

## Policy and Procedures for the Use of Controlled Drugs (CDs) on Wards, Departments and Theatres

<b>Approved By:</b>	Clinical Policy & Guideline Committee
<b>Date of Original Approval:</b>	<b>17<sup>th</sup> June 2009</b>
<b>Trust Reference:</b>	<b>B16/2009</b>
<b>Version:</b>	7
<b>Supersedes:</b>	6 – May 2022 Policy and Guideline Committee
<b>Trust Lead:</b>	Elizabeth McKechnie, Medication Safety Lead Pharmacist
<b>Board Director Lead:</b>	Andrew Furlong, Medical Director
<b>Date of Latest Approval</b>	14 <sup>th</sup> February 2025– Clinical Policy and Guideline Committee
<b>Next Review Date:</b>	<b>February 2030</b>

## CONTENTS

Section		Page
	Summary statement	4
<b>1</b>	Introduction	5
<b>2</b>	Policy Scope	5
<b>3</b>	Definitions	5
<b>4</b>	Roles and Responsibilities	6
<b>5</b>	Policy Statements	7
	5.2 Ordering of Controlled drugs	8
	5.3 Delivery and receipt	9
	5.4 Storage	10
	5.5 Key Holding and access to Controlled drugs	11
	5.6 Management of missing keys	12
	5.7 Recording in CD registers including special exemptions	12
	5.8 Stock checks and discrepancies	13
	5.9 Diversion of CDs	15
	5.10 CD stationery	16
	5.11 Prescribing	16
	5.12 Administration of CDs	18
	5.13 Self administration of CDs	19
	5.14 Patients own CDs and discharge medicines	19
	5.15 Patient controlled analgesia(PCA) / epidurals	20
	5.16 Additional requirements for high dose Morphine and Diamorphine injections	21
	5.17 Cannabinoid oils/ cannabis based medicinal products	21
	5.18 CDs used in clinical trials	21
	5.19 Return and destruction of CDs	22
	5.20 Broken or defective CDs	23
	5.21 Borrowing of CDs	23
	5.22 Ward / Theatre closure or relocation	23
	5.23 Relatives bringing in own CDs	24
<b>6</b>	Education and Training	24
<b>7</b>	Process for Monitoring Compliance	24
<b>8</b>	Equality Impact Assessment	25
<b>9</b>	Supporting References, Evidence Base and Related Policies	25
<b>10</b>	Process for Version Control, Document Archiving and Review	26

Appendices		Page
<b>1</b>	Acceptable identification for collection of controlled drugs	27
<b>2</b>	Flow diagram of processes involved in management of CDS – <b>Quick ref guide</b>	28
<b>3</b>	Requirements for common CDs	29
<b>4</b>	Guidelines for checking liquid CDs	31
<b>5</b>	Authorised Signatory List for ordering CDs	32
<b>6</b>	Authorised Signatory List – amendments between CD audit	34

7	Controlled Drug (CD) Specialist ,Leicestershire Constabulary - Responsibilities	35
8	Sample CD register	36
9	Sample order form	37

## **REVIEW DATES AND DETAILS OF CHANGES MADE DURING THE REVIEW**

---

Reviewed February 2020

- Information on the different schedules for CDs
- Information added re administration of IV morphine in Emergency department which is not witnessed by the bed space – an agreement at The Medicines Optimisation Committee

New sections :

- Section on self administration – reflects that this has now been authorised for 1 patient.
- Section on Cannabinoids
- CDs in clinical trials
- Broken or defective CDs

## **KEY WORDS**

---

Controlled Drugs, CDs,

---

## Policy and Procedures for the Use of Controlled Drugs on Wards/ Theatres and Departments summary

---

The use of Controlled drugs is governed by the Misuse of Drugs act 1971 and the Misuse of Drugs Regulations 2001 and Controlled Drug Regulations 2013 with further amendments. This policy has been developed in order for the Trust and practitioners to comply with the regulations for the management of controlled drugs and in response to changes and recommendations as a result of the Shipman enquiry.

The policy details procedures to be followed for all management of controlled drugs covering:

- The ordering, supply, prescribing and administration of Controlled drugs
- The security, documentation and stationery to be used for controlled drugs
- The procedures for destruction

This policy applies to all healthcare staff including bank or agency staff involved in the ordering, supply, prescribing and administration of Controlled drugs.

---

## **1 INTRODUCTION**

---

- 1.1 This document sets out the University Hospitals of Leicester (UHL) NHS Trusts Policy and Procedures for the management of Controlled Drugs (CDs) within wards, departments and theatres.
- 1.2 The use of Controlled Drugs is governed by the Misuse of drugs Act 1971, Misuse of Drugs Regulations 2001 and the Controlled Drug Regulations 2013 with additional amendments following the Shipman enquiry and subsequent legislation.
- 1.3 In addition The Healthcare Commissioning Board issued a safer practice notice when under the National Patient Safety Agency (NPSA/2006/12) recommending a number of actions to ensure safer practice with high dose ampoules of diamorphine and morphine, and a rapid response report to reduce dosing errors with opioids NPSA/2008/RRR05
- 1.4 This policy defines the procedures for the ordering, receipt, storage, administration and destruction of controlled drugs at ward/department level to ensure compliance with legal requirements and best practice
- 1.5 The procedures found within this policy are there to ensuring a complete auditable trail is kept for all stages and use of Controlled Drugs. .
- 1.6 This policy applies to all schedule 2 and 3 drugs outlined in the Misuse of Drugs regulations 2001

## **2 POLICY SCOPE**

---

- 2.1 This policy applies to: Medical Staff; Registered Nursing staff and Nursing Associates; Midwives; Pharmacy staff; Operating Department Practitioners; Radiographers: Allied Health Professionals/Healthcare Scientists involved in the storage, prescribing, supply administration and disposal of CDs.
- 2.2 This policy applies to all staff including portering staff involved in the transport of controlled drugs.

## **3 DEFINITIONS**

---

### 3.1 Accountable Officer

Officer in a health care organisation who is responsible for the safe management of controlled drugs as required by Controlled Drugs (Supervision and Management of Use) Regulations 2006.

### 3.2 Controlled Drug (CD)

The drugs listed in the Misuse of Drugs Regulations 2001 as amended which are subject to varying controls on prescribing, storage, handling and disposal.

### 3.3 Diversion – removal of Controlled drugs for unauthorised use

### 3.4 Schedules

The Misuse of Drugs regulations 2001 classified CDs into 5 different schedules. Controls on the management and documentation required vary according to the schedule. For all drugs within each schedule see BNF

**Schedule 1 ( CD LIC POM)**

Most Schedule 1 drugs have no therapeutic use and a home off license is required for production , possession or supply. An example would be hallucinogenic drugs eg LSD, ecstasy type substances.

**Schedule 2 (CD POM)**

Include strong opiates (eg diamorphine, morphine , methadone , oxycodone) major stimulants (eg amphetamines ) and ketamine

**Schedule 3 ( CD no register POM)**

Include minor stimulants and other drugs ( eg buprenorphine, tramadol, midazolam and phenobarbital) that are less likely to be misused ( and less harmful if misused ) than those in schedule 2.

**Schedule 4 (CD BENZ POM or CD ANAB POM)**

Split into 2 parts

- Part 1 (CD Benz POM) contain most benzodiazepines, no benzodiazepine hypnotics ( eg zopiclone) and Sativex ( a cannabinoid oromucosal mouth spray)
- Part 2 ( CD Anab POM) contains most anabolic and androgenic steroids

**Schedule 5 ( CD INV POM or CD INV P )**

Contain preparations of weak opioids ( eg codeine dihydrocodeine and morphine) that are exempt from full control when present in specifically low strengths.

---

## 4 ROLES AND RESPONSIBILITIES

---

4.1 The executive director responsible for this policy is the Medical Director.

**Chief Pharmacist:**

4.2 The Chief Pharmacist as Accountable Officer (AO) is responsible

- for the safe management of Controlled drugs within the Trust
- being involved in the investigation or breach of any Controlled drug regulations working with the CMG team and Community Drug Liaison Officer (CDLO)
- for raising concerns about the inappropriate use of CDs to the executive team
- for sharing incidents / concerns through the Local Intelligence Network (LIN)

**Clinical Management Group (CMG)**

4.3 The Clinical Director and Head of Nursing are responsible for ensuring staff within their CMG are aware of this policy

4.4 Heads of Nursing or their nominated deputy for the CMG will be responsible together with the Accountable officer / deputy for investigating incidents involving CDs in their area.

4.5 CMG Lead Pharmacists have a responsibility for ensuring all 3-6 monthly ward / departmental audits are carried out and reported to the CMG Quality and Safety Boards and Head of Nursing. The decision about frequency will be made depending on previous audit results. Concerns about poor practice / mismanagement / misappropriation should be escalated to the Accountable Officer.

## Ward / departmental staff

- 4.6 The appointed nurse, midwife, Operating Department Practitioner (ODP) or superintendent radiographer in overall charge of a ward or department is responsible for the safe and appropriate management of CDs in that area. Within theatres it is the responsibility of the nurse / ODP in charge for each theatre.
- 4.7 The Nurse, Midwife, ODP or superintendent radiographer in charge on the day can delegate control of access (i.e. key-holding) to the CD cupboard or cabinet to another Authorised individual, such as a Registered Nurse or ODP. However, legal responsibility remains with the appointed Nurse, Midwife or ODP in charge for that day.
- 4.8 All designated staff involved with the management of CDs (prescribing, ordering, preparation, administration and disposal) are required to submit a copy of their signature, area of work and professional registration number to Pharmacy for confidential use in checking and validating written records. The ward manager / theatre manager is responsible for organising this. (see appendix 5)
- 4.9 All staff involved with the management of CDs have a responsibility to follow this policy and report incidents using Datix (incident reporting system) including the inappropriate use of CDs.

## 5 POLICY STATEMENTS

---

### 5.1 Key principles :

- a. Controlled drugs are an important therapeutic intervention e.g. pain management, and, as such, must be readily accessible to patients who require strong analgesia.
- b. Controlled drugs are subject to special legislative controls because there is a potential for them to be abused or diverted, causing possible harm.
- c. Designated Healthcare staff are authorised in law, to be in possession of controlled drugs for the purposes of supply, administration or disposal in accordance with the above principles.
- d. Requirements listed in this policy apply to schedule 2 & 3 drugs unless others are specifically mentioned (please refer to appendix 3 for individual requirements). Schedule 4 & 5 generally do not require storage and register requirements unless there are individual ward / department requirements requested by the Accountable Officer or in discussion with a senior nurse from the CMG.
- e. All preparation, administration and disposal of schedule 2 CDs must in all circumstances be directly witnessed by another authorised individual.
- f. Systematic documentation and checks are required to ensure the secure management of controlled drugs and demonstrate this to the Accountable Officer.
- g. All incidents will be reported and investigated by the Accountable Officer and will be referred to the CD Local intelligence network as appropriate.
- h. Failure to comply with these good practice standards and legislative requirements could result in disciplinary action and/or criminal prosecution.
- i. All Procedures for the use of controlled drugs (CDs) on wards, departments and theatres are detailed below and must be followed.

## Procedures and Standards for the use of Controlled Drugs

### 5.2 Ordering of Controlled Drugs

- a) The registered nurse, midwife or ODP in charge for the day of a ward or department is responsible for the requisitioning of controlled drugs for use in that area. The designate Nurse, Midwife or ODP in charge can delegate the task of preparing a requisition to another assigned Practitioner however the legal responsibility remains with the most senior registered nurse, midwife or ODP in charge on that day.
- b) Agency or bank staff are **not** permitted to order CDs for an area. The exception to this is Theatres / Critical Care areas where a bank /agency member of staff may order if
- The matron for the area signs the individual off as a long term member for the area
  - The individual has read and confirmed that they will follow this policy
  - The matron confirms that the individual is required to order CDs, essential for service delivery
- c) Registered radiographers may undertake the ordering only if there are no registered nurses available or the registered nurse is unavailable as listed below:
- absence due to sickness and annual leave
  - scrubbed up for a procedure
  - 'out of hours'
  - only one nurse present
  - involved in another area of the department of Radiology.
- d) CDs are ordered in the CD Ward Order Book which has duplicate pages
- There should only be one order book in use at any one time until the last few pages when a second book may be issued. To order a new CD ward order book a stock requisition must be completed by an authorised signatory ( see section 5.10) and taken to the pharmacy department.
  - Only one item must be ordered per page
  - The pack size should be specified if known or the quantity if less than a full pack is required.
  - For controlled drugs that are not kept as stock consider how many are required for the individual patient during their stay for example if a patch is changed once a week then only 1 patch is required.
- e) The CD requisition must be signed by an authorised signatory
- A copy of the list of authorised signatories is held on the ward/department and in pharmacy department.
  - Requisitions signed by a person not on the list of authorised signatories will be referred back to the ward/department.
- f) Each ward and clinic area will have a stock list of controlled drugs (CDs) approved for that area by the nurse in charge, midwife or ODP and agreed with the CMG lead pharmacist. The stock list will reflect current usage, whilst minimising risks associated with storage of multiple



## Procedures and Standards for the use of Controlled Drugs

products and strengths. CD stock lists should be reviewed every six months or earlier if there is change in ward specialty or clinical need.

- g) CDs may be “topped up” against a defined stock list by a pharmacy technician. The pharmacy technician is responsible for checking the stock balances against the agreed stock list and preparing the CD requisition forms to replenish the stock. These requisitions must be signed by the registered nurse, midwife or ODP in charge.
- h) Pharmacists registered with the General Pharmaceutical Council employed by Deenova and working under an honorary contract with UHL within Optimed wards where Unit Dose Automated Medication Cabinet (also known as Mario Cabinet) is used can act as authorised signatory and order Schedule 3 controlled drugs (oral tramadol, oral gabapentin and oral pregabalin only) in a controlled drug order book using the process described in Section d) above.
- i) Prescriptions for CDs **not** on the ward / department stock list must be checked by a pharmacist either at ward level before ordering or by a dispensary pharmacist. When the order has not been seen by a ward pharmacist before being sent to the dispensary the following must happen : -
- Paper chart areas – the drug chart for the specific patient must accompany the order book
  - Electronic areas – the S number for the patient must be entered onto the top of the requisition page near the serial number
- j) In the case of theatres the CMG Lead Pharmacist for Anaesthetics or the Duty Pharmacist on site must be contacted before ordering non stock CDs.
- The pharmacist will annotate the CD requisition with the patient’s name and unit number and the time the drug is required for. The pharmacist will countersign the requisition.
- k) CD orders for non stock CDs which have not previously been agreed, annotated by a pharmacist or accompanied by a drug chart ( excluding those areas using electronic charts), will be referred back to the ward/department or operating department..

### 5.3 Delivery and Receipt

- a) When collected by ward/department or portering staff the person must produce their staff identity badge for inspection by pharmacy staff.
- b) Only staff holding a UHL photograph identity badge are allowed to collect controlled drugs.
- c) The member of staff should check the controlled drug, preparation and number supplied is the same as that on the requisition.
- d) Sealed containers do not need to be opened to check the number of ampoules / tablets but assume the contents are as stated on the box. Any discrepancies found on opening a box must be reported to the pharmacy department and a datix incident report completed..
- e) The member of staff must sign and print his/her name on the accepted for delivery section of the requisition. The white top copy will be removed from the order book by pharmacy staff and retained in pharmacy.
  - When the CDs are packed in a red transit bag the member of staff should check the security number on the bag matches the collection / delivery sheet. The CDs in the red transit bag are NOT individually checked.
  - The member of staff must sign and print his/her name on the delivery sheet.
- f) On receipt of a CD onto the ward/department a registered nurse / midwife /ODP or radiographer must sign and print his/her name on the “received by” section of the pink CD requisition. In addition when delivered by the pharmacy porter/distributor the nurse/midwife or

## Procedures and Standards for the use of Controlled Drugs

ODP will be asked to sign and print his/her name on the pharmacy delivery sheet.

g) It is the registered nurse / midwife/ODP or radiographers responsibility to check the CD delivered against the order / prescription and to make an entry into the register with the following information:

- ✓ Date of receipt
- ✓ Requisition number
- ✓ Words 'Received from Pharmacy'
- ✓ Quantity
- ✓ Signed for and witnessed by
- ✓ New balance

Any discrepancies with the medicines supplied and ordered must be reported to pharmacy immediately.

h) When Discharge medicines (TTOs) containing CDs are delivered to the ward/department or collected from Pharmacy they will be accompanied by a Discharge CD Delivery Form which will be signed by the person delivering the TTO to the ward. The top copy of the form is retained in pharmacy. The second copy must be signed on receipt of the TTO onto the ward/department and retained on the ward in the CD cupboard.

i) All CDs dispensed as TTOs must be entered into the Patient's Own CD register immediately upon receipt onto a ward and then signed out by two nurses / midwives/ ODPs upon discharge.

j) CDs must not be left unattended on a ward or department and must be entered into the register and locked in a CD cupboard as soon as possible after receipt.

k) Identification must be seen and recorded for collection of Out patient prescriptions ( see appendix 1)

- Patients, carers and relatives must show some form of identification with an address on. The name and address of the person collecting will be recorded in the CD register.
- Healthcare professionals collecting an Out patient prescription on behalf of a patient must show identification and a registration number if applicable. The name, address and registration number will be recorded in the CD register.

### 5.4 Storage

a) All CD schedule 2 and some schedule 3 stock and non-stock items are stored in the CD cupboard. ( see appendix 3 for requirements).

b) The Misuse of Drugs (Safe Custody) regulations 1973 provides minimum standards for the storage and security of CDs. All storage devices must meet Home Office approved standards.

Summary of requirements :

- Made of sheet steel
- Only 3 millimetre gap between door and cabinet walls
- Effective lock – at least 5 different levers, dead bolt
- If the door is greater than 914 mm vertically and 457mm wide then the door must have 2 locks

## Procedures and Standards for the use of Controlled Drugs

- Additional requirements for 2 door cupboards
  - Rigidly and securely fixed to wall or floor by 2 rag- bolts. The wall used must not be a temporary structure eg portacabin.
  - Nothing must be displayed outside the cupboard to indicate that drugs / CDs are kept within.
- c) CD cupboards must be secured to the wall or floor and be **reserved solely** for the storage of CDs. Patient's property eg watches, lighters, money must not be kept in the cupboard. CD cupboards are not for storage of prescription pads or fit for work notes.
- d) There is no requirement for a light /alarm on the cupboard but some wards have them where cupboards are sited in open areas as a method of alerting staff to when the cupboard is open.
- e) Digital locks are unsuitable for cupboards containing controlled drugs and **must not** be fitted.
- f) Advice on cabinets and suitable locations for Cupboards can be obtained from pharmacy.
- g) CD cupboards should be well maintained and where possible the following principles applied:
- Separate shelf for patients own
  - Separation of high and low strength preparations
  - Epidurals kept on a separate shelf from injectables
  - No expired medicines
  - Only patients own for those who are present on the ward.

Where CD cupboards have an inner and outer door the outer area may be used to store CDs as long as the outer meets the CD storage requirements above. The 2 keys must be kept separate from other keys and no other medicines or items which are not CDs kept in this area.

Pharmacy must be informed of expired medicines and patients own which have not been returned for prompt removal. Where there are issues with CDs not being removed in a timely manner (over 2 weeks) this must be escalated to the CMG lead pharmacist for action.

### 5.5 Key holding and Access to controlled drugs

- a) The registered nurse, midwife or ODP in charge of the ward or department area is responsible for the CD keys
- b) Spare keys cannot be kept and must be destroyed by facilities. Please contact the Medicines Management Team extn 12644 to arrange the removal of a key.
- c) The CD keys **must be separate** from the remaining drug keys to restrict access to authorised personnel only and held by the authorised individual, not placed in digital safes with other keys.
- The CD key should be returned to the nurse, midwife or ODP in charge immediately after use by another registered member of staff. In each theatre the key can be retained by the ODP/Nurse that is supporting the anaesthetist throughout the list for the duration of the operating list.
  - For the purpose of stock checking the CD keys may be given to an authorised member of pharmacy staff, a pharmacist or medicines management technician.

## Procedures and Standards for the use of Controlled Drugs

- d) Where departments close for a period regularly ( no longer than over a 3 day bank holiday weekend) for example theatres then the Controlled drug key must be placed in an allocated CD key cupboard and a record kept for when the key is removed or returned. Keys must be signed in and out of the storage area so there is a trail of who has accessed the keys.
- e) Areas where this is the case must be risk assessed by pharmacy and CMG Head of Nursing to ensure that there are no security risks eg located in an area accessible to patients . general public / unregistered staff / high volume use of CDs.

### 5.6 Management of Missing Keys

- a) If the CD keys cannot be found urgent efforts should be made to retrieve the keys as speedily as possible.
- b) Nursing, midwifery or ODP staff who have just gone off duty should be contacted.
- c) One of the following should be informed as soon as possible -senior registered nurse in charge, midwife or matron, OR the duty manager OR the midwifery manager.
- d) If the keys cannot be found a Datix incident form must be completed and forwarded to the Chief Pharmacist as Accountable Officer. It may also be appropriate to contact the police. For further guidance on reporting and management (appendix 7)
- e) Arrangements for ensuring security of CDs and patient care must be made in discussion with the senior member of nursing/midwifery staff and senior CMG pharmacist.
- f) Out of hours, a dose may be provided from another ward, as long as this is fully documented in that ward's CD register for the specific patient and their location in accordance with a valid prescription for that patient.
- g) Replacement of locks can only be on the authority of the Accountable Officer/designated deputy or pharmacy service second on call and the Trust local security management advisors.

### 5.7 Recording in CD Registers ( see appendix 8 )

- a) A record of CDs received and administered must be kept in a Controlled Drug Record Book (Register) using indelible ink. Areas where there is a high usage of CDs may need to use more than one register. Each ward will in addition have a Patient's Own Controlled Drug Register.
  - There should be a separate CD register for each theatre
- b) The registered nurse, midwife, ODP or superintendent radiographer in charge is responsible for keeping the CD Register up to date and in good order.
- c) There should be a separate page for each drug, each strength and each unit size e.g. ampoule size or bag, so that a running balance can be kept. Entries should be made in chronological order. The form ( ie capsule, ampoule, vial, liquid ) must be included within the CD title.

## Procedures and Standards for the use of Controlled Drugs

- d) All entries must be signed by a registered nurse, midwife or ODP and should be witnessed preferably by a second registered nurse, midwife or ODP. If a second registered nurse or midwife is not available the transaction can be witnessed by another registered practitioner (eg doctor, pharmacist or pharmacy technician).
- a combination of 2 radiographers or a radiographer and doctor may make entries into the register when no registered nurse is present
- e) A new page should not be started until all lines have been used. At the end of the page the balance should be transferred to a new page. The new page number should be added to the bottom of the finished page and the index updated. As a matter of good practice the transfer should be witnessed.
- f) Where books are damaged or spoiled or a new register is to be used any remaining lines must be crossed through with a single diagonal line to prevent further entries.
- g) If a mistake is made in the CD register it should be **bracketed** allowing for the original entry to be seen and then signed, dated and witnessed. The witness should also sign the correction.

Eg if 5 ampoules had been entered in error instead of 10 ampoules

Diamorphine 5mg (**5amps**) 10amps.

- There **must be no crossings** out in CD registers and liquid paper correction fluid (eg Tippex™) must NEVER be used.
  - Pages or part pages must NEVER be ripped out of the CD book
- h) On receipt of all CDs ordered in a CD requisition book the following details must be recorded on the appropriate page in the ward CD register:
- Date of entry
  - Serial number of requisition
  - Quantity received
  - Name / signature of nurse/authorised person making entry
  - Name/signature of witness
  - Balance in stock

Eg. 12/2/2008 serial no. 42 ten amps *A. Sample E Another* 30 ampoules

- i) When recording CDs retrieved from pharmacy, the number of units received should be recorded in words not figures (e.g. ten, not 10 ) to reduce the chance of entries being altered.

### **Special Exceptions** ( refer to Appendix 3)

- j) Midazolam must be stored in a CD Cupboard and records kept for all wards/ departments except endoscopy where it must still be ordered in a CD order book but there is no requirement to register each entry.
- k) Ketamine liquid and injection is handled as a full CD within UHL and must be entered in the CD Register.

## 5.8 Stock Checks & discrepancies

## Procedures and Standards for the use of Controlled Drugs

- a) The stock balance of all CDs entered in the CD register and Patients own CD register should be checked and reconciled with the amounts in the cupboard with sufficient frequency to ensure that discrepancies can be identified in a timely way. **The frequency of such checks must be at the end of every shift.**

- Wards must check twice daily
- Areas which open and close frequently must check upon opening and then when closing the area.

The frequency of checks may be increased if necessary at the request of Pharmacy or Senior Nursing staff if there are concerns regarding stock control of Controlled Drugs. In addition, stock checks should be carried out by pharmacy staff every 3 -6 months.

- b) The registered nurse, midwife, ODP or superintendent radiographer in charge is responsible for ensuring that regular CD stock checks are carried out by staff in the ward or department.
- c) Two registered nurses, midwives, ODPs or registered health professionals should perform this check.
- d) The check should involve checking all balances within the CD register with the contents of the CD cupboard and that signatures are known to ward staff. There is no requirement to open packs with intact tamper evident seals for stock checking purposes.
- e) Stock balances of liquid medicines should generally be checked by visual inspection but periodic volume checks may be helpful. The balance must be confirmed to be correct on completion of a bottle. (see appendix 5 for guidance on checking liquid CDs)
- f) A record made of this check must be entered into the Blue CD stock check book, signed and witnessed by two registered nurses/ midwives/ ODPs. To obtain the book please order from the Print Room.
- g) If a discrepancy is found the ward manager and the senior pharmacist on duty must be informed. The discrepancy must be investigated without delay. Checks should be made back through the register from when the last check was made until when the discrepancy was discovered to identify any errors. In the first instance the following should be carefully checked:
- All requisitions received have been entered onto the correct page of the CD register.
  - All CDs administered have been entered into the CD register.
  - Items have not been accidentally put into the wrong place in the CD cupboard or other storage area/trolley.
  - Arithmetic to ensure that balances have been calculated correctly.
  - CDs returned to patients and no entry made
  - Look around the treatment room, especially bins or anything stored directly below the cupboard. Search the pharmacy green returns bin.
  - Strips of tablets can fall out of worn packaging and then get trapped behind loose shelving

If the error or omission is traced, the registered nurse, midwife or ODP in charge should make an entry in the CD register, stating the reason for the entry and the corrected balance. This entry should be witnessed by a second registered nurse, midwife, ODP, pharmacist, pharmacy technician or doctor. Both persons should sign the CD register.

- h) If no errors or omissions are detected then the discrepancy must be reported to the senior registered nurse /matron on duty and the Pharmacy Department who must ensure an independent check is undertaken. A datix record must be completed.

## Procedures and Standards for the use of Controlled Drugs

- i) If this independent check does not resolve the discrepancy then the registered nurse/midwife in charge must contact the following:

Normal working hours 9am- 6pm:

- CMG Head of Nursing or their deputy
- Duty Manager
- Chief Pharmacist [Accountable Officer] /deputy chief pharmacist.
- **If a criminal offence is suspected** inform the Trust senior manager on call via switchboard before police are called.

Out of hours:

- Nurse bleep holder
- Duty Manager, who will inform the On call pharmacist
- **If a criminal offence is suspected**, inform the Trust senior manager on call before police are called
- Inform Chief Pharmacist [Accountable Officer] when normal hours resume

- j) To assist further investigation :

- Collate a list of all staff on duty between when the balance was last checked as correct and the discrepancy detected.
- Collect statements from staff who have had access to the controlled drug cupboard during this time.

- k) The Chief Pharmacist [Accountable Officer] will liaise with the Controlled Drug specialist, Leicestershire Constabulary (see Appendix 7) for incidents where there is a suspected criminal offence involving controlled drugs.

### 5.9 Diversion of CDs

- a) Diversion of CDs is when staff remove CDs for their own personal use. Unfortunately this does occur and staff should be aware that this can happen when investigating a discrepancy which cannot be resolved.
- b) Diversion of CDs is a criminal offence and staff who are found in possession of a CD for which they have no prescription will be dealt with under the Disciplinary Policy A6/2004
- c) Signs to consider, although not exhaustive
- a change in behaviour over a period of time
  - a large upheaval or significant event either in work or at home which could cause pressure/ stress
  - recent painful accident or operation
  - difficulty in sleeping
  - constantly late to work when previously punctual



## Procedures and Standards for the use of Controlled Drugs

- disappearing for periods of time during a shift
- d) Diversion is more likely to occur for schedule 4 and 5 medicines for example codeine, dihydrocodeine or benzodiazepines
- e) If it is thought that higher usage of a schedule 4 or 5 is being requested but patients are not being prescribed doses then this should be discussed with the CMG Lead Pharmacist and matron for the area.
- f) Data can be obtained from Pharmacy computer systems and emeds to review supply figures against usage. Advice can be sought from the Medication Safety Lead Pharmacist.
- g) Where the reports indicate there is a potential problem then a plan should be agreed between the CMG lead Pharmacist and matron in discussion with the Accountable Officer or deputy.

### 5.10 CD stationery

- a) CD order books and registers must be kept locked away with restricted access.
- b) CD registers and order books must be ordered by an authorised signatory using a stock requisition or via the pharmacy team. A signature will be required on receipt.
- c) Only one CD requisition book per ward or department should be in use.
- d) When a new CD register is started the balance of stock should be written into the new book and witnessed by a registered nurse, midwife, registered health professional or by an appropriately trained healthcare assistant, student nurse.
- e) CD registers and all associated records must be kept on wards for 2 years from the date of the last entry made and can only be destroyed as part of confidential waste. Completed registers and order books do not need to be stored locked in the Controlled drug cupboard.
- f) Lost CD registers or order books must be reported to pharmacy and a datix incident report completed.
- g) Registers in place :
  - Ward register
  - Patients own register
  - Theatre register

### 5.11 Prescribing

- a) Private prescriptions cannot be issued for Controlled drugs
- b) General Points re prescribing Opioids:
  - Consider the patient parameters for example age, weight and renal function. There have been deaths reported nationally associated with opioid naïve patients receiving high doses of injectable opiates ( eg doses of morphine 30mg or above)
  - Confirm any recent opioid dose, formulation and frequency of administration including the use of breakthrough doses.

## Procedures and Standards for the use of Controlled Drugs

- Ensure dose titration is appropriate and safe, never increase doses by more than 50% – refer to the BNF or UHL palliative care guidelines
- Ensure the prescription is clear including the formulation to be used

### c) Controlled Drugs for Outpatient and Discharge Prescriptions

By law, the prescription must always state

- the name and address of the patient
- the patient's NHS or hospital number
- in the case of a preparation, the form and the strength of the preparation
- the dose, 'as directed' is not acceptable
- the total quantity of the preparation, or the number of dose units, **in both words and figures**,

e.g. morphine sulphate controlled release (MST) tablets, 30 mg bd - fourteen (14) x 30 mg tablets.

The above can be handwritten or be computer generated. The prescriber's signature must be handwritten and not computer generated. Initials are not acceptable. ICE / Nervecentre discharge letters must be printed and signed by the prescriber against the CD prescription. If pre printed sticky labels are used, including the use of addressographs, prescribers should also sign on the sticky label to ensure that sticky labels are not tampered with or another sticky label is not placed on top of the one that the prescriber has signed for.

Any manuscript changes to prescriptions should be signed by the prescriber

A maximum of 30 days supply can be prescribed and prescriptions will only be valid for 28 days from date of issue. In circumstances where the patient is known to be a drug abuser, no more than 24 hours supply of controlled drugs should normally be given.

Methadone, for patients on Opioid substitution treatment, must not be prescribed on discharge. It is expected that the patient will revert to normal supply arrangements. Please refer to the Opioid Dependence Management of adult Patients guideline B67/2019

Where a Community Nurse is to administer medication, a copy of the prescription, containing the name, address and medicine details, signed and dated by the medical practitioner, must be provided.

### d) Supplementary Prescribers

A supplementary prescriber, when acting in accordance with an agreed individual clinical management plan (CMP), may prescribe and administer and/or supply or direct any person to administer any CD provided that the CD is included in the CMP.

### e) Non-medical Independent Prescribers

Nurse and Pharmacist Independent Prescribers may prescribe CDs within their competence, except diamorphine, dipipanone or cocaine for the treatment of addiction. See Policy for Non-Medical Prescribing B18/2004

### f) Registered midwives are permitted under The Medicines Act 1968 and subsequent amendments to administer specified CDs to women in their care, without a prescription The

## Procedures and Standards for the use of Controlled Drugs

CD administered must appear on the UHL Maternity Services list of Midwifery Exempt Drugs. (Please refer to Policy for supply and administration of medicines by midwives C70/2007)

- g) The written requirements for controlled drugs on inpatient medicine charts or anaesthetic charts should include:
- Drug name, strength and form
  - Route
  - Dose
  - Frequency
  - Start date
  - Include a finish date where appropriate
  - Signature of prescriber
- h) Where separate charts are used eg epidural charts, anaesthetic charts, prescribers must indicate on the patient's main chart drugs to be avoided immediately post operatively and/or indicate when further doses of drugs, previously given in theatre, are due.

### 5.12 Administration of CDs.

- a) Administration of CDs must comply with the Leicestershire Medicines Code and the UHL Administration of Injectable Drugs Policy B25/2010.
- confirm the dose is correct and safe for the patient
  - look at previous doses
  - be careful when selecting the formulation – is it prolonged release or immediate release? Oxycodone is a particular medicine where there are frequent errors in miss selection
- b) Naloxone must be available in any area where an injectable opioid is administered. Please refer to IV Naloxone monograph on Medusa for information about administration.
- c) Controlled Drugs may be administered against a Trust approved Patient Group Direction (PGD) for certain indications. Please refer to the UHL Policy B43/2005
- d) Nursing associates are allowed to check or administer CDs via oral, transdermal (patches, intramuscular (IM), subcutaneous (S/C) routes but not by the IV route.
- e) Trainee nurses, midwives and nursing associates are permitted to prepare and administer controlled drugs via the following routes; oral, transdermal (patches, intramuscular (IM), subcutaneous (S/C) only under direct supervision of a registered nurse/ midwife/ practitioner. Trainees are **not** allowed to administer CDs by the IV route.
- f) A second registered practitioner must directly witness the preparation, administration and disposal of any residual doses. Trainees are **not allowed** to be the second witness for Controlled Drugs but may act as a third witness to gain experience. Where a second registered nurse, midwife, nursing associate or ODP is not available this may be carried out by a Pharmacist, medical practitioner or radiographer.
- g) Both staff members must be present during the whole of the administration procedure. They must both witness:
- The preparation of the CD to be administered. The multiple use of an ampoule for

## Procedures and Standards for the use of Controlled Drugs

several doses / patients is not allowed. (Please refer to the multi-dose vial policy B42/2008)

- The CD being administered to the patient
- The destruction of any surplus drug (e.g. part of an ampoule infusion not required)

In the case of theatres this will be at the end of the procedure.

- h) The exception to the above is the administration of IV morphine in the Emergency department where the administration is not witnessed. IV morphine is prescribed as a range and the registered professional administering can give over a period of several minutes titrating according to the patient's pain score. A second registered professional must witness the preparation, identify the correct medication and patient and witness any destruction.
- i) A record must be entered onto the appropriate page of the CD register recording the date and time, patient's name and quantity administered and signed for as described in section 5.8
- j) If part of a vial / ampoule is administered to a patient, the registered nurse, midwife or ODP should record the amount given and the amount wasted eg. "2.5mg given and 2.5mg wasted". This should be witnessed by a second registered nurse, midwife, registered practitioner who should sign the record. Part used PCA bags must not be left in the treatment room in drip stands as these could potentially be wheeled away. The quantity destroyed should be documented and witnessed immediately following discontinuation of treatment.
- k) Individual dose of CDs which have been prepared but not administered must be destroyed by a registered nurse, midwife or ODP on the ward or department in the presence of a witness (registered practitioner) and the reason documented in the CD register.
- l) Where an entry has been made in the CD register and it is discovered the dose is no longer needed as long as the packaging is still intact (ampoule not broken or removed from sealed case, tablets not removed from foil strips) then the CD can be returned to the CD cupboard. A line below in the register needs to be made to state why the CD was not required and the balance adjusted.

### 5.13 Self administration of CDs

- a) Self administration of CDs is not allowed for schedule 2 or 3 drugs unless in exceptional circumstances.
- b) If a patient requires schedule 2 or 3 self administration then this must first be approved by the Accountable Officer.
- c) Self administration must then follow the Self Administration of Medicines UHL Policy B13/2004

### 5.14 Patient's own CDs and discharge medicines

- a) Medicines labelled for a specific named patient must never be used to treat another patient, and where possible be stored separately from stock CD medicines. Labels must not be

## Procedures and Standards for the use of Controlled Drugs

removed to use the medicine as ward stock.

- b) The Trust encourages the use of patient's own medicines that are suitable for use, including controlled drugs. These remain the property of the patient, but their secure storage is the responsibility of the Trust and must be within the CD cupboard.
- c) Patient's own CDs may be used during the patient's hospital stay as long as they are deemed suitable for use: Check :-
  - The identity and condition of the drug is suitable
  - Controlled Drug is within expiry
  - If there is any doubt about suitability of the drug for use it must not be used. Seek advice from the Pharmacy team.
- d) Patient's own CDs that are not administered during their stay should not routinely be stored on the ward, but returned home with a relative, where appropriate, or to Pharmacy for destruction (see Section 5.16 Return and Destruction of CDs). Verbal consent from the patient should be obtained wherever possible when being sent for destruction as it is the patient's property.
- e) All patient's own medicines retained on the ward should be entered into the ward Patient's Own CD register.
- f) Medicines supplied by the Pharmacy Department against a discharge letter must be entered into the Patient's Own CD register until the patient is discharged. If the patient is not discharged or the CDs are no longer required and as long as the patient has not signed to accept them they may be returned to Pharmacy. The CDs should be kept in the CD cupboards and highlighted to Pharmacy staff visiting the ward that they are to be returned.
- g) If a patient has brought their own Controlled drugs into hospital and is then transferred to another ward the CDs should be transferred in accordance with procedures for transferring patients own property within the Management of Patient Property Policy (B24/2007)
  - If the patient is able to take responsibility for their own belongings then the patient must sign the CD out of the Patient own register and must be witnessed by a registered professional.
  - If the patient is unable to take responsibility for their valuables then it must be signed out by a registered nurse and witnessed by another registered professional who is then responsible for security of the CD until the patient arrives at the next ward.
- h) The receiving ward must check the CDs, place in a CD cupboard and make an entry in the patient's own controlled drug register. This entry must be made and witnessed by a registered healthcare professional.
- i) Patients must sign the Patient's Own CD register for receipt of their CDs upon discharge.
- j) If the CDs are given to a carer that person's name and address must be recorded in the Patient's Own CD register and that person is asked to sign the register.
  - The nurse must check the carer's identification (See Appendix 1 for appropriate forms of identification)

## Procedures and Standards for the use of Controlled Drugs

### 5.15 Patient Controlled Analgesia (PCA) / epidurals

- a) All staff involved in the care of patients receiving patient controlled analgesia should refer to the UHL policy and procedure for administration of Patient controlled analgesia B17/2003
- b) A record must be entered onto the appropriate page of the CD register recording the date and time, patient's name and quantity administered and signed for by an registered nurse / clinician and a witness ( registered nurse ) .
- c) The anaesthetist or nurse should document in the patient's observation charts for PCA/epidurals the amount administered when the patient is moved from theatre to the ward

### 5.16 Additional requirements for High Dose Morphine and Diamorphine Injections

This applies to ampoules of 30mg or greater strength of morphine or equivalent.

- a) It is recommended wherever possible that these ampoules are stored in a separate area of the CD cupboard to other opiate injections.
- b) The pharmacist will provide information and clarify safe use of high dose opiate, particularly for non-stock issues. ( NPSA Safer Practice Notice 12 : Ensuring safer use with high dose ampoules of diamorphine and morphine and NPSA/2008/ RRR05 Reducing opioid dosing errors with Opioid medicines )
- c) Ensure respiratory rate and BP observations are carried out after intravenous administration for the first hour following administration.
- d) The pharmacist will monitor the use of high dose opiates and return any remaining to pharmacy as soon as the patient no longer requires the medication.

### 5.17 Cannabinoid Oils / Cannabis based medicinal products

- a) There are a wide range of cannabis based products, with varying constituents including tetrahydrocannabinol (THC) and covered by different aspects of legislation:

- 1) *Unlicensed Cannabidiol (CBD) products*

A range of products marketed as herbal or nutritional supplements. As long as no THC is listed with no medicinal claims they can be treated as per the Leicestershire Medicines Code, Chapter 18 Complementary and alternative medicines.

- 2) *Licensed / synthetics*

Pure cannabidiol (CBD) licensed in the UK are treated as a schedule 2 CD

Sativex - licensed for treatment for spasticity in multiple sclerosis is a schedule 4 CD which does not need CD storage or registering.

There are a range of synthetic products which are not classified as schedule 2 eg Nabilone used in the treatment of resistant nausea and vomiting caused by chemotherapy

## Procedures and Standards for the use of Controlled Drugs

### 3) Cannabis Based products for medicinal use (CBPM)

CBD/THC Cannabis-based products for medicinal use (CBPM's) which are currently unlicensed. Discuss with a pharmacist to confirm the product source, content and legality and treat as a schedule 2 CD – store in the CD cupboard and enter into the CD Patients own register.

### 5.18 CD used in clinical trials

- a) Controlled drugs listed as schedule 2 or 3 will require full storage in a CD cupboard and documentation in CD registers.
- b) Ordering and additional controls will be specified within the Trial protocols once approved
- c) Currently there are no CDs which require storage within a refrigerator. If a trial medicine requires storage at a low temperatures this must be discussed and approved by the Accountable officer

### 5.19 Return and Destruction of CDs

- a) Controlled drugs no longer required at ward level, including out of date stock CDs and patients own CDs, must be removed by an authorised member of the pharmacy department (pharmacist or pharmacy technician) and returned to Pharmacy.
- b) Unwanted CDs must be stored in an appropriate section of the CD cupboard until they can be returned to pharmacy or destroyed. CDs must never be returned from wards or departments in pharmacy supply boxes or transport bags or placed in green pharmacy return bins.
- c) All returns from a ward or department of CDs to Pharmacy for re-use or destruction must be witnessed by a registered nurse, midwife or ODP from that clinical area in conjunction with the member of pharmacy staff returning the CD.
- d) An entry must be made in the ward/departmental CD register for all returns or destructions in the appropriate section by the registered nurse, midwife, ODP pharmacist or pharmacy technician. The balance must be amended and the entry witnessed and signed by a second registered nurse, midwife or ODP from the clinical area at the time of return or destruction.
- e) CDs which do not require a register eg tramadol capsules/ pregabalin and gabapentin **must** still be returned through pharmacy staff rather than being placed in the green pharmacy returns bins. The drug requires denaturing within the pharmacy department.
- f) CDs returned from a ward / department must be documented and transported to pharmacy in accordance with Pharmacy SOPs
- g) Expired stock must always be returned to pharmacy for destruction. Part used or surplus CD's may be destroyed on the ward as shown in Table 1.

Table 1:

Quantity/type of CD	Method of Disposal
Small amounts of CD, for example:  the surplus when a dose smaller than the total quantity in an ampoule/vial is drawn up,	Empty remaining contents into a yellow sharps bin. The empty vial or ampoule should then also be put in the sharps bin.

## Procedures and Standards for the use of Controlled Drugs

when a dose is drawn up but not used.  To correct the extra mls (overage) of a bottle when at the end of the bottle.	
Larger quantities of CD, for example:  part used PCA syringe or infusion bag.	Empty contents into a DOOP / DOOM container. The empty syringe/bag should then be put in the sharps bin.
Larger quantities of CD, for example: box of ampoules/vials, or tablets.	Return to the Pharmacy for disposal.
<b>Patient's Own CDs</b> if these are not returned to the patient	Return to the Pharmacy for disposal.

### 5.20 Broken or Defective Controlled Drugs

- a) Where there is accidental breakage of ampoules, vials or bottles or where a tablet has been dropped on the floor the CD must be safely disposed of in the clinical area in the presence of two registered practitioners.
- b) The CD which has been broken must be accounted for in the CD register. An entry on the appropriate page must be recorded stating the reason for the accidental damage and signed by both registered practitioners. The remaining balance must be checked by both registered practitioners.
- c) If the CD is thought to be defective then it must be kept in the CD cupboard and labelled 'do not use'. The Pharmacy department must be informed at the earliest opportunity during normal opening hours to come and remove the CD.
- d) A Datix incident form must be completed to record all incidents of breakages or defective CDs

### 5.21 Borrowing of CDs

- a) CDs **cannot** be transferred between registers from one ward/ department / theatre to another. This would count as a ward supplying another ward which is illegal as wards are not licensed to supply CDs
- b) An individual dose may be given to a patient from another ward, as long as this is fully documented in the lending ward's CD register for the specific patient and in accordance with a valid prescription for that patient. The administration should be undertaken immediately and be witnessed on the 'borrowing' ward. The senior registered nurse/midwife or ODP on duty should be informed and may act as the witness.

### 5.22 Ward / Theatre closure or relocation

- a) If the ward is physically transferring to a new location the balance for all CDs must be checked on removal from a cupboard and then re-checked when placed in the new ward CD cupboard. This must be witnessed and a record made of both signatures by registered nurse, midwife, ODP or pharmacist / pharmacy technician.
- b) If the ward is permanently closing and not re-locating all CDs must be returned to pharmacy as described in section



## Procedures and Standards for the use of Controlled Drugs

- c) If the ward is a temporary closure the CDs together with the register must be checked by two individuals, the nurse in charge, midwife or ODP and another registered individual. A record must be made for each CD in the CD registers stating that this was checked and correct at the time and placed in a transit bag with the register. This should be sealed and a record kept of the security seal or tag. If no transit bag is available place in a sealed envelope signed and dated across the seal to make it tamper evident.
- d) The CD cupboard key(s) must not be placed in the red CD bag. The CD key(s) must be stored safely in the security office with a full audit trail, the handover of the CD key(s) witnessed by two registered practitioners
- e) The sealed bag must be taken to Pharmacy for safe keeping by one of the individuals securing the bag and an entry made in the pharmacy register by the receiving pharmacist or pharmacy technician documenting the ward, and security seal and witnessed by the individual bringing the bag.
- f) Upon the ward opening after a temporary closure the nurse in charge, midwife or ODP must collect the bag kept in safe keeping from the Pharmacy Department. This must be signed for against the pharmacy record and signed as witnessed by a pharmacist or pharmacy technician.
- g) The transit bag must be opened on the ward and each controlled drug must be checked by two individuals, the nurse in charge, midwife or ODP and another registered individual as correct against the entry in the register before placing in the CD cupboard. A record must be made against each entry recording that that this was checked and correct upon return to the ward.

### 5.23 Relatives bringing in own CDs

- a) If a patients relative or carer is staying in UHL accommodation and has brought in their own Controlled drugs for their own personal use then they should be made aware that they are responsible for the security of those medicines at all times.
- b) The CD must remain with them at all times unless it is left in a locked secure room / cupboard within their accommodation.

## 6 EDUCATION AND TRAINING REQUIREMENTS

- 6.1 Staff who are involved in prescribing, supplying, administering or disposing of controlled drugs should be identified at induction and receive appropriate training to enable them to carry out their duties.
- 6.2 Any member of staff who is unfamiliar with the policy and procedure for the safe handling and secure management of CDs should not undertake these duties and seek further advice from their line manager and training from their CMG /professional training lead.

- 6.3 Basic training is through familiarisation with Trust Controlled drug Policy and procedures. Nurses, midwives and ODPs who are authorised to undertake activities associated with CDs will be required to provide a specimen signature to the pharmacy department (appendix 8 & 9)
- 6.4 A basic power point presentation is available on INsite containing all the key points within this policy and should be used in conjunction with reading this policy but may be helpful as a refresher. Search using CD or controlled drugs

## 7 PROCESS FOR MONITORING COMPLIANCE

- 7.1 Adherence to this Policy will be through the 3-6 monthly controlled drug audits and the monitoring of reported incidents through the Datix incident reporting system

Element to be monitored	Lead	Tool	Frequency	Reporting arrangements
Documentation storage, destruction of CDs	CMG lead pharmacists	Ward / department audit tool	3-6 monthly	Directly to ward manager Summary of findings to CMG Head of Nursing & pharmacist
Incidents involving CDs	Medication safety Pharmacist	Datix	Quarterly – Local Intelligence Network (LIN) reports	Medicines Optimisation Committee
Prescribing of CDs – exceptional usage figures	Medication safety pharmacist reporting to Accountable officer high usage concerns.	JAC – issue data. EPMA when available	Monthly	For exceptional usage Initial investigation at CMG level – clinical and lead pharmacist Bi- monthly Report to Medicines Optimisation Committee

## 8 EQUALITY IMPACT ASSESSMENT

- 8.1 The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.
- 8.2 As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

## 9 SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES

- Guidance on the Safe Management of Controlled Drugs in Secondary Care in England (Gateway ref 8913). Department of Health. October 2007
- Misuse of Drugs Act and Misuse of Drugs Regulations at [www.opsi.gov.uk](http://www.opsi.gov.uk)
- NPSA Safer Practice Notice 12 : Ensuring safer use with high dose ampoules of diamorphine and morphine. 2006 - NHS Commissioning Board

- NPSA/2008/ RRR05 Reducing Opioid dosing errors with Opioid medicines
- NICE guideline NG46 April 2016 Controlled drugs : safe use and management
- Medicines, Ethics and Practice 2021 Royal Pharmaceutical Society
- Pharmacy Standard Operating Procedures for Controlled Drugs
- Leicestershire Medicines Code
- UHL Multi-dose vial policy B42/2008
- UHL Self administration of medicines policy B13/2004
- UHL Policy and procedure for administration of Patient controlled analgesia B17/2003
- UHL Opioid Dependence Management of adult Patients guideline B67/2019
- UHL Illicit substances Policy B46/2009
- UHL Patient Group Directions Policy B43/2005

## **10 PROCESS FOR VERSION CONTROL, DOCUMENT ARCHIVING AND REVIEW**

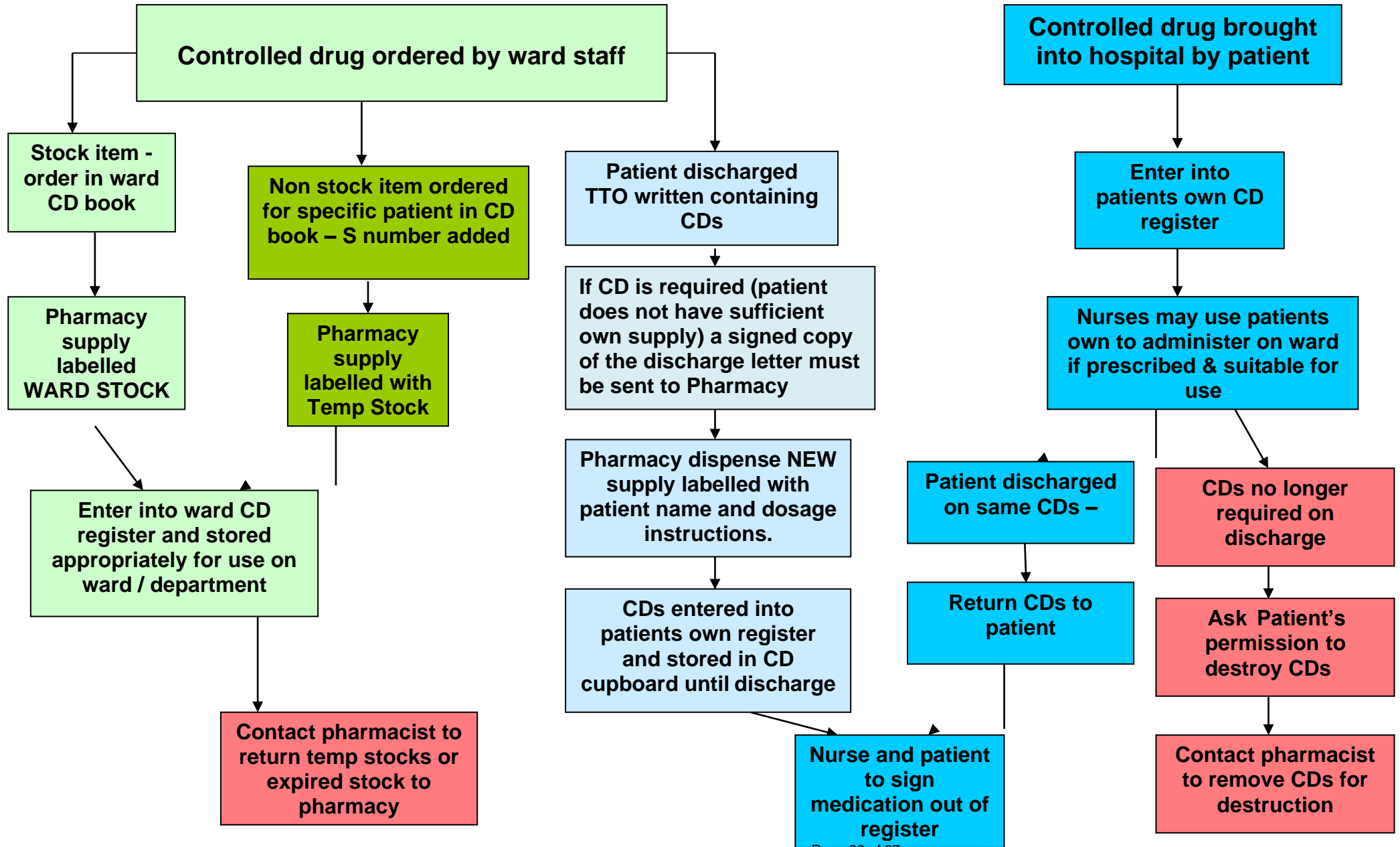
---

- 10.1 The updated version of the Policy will be uploaded and available through INsite Documents and the Trust's externally-accessible Freedom of Information publication scheme. It will be archived through the Trusts PAGL system
- 10.2 This Policy will be reviewed every three years or sooner in response to clinical or risk issues.

## **Appendix 1 – Acceptable identification for collection of Out Patient Prescriptions controlled drugs**

Prof registration number for healthcare professional  
Driving licence (incl photo)  
Any official photo ID  
Passport  
Cheque guarantee, debit or credit card  
Birth/marriage certificate  
Cheque book  
2 different utility bills (NOT mobile phone)  
Pension or benefit book  
Council tax payment book  
Bank or building Soc statement within last 6months  
Store charge card – not loyalty card  
Council rent book  
National savings book

Appendix 2 Reference guide for the steps / processes involved in the management of CDs



### Appendix 3 Requirements for common CDs

CD – all forms unless specified.	Schedule	Order in CD Book	Signed delivery & receipt	Store in CD Cupboard	Record in CD Register	Handwritten <sup>1</sup> Dr's signature on prescription	Quantity in words & figures on prescription	ID requirements for Out- & Discharge patient prescriptions from Pharmacy
Alfentanil	2	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Cocaine	2	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Codeine Injection	2	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Dexamfetamine	2	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Dipipanone (Diconal)	2	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Diamorphine	2	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Dihydrocodeine Injection	2	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Fentanyl	2	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Hydromorphone	2	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Ketamine	2	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Methadone	2	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Methylphenidate	2	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Morphine [see 10mg in 5ml oral solution at end of table]	2	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Oxycodone	2	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Pethidine	2	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Remifentanil	2	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Tapentadol	2	Yes	Yes	Yes	Yes	Yes	Yes	Yes

CD- all forms unless specified.	Schedule	Order in CD Book	Signed delivery & receipt	Store in CD Cupboard	Record in CD Register	Handwritten <sup>2</sup> Dr's signature on prescription	Quantity in words & figures on prescription	ID requirements for Out- & Discharge patient prescriptions from Pharmacy
Buprenorphine	3	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Gabapentin	3	Yes	Yes	No	No	Yes	Yes	Yes
Midazolam	3	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Pentazocine	3	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Phenobarbitone	3	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Pregabalin	3	Yes	Yes	No	No	Yes	Yes	Yes
Temazepam	3	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Tramadol oral	3	Yes	Yes	No	No	Yes	Yes	Yes
Tramadol Injection	3	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Morphine Oral Solution 10mg/5mL. NB the concentrated solution 100mg /5ml is schedule 2	5	Yes	Yes	No	No	No	No	No

## Appendix 4 Liquid CDs

### ADMINISTRATION OF LIQUIDS

- When a new bottle is opened write the date of opening on the label. Liquid expiry dates can vary once the bottle has been opened, check information on the bottle. If no expiry date is present then it must be 6 months after opening the bottle.
- A bung which fits to the ENFit syringes must be placed in the bottle.
- Doses must be drawn up using an oral syringe (to ensure accurate dosing).
- The dose drawn up must be second checked and entered into the register as per section

### CHECKING BALANCES

- Liquid balances do not need to be measured on a daily basis, a visual inspection is sufficient unless there is clearly a discrepancy. In this instance a volume check is required. The liquid should be measured using a disposable measure.
- Manufacturers often fill the bottle with a small overage which can vary but repeated use of liquids can result in volume changes. When a bottle has been finished the balance in the register should be corrected to either zero or the quantity remaining in full bottles.

The following table is a guide to determining if there is a discrepancy which requires investigation. If a discrepancy is found please follow section 5.8

Quantity in Bottle	Action
100ml bottle is empty (register states there should be some)	If register says there should be 10ml or less this is ok. Record: 'nil left, accuracy ok'
300ml bottle is empty (register states there should be some)	If register says there should be 30ml or less this is ok. Record: 'nil left, accuracy ok'
100ml bottle is not empty (register states nil)	If there is less than 15ml left in the bottle this is ok. Record: 'Some left, further doses given and accuracy ok.'
300ml bottle is not empty (register states nil)	If there is less than 35ml left in the bottle this is ok. Record: 'Some left, further doses given and accuracy ok.'

### RETURNING LIQUIDS

- Liquids will need a balance check ( measurement of the liquid to be removed) prior to returning to the Pharmacy Department.
- Upon return to Pharmacy the liquid must be volume checked again and witnessed by registered pharmacy professionals.



**Appendix 5:**

University Hospitals of Leicester NHS Trust  
Department of Pharmacy

***Authorised signature list for ordering Controlled Drugs from Pharmacy***

- A copy of this form can be kept on the ward / clinical area e.g. taped to the inside front cover of the current CD book
- When changes are made to the signature list, please send an individual amendment form to pharmacy for the attention of the CD Technician
- Before any new names can be entered onto this list, they must first be sanctioned by the relevant ward/ departmental manager
- **PHARMACY WILL NOT SUPPLY CONTROLLED DRUGS TO ANY WARD / AREA IF THE SIGNATORY IS NOT ON THE CURRENT LIST FOR THAT WARD / AREA, HELD IN PHARMACY**

Ward / Area \_\_\_\_\_ Site: \_\_\_\_\_

CMG: \_\_\_\_\_

Name (block capitals)	Job Title	Usual signature

I authorise the above staff to order controlled drugs for named ward/dept

Signed \_\_\_\_\_ Print Name : \_\_\_\_\_

Job Title : \_\_\_\_\_ Date : \_\_\_\_\_

# Authorised signature list for ordering Controlled drugs from Pharmacy

Continuation sheet : - Ward/dept \_\_\_\_\_

Name (block capitals)	Job Title	Usual signature

I authorise the above staff to order controlled drugs for named ward/dept

Signed \_\_\_\_\_ Print Name : \_\_\_\_\_

Job Title : \_\_\_\_\_ Date : \_\_\_\_\_

**Appendix 6:**

University Hospitals of Leicester NHS Trust  
Department of Pharmacy

***Authorised signature for ordering Controlled Drugs from Pharmacy***

Please send to Dispensary Team Leader within the pharmacy department

Ward / Area \_\_\_\_\_ Site: \_\_\_\_\_

CMG: \_\_\_\_\_

Change in Name :

Previous name	New Name (block capitals)	Job Title	Usual signature

New staff :

Name (block capitals)	Job Title	Usual signature

I authorise the above staff to order controlled drugs for named ward/dept

Signed \_\_\_\_\_ Print Name : \_\_\_\_\_

Job Title : \_\_\_\_\_ Date : \_\_\_\_\_

## Appendix 7 :

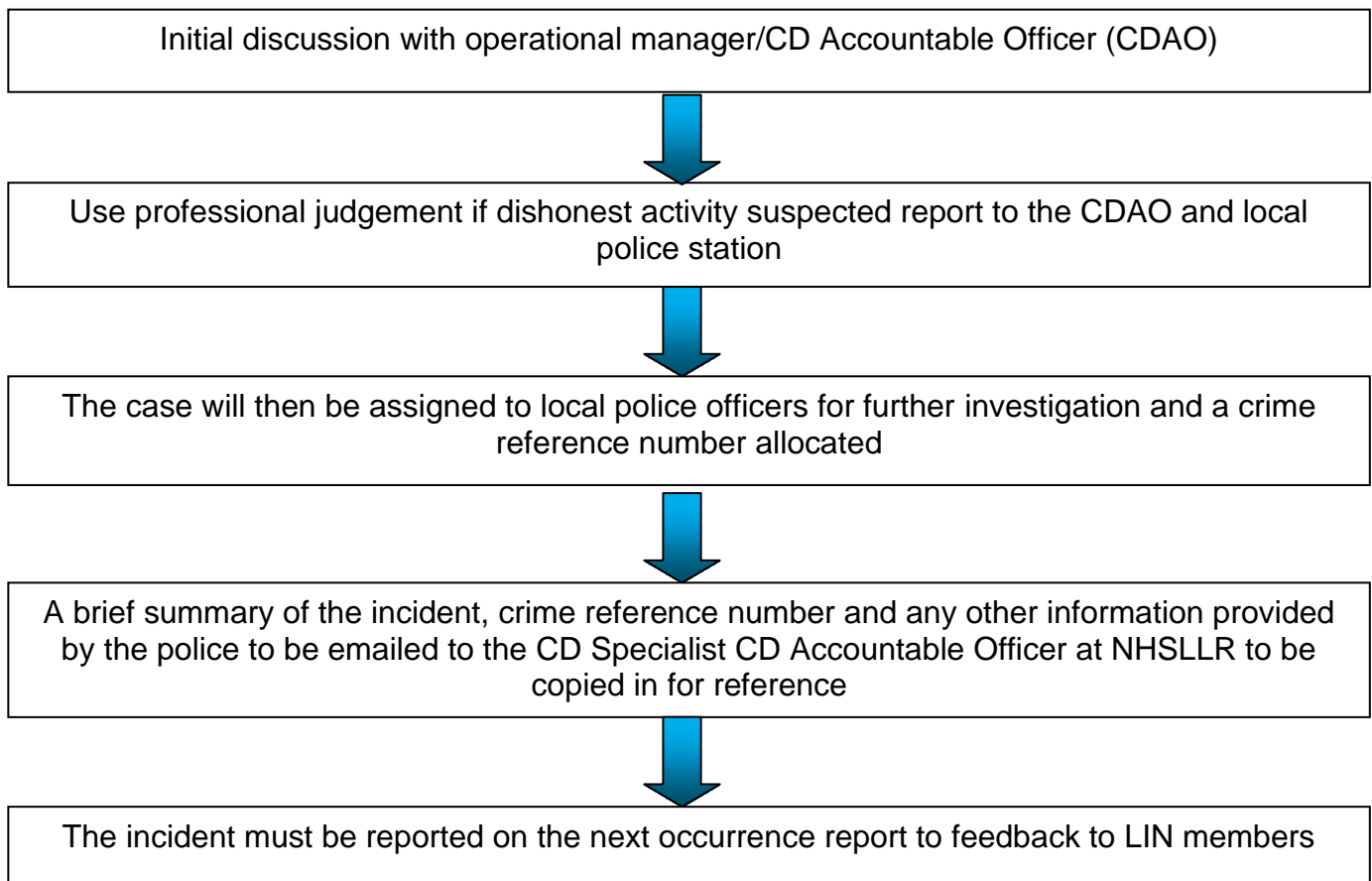
### Controlled Drug (CD) Specialist – Leicestershire Constabulary - Responsibilities

The main responsibilities include:

- Receive and catalogue CDs during police arrests
- Reduce forensic testing's using knowledge and intelligence with the aid of Home Office tests to enable local testing's for drug abuse
- To provide comments on drug related cases – to provide formal information in court when requested to do so
- Single point of contact for Leicestershire CD Accountable Officers and their organisations

### Process for Reporting a Controlled Drug Related Crime (Flow Chart)

This process should be followed when there is a suspicion of theft or misuse of CDs



## Controlled Drug Registers

The controlled drug register is a legal document and therefore should be filled out correctly in indelible pen

### Heading -

MUST include the **NAME**, **FORM** and **STRENGTH** of the preparation



On receipt of all CDs ordered in a CD requisition book the following details must be recorded on the appropriate page in the ward CD register:

- Quantity received
- Date of entry
- Serial number of requisition
- Name / signature of nurse
- Name / signature of witness
- Balance in stock

NAME, FORM OR PREPARATION AND STRENGTH... <u>Morphine sulphate ampoules 10mg in 1ml</u> <b>5</b>										
AMOUNT(S) OBTAINED			AMOUNT(S) ADMINISTERED							
Amount	Date received	Serial No of requisition	Date	Time	Patient's name	Amount given	Given by (signature)	Witnessed by (signature)	STOCK BALANCE	
<b>ten</b>	<b>02/05/16</b>	<b>52</b>			<i>H Potter / H Grainger</i>				<b>10</b>	

When a CD is required the following details must be entered onto the appropriate page of the CD register in:

- Date and time of entry
- Patients name
- Quantity administered
- Name / signature of nurse
- Name / signature of witness
- Balance in stock remaining

NAME, FORM OR PREPARATION AND STRENGTH... <u>Morphine sulphate ampoules 10mg in 1ml</u> <b>5</b>										
AMOUNT(S) OBTAINED			AMOUNT(S) ADMINISTERED							
Amount	Date received	Serial No of requisition	Date	Time	Patient's name	Amount given	Given by (signature)	Witnessed by (signature)	STOCK BALANCE	
<b>ten</b>	<b>02/05/16</b>	<b>52</b>			<i>H Potter / H Grainger</i>				<b>10</b>	
			3/5/16	12.30	John Smith	10mg	<i>H Potter</i>	<i>S Wizard</i>	<b>9</b>	

**There must be no Crossings OUT.** If an error is made please bracket sign, countersign and date  
 Appendix 9 – to be used for stock or non stock CDs

If not stocked on an eMeds ward please write the S number of the patient on the requisition, otherwise send paper chart with order.

<b>ORDER FOR CONTROLLED DRUGS</b>			Serial No
..... <i>LGH</i> .....Hospital		<i>Insert S number if eMeds ward &amp; not stock</i>	
Ward or Department .....25.....			
Name of Preparation	Strength	Quantity	
<i>Morphine sulphate injection</i>	<i>10mg</i>	<i>10 ampoules</i>	
(Each preparation to be ordered on a separate page)			
Ordered by ..... <i>H Potter</i> .....		HELEN POTTER..... Date ..... 14/2/2019...	
(signature of sister or Acting sister)		(print name above)	
Supplied by ..... <i>H Grainger</i> .....		HILARYGRAINGER ..... Date ..... 14/2/2019...	
(Pharmacists signature)			
Accepted for delivery ..... <i>R Weasley</i> .....		ROBERT WEASLEY ..... Date ... 14/2/2019.....	
(signature of messenger or bag number )			
Received by ... <i>H Potter</i> .....		HELEN POTTER ..... Date..... 14/2/2019...	
(To be signed by the ward in the presence of the messenger )			