 The **Chief Medical Officer** is the Executive Lead responsible for this policy covering safe medicines practice within the Trust, but will delegate authority for the operational implementation and on-going management of this policy to the **Accountable Officer**.

- 3.4 Regulations made under the Health Act 2006 require the Trust to appoint an **Accountable Officer**, responsible for the safe and effective use of Controlled drugs in their organisation.
- 3.5 The **Trust** is accountable through the **Accountable Officer** for ensuring the safe management of Controlled drugs. The **Trust** has a responsibility to assure the quality of its CD management as an integral part of its clinical governance processes.
- 3.6 The **Care Quality Commission** is responsible for overseeing the management of Controlled drugs by healthcare organisations in England.
- 3.7 The **registered nurse in charge** is responsible for the safe and appropriate management of Controlled drugs in their area.
- 3.8 All staff involved in the handling of Controlled drugs must follow the processes outlined in this policy and the Standing Operating Procedures relevant to their practice.

4.0 PROCESS DESCRIPTION

Accountable Officer

- 4.1 The Trust must ensure that it has an Accountable Officer in place at all times and that the Accountable Officer is registered with the Care Quality Commission.
- 4.2 The Accountable Officer must be an Executive Director of the Trust or someone who reports directly to an Executive Director. The Accountable Officer must not personally be involved in the routine prescribing, supply, administration or disposal of Controlled drugs.
- 4.3 The Accountable Officer for Somerset Partnership is the Chief Pharmacist and reports directly to the Chief Medical Officer with regards to Accountable Officer responsibilities.
- 4.4 The Accountable Officer is responsible for all aspects of the safe and secure management of Controlled drugs in the organisation. This includes ensuring that the organisation has safe systems in place for the management and use of Controlled drugs, monitoring and auditing of the management systems and investigation of concerns and incidents related to Controlled drugs. The Accountable Officer must assess, investigate and retain records of concerns regarding management or use of Controlled drugs by relevant individuals. The Accountable Officer is responsible for ensuring that adequate training is provided by the Trust for all relevant staff that handle Controlled drugs.
- 4.5 The Trust will provide its Accountable Officer with the funds and other resources necessary to enable him to carry out his responsibilities as its Accountable Officer. This will include investigative and administrative support.
- 4.6 During short periods of absence of Accountable Officer the Deputy Chief Pharmacist will cover the role of Accountable Officer.

- 4.7 If staff have concerns about the practice of the Accountable Officer they should approach the Chief Medical Officer.

Local Intelligence Network

- 4.8 The Trust collaborates with the Local Intelligence Network (known as the CD LIN) of other healthcare organisations, police forces, social services authorities and the relevant inspection and regulatory bodies to enable them to share information about potential CD offences and potential or actual systems failures.

Policy and Procedures

- 4.9 Each of the activities that relate to Controlled Drugs, regardless of where in the organisation they occur, must be described in a Standard Operating Procedure (SOP).
- 4.10 Standard Operating Procedures will be formally approved by the Accountable Officer and the Medicines Oversight Group. They will be kept up to date, reflecting current legal and good practice requirements for Controlled drugs.
- 4.11 Healthcare staff in the organisation must work to Standard Operating Procedures that are appropriate to their area of work.
- 4.12 The activities covered by Standard Operating Procedures are listed below. Additional SOPs may be developed according to operational needs. All SOPs are available on the Staff Intranet under [Operational Services>Medicines>Controlled Drugs](#).
1. Requisitioning Controlled Drugs
 2. Receipt of Controlled Drugs
 3. Storage of Controlled Drugs
 4. Key-holding and access to Controlled Drugs
 5. Record-keeping of Controlled Drugs
 6. Management of Controlled Drugs that are the patient's property
 7. Disposal/Destruction of Controlled Drugs on wards
 8. Prescribing Controlled Drugs for inpatients/discharge patients
 9. Administration of Controlled Drugs
 10. Controlled Drugs stationery
 11. Access to Controlled Drugs Out of Hours
 12. Controlled Drugs checks by ward staff
 13. Controlled Drugs checks by Medicines Management staff
 14. Discrepancies and diversion of Controlled Drugs
 15. Dealing with illegal substances
 16. Monitoring the prescribing of Controlled Drugs
 17. Handling of Controlled Drugs in the community

5.0 TRAINING/COMPETENCE REQUIREMENTS

- 5.1 The Trust will work towards all staff being appropriately trained in line with the organisation's Staff Mandatory Training Matrix (training needs analysis). All training

documents referred to in this policy are accessible to staff within the Learning and Development Section of the Trust Intranet.

- Medicines Management
- Medicine Management Competency Assessment
- Anaphylaxis
- Basic Life Support

5.2 All staff who are involved in the prescribing, administering or disposing of Controlled drugs need to be familiar with the Standard Operating Procedures.

5.3 Staff should receive appropriate training on local Standard Operating Procedures for Controlled drugs when they first become involved in prescribing, administering or disposing of Controlled drugs and then regularly thereafter as described in the Mandatory Training Matrix.

5.4 Staff will be informed and, if necessary receive additional training when Standard Operating Procedures are revised or amended and when new CD products or systems are introduced.

6.0 MONITORING COMPLIANCE AND EFFECTIVENESS

Monitoring arrangements for compliance and effectiveness

6.1 The Accountable Officer must provide quarterly reports to the Medicines Oversight Group.

Responsibilities for conducting the monitoring

6.2 Appropriate arrangements must be in place for monitoring and auditing the management and use of Controlled drugs. These must include:

- Regular stock balance and record checks by ward staff (see SOP CD12).
- Monthly review and report by ward staff.
- Periodic inspections of wards by medicines management staff (see SOP CD13).
- Monthly monitoring and analysing of prescribing by medicines management team.
- Accountable Officer will analyse and respond to untoward incidents as and when they occur.

Methodology to be used for monitoring

6.3 Prescribing will be monitored using ADiOS or similar computer software.

Any incident involving Controlled Drugs must be reported to the Accountable Officer without delay.

7.0 COUNTER FRAUD

- 7.1 The Trust is committed to the NHS Protect Counter Fraud Policy – to reduce fraud in the NHS to a minimum, keep it at that level and put funds stolen by fraud back into patient care. Therefore, consideration has been given to the inclusion of guidance with regard to the potential for fraud and corruption to occur and what action should be taken in such circumstances during the development of this procedural document.
- 7.2 Loss or theft of any CD stationery which may be used to order controlled drugs should be reported without delay to the registered nurse in charge, supply pharmacy staff and the Accountable Officer.
- 7.3 If no errors or omissions can be traced any discrepancy in controlled drug stocks should be reported to the Accountable Officer.
- 7.4 Any loss of controlled drug stocks or controlled drug stationery will be investigated by the Accountable Officer and the Trust Counter Fraud Manager and reported to the police where appropriate. Details of the investigations or intelligence gathered by the Accountable Officer will not ordinarily be disclosed upon request in accordance with the law enforcement “exemption” (Section 31) of the Freedom of Information Act 2000.

The Accountable Officer has the ability to process and share special categories of personal data (sensitive personal data) in accordance with the Accountable Officer’s statutory duties and responsibilities under the exemptions set out in General Data Protection Regulation ((EU) 2016/679) (GDPR) Article 9(2)(g) and Data Protection Act 2018 Section 10 and Part 2 of Schedule 1.

- 7.5 Any member of staff who suspects fraudulent activity involving Controlled Drugs or their management should report this to their Line Manager or Counter Fraud Manager and the Accountable Officer.

8.0 REFERENCES

- 8.1 The management of Controlled Drugs is governed by the following legislation and guidance:
- Misuse of Drugs Act (1971) and its associated regulations
 - Health Act 2006
 - Controlled drugs (Supervision of Management and Use) Regulations 2013
 - Safer Management of Controlled drugs: (1) Guidance on Strengthened Governance Arrangements (DH 2007)
 - Safer Management of Controlled drugs: a guide to good practice in secondary care (England) (DH 2007)
 - The Safe and Secure Handling of Medicines (2005): A revision of the Duthie Report (1988)
 - Royal Pharmaceutical Society: Professional guidance on the safe and secure handling of medicines (2018)
 - Misuse of Drugs (Safe Custody) Regulations 1973
 - The Human Medicines Regulations 2012

8.2

Cross-reference to other procedural documents:

- Anti-Fraud, Bribery and Corruption Policy
- Healthcare Waste (Clinical Waste) Policy
- Searching Mental Health Inpatients, Visitors and Personal Property Policy
- Substance Use Management on Trust Premises Policy
- Syringe Driver Policy
- End of Life Care Policy
- Just in Case Policy
- Learning Development and Mandatory Training Policy
- FP10 Prescription Form Policy
- Medicines Policy
- Risk Management Policy and Procedure
- Staff Training Matrix (Training Needs Analysis)
- Untoward Event Reporting Policy and Procedure
- Whistleblowing Policy
- Record Keeping and Records Management Policy

All current policies and procedures are accessible in the policy section of the public website (on the home page, click on 'Policies and Procedures'). Trust Guidance is accessible to staff on the Trust Intranet.

9.0 DOCUMENT CONTROL

Document Author		Accountable Officer for Controlled Drugs	
Lead Owner		Chief Medical Officer	
This Version	8	Status	Final
Replaces	7		
Approval date	12 June 2019	Where	Medicines Oversight Group
Ratification date	12 July 2019	Where	SP Policy Review Group
Date of issue	12 July 2019	Review date	July 2022
Applies to	All staff involved with Controlled Drugs	Exclusions	

CONTROLLED DRUG SCHEDULE

Schedules	Drugs (<i>Not comprehensive</i>)	Requisitions	Storage in CD Cupboard	Records in CD record book	Prescription requirements	Validity of FP10s and discharge prescriptions	Disposal
Schedule 2 CD	Alfentanyl Dipipanone Diamorphine Dexamfetamine Fentanyl Medicinal cannabis Methadone Methylphenidate Morphine Oxycodone Lisdexamfetamine Tapentadol	Yes	Yes	Yes	Yes	28 days	Destruction on ward in presence of Authorised Witness
Schedule 3 CD No Reg	Buprenorphine Midazolam Phenobarbitone Temazepam Tramadol Gabapentin Pregabalin	Yes Yes Yes Yes Yes Yes Yes	Yes No No Yes ² (stock) No No No	Yes ¹ No No No No No No	Yes Yes Yes Yes Yes Yes Yes	28 days 28 days 28 days 28 days 28 days 28 days 28 days	Destruction on ward in presence of Authorised Witness ¹
Schedule 5 CD Inv	Morphine Sulfate (Oramorph) 10mg in 5ml	Yes ¹	No	No	No	6 months	Dispose of as any other pharmaceutical waste

Note: This applies to both stock and Patients' Own Drugs except where specified for Discharge Prescriptions (see below)

¹ Trust agreed position not legal requirement

² Not necessary for Discharge prescriptions