Cumbria Partnership NHS Foundation Trust

CONTROLLED DRUGS POLICY (CPFT)

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Accountable Director	Medical Director
Policy Author	CPFT Chief Pharmacist

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Policy On A Page

SUMMARY & AIM

This policy defines the mandatory requirements of the Trust with regard to all aspects of the handling of Controlled Drugs. It is the overarching policy for the management of Controlled Drugs in the Trust. It defines the responsibilities of staff who manage and handle Controlled drugs. It is supported by Standard Operating Procedures (SOPs - see Key Requirements).

TARGET AUDIENCE:

This policy applies to all employees of Cumbria Partnership NHS Foundation Trust including employees not working on Trust premises. The policy also applies to members of staff who are not directly employed by the Trust but who act in a professional capacity within the Trust through a service level agreement or contractual arrangement

TRAINING:

Two e-learning sessions are available for the following groups of staff:
Registered nurses
Non-registered staff who may be required to witness CD tasks in in-patient units

KEY REQUIREMENTS

SOPs relating to this Policy are to be found on the CPFT staff intranet Medicines management SOPs page.

The SOPs must be followed by staff for the management of any aspect of the handling of CDs, including ordering, storage, security, recording, prescribing, monitoring, administration, checking, destruction, use in community teams, and investigation of discrepancies.

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1. INTRODUCTION

This document lays down policy for all staff that may be involved in the prescribing, acquisition, storage, administration and destruction of Controlled Drugs. It defines the mandatory requirements of the Trust. The associated Standard Operating Procedures identify the wide range of activities associated with the handling of Controlled Drugs and the particular care that is needed. The SOPs are accessed on the Trust staff web pages on the Medicines Management pages.

This policy complies with all legal requirements and relevant national guidance – see references for details

2. PURPOSE

This policy is a supplement to the Medicines Policy POL 001/013/002. This policy and the SOPs provide additional guidance to ensure that Controlled Drugs are handled safely and in accordance with legislation.

3. CONTROLLED DRUGS PROCEDURE GUIDANCE:

The safe and secure handling of Controlled Drugs is the responsibility of every member of staff and healthcare professional, who must ensure that they work within their respective professional guidelines, level of competence, ethics and codes of conduct.

All healthcare professionals are accountable for their actions. This accountability cannot be delegated, nor can anyone else answer for the actions of an individual healthcare professional.

The policy is intended to ensure the safe and secure handling of CDs complies with current legislation, relevant safety alerts and good practice guidance.

Controlled Drugs SOPs are held on the Trust intranet medicines management pages.

The SOPs must be followed by staff for the management of any aspect of the handling of CDs, including ordering, storage, security, recording, prescribing, monitoring, administration, checking, destruction, use in community teams, and investigation of discrepancies.

It is acceptable to keep a printed copy of regularly used current SOPs near to the CD cupboard, provided the printed copy is regularly verified against the on-line version to ensure it is up-to-date. This verification can be done at the 3 monthly CD check by pharmacy team.

3.1 SOPs in Lloyds Pharmacy

Lloyds pharmacy supply medicines to some parts of the trust. Lloyds Pharmacy staff will follow Lloyds Pharmacy CD SOPs for the management of CDs in the pharmacy. These SOPs will be approved by the Trust Chief Pharmacist. Lloyds Pharmacy will have access to, and follow, the Trust CD policy and SOPs for management of CDs on wards and teams

3.2 SOPs for HMP Haverigg

A set of Standard Operating Procedures (SOPs) for CDs has been approved by the Medicines Management Committee and the Accountable Officer for use by Trust staff within HMP Haverigg. These are published on the staff intranet.

When guidance on CDs is required by HMP Haverigg staff, which is not included within the HMP Haverigg CD SOPs, the Trust CD policy must be referred to.

3.3 The legal requirements for Controlled Drugs

These are summarised in the SOPs.

Some CDs have been designated a higher level of control in the trust than legally necessary to reduce the risk of diversion and to reduce confusion about how to manage CDs with various exemptions. The SOP Summary of Legal Requirements is maintained up to date and must be referred to for details. If a ward or team manager wishes to designate medicines to a higher level of control than legally required or than in trust policy, pharmacy advice must be obtained and a local SOP produced with pharmacy approval.

For safety risk management reasons, Methotrexate (oral), and potassium chloride injection (10%, 15%, 20%) are also treated as Schedule 2 CDs in the Trust. Supplying pharmacies may not require CD requisitions for these products.

3.4 Safe prescribing, administration and monitoring of CDs

Refer to Controlled Drugs SOPs for detailed requirements for safe prescribing, safe administration and monitoring of patients prescribed Controlled Drugs

Refer to Medicines policy and formulary guidance for recommended and approved products in the local health economy

3.5 Patient Group Directions (PGDs)

Restrictions apply to the range of CDs which can be supplied or administered under a PGD. Refer to pharmacy team for advice and NCUHT Guidance on Patient Group Directions

3.6 Concerns relating to unusual, inappropriate prescribing or over-prescribing

Individuals raising concerns will be supported in doing so. Individuals will also be supported where concerns are raised about them, or where they wish to raise concerns about their own performance.

Any concerns relating to unusual, inappropriate prescribing or over-prescribing of CDs must be brought to the attention of the Accountable Officer or Chief Pharmacist immediately.

Many concerns can be rectified at a local level e.g. a false positive may occur where an apparent prescribing anomaly is due to the caseload of a particular prescriber. However, if patient safety is thought to be at risk immediate action must be taken in accordance with the Trust incident policy.

Where there are any serious concerns about any element of the management and use of CDs the Cumbria Local Intelligence Network (LIN) will be informed by the Accountable Officer.

Immediate referral to the relevant regulatory body must be considered where there are serious concerns about an individual's fitness to practice

3.7 Concerns Relating to Diversion of Controlled Drugs

Refer also to SOP for investigation of discrepancies

Any concerns relating to the diversion of CDs must be brought immediately to the attention of the Accountable Officer and the Chief Pharmacist. If this occurs out-of-hours the on-call manager must be informed. The on-call manager must risk-assess any further actions taken at the time and inform the Chief Pharmacist and the Accountable Officer the next working day.

Audits will be instigated to aim to confirm whether a problem exists.

If a problem is confirmed or there is the suspicion of diversion and this cannot be excluded, then the police will be informed by the Accountable Officer.

Where there are any serious concerns about any element of the management and use of CDs the LIN will be informed by the Accountable Officer

If it is proven that a member of staff has been taking CDs from any area their relevant regulatory body will be informed

3.8 Management of illicit/unidentified substances

Refer to Searching of service users' person, room and personal belongings policy (POL/001/003)

3.9 Clinical Trials Involving Controlled Drugs

It is not anticipated that the Trust will undertake clinical trials involving controlled drugs, however if necessary the Accountable Officer and the Head of Pharmacy will

be involved in the approval process and ensure that all necessary requirements regarding storage, records, labelling, disposal, and returns are followed.

4. TRAINING AND SUPPORT

Refer to Trust Training Needs analysis.

5. PROCESS FOR MONITORING COMPLIANCE

The process for monitoring compliance with the effectiveness of this policy is as follows:

Aspect being monitored	Monitoring Methodology	Reporting		
		Presented by	Committee	Frequency
Compliance with SOPs	Pharmacy quarterly CD checks	Chief Pharmacist	Medicines Management Committee	Annual
Reporting of Incidents	AO reports to LIN and MMC	AO/Chief Pharmacist	Cumbria LIN	3 monthly
Policy Compliance	NICE CD audit tool and/or CQC self-assessment	AO/Chief Pharmacist	Medicines Management Committee	Annual

Wherever the above monitoring has identified deficiencies, the following must be in place:

- Action plan
- Progress of action plan monitored by the Medicines Optimisation Committee minutes
- Risks will be considered for inclusion in the appropriate risk registers

6. REFERENCES:

- The Controlled Drugs (Supervision of Management and Use) regulations 2013
- Controlled drugs: Safe use and management NG46 NICE (2016)
- Safer Management of Controlled Drugs. A guide to good practice in secondary care (England). Department of Health. May 2007.
- Human Medicines regulations 2012
- Misuse of Drugs Regulations 2001
- Misuse of Drugs Act 1971
- Health Act 2006
- NPSA Rapid response report (NPSA/2008/RRR05) Reducing dosing errors with opioid medicines July 2008
- Medicines, Ethics and Practice – Royal Pharmaceutical Society of Great Britain - Use most recent version., log-in required
- NPSA Rapid Response report; Reducing risk of overdose with midazolam injection in adults Dec 2008
- NPSA Rapid Response reports; ensuring safer practice with higher dose ampoules of morphine and diamorphine May 2006.

- NPC. A guide to good practice in the management of controlled drugs in primary care (England) Third Edition December 2009
- The Safe and Secure Handling of Medicines - A Team Approach, The Royal Pharmaceutical Society of Great Britain (RPSGB) March 2005.
- Special waste regulations 1996
- Control of substances hazardous to health regulations 1999

7. ASSOCIATED DOCUMENTATION:

- Medicines Policy

8. DUTIES (ROLES & RESPONSIBILITIES):

At a local level, the Trust as a designated body is accountable, through the Accountable Officer, for ensuring the safe management of Controlled Drugs.

Employees are responsible for all general duties governing the use of medicines which are set out in the Medicines policy.

Only those employees who are legally entitled to carry out processes involving Controlled Drugs may do so.

Tasks cannot be delegated to a member of staff who is not legally entitled, authorised or appropriately trained to carry out those tasks.

Duties for Medicines are set out in the Medicines policy and in addition:

8.1 Chief Executive / Trust Board:

The Chief Executive and Trust Board jointly have overall responsibility for the strategic and operational management of the Trust, including ensuring that Trust policies comply with all legal, statutory and good practice requirements.

8.2 Executive Director: Medical Director

All policies have a designated Executive Director and it is their responsibility to be involved in the development and sign off of the policies, this should ensure that Trust policies meet statutory legislation and guidance where appropriate. They must ensure the policies are kept up to date by the relevant author and approved at the appropriate committee.

8.3 Accountable Officer (AO):

The appointment of an Accountable Officer is a requirement of the Controlled Drugs (Supervision of the management and use) Regulations 2006. The identity of the Trust's Accountable officer is recorded on the CQC website and on the Trust intranet – Medicines Management pages. The regulatory requirements for Accountable Officers are set out in full in *The Controlled Drugs (Supervision of Management and Use) Regulations 2013 Information about the regulations (DoH).*

The AO is responsible for all aspects of the safe and secure management of CDs including. Duties include:

- Ensuring that safe systems are in place for the management and use of CDs, monitoring and auditing the management systems and investigation of concerns and incidents relating to CDs.
- Ensuring staff receive appropriate training
- Ensure that there are adequate and up-to-date SOPs in place in relation to the management and use of controlled drugs within their organisation.
- Authorising Pharmacists and Pharmacy technicians to witness destruction of CDs
- Sharing any concerns about the use or management of CDs with the Cumbria Local Intelligence Network (LIN).
- Ensuring CQC is informed when there is a change of Accountable Officer.

If staff have any concerns about the actions of the Accountable Officer, they must report these to the Trusts Director of Quality and Nursing or to the Head of NHS Cumbria Local Intelligence Network

The identity of the Accountable Officer for CDs is notified to staff on the CD SOPs on the intranet medicines management pages.

8.4 Chief Pharmacist:

As for Pharmacists and

- Monitoring Trust wide data on CD use including FP10s
- Collating records of pharmacy CD checks
- Collating CD medicines incidents and reporting these to the Accountable Officer to prepare the 3 monthly LIN report.
- Assisting with investigations relating to the use or misuse of CDs.
- Supporting the Accountable Officer to compile quarterly reports and to deputise for the Accountable Officer at LIN meetings if necessary.

8.5 Appointed Nurse in Charge / Registered Health Professional in charge (Ward/Team Manager or Equivalent)

The appointed nurse or registered health professional in charge of a ward or department is responsible for the safe and appropriate management of CDs in that area.

Their duties include:

- Ensuring policy is available and SOPs are followed
- Ensuring appropriate staff attend relevant training for CDs and medicines management
- Ensuring a record is kept of staff signatures and signed initials (of those staff authorised to administer, order, check CDs. This can be the same as the Accountability Record).

- Ensuring stock checks are carried out
- Ensuring CD Record Book is kept up to date and accurate
- Ensuring safe management of the CD cupboard keys
- Ensuring action is taken to ensure security of CDs if lock is broken and/or security compromised
- Ensuring discrepancies and errors are reported and investigated
- Ensure they are familiar with usual starting dose, frequency of administration, standard dosing increments, symptoms of overdose, common side effects of CDs.

The appointed nurse or registered health professional in charge can delegate control of access (i.e. key-holding) to the CD cupboard to another registered nurse or health professional. However, legal responsibility for the management of the process remains with the appointed nurse or health professional in charge. Whilst the task can be delegated, the responsibility cannot. If the team manager is not a registered health professional, there must be a registered health professional designated for medicines in the team.

8.6 Registered Nurses:

- Follow Trust policy and SOPs
- Complete local pharmacy CD signature authorisation documentation
- Follow Nursing and Midwifery Council standards and guidance
- Be familiar with the CD policy and the legal requirements relating to CDs
- Complete mandatory training on the handling of CDs

8.7 Student Nurses:

In their final year may act as fully registered nurses, provided they are witnessed by a fully registered nurse. They must have received the Trust training session. CD orders written by final year students must be countersigned by a fully registered nurse. Other student nurses may act as witnesses provided they have received the Trust training session. Newly registered nurses should repeat the Trust training session within the first year after registration if required to handle controlled drugs

8.8 Healthcare Assistants and Assistant Practitioners:

Healthcare assistants and assistant practitioners who are required to witness the receipt, recording, administration or weekly checks of CDs must:

- Follow Trust policy and SOPs
- Sign medical records signature record
- Be familiar with the CD policy and the legal requirements relating to CDs
- Complete mandatory training on the handling of CDs

8.9 Pharmacists:

Pharmacists are responsible for:

- Monitoring adherence to the Trust policy.

- Ensuring the security and management of CDs on wards/departments is checked by pharmacy team each quarter year.
- Recording the CD check in the CDRB and providing records of the check to the Head of Pharmacy.
- Assisting in the investigation of any incident involving CDs.
- Witnessing the destruction of CDs (when authorised to do so by Accountable Officer).
- Reporting any concerns about the management or prescribing of CDs to the Accountable Officer and the Head of Pharmacy.
- Support Trust staff to ensure implementation of the policy.
- Checking the monthly or quarterly usage of Controlled Drugs on the ward/team.

8.10 Pharmacy Technicians:

- Monitoring adherence to the Trust policy.
- Checking the security and management of CDs on wards/departments each quarter year.
- Recording the check in the CDRB and providing records of the check to the Head of Pharmacy.
- Assisting in the investigation of any incident involving CDs.
- Reporting any concerns about the management or prescribing of CDs to the Accountable Officer and the Head of Pharmacy.
- Support trust staff to ensure implementation of the policy.
- Witnessing the destruction of CDs (when authorised to do so by Accountable Officer).
- With the clinical pharmacist , checking the monthly or quarterly usage of CDs on the ward/team

8.11 Prescribers:

- Ensure they are familiar with the policy and the legal requirements relating to CDs
- Report errors and near misses
- Write all prescriptions in accordance with CD regulations
- Countersigning ward CD orders, and signing FP10CDF orders
- Medical doctors who have achieved provisional registration with the GMC (F1 Doctors) are permitted to prescribe CDs (and other POMs) on inpatient, discharge and outpatient forms so far as this is necessary for the purposes of their employment as defined in the Medical Act 1983.

8.12 Non-Medical Independent Prescribers:

Non-Medical Independent Prescribers are responsible for ensuring that they prescribe, administer, or direct anyone to administer CDs solely for specified medical conditions and by specified routes of administration (see Appendix 4)

Non-medical Independent Prescribers can legally countersign ward CD orders, where the CD is to be requisitioned from a separate organisation

Community Practitioner Nurse Prescribers may only prescribe those products and medicines specified in the Nurse Prescribers' Formulary for Community Practitioners. No CDs are included in this formulary.

8.13 Associate Director of Estates:

- Ensure the Trust complies with the Environmental (Permitting) England and Wales Regulations 2010 by holding valid T28 exemption certificates to permit denaturing of CDs. A valid T28 certification must be held for each location where CDs are denatured.
- Ensure that storage for CDs is provided in new builds and refurbishments. Such storage must comply with the Misuse of drugs (Safe Custody) Regulations 1973.

8.14 Approving Committee Responsibilities:

The Chair of the approving committee will ensure the policy approval is documented in the final section of the Checklist for Policy Changes. The committee will agree the approval of the final draft of the policy.

9. ABBREVIATIONS / DEFINITION OF TERMS USED

TERM USED	DEFINITION
Accountable Officer (AO)	The designated person who is responsible for securing safe and effective management of Controlled Drugs in the Trust
Controlled Drug (CD)	A drug which must be managed according to legal requirements
Controlled drug record book (CDRB)	The bound book in which all records of Controlled Drugs receipts, administration, checks, returns and destructions are recorded in a ward or team
Lloyds Pharmacy	Provider of medicines supply services to wards/teams in North Cumbria part of the Trust
Local Intelligence Network (LIN)	A local network set up to share information relating to the governance arrangements for CDs
Opioid or Opiate	Morphine or substances resembling morphine, with similar potency and pain relieving or other characteristics
Prescription Only Medicine (POM)	These medicines can only be supplied or administered if a prescription, or other form of authorisation is in place (refer to Trust Medicines Policy for further details)
Standard Operating Procedure (SOP)	The approved procedure which is to be followed for each activity. For CDs these are held on the medicines management intranet pages
To Take Out medicines (TTO)	Medicines dispensed for a patient discharge
University Hospitals Morecambe Bay Trust (UHMBT)	Provider of dispensed medicines to wards/teams in South Cumbria

DOCUMENT CONTROL

Equality Impact Assessment Date	03/11/11 (no changes to EIA in 2016 and 2019)
Sub-Committee & Approval Date	Medicines Optimisation Committee 04/01/2019

History of previous published versions of this document:

Version	Ratified Date	Review Date	Date Published	Disposal Date
CPFT	2016	2018		
CPFT	2013	2016		
CPFT	2011	2013		
CPFT	2009	2011		
CPFT	2007	2009		

Statement of changes made from version

Version	Date	Section & Description
	Jan 2019	• Expiry of previous policy extended from 2 years to 3 years, including amendment to new CPFT trust policy format.
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List of Stakeholders who have reviewed the document

Name	Job Title	Date
Paul Fieldhouse	Director of pharmacy and Medicines Optimisation	04/01/2019
	Medicines Optimisation Committee members	04/01/2019