Somerset Partnership NHS
NHS Foundation Trust

CONTROLLED DRUG POLICY

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DOCUMENT CONTROL

Reference	**Version**	**Status**	**Author**
AB/Oct14/CDP	7	Final	Accountable Officer for Controlled drugs
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1. 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.

2. PURPOSE & SCOPE

2.1 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.

2.2 The policy applies to all areas where Controlled drugs are used and to all staff who handle Controlled drugs.

3. DUTIES AND RESPONSIBLITIES

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 **Medical Director** 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. EXPLANATIONS OF TERMS USED

4.1 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.

4.2 The levels of control required are summarised below:-

CONTROLLED DRUGS SCHEDULES

Schedules	Drugs *(Not comprehensive)*	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 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	Yes	Yes	Yes[1]	Yes	28 days	Destruction on ward in presence of Authorised Witness[1]
	Midazolam	Yes	No	No	Yes	28 days	
	Phenobarbitone	Yes	No	No	Yes	28 days	
	Temazepam	Yes	Yes[2] (stock)	No	Yes	28 days	
	Tramadol	Yes	No	No	Yes	28 days	
Schedule 5 CD Inv	Morphine Sulfate 10mg in 5ml (Oramorph)	Yes[1]	No	No	No	6 months	Dispose of as any other pharmaceutical

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

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.

5. POLICY

Accountable Officer

5.1 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.

5.2 The Accountable Officer should be an Executive Director of the Trust or someone who reports directly to an Executive Director. The

Accountable Officer should not personally be involved in the routine prescribing, supply, administration or disposal of Controlled drugs.

5.3 The Accountable Officer for the Somerset Partnership is the Chief Pharmacist.

5.4 The Accountable Officer is responsible for all aspects of the safe and secure management of Controlled drugs in the organisation. This includes ensuring that safe systems are 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.

5.5 The Trust must provide its Accountable Officer with the funds and other resources necessary to enable him to carry out his responsibilities as its Accountable Officer. This should include investigative and administrative support.

5.6 During the absence of the Accountable Officer the Medical Director will cover the role of Accountable Officer.

5.7 If staff have concerns about the practice of the Accountable Officer they should approach the Medical Director.

Local Intelligence Network

5.8 The Trust must collaborate with the local intelligence network 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

5.9 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).

5.10 Standard Operating Procedures should be formally approved by the Accountable Officer and the Trust Drugs and Therapeutics Group. They should be kept up to date, reflecting current legal and good practice requirements for Controlled drugs.

5.11 Healthcare staff in the organisation must work to Standard Operating Procedures that are appropriate to their area of work.

5.12 The activities covered by Standard Operating Procedures are listed below and are appended to the policy.

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. Issuing Controlled Drug stationery
12. Access to Controlled drugs Out of Hours
13. Controlled drugs checks by ward staff
14. Controlled drugs checks by medicines management staff
15. Discrepancies and diversion of Controlled drugs
16. Dealing with illegal substances
17. Monitoring the Prescribing of Controlled drugs
18. Handling of Controlled drugs in the Community

6. TRAINING REQUIREMENTS

6.1 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

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

6.3 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.

6.4 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.

7. EQUALITY IMPACT ASSESSMENT

7.1 All relevant persons are required to comply with this document and must demonstrate sensitivity and competence in relation to the nine protected characteristics as defined by the Equality Act 2010. In addition, the Trust has identified Learning Disabilities as an additional tenth protected characteristic. If you, or any other groups, believe you are disadvantaged by anything contained in this document please contact the Equality and Diversity Lead who will then actively respond to the enquiry.

8. MONITORING COMPLIANCE AND EFFECTIVENESS

Monitoring arrangements for compliance and effectiveness

8.1 The Accountable Officer must provide quarterly reports to the Drugs and Therapeutics Group.

Responsibilities for conducting the monitoring

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

- Weekly stock balance and record checks by ward staff.
- Monthly review and report by ward staff.
- Quarterly inspections of wards by medicines management staff.
- 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

Prescribing will be monitored using Adios or similar computer software.

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

9. COUNTER FRAUD

9.1 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.

9.2 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.

9.3 If no errors or omissions can be traced any discrepancy in controlled drug stocks should be reported to the Accountable Officer.

9.4 Any loss of controlled drug stocks or controlled drug stationery will be investigated by the Accountable Officer and the NHS Protect Counter Fraud Specialist and reported to the police where appropriate.

9.5 Any member of staff who suspects fraudulent activity should report this to their Line Manager and the Accountable Officer.

10. RELEVANT CARE QUALITY COMMISSION (CQC) REGISTRATION STANDARDS

10.1 Under the **Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3), the fundamental standards** which inform this procedural document, are set out in the following regulations:

Regulation 9:	Person-centred care
Regulation 10:	Dignity and respect
Regulation 11:	Need for consent
Regulation 12:	Safe care and treatment
Regulation 13:	Safeguarding service users from abuse and improper treatment
Regulation 15:	Premises and equipment
Regulation 16:	Receiving and acting on complaints
Regulation 20:	Duty of candour
Regulation 20A:	Requirement as to display of performance assessments.

10.2 Under the **CQC (Registration) Regulations 2009 (Part 4)** the requirements which inform this procedural document are set out in the following regulations:

Regulation 16:	Notification of death of service user
Regulation 17:	Notification of death or unauthorised absence of a service user who is detained or liable to be detained under the Mental Health Act 1983
Regulation 18:	Notification of other incidents

10.3 Detailed guidance on meeting the requirements can be found at http://www.cqc.org.uk/sites/default/files/20150311%20Guidance%20for%20providers%20on%20meeting%20the%20regulations%20FINAL%20FOR%20PUBLISHING.pdf

11. REFERENCES, ACKNOWLEDGEMENTS AND ASSOCIATED DOCUMENTS

11.1 References

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)
Misuse of Drugs (Safe Custody) Regulations 1973
The Human Medicines Regulations 2012

11.2 **Cross reference to other procedural documents**

Development & Management of Procedural Documents

Just in Case Policy

Learning Development and Mandatory Training Policy

Medicines Policy

Risk Management Policy and Procedure

Staff Training Matrix (Training Needs Analysis)

Untoward Event Reporting Policy and procedure

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.

12 APPENDICES

12.1 For the avoidance of any doubt the appendices in this policy are to constitute part of the body of this policy and shall be treated as such.

Appendix A	CD Standard Operating Procedure 1 - Requisitioning Controlled Drugs
Appendix B	CD Standard Operating Procedure 2 - Receipt of Controlled Drugs
Appendix C	CD Standard Operating Procedure 3 - Storage of Controlled Drugs
Appendix D	CD Standard Operating Procedure 4 - Key-holding and access to Controlled Drugs
Appendix E	CD Standard Operating Procedure 5 - Record-keeping of Controlled Drugs
Appendix F	CD Standard Operating Procedure 6 - Management of Controlled Drugs that are the patient's property

Appendix G	CD Standard Operating Procedure 7 - Disposal/Destruction of Controlled Drugs on Wards
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Appendix N	CD Standard Operating Procedure 14 - Controlled Drugs checks by medicines management staff
Appendix O	CD Standard Operating Procedure 15 - Discrepancies and diversion of Controlled drugs
Appendix P	CD Standard Operating Procedure 16 - Dealing with illegal substances
Appendix Q	CD Standard Operating Procedure 17 - Monitoring the Prescribing of Controlled Drugs
Appendix R	CD Standard Operating Procedure 18 - Handling of Controlled Drugs in the Community

Appendix A

CD Standard Operating Procedure 1

TITLE	REQUISITIONING CONTROLLED DRUGS
Purpose	To ensure that all requisitioning for controlled drugs comply with the requirements of the Misuse of Drugs Act and Trust Policy
Scope	Applies to all registered nurses requisitioning controlled drugs and medical staff
Responsibilities	Registered nurse in charge of the ward and medical staff

1. PROCEDURE

1.1 The registered nurse in charge of the ward is responsible for the requisitioning of controlled drugs for use in that area. The registered nurse in charge can delegate the task of preparing a requisition to another registered nurse but the responsibility remains with the registered nurse in charge.

1.2 A form of authorisation should be completed for all registered nurses who may need to order controlled drugs. The completed forms should be available in the supply pharmacy for validation. Only nurses who have this authorisation should order controlled drugs.

1.3 In addition an authorised doctor or independent prescriber must countersign all requisitions for controlled drugs.

1.4 Requisitions for controlled drugs for ward stock must be written in the CD order book.

1.5 Requisitions to Yeovil District Hospital for discharge medicines that include a controlled drug must be written in the CD order book.

1.6 A separate page must be used for each item. Ensure that the carbon is placed between the white and pink sheets of the requisition and it is the correct way round.

1.7 The requisition must be completed clearly and include the following:

- Name and address of ward
- Drug name, strength and form
- Quantity in words and figures
- Date
- Signature and printed name of authorised registered nurse
- Signature and printed name of authorised doctor

1.8 **For units supplied by Lloydspharmacy only -** a Controlled Drug (CD) Order Alert Form should also be completed and faxed to the supply pharmacy and the driver will then collect the completed CD order book on the next scheduled delivery.

1.9 The CD order book with completed white and pink copies must be sent to the supply pharmacy as the controlled drugs cannot be released until the CD order book is received.

2. ADDITIONAL INFORMATION

2.1 Temazepam, tramadol, midazolam, phenobarbitone and morphine sulfate oral solution 10mg in 5ml will all be requisitioned in the controlled drug order book.

2.2 The quantity ordered for stock should be in an original pack size.

2.3 The ward manager / hospital matron should ensure that a form of authorisation is completed for all registered nurses who may need to order controlled drugs. The completed form should be sent to the supply pharmacy and a copy emailed to the Accountable Officer for the Trust. Ward managers should have a blank copy of the authorisation form, which is also available from the Accountable Officer for the Trust (01823 368265).

2.4 Human Resources will collect the signatures of all doctors employed by or contracted to work in the Trust. Within the Mental Health Directorate they will check that the doctor is on the GMC register and that there are no restrictions relating to controlled drugs. HR will authorise the signatures and will be responsible for faxing a copy to the supply pharmacy and to the Accountable Officer. Within the Community Health Directorate, the Community Hospital Matron will identify each doctor who will authorise controlled drugs at their community hospital and notify HR. HR will check that the doctor is on the GMC register and that there are no restrictions relating to controlled drugs. HR will authorise the signatures and will also be responsible for faxing a copy to the supply pharmacy, the relevant community hospital matron and to the Accountable Officer.

2.5 It is a legal requirement that orders are signed by a medical practitioner or independent prescriber. Additionally the doctor countersigns the order as an independent verification that the controlled drugs ordered are to be used within the requesting ward within the Trust. The doctor will not be responsible for the management and accountability for the controlled drugs within the ward. This responsibility lies with the registered nurse in charge of the ward.

2.6 The responsibilities of the doctor will be:

- To witness the signature of the registered nurse who has completed the requisition order
- To confirm the signature of the registered nurse as being that of the nurse in charge of the ward at the time
- To confirm that there is either a patient on the ward prescribed that CD or that there is a planned elective admission of a patient known to be prescribed that CD.

2.7 The returned order book should have the date and signature of the person issuing from the pharmacy (on pink copy).

2.8 The CD order book should be stored securely and access to it should be restricted. It should be kept in a locked cupboard or drawer.

2.9 Only one CD stock order book should normally be in use at any time, but a maximum of two are allowed when required to obtain supplies from Yeovil District Hospital.

Appendix B

C D Standard Operating Procedure 2

TITLE	RECEIPT OF CONTROLLED DRUGS
Purpose	To ensure that the receipt of all stock controlled drugs complies with the requirements of the Misuse of Drugs Act and Trust Policy
Scope	Applies to registered nurses involved in the process of receiving controlled drugs
Responsibilities	Registered nurse in charge of the ward or clinician with responsibility for CD stock at the location

1. PROCEDURE

1.1 A registered nurse or relevant clinician must receive controlled drugs when they are delivered to the ward or relevant location (e.g. dental clinic). They must sign the transport sheet confirming that they have received the container.

1.2 Controlled drugs delivered to the ward or relevant location must be dealt with as soon as possible. On no account should the controlled drugs be left unattended.

1.3 The registered nurse or relevant clinician must check the controlled drugs against the requisition, including the name and strength of the drug, the formulation and number ordered and received. Any tamper evident seals on packs should be left intact when they are checked.

1.4 If correct then the received by section of the requisition (pink copy) in the order book must be signed and dated.

1.5 Any unendorsed discrepancy must be reported to the supply pharmacy immediately.

1.6 The Controlled drugs (except temazepam, tramadol, midazolam, phenobarbitone and morphine sulfate oral solution 10mg in 5ml) must be entered into the CD record book on the appropriate page including a note of any discrepancy. The running balance must be updated and must tally with the quantity that is physically present. This must be witnessed by a second registered nurse or other registered health professional.

1.7 The controlled drugs must be placed in the controlled drugs cupboard.

1.8 If controlled drugs sent in error cannot be safely used on the ward or at the location the supply pharmacy should arrange for their return. An untoward event form should be completed.

2. ADDITIONAL INFORMATION

2.1 All controlled drugs must be delivered to the all relevant sites in a secure, locked or sealed, tamper evident container. The person who conveys the controlled drugs acts as a messenger. If the box is not locked or the tamper evident seal is broken the controlled drug will not be accepted and the supplying pharmacy will be informed immediately by telephone. An untoward event form must be completed.

2.2 Refer to Appendix E, Standard Operating Procedure CD 5 for full requirement for recording in CD record book.

2.3 The receipt of controlled drugs dispensed for discharge should be recorded in the CD record book. Refer to Appendix F, Standard Operating Procedure CD 6 for details.

2.4 In exceptional circumstances, where a second nurse or another registered health professional is not available on site, a healthcare assistant can witness the receipt of controlled drugs.

2.5 The CD order book and CD record book must be stored in a locked drawer or cupboard when not in use.

CD Standard Operating Procedure 3

TITLE	STORAGE OF CONTROLLED DRUGS
Purpose	To ensure that the storage of all controlled drugs complies with the requirements of the Misuse of Drugs Act and Trust Policy
Scope	Applies to all registered nurses involved with controlled drugs
Responsibilities	Registered nurse in charge of ward or clinician with responsibility for CD stock at the location

1. PROCEDURE

1.1 Controlled drugs must be stored in the CD cupboard when not in use as detailed in 4.2.

1.2 CD cupboards must be locked when not in use.

1.3 All controlled drugs brought in to an inpatient ward by the patient must be stored in the CD cupboard, clearly marked and kept separate from ward stock.

1.4 On inpatient wards: Controlled drugs dispensed for discharge should be stored in the CD cupboard but temazepam, tramadol, midazolam, phenobarbitone and morphine sulfate oral solution 10mg in 5ml dispensed for discharge, do not need to be stored in the CD cupboard.

1.5 The CD cupboard should be reserved solely for the storage of controlled drugs. No other drugs or items should be stored in the CD cupboard.

1.6 Keys for the CD cupboard must only be available to members of staff who can lawfully be in possession such as registered nurses, clinician with responsibility for the CD stock, and pharmacy staff.

2. ADDITIONAL INFORMATION

2.1 Storage arrangements for controlled drugs must comply those advised in the Duthie Report and CD cupboards and their fixing must conform to the specification set out in British Standard BS2881:1989 and Health Building Note 29.

2.2 The lock on the CD cupboard must be different to any other lock on the unit.

2.3 Controlled drugs delivered to the ward must be dealt with by a registered nurse or relevant clinician as soon as possible and should not be stored in the transport container. Refer to Appendix B, CD Standard Operating Procedure 2.

CD Standard Operating Procedure 4

TITLE	**KEY HOLDING AND ACCESS TO CONTROLLED DRUGS**
Purpose	To ensure that key-holding and access to controlled drugs complies with the requirements of the Misuse of Drugs Act and Trust Policy
Scope	Applies to all registered healthcare staff handling controlled drugs
Responsibilities	Registered nurse in charge of ward or clinician with responsibility for CD stock at the location

1. PROCEDURE

1.1 The registered nurse in charge or relevant clinician (e.g. Dentist) is responsible for the key to the CD cupboard. The CD cupboard key should be kept on their person or under their direct control at all times.

1.2 Key holding may be delegated to other suitably trained registered health professionals but the legal responsibility rests with the registered nurse in charge or the clinician with responsibility for the location.

1.3 The controlled drug key must be kept separate from all other keys and should be easily identifiable.

1.4 Controlled Drug keys for CD cupboards must remain within the confines of Trust premises at all times. (Exception: decommissioned CD storage cupboards)

1.5 Keys for the CD cupboard must only be available to members of staff who can lawfully be in possession for example registered nurses, dentists, and pharmacy staff.

1.6 Duplicate keys must be labelled and stored in an approved locked secure location in a tamper evident container. A log must be maintained of any access to these keys.

2. PROCEDURE FOR MISSING CD KEYS

2.1 If the CD keys are missing and cannot be found then urgent efforts should be made to retrieve the keys as speedily as possible e.g. by contacting relevant staff who have just gone off duty or others who may have been given authorised access to the keys.

2.2 Any staff member who has taken the CD key off Trust premises is expected to return it immediately.

2.3 If the keys cannot be found the registered nurse in charge or clinician with responsibility for CD stock must ensure that the controlled drugs in stock are secure and that patient care is not impeded.

2.4 The spare key should be signed out for temporary use by the registered nurse in charge or matron / unit manager.

2.5 The duty manager should be informed and an untoward incident form must be completed.

2.6 Should the key not be found within two working days then arrangements should be made to change the cupboard lock.

2.7 Stocks should be checked and verified at each shift change whilst the spare key is in use.

Appendix E

CD Standard Operating Procedure 5

TITLE	RECORD KEEPING OF CONTROLLED DRUGS
Purpose	To ensure that recording of controlled drugs complies with the requirements of the Misuse of Drugs Act and Trust Policy
Scope	Applies to all staff involved with CD record keeping
Responsibilities	Registered nurse in charge of ward or clinician with responsibility for CD stock at the location

1. PROCEDURE

1.1 Controlled drugs held as stock must be recorded in the CD record book as described in 4.2.

1.2 All entries should be signed by a registered nurse or relevant clinician and should be witnessed by a second registered nurse or other registered health professional.

1.3 Each page in the CD record book must specify at the head of the page the generic name, brand name (if applicable), strength and form of the drug to which the entries on that page relate.

1.4 Each drug and each strength and each form must be on separate pages so that a running balance can be kept easily.

1.5 Entries should be in chronological order in ink or be otherwise indelible.

1.6 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 witnessed by a second registered nurse or other registered health professional. The witness should also sign the corrections. There should be an explanation for the correction. If in doubt of correct actions to take contact a member of the Medicines Management Team.

1.7 No entries in the CD record book must be overwritten, crossed-out, erased or otherwise obscured or obliterated.

2. TRANSFER TO A NEW PAGE

2.1 On reaching the end of a page, the balance should be transferred to the next available page and the following details recorded:

- At the bottom of the finished page, record the new page number where the balance has been transferred to.

- On the new page, record the quantity transferred and the page number where the balance has been transferred from.
- Update the index at the front of the CD record book with the new page number.
- The transfer should be witnessed and signed by a second registered nurse or other registered health professional.

3. PROCEDURE FOR CONTROLLED DRUGS RECEIVED

3.1 Controlled drugs received from pharmacy should be recorded on the relevant page in the CD record book and the following details recorded:

- Date of receipt and entry
- Name of pharmacy making supply
- Serial number of requisition
- Quantity received
- Balance in stock
- Signature of registered healthcare professional making the entry
- Signature of witness
- Name, strength and form (should be specified at head of page)

3.2 When recording controlled drugs received from pharmacy, the number of units received should be recorded in words not figures to reduce the chance of entries being altered.

3.3 For liquid preparations of controlled drugs it is advisable to commence a new page in the CD record book when a new supply is received. This is in order for balances to be checked before a new bottle is started. This is an exception to other forms of preparations when a new supply should be added to the running balance in stock.

4. ADDITIONAL INFORMATION

4.1 The registered nurse in charge or clinician with responsibility for CD stock at the location is responsible for keeping the CD record book up to date and in good order.

4.2 In exceptional circumstances, where a second nurse or another registered health professional is not available on site, a healthcare assistant can witness entries in the controlled drug record book.

4.3 Patient's own controlled drugs must not be added to stock controlled drugs. They should be entered in a separate record book (Community Health) or on a new separate page at the back of the record book (Mental Health). Refer to Appendix F, CD Standard Operating Procedure 6.

4.5 Dispensed CD discharge medicines must be recorded in the CD record book. Refer to Appendix F, CD Standard Operating Procedure 6, 1.2.

4.6 After every administration, the balance in stock in the CD record book, of the CD preparation used, should be checked against the stock in the cupboard. If a discrepancy is found this should be investigated without delay. Refer to Appendix O, CD Standard Operating Procedure 15.

4.7 CD records must be kept for a period of at least two years from the date when the last entry was made, but if they contain a record of destruction of a controlled drug they must be kept for seven years. These should then be destroyed as confidential waste.

Appendix F

CD Standard Operating Procedure 6

TITLE	**MANAGEMENT OF CONTROLLED DRUGS THAT ARE THE PATIENT'S PROPERTY**
Purpose	To ensure that the management of patient's own controlled drugs complies with the Misuse of Drugs Act and Trust Policy
Scope	Applies to all staff involved in management of controlled drugs
Responsibilities	Registered nurse in charge of ward

1. PROCEDURE

1.1 Controlled drugs brought in by a patient on admission must be stored in the CD cupboard, clearly marked and kept separate from ward stock.

1.2 Patient's own controlled drugs, including controlled drugs dispensed for discharge or leave, must either be recorded in a separate controlled drug record book solely for this purpose or on the next available page at the back of the record book.

1.3 A separate entry must be made in the CD record book on a new page and marked as 'Patient's own' with the name of the patient. The quantity must be counted and entered. This must be witnessed by a second registered nurse or other registered health professional.

1.4 If the patient's own CD is to be administered to the named patient on the ward they must be positively identified and rated as suitable for use using the 'Algorithm for use of Patient's Own Drugs' (Medicines Policy). An entry of the administration must be made in the CD record book.

1.5 Patient's own controlled drugs must never be administered to any other patient.

1.6 If patient's own controlled drugs are not required for administration on the unit then one of the following procedures should be followed and all actions should be recorded:

- If the patient wishes the medicines may be returned home via an identified adult. Responsibility for security is given to the adult.

- If the patient agrees for disposal a 'Patient Medicine Disposal Form' should be completed. Refer to Appendix G, CD Standard Operating Procedure 7.

- The controlled drugs may be stored temporarily on the ward if the above alternatives are not suitable.

1.7 If the controlled drugs are returned to the patient on discharge or handed to an identified responsible adult as above, this must be recorded in the CD record book by a registered nurse and witnessed by a second registered nurse or other registered health professional.

1.8 If the medicines are not safe and/or appropriate for use, then the patient should be advised and encouraged to agree to their safe disposal. Refer to Appendix G, CD Standard Operating Procedure 7.

1.9 If the patient lacks capacity to consent the medicines can be retained if it is in the best interest of the patient. Evidence of a capacity test relevant to the decision to retain a patient's medicines should be documented and the reason why this was thought to be in the patient's best interest.

1.10 If the patient has capacity the drugs may be removed for disposal without consent if a clinical decision is made that returning the drugs poses significant risk of serious harm to the patient or others. The Trust will support clinical staff in making reasonable decisions in the balance between the legal duty of care to the patient and legal possession of the drugs. Full details of the identified risk and action must be documented in the patient record.

1.11 When dispensed controlled drugs are handed to the patient they must be booked out of the CD record book following instructions in 1.7 and the patient or carer asked to countersign the entry to confirm receipt.

2. ADDITIONAL INFORMATION

2.1 Dispensed CD discharge medicines should be stored in the CD cupboard. They should be clearly marked in a sealed bag and kept separate to ward stock. Temazepam, tramadol, midazolam, phenobarbitone and morphine sulfate oral solution 10mg in 5ml, dispensed for discharge, do not need to be stored in the CD cupboard.

2.2 In exceptional circumstances, where a second nurse or another registered health professional is not available on site, a healthcare assistant can witness entries in the controlled drug record book.

Appendix G

CD Standard Operating Procedure 7

TITLE	DISPOSAL OF CONTROLLED DRUGS
Purpose	To define the process for the safe and secure disposal of controlled drugs that complies with current legislation
Scope	Applies to all staff involved with handling controlled drugs and staff authorised by the Accountable Officer to witness the destruction of controlled drugs
Responsibilities	Registered nurse in charge or clinician in charge of clinical area and Chief Pharmacist

1. PROCEDURE

1.1 Controlled drugs cannot be returned to the Trust's supply pharmacy/pharmacies.

1.2 Controlled drugs will be destroyed on the ward or at sites authorised to hold CD stocks, in the presence of an Authorised Witness, using a denaturing kit designed for that purpose.

2. AUTHORISED WITNESS

2.1 This is a person authorised by the Accountable Officer for Controlled Drugs to witness the destruction of controlled drugs. Authorised witnesses will be issued with a letter of authorisation, valid for up to two years, signed by the Accountable Officer.

2.2 A list of Authorised Witnesses is available on the Trust Intranet or from the Accountable Officer for Controlled drugs (Tel 01823 368265).

Procedure

2.3 If controlled drugs are out of date or unusable the drug/s should be segregated from other controlled drugs in the CD cupboard and clearly marked for disposal.

2.4 Ward staff or relevant team staff should contact an Authorised Witness and arrange for them to attend the ward at the next available opportunity to oversee the denaturing of the relevant drug(s).

2.5 Ward or team staff should provide the correct denaturing kit depending on the type, form and quantity of drug/s. The recommended denaturing kit is Den Kit as this does not require solid dosage forms to be crushed prior to addition.

2.6 The Authorised Witness must identify herself/himself using an ID badge (if they are not already known to staff). Staff may request presentation of the letter of authorisation (see 2.1 above) if desired.

2.7 The process must be undertaken by the nurse in charge of the ward, or a suitable healthcare professional with relevant competencies nominated by the senior clinician with responsibility for the clinical area and in the presence of the Authorised Witness.

(Seek advice from the Accountable Officer if in doubt of who can nominate a suitable healthcare professional or who would be a suitable healthcare professional.)

2.8 The controlled drugs for disposal are placed in the denaturing kit following the correct process outlined below.

2.9 The nominated member of staff undertaking the destruction and the Authorised Witness must record the disposal in the CD record book and the following details must be included:

- Date
- Name, form and strength of drug (specified at head of the page)
- Reason for disposal
- Quantity removed for disposal
- Balance remaining
- Signature of nominated member of staff
- Signature of 'Authorised Witness'

Where staff involved in the destruction are registered healthcare professionals it is best practice to annotate signatures with professional registration numbers.

2.10 The Authorised Witness must ensure the record of controlled drug destruction form (see Appendix 1 of this SOP) is completed and a copy of the form is sent to the Accountable Officer for Controlled Drugs at the address shown on the form.

3. DENATURING PROCESS

3.1 Controlled drugs must be destroyed using a denaturing kit designed for that purpose. No other method of destruction may be used. Refer to Appendix 1, CD Standard Operating Procedure 9 for part doses not administered to patients.

3.2 Always read the instructions on the outside of the denaturing kit BEFORE starting the process and follow the kit manufacturer's instructions as they vary depending on the make of the kit.

3.3 During the denaturing of all controlled drugs, gloves should be worn.

3.4 Shake the container to loosen the granules prior to use.

3.5 To denature the drugs, the following must be done:

- Solid dose formulations should be removed from packaging.
- Patches should be folded onto themselves so they cannot be opened again.
- Ampoules must be opened and the drug emptied into the kit. The emptied ampoule can be added to the kit.
- Liquids can be added directly to the container. Liquid containers should be rinsed into the kit to remove final traces of the CD. **Please note – liquids should be added at the end of the process as the kit will rapidly solidify following their addition.**

3.6 Add the drug to the kit no higher than the level indicated on the container. Never overfill the container as this may reduce the effectiveness of the kit.

3.7 Add cold tap water to the kit to the level specified on the container.

3.8 Replace the lid securely and shake thoroughly for at least 30 seconds.

3.9 The kit contents will form a gel within a few minutes but it may take up to 24 hours for the CD contents to be denatured.

3.10 The nurse in charge should ensure that the kit is stored in the CD cupboard for 24 hours and then disposed of as pharmaceutical waste.

4. PATIENT'S OWN DRUGS

4.1 Patient's own drugs are the property of the patient so consent must be obtained before they are removed for destruction.

4.2 Removal for destruction of patient's own CDs will only occur in the inpatient setting. 4.3 to 4.5 below only applies to inpatient wards and staff.

4.3 A 'Patient Medicine Disposal Form' should be completed and kept on the ward. See Medicines Policy.

4.4 Patient's own controlled drugs may be denatured by two registered nurses one of whom will act as the witness.

4.5 The disposal must be recorded on the appropriate page of the controlled drug record book.

5. UNUSED PREPARED OR PART ADMINISTERED DOSES

5.1 See Standard Operating Procedure CD 9 sections 1.4 and 1.6 for the disposal of unused prepared or part administered doses. Unused prepared or part administered doses may also, where appropriate, be

denatured on the ward, following the denaturing process outlined above, by two registered nurses one of whom will act as a witness.

5.2 The disposal must be recorded on the appropriate page of the controlled drug record book.

6. ADDITIONAL INFORMATION

6.1 CD records must be kept for a period of at least two years from the date when the last entry was made, but if they contain a record of destruction of a controlled drug they must be kept for seven years. These should then be destroyed as confidential waste

Appendix 1

Somerset Partnership NHS
NHS Foundation Trust

RECORD OF CONTROLLED DRUG DESTRUCTION

Hospital / Site / Location:	**Ward or Team / unit:**

Details of person destroying Controlled drugs		**Witnessed by an authorised person**	
	Print name		Print name
	Position		
	Signature		Signature
	Date		Date

PRODUCTS DESTROYED

Stock or Patient Name	**Name & Strength of Drug**	**Form**	**Qty**	**Reason for destruction**		**Destroyed by**	**Witnessed by**
				Expired	No longer needed		

Please send or email (sharon.drew@sompar.nhs.uk) a copy of this form to the Accountable Officer for Controlled Drugs, Medicines Management, Cheddon Lodge, Cheddon Road, Taunton, Somerset TA2 7AZ

Appendix H

CD Standard Operating Procedure 8

TITLE	**PRESCRIBING CONTROLLED DRUGS FOR INPATIENTS/ DISCHARGE PATIENTS/ OUTPATIENTS**
Purpose	To ensure that the prescribing of controlled drugs comply with the Misuse of Drugs Act and Trust Policy
Scope	Applies to all medical staff and non-medical prescribers
Responsibilities	Individual prescribers

1. PROCEDURE

Inpatient Prescribing

1.1 The written requirements for controlled drugs on inpatient medicine charts, community medicines administration record sheet or on RiO electronic inpatient prescribing module are the same as for other medicines and are as follows:

- Drug name and form
- Route
- Dose
- Frequency (if prescribed 'when required' a minimum interval for administration should be specified and a maximum total quantity to be administered in 24 hours)
- Start date
- Include a finish date where appropriate
- Signature of prescriber

The patient's name, patient number and allergy status should also be written on the chart.

Prescribing for Discharge or Outpatients

1.2 Controlled drugs for discharge or outpatients must be written in accordance with the requirements of the Misuse of Drugs Regulations. They should be prescribed either on the appropriate prescription form to be dispensed by the supply pharmacy or on a FP10 to be dispensed at any community pharmacy.

1.3 A prescription for Schedule 2 and 3 Controlled drugs must contain the following details:

- The patient's full name, address and where appropriate age
- The name of the drug
- The form of the drug, even if only one form exists
- The strength of the preparation, where appropriate

- The dose to be taken
- The total quantity of the preparation, or the number of dose units to be supplied in both words and figures

1.4 The prescription must be dated, indelible and can be hand written or computer generated.

1.5 The prescription must be signed by the prescriber with their usual signature in their own handwriting.

1.6 No more than 30 days supply should be prescribed as a matter of good practice. There may be circumstances where there is a genuine need to prescribe a supply for more than 30 days. Where the prescriber believes that it is in the clinical interest of the patient to prescribe a supply for more than 30 days and would not pose an unacceptable threat to patient safety the prescriber should make a note of the reasons in the patient's notes.

2. ADDITIONAL INFORMATION

2.1 Controlled drugs cannot be released until the original prescription is received by the supply pharmacy. **For those units supplied by Lloydspharmacy**, a Controlled Drug (CD) Alert Form should also be completed and faxed to them. The driver will then collect the prescription form on the next scheduled delivery.

2.2 Controlled drugs must be prescribed by professionals who are competent to do so and who receive regular training and support on the safe management of controlled drugs.

2.3 Medical doctors who have not achieved full registration with the GMC are permitted to prescribe controlled drugs for inpatient use but are not permitted to prescribe controlled drugs for discharge prescriptions or for outpatients.

2.4 Supplementary prescribers are permitted when acting under and in accordance with the terms of an agreed individual clinical management plan (CMP) to prescribe and administer and/or supply or direct any person to administer any CD provided that the CD is included in the CMP.

2.5 Nurse independent prescribers are permitted to prescribe, administer or direct anyone to administer schedule 2, 3, 4 and 5 controlled drugs. They are not allowed to prescribe diamorphine, dipipanone or cocaine for the treatment of addiction but may prescribe these items for treating organic disease or injury.

2.6 Community practitioner nurse prescribers are not authorised to prescribe any controlled drugs.

2.7 It is the responsibility of each individual non-medical prescriber to ensure that he or she does not exceed their authority when prescribing controlled drugs.

2.8 Verbal prescriptions must not be given for controlled drugs including temazepam and tramadol.

2.9 Controlled drugs (including temazepam and tramadol) must not be dispensed from ward stock by doctors or nurses to supply to patients for leave or discharge.

Appendix I

CD Standard Operating Procedure 9

TITLE	ADMINISTRATION OF CONTROLLED DRUGS
Purpose	To ensure that administration of controlled drugs complies with the requirements of the Misuse of Drugs Act and Trust Policy
Scope	Applies to all staff involved in the administration of controlled drugs
Responsibilities	Registered nurse or doctor performing the administration

1. PROCEDURE

1.1 All controlled drugs should be administered on inpatient units by two registered nurses or one registered nurse and a doctor. In exceptional circumstances when only one registered nurse is available on site or a doctor is not immediately available, another health professional, student nurse or healthcare assistant may act as a witness.

Both individuals should witness:

- The preparation of the CD.
- The CD being administered to the patient.
- The destruction of any surplus drugs.

1.2 A record must be made in the ward CD record book for controlled drugs administered and the following details must be recorded:

- Date and time when dose administered
- Name of patient
- Name, strength and form in which administered (specified at head of each page)
- Quantity administered
- Signature of registered nurse or doctor who administered the dose
- Signature of witness
- Balance in stock

1.3 The balance in stock of the CD preparation used must be checked against the stock in the cupboard. If a discrepancy is found this must be investigated without delay. Refer to Appendix O, CD Standard Operating Procedure 15.

1.4 If part of a CD preparation is administered to a patient (such as half a tablet) both the dose administered and the amount wasted must be recorded in the CD record book by the registered nurse, doctor, or dentist who administered the dose. The witness should also sign the CD record book. The disposal of the wasted proportion of the unadministered controlled drug may be done by

emptying into a sharps bin or a medicines waste bin, or if appropriate denatured as in CD Standard Operating Procedure 7.

1.5 The administration must also be recorded on the patient's prescription chart.

1.6 If an individual dose is prepared but not administered it must be disposed of on the ward or in the relevant clinical area by the registered nurse, doctor, or dentist in the presence of a witness. The disposal of the prepared but unused controlled drug may be done by emptying the dose into a sharps bin or a medicines waste bin, or if appropriate denatured as in Standard Operating Procedure CD 7. Full details must be recorded in the CD record book by the registered nurse or doctor and the witness should also sign the CD record book.

2. ADDITIONAL INFORMATION

2.1 **It is essential to measure liquid medicines accurately. Medicine pots must not be used to measure CD liquids. Oral syringes or measuring cylinders must be used to measure liquids accurately, e.g. to measure 37ml of Methadone use a measuring cylinder for 30ml and an oral syringe (10ml syringe) to measure 7ml.**

2.2 Controlled drugs must never be prepared in advance for administration at a later time.

2.3 The general guidance on the safe administration of medicines in the Trust Medicine Policy must be followed.

Appendix J

CD Standard Operating Procedure 10

TITLE	CONTROLLED DRUGS STATIONERY
Purpose	To ensure that storage and usage of CD stationery complies with the Misuse of Drugs Act and Trust Policy
Scope	Applies to all staff who handle CD stationery
Responsibilities	Registered nurse in charge of ward, Medicines Management Team

1. PROCEDURE

1.1 All stationery which is used to order controlled drugs is controlled stationery. This includes CD order books and FP10s.

1.2 CD stationery should be stored securely and access to it should be restricted. CD stationery which is kept on wards should be kept in a locked cupboard or drawer.

1.3 CD order books should be ordered on a written requisition from:-

- **Units supplied by Lloydspharmacy** - the Medicines Management Team at Cheddon Lodge, Taunton. (The white copy of the requisition should be faxed to the Medicines Management Team at Cheddon Lodge, Cheddon Road, Taunton. The fax number is 01823 368261).
- **Units supplied by Yeovil District Hospital** – the white copy of the requisition should be sent to the Pharmacy at Yeovil District Hospital.

1.4 One of the requisitions in the CD order book should be used for this purpose and should be signed by a registered nurse, authorised to order controlled drugs. Refer to Appendix A, CD Standard Operating Procedure 1.

1.5 On receipt of the CD order book the registered nurse will sign and date the received by section of the pink copy of the requisition.

1.6 Any unused CD stationery should be returned to the supplier or the Medicines Management Team (see above for further details).

1.7 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 for Controlled Drugs.

1.8 Once a CD record book or an order book is complete it should be sealed and stored securely.

1.9 CD order books and CD record books must be kept for a period of at least two years from the date of the last entry, but if they contain a record of

destruction of a controlled drug they must be kept for seven years. These should then be destroyed as confidential waste.

2. ADDITIONAL INFORMATION

2.1 When starting a new CD record book the balance of stock for all preparations should be transferred from the old CD record book to the new book. This transfer must be carried out by a registered nurse and witnessed by a second registered nurse or other registered health professional or in exceptional circumstances a healthcare assistant. Both the nurse and witness must sign each entry made.

2.2 For units supplied by Lloydspharmacy any unused CD stationery should be returned to the Medicines Management Team at Cheddon Lodge, Taunton.

2.3 CD order books will be individually numbered.

Appendix K

CD Standard Operating Procedure 11

TITLE	**ISSUING CONTROLLED DRUGS STATIONERY**
Purpose	To ensure that issue of CD stationery complies with the Misuse of Drugs Act and Trust Policy
Scope	Applies to all **medicines management staff** who issue CD stationery
Responsibilities	**Controlled Drugs Accountable Officer**

1. PROCEDURE

1.1 All stationery which is used to order controlled drugs is controlled stationery and includes CD order books and FP10s.

1.2 CD stationery must be stored securely in a locked cupboard and access to it should be restricted.

1.3 CD order books will be individually numbered.

1.4 Units supplied by Lloydspharmacy must follow 1.4 to 1.10. CD order books and CD record books should be ordered on a written requisition. One of the requisitions in the CD order book must be used for this purpose and must be signed by a registered nurse, authorised to order Controlled Drugs. Refer to Appendix A, CD Standard Operating Procedure 1.

1.5 The white copy of the requisition must be faxed to the Medicines Management Team at Cheddon Lodge, Taunton (Fax 01823 368261)

1.6 For each supply of controlled stationery the Medicines Management team will record the date, ward, name of person ordering stationery, type of stationery issued, quantity and serial number. The member of staff making the supply will sign the entry.

1.7 CD order books will be delivered to the ward or relevant clinical area by a messenger.

1.8 On receipt of the CD order book the registered nurse or relevant registered healthcare professional will sign the received by section of the pink copy of the requisition.

1.9 The messenger will take a copy of the pink requisition form once the registered nurse or relevant registered healthcare professional has signed for receipt. The copy will be filed with the supply records at Cheddon Lodge, Taunton.

1.10 Any unused CD stationery, returned to the medicines management team, will be recorded as a return in the supply record.

2. ADDITIONAL INFORMATION

2.1 Loss or theft of any CD stationery which may be used to order controlled drugs must be reported without delay to the Accountable Officer for Controlled Drugs (Tel 01823 368265).

2.2 Only one CD order book should normally be in use at any time but a maximum of two are allowed when required to obtain supplies from Yeovil District Hospital.

Appendix L

CD Standard Operating Procedure 12

TITLE	ACCESS TO CONTROLLED DRUGS OUT OF HOURS
Purpose	To ensure that accessing controlled drugs out of hours complies with the requirements of the Misuse of Drugs Act and Trust Policy
Scope	Applies to all registered nurses and medical staff
Responsibilities	Registered nurses in charge of ward and medical staff

1. PROCEDURE

1.1 Every effort should be made to avoid the need to obtain a supply of controlled drugs outside of the routine opening hours of the supply pharmacy.

1.2 If a patient on a ward is prescribed a controlled drug then adequate stock levels should be maintained by ordering and reordering in a timely manner.

1.3 Controlled drugs for a planned admission of a patient known to be prescribed controlled drugs should be ordered in advance.

1.4 If a supply of a CD is required for administration to a patient and the supply pharmacy is closed, the following options should be considered:

- If the patient has been admitted with a supply of their own drug then this can be administered to the patient if the drug can be positively identified using the 'Algorithm for use of Patient's Own Drugs' in the Medicines Policy.
- Full details must be recorded in the CD record book. See CD Standard Operating Procedure 6.

1.5 The CD can be prescribed for an individual patient on a hospital FP10 prescription and dispensed in a community pharmacy.

- The prescription must comply with the controlled drug regulations as in CD Standard Operating Procedure 8

- The dispensed CD received on the ward must then be treated as Patient's Own Drugs. It must be entered in the ward CD record book as patient's own and must only be administered to that named patient.

1.6 Single doses may be administered to a patient on one ward from stock held on another ward.

- Full details of the administration must be recorded in the CD record book of the ward holding the stock.
- **Stock must not be transferred from one ward CD record book to another.**
- **Stock controlled drugs must not be transferred from one ward to another ward.**

2. ADDITIONAL NOTES

2.1 Nurses collecting controlled drugs, on behalf of a patient, from a pharmacy may be asked for their name, address, professional registration and to prove their identity.

2.2 Patient's own controlled drugs should be transferred from one ward to another ward with the patient, in a safe manner in line with all other medicines belonging to that patient.

2.3 Entries must be made in the appropriate CD record books on both wards when patient's own controlled drugs are transferred.

Appendix M

CD Standard Operating Procedure 13

TITLE	CONTROLLED DRUG CHECKS BY WARD STAFF
Purpose	To ensure CD ward stock checks performed by ward staff comply with the requirements of the Misuse of Drugs Regulation and Trust Policy
Scope	Applies to all ward staff undertaking CD stock checks
Responsibilities	Registered nurse in charge of ward

1. PROCEDURE

1.1 CD stock checks should be carried out every seven days and should include the following:

- The levels of drugs in stock (including patient's own) should be checked against the balances recorded in the CD record book. **All drug balances recorded in the CD record book must be matched with the level of drugs actually held.**
- It is not necessary to open packs with intact tamper-evident seals for stock checking purposes.
- Stock balances of liquid medicines should be checked by visual inspection.
- Record the stock check in the ward CD record book including wording such as 'check of stock level' and confirming the stock is correct. An entry should be made on each current page of the record book.
- The record should state the date and time of the check.
- The record should be signed by the registered nurse or relevant registered healthcare professional depending on setting and witnessed by a second registered nurse or registered healthcare professional, other registered health professional or healthcare assistant.
- To enable the records of weekly stock checks to be easily identified in the controlled drug record book entries must be made in red pen.

1.2 If a discrepancy is found it must be investigated without delay. Refer to Appendix O, CD Standard Operating Procedure 15.

1.3 Controlled drug records since the last weekly check should also be checked for completeness including:-

- Orders in the controlled drug order book for completeness including signature of the nurse receiving the controlled drugs ordered. Refer to Appendix A & B, Controlled Drug Standard Operating Procedures 1 & 2.

- Records of receipt (including patient's own) in the controlled drug record book for completeness. Refer to Appendix E, CD Standard Operating Procedure 5

- Records of administration (including patient's own) in the controlled drug record book for completeness. Refer to Appendix I, CD Standard Operating Procedure 9

- Where possible records of administration should be reconciled with the appropriate prescription and administration chart.

2. Additional Information

2.1 Particular attention needs to be taken of liquid medicines and any stock adjustments made when bottles are finished and for controlled drugs stocked but not in current use. See CD SOP 15.

2.2 The ward manager, Ward Sister or named clinician responsible for CD stock held at the site / unit is responsible for ensuring that regular controlled drugs stock and record keeping checks are carried out by staff every seven days and for ensuring that any discrepancies are dealt with promptly and appropriately.

Appendix N

CD Standard Operating Procedure 14

TITLE	**CONTROLLED DRUG CHECKS BY PHARMACY STAFF**
Purpose	To ensure CD ward stock checks performed by pharmacy staff comply with the requirements of the Misuse of Drugs Regulations and Trust Policy.
Scope	Applies to all pharmacy staff undertaking CD stock checks
Responsibilities	Chief Pharmacist

1. PROCEDURE

1.1 The current version of the ward CD inspection form (For an example see Appendix 1 of this SOP) should be completed for the CD stock check procedure. For the current version of the CD inspection form contact Medicines Management at Cheddon Lodge, Cheddon Road, Taunton (Tel: 01823 368265)

1.2 The stock check procedure should include the following:

- The levels of drugs in stock should be checked against the balances recorded in the CD record book. All drug balances recorded in the CD record book must be matched with the level of drugs actually held.
- It is not necessary to open packs with intact tamper-evident seals for stock checking purposes.
- Record the stock check in the ward CD record book including date, time and signature. An entry should be made on each current page of the record book.
- A sample of CD requisition copies should be checked to ensure that they have been entered correctly in the CD record book.
- Pink copy is signed, dated and countersigned where appropriate. This is not a random check and should be from the previous time checked by Pharmacy to give you e.g. 8 out of 10 as indicated on the form.
- Any exceptional usage of controlled drugs should be recorded.
- Any patient's own controlled drugs held on the ward should be checked.
- The quality and completeness of record keeping should be checked. Particular attention should be taken of liquid medicines and any stock adjustment made when bottles are emptied.

- The physical security arrangement for the storage of controlled drugs, CD stationery and the key holding policy should be checked.

- Check that all weekly stock checks and monthly ward manager checks have been done whilst controlled drugs have been held.

1.3 On completion of the stock check, discuss any relevant issues with the nurse in charge.

1.4 If a discrepancy is found it should be investigated without delay. Refer to Appendix O, CD Standard Operating Procedure 15

1.5 Report any discrepancies or issues of concern to the Accountable Officer for Controlled Drugs.

1.6 A copy of the completed CD inspection form should be sent to the Accountable Officer for audit purposes.

2. ADDITIONAL INFORMATION

2.1 Stocks of controlled drugs held on wards should be checked by a pharmacist or authorised pharmacy technician at least every three months.

2.2 To ease identification of quarterly stock checks it is recommended that entries in the controlled drug record book are made in green pen.

Appendix 1

Controlled Drug Pharmacy Inspection Form

Completed By:_____ **Profession:**_____

Ward:_____ **Date Audit Covers:**

Keys

		YES	NO
1	Are the keys to the Controlled Drugs cabinet retained by the senior nurse in charge and kept on their person throughout their shift?		
2	Are duplicate keys labelled and stored in a locked secure location in a tamper evident container?		
3	Is the Controlled Drugs Key separate from all other keys?		
4	Is there a list of authorised signatories for personnel with authority to order stock and the registered medical practitioners?		

Order Book

		YES	NO	NO CONTROLLED DRUGS ORDERS
5	Has the name of the hospital been recorded?			
6	Has the ward or department been recorded?			
7	Has the name of preparation been recorded?			
8	Has the strength been recorded?			
9	Has the quantity ordered been recorded?			
9a	Has this been recorded in words and figures?			
10	Has the Sister or Acting Nurse in charge signed the ordered by?			
10a	Has the Sister or Acting Nurse in Charge printed their name above signature?			
10b	Has the Sister or Acting Nurse in charge dated the ordered by?			
11	Has the order been countersigned by a Medical Practitioner?			

11a	Has the Medical Practitioner printed his/her name against their signature?			

12	Has the Pharmacist signed the supplied by?			
12a	Has this been dated?			

13	Has the 'Messenger' signed the accepted for delivery?			
13a	Has this been dated?			

14	Has a member of trained staff signed the received by?			
14a	Has this been dated?			

15	Are there any pages missing in the order book?			
16	Has all stock supplied been added correctly to the CD Record Book			

Controlled Drug Record Book

		YES	NO	NO CONTROLLED DRUGS IN STOCK
17	Have all entries been recorded in ink?			

18	Has the Name, Form of Preparation and Strength of the drug been recorded?			

19	Has the amount been recorded in words?			

20	Has the date received been recorded?			

21	Has the Serial No. of Requisition been recorded?			

22	Has the "date" for administration/destruction been recorded?			

23	Has the "time" for administration/destruction been recorded?			

24	When administering CD's, has the "amount given" for administration been recorded?			

25	Has a signature been provided by the Health Professional 'giving' / 'destroying' the drug?			

26	Has a signature been provided by the witnessing Health Professional?			

27	Has the stock balance been recorded?			
28	Has the weekly stock check been done?			
28a	Has the date and time of the check been recorded?			
29	Is this recorded in red ink?			

		YES	NO	NO ERRORS
30	If there are any errors have these been corrected and documented according to the SOP?			

		YES	NO	N/A
31	If there is any exceptional usage, is this justified and evidenced?			

POD's

		YES	NO	NO ENTRIES THIS MONTH
32	Have all entries been recorded in ink?			
33	Has the Name, Form of Preparation and Strength of the drug been recorded?			
34	Has the amount received been recorded?			
35	Has the date received been recorded?			
36	Has the Serial No. of Requisition been recorded?			
37	Has the "date" for administration/destruction been recorded?			
38	Has the "time" for administration/destruction been recorded?			
39	When administering CD's, has the "amount given" for administration been recorded?			
40	Has a signature been provided by the Health Professional 'giving' / 'destroying' the drug?			
41	Has a signature been provided by the witnessing Health Professional?			
42	Has the stock balance been recorded?			

43	Has the weekly stock check been done?			

44	Is this recorded in red ink?			

		YES	NO	NO ERRORS
45	If there are any errors have these been corrected and documented according to the SOP?			

		YES	NO
46	Were POD's returned to patient on discharge?		

Discrepancies

If any answers to the questions are 'no' please record this below explaining why they are answered no.

Question Number	Requisition No. / Page No.	Discrepancy Details

Appendix O

CD Standard Operating Procedure 15

TITLE	DISCREPANCIES / DIVERSION OF CONTROLLED DRUGS
Purpose	To ensure that discrepancies are investigated to comply with the requirements of the Misuse of Drugs Act and Trust Policy
Scope	Applies to all staff who handle controlled drugs
Responsibilities	Registered nurse in charge of ward or clinician with responsibility for CD stock at the location

1. PROCEDURE

1.1 Any discrepancy between the balance recorded in the CD record book and actual quantity in stock must be investigated without delay.

1.2 In the first instance the following must be checked:

- All requisitions received have been entered into the correct page of the CD record book
- All controlled drugs administered have been entered into the CD record book
- Items have not been accidentally put into the wrong place in the stock cupboard
- Check the arithmetic to ensure that balances have been calculated correctly

1.3 If the error or omission is traced, the registered nurse in charge should make an entry in the CD record book, clearly stating the following:

- Reason for the entry
- Date of the error or omission
- Corrected balance
- Signature of the person carrying out the amendment
- Signature of witness.

1.4 An untoward event form must be completed and the reference number added to the CD record book entry.

1.5 If no errors or omissions can be traced the discrepancy should also be reported to the Trust medicines management staff and to the Accountable Officer for Controlled Drugs. The CD record book should be dated, signed and endorsed with “Error identified – unresolved but escalated to Medicines Management” and the correct balance stated.

2. ADDITIONAL INFORMATION

2.1 The balance recorded in the CD record book should be reconciled against the stock of every product in the CD cupboard by ward staff every 7 days. Refer to Appendix M, CD Standard Operating Procedure 13.

2.2 A stock check of the balance of an individual CD should be checked every time that preparation is handled.

2.3 Liquid medicines should be checked by visual inspection but the balance must be confirmed on completion of a bottle.

2.4 At the end of each bottle, if there is any remaining controlled drug liquid when the stock balance is zero, the volume of liquid controlled drug should be measured and checked by two registered nurses. An entry should be made in the CD record book along the lines of “Balance zero - but liquid remaining in bottle”. The balance should be adjusted to the actual balance in the record book and signed by the two registered nurses. Once the balance is corrected, the remaining controlled drug liquid can be used to administer a dose to a patient or be marked for destruction as in CD Standard Operating Procedure 7.

2.5 If the measured volume of a liquid controlled drug is more than the recorded stock balance and the discrepancy is more than 5ml per 100ml (measured at the end of the bottle) then an untoward event form must be completed and the Accountable Officer informed

2.6 All discrepancies of a liquid controlled drug where the measured volume is less than the recorded stock balance must be reported as an untoward event and the Accountable Officer informed. An entry should be made in the CD record book along the lines of “No balance remaining in bottle “and the balance should be corrected to zero.

2.7 All stocks of controlled drugs held on wards will be checked by a pharmacist or authorised pharmacy technician at least every 3 months.

Appendix P

CD Standard Operating Procedure 16

TITLE	**DEALING WITH ILLEGAL CONTROLLED DRUGS / SUBSTANCES**
Purpose	To ensure that the removal of illegal substances complies with the Misuse of Drugs Act and Trust Policy
Scope	Apples to all staff who handle unidentified substances
Responsibilities	Registered nurse in charge of ward

1. PROCEDURE

1.1 If staff are unsure whether a substance handed in by / found on a patient may be an illegal controlled drug then they should contact the police for advice.

1.2 If police are informed and asked to take possession of the suspected illegal CD, it should be dealt with by two members of staff, one of whom should be a registered nurse, as follows:

- Wear disposable gloves and retain the substance – exceptions are syringes which must be disposed of in the sharps bin immediately.
- Place the item in a bag or envelope labelled with the date and time, ward, by whom it was found/received and where it was found.
- Seal the package and store in the CD cupboard.
- An entry should be made in the CD record book on a page, designated for suspected illegal CD/ substances, at the back of the book. The entry should include the date, time and signature of registered nurse and witness.
- Inform the registered nurse in charge and the Accountable Officer for Controlled Drugs.
- An untoward event form should be completed.
- An entry should be made in the patient's record if appropriate.
- Do not hand the substance back to the patient.

1.3 The removal by the police must be recorded in the CD record book including the signature of the registered nurse and police officer.

2. ADDITIONAL INFORMATION

Police Contact Numbers:
Non-emergency 24 hours – 0845 4567000
Queries relating to policy or procedures (drug strategy) 01275 814576 or 01275 816628

Appendix Q

CD Standard Operating Procedure 17

TITLE	**MONITORING THE PRESCRIBING OF CONTROLLED DRUGS**
Purpose	To identify the supply and prescribing of unusual presentations or abnormally high quantities of controlled drugs to comply with the Misuse of Drugs Act and Trust Policy
Scope	Applies to all medicines management staff involved in the monitoring process
Responsibilities	Chief Pharmacist

1. PROCEDURE

1.1 The following checks should be carried out each month:

- Data of drugs received from the supply pharmacies, should be examined for any unusual presentations or abnormally large quantities of Controlled drugs.
- ePACT data of drugs prescribed on FP10 prescriptions should be examined, using the CD Tags in the system, for any unusual prescribers, presentations or abnormally large quantities of controlled drugs.
- ePACT data of drugs prescribed on FP10 prescriptions should be examined for any controlled drugs prescribed, by non-medical prescribers.
- The ADIoS (Abusable Drugs Investigational Software; Rx-Info Ltd) will be used to identify anomalies requiring further investigation
- A report of all controlled drugs prescribed on the electronic prescribing system should be run each month and checked for any unusual prescribers, presentations or abnormally large quantities of controlled drugs.
- A record of these checks should be kept in a database, which can be monitored by the Accountable Officer.
- If any drugs, quantities or prescribing practices cause concern further detailed examination of the data must be carried out to include trends in prescribing.

- If appropriate the supply pharmacy should be asked for a more detailed report from their records.

- If appropriate a request for return of an individual prescription should be made to the NHS BSA.

- Any reports causing concern should be reported to the Accountable Officer for investigation and to the Medical Director, Security Officer, Counter Fraud or Police as appropriate.

Appendix R

CD Standard Operating Procedure 18

TITLE	**HANDLING OF CONTROLLED DRUGS IN THE COMMUNITY**
Purpose	To ensure that the handling of controlled drugs in the community complies with the requirements of the Misuse of Drugs Act and Trust Policy.
Scope	Applies to all community medical and nursing staff
Responsibilities	Chief Pharmacist

1. THIS STANDARD OPERATING PROCEDURE SHOULD BE READ IN CONJUNCTION WITH:-

1.1 All other CD Standard Operating Procedures

2. THE FOLLOWING OUTLINES PROCEDURES THAT ARE UNIQUE FOR COMMUNITY NURSES.

Storage

2.1 Staff caring for a patient in the community should advise the patient and / or their carer on the safe storage of controlled drugs in their home.

Patient's Own drugs

2.2 Controlled drugs supplied by a GP from their own stock can only be administered if they are supplied in a container with the following information provided:-

- The patient's name
- The patient's address
- Drug name and strength
- Quantity of drug supplied
- Date dispensed
- Name of GP dispensing

2.3 Where a syringe driver is commenced and the patient has a Just in Case box in situ all medication should be kept together in one container. All prescribing, whether for anticipatory medication, regular medication, or syringe driver medication will be on the same Medication Administration Record. The Just in Case box may be kept in the home so that the laminated drug pathways and the patient information sheet remain available.

2.4 In exceptional circumstances when a clinical decision is made that retaining drugs in a patient's home is inappropriate, and the patient agrees, controlled drugs may be removed from a patient's home and stored in a suitable controlled drug cupboard in a team base or in a community hospital. The

controlled drugs must not be added to the controlled drug book contents or any of the balances within. There must however be appropriate documentation retained with the controlled drugs to identify the patient, the contents and the community team medical or nursing staff member who is responsible for the controlled drugs. The patient's consent must be documented in the notes.

2.5 If the patient lacks capacity to consent to the removal of the controlled drugs the medicines can be removed if it is in the best interest of the patient. Evidence of a mental capacity test relevant to the decision to remove a patient's medicines should be documented and the reason why this was thought to be in the patient's best interest. The capacity test should be done by a doctor or nurse. The Trust will support clinical staff in making reasonable decisions in the balance between the legal duty of care to the patient and legal possession of the drugs. Full details of the identified risk and action must be documented in the patient record.

2.6 Storage requirements and key holding must comply with the relevant Standard Operating Procedures (refer to Appendix C & D, CD Standard Operating Procedure 3 & 4). A controlled drug stock card must be completed and a running balance maintained. The staff member removing the controlled drugs for storage remains responsible for returning the controlled drugs in a timely manner to the patient or to the appropriate location for destruction.

3. ADMINISTRATION

3.1 Controlled drugs can be administered to a patient in their own home by a registered nurse without a witness.

3.2 Any unused part of the prepared or administered dose must be accounted for on the controlled drug stock card

4. RECORD KEEPING

4.1 All controlled drugs stored in a patient's home must be recorded on a controlled drug stock card.

4.2 A running balance must be maintained for each controlled drug. Any discrepancies must be reported to the nurse's line manager who will inform the medicines management team and the Accountable Officer for the Trust. A Trust incident form must be completed.

4.3 Controlled drugs removed from the Just In Case box and combined with a patient's own stock of medicines must be appropriately recorded on the controlled drug stock card.

4.4 Controlled drugs administered from a Just In Case Box must be documented in accordance with the Just In Case Policy.

5. TRANSPORTATION

5.1 Nurses should not normally transport controlled drugs. In circumstances where there is no other reasonable alternative, nurses can transport controlled drugs that have been dispensed for a patient as long as they obtain permission to do so from their line manager or the on-call manager, who will also inform the Accountable Officer.

5.2 Nurses collecting controlled drugs, on behalf of a patient, from a pharmacy may be asked for their name, address and professional registration and to prove their identity.

5.3 Any controlled drug transported must be stowed securely, kept out of sight and taken directly to the patient.

6. DISPOSAL OF CONTROLLED DRUGS

6.1 Community nurses may dispose of any part used or unused prepared doses of controlled drugs by emptying them into a sharps bin, labelled “mixed pharmaceutical waste”.

6.2 Community nurses must not dispose of any unopened or unprepared controlled drugs. Patients or their representatives should be advised to return all remaining controlled drugs to the place that dispensed them for safe destruction. Staff must ensure that they clearly document on the controlled drug stock card the total amount and of medication that will be returned.

6.3 If, in exceptional circumstances, it is essential that the nurse removes unprepared controlled drugs from the patient’s home they must obtain permission from their line manager or the on call manager, who will also inform the Accountable Officer. The drug removal must be undertaken by two members of staff, at least one of whom must be a registered nurse. The removal must be documented on the controlled drug stock record and the record must be countersigned. The controlled drugs must be delivered straight to the community pharmacy for disposal. A signed receipt must be obtained from the pharmacist and this must be retained with the controlled drug stock record. If this happens out of normal working hours for the place that dispensed them, the controlled drugs may be stored in the community team base or a community hospital in a controlled drug cupboard. The controlled drugs must not be added to the community team based controlled drug book contents or any of the balances within. There must however be appropriate documentation retained with the controlled drugs to identify as a minimum, the patient, the total amounts of the contents and the community team medical or nursing staff member who is responsible for the controlled drugs. The staff member removing the controlled drugs for storage remains responsible for taking the controlled drugs, in a timely manner, to the community pharmacy for destruction.

Somerset Partnership NHS
NHS Foundation Trust

Controlled Drug STOCK CARD

Patient's Name: …… **Name, Strength and Form of Drug** …….

Date	Time	Quantity Received	Received from	Dose Given	Comments	Signature	Print Name	Witness Signature	Print Name	Balance