University Hospitals of Derby and Burton NHS Foundation Trust

TRUST POLICY FOR CONTROLLED DRUGS (UHDB)

Reference Number	**Version:**	**Status**	**Author:**
POL-CL/2651/18	V1 (merged)	Final	Medicines Safety Officer

Version / Amendment History	Version	Date	Author	Reason
	1.0	January 2021	Medicines Safety Officer	Merging Burton and Derby policies.

Intended Recipients: Staff involved in prescribing, supplying, administering or disposing of controlled drugs

Training and Dissemination: Disseminate via Controlled Drug Newsletters, Trust intranet and Quality and Safety newsletter. All Divisional Directors, DMD's and DND's will be sent a copy of this Policy to facilitate email cascade. It is then responsibility of the ward and department managers to inform their staff of the Policy and any updates received.

Staff involved in prescribing, supplying, administering or disposing of controlled drugs should receive appropriate training to enable them carry out their duties.

Initial induction training is included in medicines management training during newly qualified nurse / midwife / pharmacist inductions. Familiarisation with the Trust Controlled Drug policy and procedures should be included in local inductions. Understanding is confirmed and embedded through ward based competency checks and completion of core modules within the Medicines Management e-learning program. A summary refresher and Policy / Guideline signposting is included on the 2-yearly essential-to-role medicines management training.

Practitioners who are authorised to undertake activities associated with CDs will be required to provide a specimen signature to pharmacy for the purpose of verifying prescriptions, CD orders and records, and as an indication that they have understood and will comply with Trust policy and procedures.

Any member of staff who is unfamiliar with the policy and procedures for the safe handling and secure management of CDs should not undertake these duties, and seek further training.

To be read in conjunction with: Medicines Management (Medicines Codes) - Trust Policy and Procedure

In consultation with and Date: Medicines Safety Group (MSG), Chief Nurses		
EIRA stage One	Completed Yes / No	*Delete as appropriate*
stage Two	Completed Yes / No	*Delete as appropriate*
Approving Body and Date Approved		
Date of Issue	February 2021	
Review Date and Frequency	August 2024 (3 years)	
Contact for Review	Chief Pharmacist and Accountable Officer for Controlled Drugs	
Executive Lead Signature	Executive Medical Director	

Contents

1. Introduction

This Policy, together with the associated standard operating procedures (SOPs), provide guidance to all University Hospitals of Derby & Burton (the Trust) staff on the safe and secure handling and storage of controlled drugs (CDs) in accordance with the legal requirements of the Medicines Act, the Misuse of Drugs Act (1971 and amendments), Misuse of Drugs Regulations (2001 and amendments) and changes introduced by the Health Act (2006).

Principles of good practice have also been applied from guidance specified by the Department of Health, the Care Quality Commission (CQC) and the General Pharmaceutical Council.

The Health Act 2006 introduced the requirement for NHS bodies to appoint an Accountable Officer to monitor the use of controlled drugs within their organisation and take appropriate action where necessary. This Act also requires healthcare organisations to have standard operating procedures in place for the use and management of CDs by all healthcare professionals and staff who they employ or with whom they contract.

2. Purpose and Outcomes

The purpose of the Policy is to align Controlled Drug (CD) use and management with legislation and national good practice guidance.

Controlled drugs are subject to special legislative controls because there is a potential for them to be abused or diverted, causing possible harm. This document is designed to ensure the secure management of CDs, by balancing accessibility for patient care and minimising the risk of loss or diversion. Failure to comply with policy and legislative requirements could result in disciplinary action and / or criminal prosecution.

The Policy and related procedures will ensure that:-

- Staff are clear on the standards that are expected of them in relation to the handling and storage of CDs
- All legislation and guidance is adhered to with respect to controlled drugs
- Patients, staff and visitors are not put at risk as a result of the incorrect handling of CDs.

Risks associated with the incorrect handling and storage of controlled drugs are reduced to a minimum by ensuring:

- Preparation, administration and disposal of CDs requiring safe custody are directly witnessed by a second registered practitioner
- Robust systems are provided for the safe procuring, storing, supplying, transporting, prescribing, administering, recording and disposal of CDs
- Systematic documentation and checks are maintained to assure the secure management of controlled drugs and demonstrate this to the CD Accountable Officer (CDAO)
- All CD incidents are reported via Datix and reviewed by the CDAO or their assigned investigator. These will be referred to the CD Local Intelligence network (CDLIN) as appropriate.

3. Definitions Used

Controlled Drugs (CDs)

The drugs listed in schedule 1-5 of the Misuse of Drugs regulations 2001 (as amended). Drugs listed in different schedules have different legislative requirements. Trust Policy states what level has been applied locally and this will comply with at least the minimum legislative requirements. The Trust has additional security measures in place to include other substances that are open to abuse, are high risk medicines or 'controlled' for other reasons. These substances include mifepristone and strong potassium chloride injection / solutions.

The 2001 Regulations classify CD's into five schedules according to the different levels of control attributed to each:

- Schedule 1 (CD Lic POM)
- Schedule 2 (CD POM)
- Schedule 3 (CD No Register POM)
- Schedule 4 (CD Benz POM and CD Anab POM)
- Schedule 5 (CD INV P and CD INV POM)

The legal and local requirements pertaining to the main groups of CDs are summarised in Table 1.

Controlled Drugs [requiring safe custody]

In every day practice, it is common that nursing, midwifery and theatre staff often refer to "CDs" only in relation to those with additional safe custody and register requirements (for example, it would be unusual to refer to diazepam as a controlled drug, even though it appears in schedule 4).

The definition Controlled Drugs [requiring safe custody] has therefore been used for emphasis throughout this policy and the supporting SOPs. The definition includes all CDs in schedule 2 (CD POM) as per legislation, and also includes other schedule 3 drugs which - by law or through this policy – are stored in CD cupboards and recorded in registers (table 1 identifies these medicines).

Duty Pharmacist

The ward / department pharmacist during core hours or the on-call pharmacist overnight and at weekends.

Appointed Practitioner (nurse/ODP/midwife)

The person in overall charge of a ward or department. In most cases the ward manager / senior sister.

Designated Practitioner (nurse/ODP/midwife)

The person in charge of a specific shift and holding responsibility for key-holding and security during that period.

Assigned Practitioner (nurse/ODP/midwife)

The CD keys (and therefore safe custody) may be delegated by a designated practitioner to other Nurses / ODPs /Midwives as necessary for clinical and operational tasks.

Pharmacists / Pharmacy Technicians may also be considered as appropriate staff to be assigned responsibility (by the designated practitioner) to access controlled drugs.

Registered Practitioner

In the context of this Policy, this includes nurse, midwife, ODP, Doctor, Pharmacist or Pharmacy Technician (or other registered professionals who have been trained to prescribe, administer or check controlled drugs).

> Registered Nursing Associates and Registered Physician's Associates are NOT included in the definition unless specifically identified in this policy or cited as an extended scope elsewhere in UHDB policy (e.g. Medicines Policies).

4. Key Responsibilities / Duties

Controlled Drug Accountable Officer (CDAO)

CDAOs are responsible for all aspects of controlled drugs management within their organisation. The roles and responsibilities of CDAOs, are governed by the Controlled Drugs (Supervision of Management and Use) Regulations 2013. These include implementing procedures and training for the safe management of CDs and supporting best practice for the prescribing, supply, administration and monitoring of CDs. The CDAO creates regular organisational "occurrence reports" for CDs which are shared internally with the Medicines Safety Group (MSG) and Quality Improvement Group (QIG) and shared externally with the CD Local Intelligence Network.

The CDAO must be a senior manager within the organisation who does not routinely supply, administer or dispose of CDs drugs as part of his/her duties. At UHDB the CDAO is the Chief Pharmacist. The CDAO Accountable Officer must be registered with the CD Regulation team at the CQC. When the CDAO changes, the CQC must be promptly notified.

Controlled Drug Local Intelligence Network (CD LIN)

A network of CDAOs coordinated by the CDAO at the NHS England Local Area Team (NHS North Midlands; incorporating Derbyshire, Staffordshire, Nottinghamshire & Shropshire). The priority of the CD LIN is to share intelligence and ensure all reasonable steps are taken to improve patient and public safety with regards to the safe and secure handling, management and use of CDs.

Quality Improvement Group

Receives quarterly CD LIN occurrence reports and an annual CDAO report. The latter will include a summary of CD audits conducted across the Trust.

Medicines Safety Group (MSG)

Supports the development and update of this policy and associated SOPs and coordinates implementation, dissemination and on-going training strategies to embed legal and good practice standards.

MSG reviews the quarterly CD LIN occurrence reports, and the results of the annual Controlled Drugs audit, and will recommend actions to the Quality Improvement Group where appropriate. Results will also be provided to Divisions in order for any local issues to be addressed.

Pharmacy CD Management Group

Will review quarterly CD audits undertaken by the pharmacy team.

Medicines Safety Officer (MSO)

Chairs the Medicines Safety Group and deputises for the CDAO.

Divisions

It is the responsibility of the Divisional Medical Directors, Divisional Directors and Divisional Nurse Directors to ensure that all staff are trained to carry out the tasks required of them in the prescribing, administration and management of CD's.

Business unit General Managers / Clinical Directors / Matrons

Oversee the application of this Policy into their services and ensure its implementation is undertaken within their management structure, with the necessary controls to achieve the Policy's Purpose & Outcomes. They will liaise with members of the Pharmacy department to obtain expert advice when necessary. They will promote the Policy to consultants, senior sisters and other clinical managers who will disseminate, in turn, to their teams.

Matrons will be responsible for ensuring the Trust annual CD audit is completed within their areas and for coordinating action plans for any areas of non-compliance.

Nurse / Midwife / Operating Department Practitioner (ODP) in charge

The **appointed nurse**, midwife or ODP in overall charge of a ward or department is responsible for the safe and appropriate management of CDs in that area. In the event of any discrepancies or apparent loss of CDs, they are responsible for ensuring Pharmacy is informed and that an incident report is made using the Trust Incident Reporting Scheme (Datix).

Nurse / Midwife / Operating Department Practitioners (ODP)

The **designated** Nurse, Midwife or ODP in charge of a shift can delegate control of access (i.e. key-holding) to the CD cupboard to another **assigned** practitioner, such as a registered nurse or ODP.

All members of staff involved in delivery of the service relating to CDs must keep up to date with this Policy and the relevant associated procedures. All staff that order and administer CDs will be required to sign that they have read and understood the Policy and provide a specimen signature.

Registered Pharmacy staff (Pharmacists and Pharmacy Technicians)

Are responsible for providing information and advice to the Trust's staff on this Policy and the legislation and guidance supporting it. Registered Pharmacy staff will undertake regular audits on wards / departments in relation to the safe handling and storage of CDs. Registered Pharmacy staff will remove any CDs no longer required from that ward / department and will assist, when requested, with the training of Trust staff on the storage and handling of CDs.

Non-Registered Pharmacy Staff (ATO / SATO)

Will only perform roles specifically defined in Pharmacy CD SOPs (e.g. dispensing / compounding) and cannot undertake the roles for 'Pharmacy' staff outlined in this Policy

(with the exception of messenger / courier as aligned with other roles for non-registered staff in the transport of CDs, outlined in this Policy).

Non-Registered Staff

Have a minimal role in Controlled Drugs beyond acting as a messenger/courier in the transport of CDs.

5. Controlled Drug Policy Requirements

5.1 CD Schedules

Table 1 outlines commonly used CDs at UHDB and any additional local measures that may apply within this Policy over and above legislation.

The schedule of any given CD can be confirmed by checking the current British National Formulary (BNF) monograph under the 'Medicinal Forms' heading.

Alternatively, the Department of Health publish updates to the schedules outlined in the Misuse of Drugs Regulations 2001[1]

Examples:

- **Schedule 2 (CD POM)**

Schedule 2 includes opiates (e.g. diamorphine, morphine, methadone, oxycodone, pethidine), major stimulants (e.g. amphetamines), quinalbarbitone and ketamine.

- **Schedule 3 (CD NO REG POM)**

Schedule 3 Controlled Drugs include minor stimulants and other drugs (such as buprenorphine, temazepam, tramadol, midazolam, gabapentin, pregabalin and phenobarbital)

- **Schedule 4 (CD BENZ POM OR CD ANAB POM)**

Part I (CD Benz POM)

---

[1] https://www.gov.uk/government/publications/controlled-drugs-list--2

Contains most of the benzodiazepines (such as diazepam), non-benzodiazepine hypnotics (such as zopiclone).

Part II (CD Anab POM)
Contains most of the anabolic and androgenic steroids, together with clenbuterol (an adrenoceptor stimulant) and growth hormones.

- **Schedule 5 (CD INV POM OR CD INV P)**

Schedule 5 contains preparations of certain Controlled Drugs (such as codeine, pholcodine and morphine) that are exempt from full control when present in medicinal products of specifically low strengths (e.g. Morphine 10mg in 5ml solution is schedule 5 compared with most other morphine formulations in schedule 2).

Table 1 - Summary of various characteristics of controlled drugs (Schedules 2, 3, 4 and 5)					
Schedule	**Schedule 2**	**Schedule 3**	**Schedule 4, Pt I**	**Schedule 4, Pt II**	**Schedule 5**
Designation	CD POM	CD No Reg POM	CD Benz POM	CD Anab POM	CD Inv POM/ CD Inv P
Safe custody (CD cupboard) required	Yes, except quinalbarbitone	Yes, except tramadol, gabapentin pregabalin and phenobarbital **Local practice: Midazolam, buprenorphine & Temazepam kept in CD cupboard**	No	No	No
CD Prescription requirements (as per 5.6)	Yes	Yes	No	No	No
Requisitions necessary?	Yes – CD Requisition Book	Yes – CD requisition Book for midazolam, buprenorphine & temazepam **Local Practice: Tramadol, gabapentin, pregabalin and phenobarbital ordered on UHDB paper requisition form (available on intranet).**	No	No	No
Records to be kept in CD Register	Yes	**Local practice: Yes, record all* except tramadol, gabapentin, pregabalin and phenobarbital**	No	No	No
Signed delivery & receipt	Yes	Yes	No	No	No
Emergency supplies Allowed	**Emergency Supplies not permitted from UHDB pharmacies**				
Validity of prescription	28 days	28 days	28 days	28 days	6 months (if POM)
Maximum duration that may be prescribed	30 days as good practice	30 days as good practice	30 days as good practice	30 days as good practice	**Local practice: 30 days as good practice**
	All requests for more than 30 days' supply must be made to the UHDB CD Accountable Officer or Deputy, and will only be permitted in exceptional circumstances.				

*Register entries are required at UHDB for temazepam, buprenorphine & midazolam

5.2 Governance

Standard Operating e Procedures (SOPs) have been developed within the appendix of this policy and should be adopted by all clinical areas across UHDB to deliver the Policy purpose and outcomes.

No local SOPs relating to CDs should be developed or implemented without the approval of the CDAO with the following exceptions:

a) Individual areas are encouraged to develop an SOP for management of CD keys, including documented handover and the storage of spare keys and management of controlled drug stationery in their areas (following the policy requirements identified in Section 5.3)

b) Pharmacy SOPs exist which cover the responsibilities within the Pharmacy and the interface with the wards/department and will include all aspects of stock control / security, issue and supply to patients, control of CD stationery and signature verification.

Clinical guidelines involving controlled drugs should include the Medicines Safety Group in the consultation phase via uhdb.mso@nhs.net

5.3 Safe and Secure Handling of Controlled Drugs on Wards and Departments:

Security, monitoring, ordering, receipt, & issue

5.3.1 Controlled Drug Stationery

Definition: Controlled stationery which is used to order, return or distribute controlled drugs should be stored securely and access to it should be restricted. This includes:

- CD requisition books (order book)
- CD record books (registers) - Separate registers are held for ward stock, patients' own CDs and CDs used in theatre or emergency departments
- CD Discharge Prescriptions / Outpatient Prescriptions.

Note that UHDB paper requisitions[2] for those schedule 3 medicines which are NOT required to be kept in the CD cupboard (Table 1) may be printed from the intranet but should be maintained securely on the ward as below.

Secure storage: CD stationery which is kept in wards, theatres or departments must be kept in a secure medicines cupboard that is locked. Where possible, the CD order book should be kept in the CD cupboard. Where this is not possible then it should be stored in another locked medicines cupboard.

Stocks of CD stationery held in the Pharmacy are kept securely in the CD room or designated locked cabinet. The CD room must be kept locked when no-one is present to supervise the room.

[2] For tramadol, gabapentin, pregabalin and phenobarbital: Use CD3NP for named inpatient items & CD3ST for stock.

Supply of CD stationery: CD stationery should be issued from the Pharmacy against a requisition. CD order books are numbered sequentially to provide a means of tracking.

The Pharmacy keeps a record of all controlled stationery as outlined in the Pharmacy CD SOPs.

Loss or theft of CD stationery: Loss or theft of CD stationery which may be used to order CD's is to be treated in the same way as discrepancies identified with the medicine stock itself. Refer to CDSOP9 for actions to take including report on Datix immediately and escalation.

Use of CD stationery: Only one CD requisition book per ward or department should normally be in use (although wards with high turnover of palliative care syringes or other pre-filled syringes may have separate books to facilitate orders from different pharmacy sections e.g. stock from dispensary and syringes from the aseptic service). When a new CD register is started, the balance of CD's in stock should be written into the new book promptly by a registered practitioner (witnessed by a second registered practitioner).

Storage of completed ward requisition books, CD requisition sheets and CD registers by wards and departments: Ensure the front of the book and any index is clearly crossed through and marked as 'Discontinued – retain securely for two years from DD/MM/YYYY'. This must then be retained in a locked cupboard or office for a minimum of two years from the date of the last entry. Note that pharmacy service SOPs may include longer periods of record keeping for some forms of CD documentation in accordance with legislation and NICE guidance.

5.3.2 Security of Controlled Drugs

The appointed practitioner in overall charge of a ward or department is responsible for the secure storage and safe use of the controlled drugs.

If a ward or department is due to close (for any period other than as per the regular weekly schedule for that department), then follow CDSOP8. The safe and secure storage of medicines must be maintained even when wards or departments are closed, and remain the responsibility of the appointed practitioner in charge. The keys for all medicine cupboards must be stored securely in a designated area during periods of routine closure.

The Misuse of Drugs (Safe Custody) Regulations 1973 provides minimum standards for the storage and security of CDs. CD cupboards must be secured to the wall or floor and must be reserved solely for the storage of CDs. Areas wishing to purchase or replace CD cupboards must contact the CDAO who will advise on specifications in accordance with current British Standards. The connection of a warning light to the nurse-call system or other indicator is not a legal requirement, but if it is practical to connect such indicators in facilities or areas then there is DOH Health Technical Memorandum to support this as a good practice requirement.

All Schedule 2 and some Schedule 3 (see table 1) CDs supplied as stock or temporary stock by the hospital pharmacy must be stored in a locked CD cupboard prior to clinical use. This includes all original containers and part-used stock, or ready to administer products containing CDs e.g. pre-filled syringes / cassettes for PCA or palliative care.

Patient's own prescribed CDs are those which are either brought in from home or dispensed from pharmacy against a discharge/outpatient prescription with **full administration directions.** If these require safe custody (schedule 2 and some schedule 3 as per table 1) then they should be stored in a CD cupboard and appropriate

register entries made (see section 5.3.5). However, where necessary to support self-administration, the appointed practitioner in overall charge of the ward may agree to store patient's own CDs in a bedside medicine locker but only in accordance with section 5.7.1 (Self Administration) of this Policy.

CD cupboards MUST always be kept locked when not in use and the lock must NOT be common to any other lock in the hospital. Two sets of keys should be available; one in use which is the responsibility of the designated practitioner in charge of the shift, and a spare set locked away in a secure key cabinet with access strictly limited to the appointed practitioner in overall charge of an area, their senior managers within the business unit or division or the pharmacy department.

CD keys MUST be kept on a separate key ring to other medicine keys to ensure that Designated Practitioners in charge of the shift can retain oversight for who has access to CD stock (they may delegate key-holding to an assigned practitioner if necessary). The keys must NOT be handed to unauthorised or non-registered staff, including medical staff or non-registered pharmacy staff. The CD keys may be handed to a Pharmacist or Pharmacy Technician for the purpose of stock checks and / or audit upon presentation of their Trust ID badge.

In areas where CD infusion products are administered e.g. PCA, epidural or T34 (palliative care syringe driver), the relevant pump keys may be attached to the CD key ring.

If CD keys go missing, urgent efforts should be made to retrieve the keys as quickly as possible e.g. by contacting staff who have just gone off duty. Failure to locate the keys during the shift MUST be reported to the practitioner in charge of the shift and reported on Datix. The duty Pharmacist must be informed, who will advise any action to secure the CD stock and arrange supply of (or agree access to) CDs for urgent clinical use. Out of Hours in these circumstances, the pharmacist may verbally authorise access to doses from another ward, as long as registered staff fully document this in that ward's CD register for the specific patient and their location, and in accordance with a valid prescription (including medicine charts / electronic prescribing) for that patient.

Replacement of locks MUST only be on the authority of the CDAO) or deputy (the MSO) who will arrange this via Trust Security Advisor. Complete the 'request form for replacement of a key or lock', available on the Medicines Intranet

Where access is restricted due to missing or lost keys, a Datix incident report must be completed and highlighted to the CDAO.

5.3.3 Ordering & Receipt of Stock or Inpatient supplies of Controlled Drugs from Pharmacy

See Appendix CDSOP1 and CDSOP2 for procedure and practice guidance.

5.3.4 Recording administration of inpatient Controlled drugs

See Appendix CDSOP4 for procedure and practice guidance (see also theatre practice in Section 5.10 – Authorised exceptions).

5.3.5 Managing Patient's Own Controlled Drugs

Patient's own CDs are those which are either brought in from home or dispensed from pharmacy against a discharge / outpatient prescription and so always include **full administration directions on the label.**

The Trust encourages the use of patient's own medicines wherever possible, including controlled drugs. These remain the property of the patient, but their secure storage is the responsibility of the Trust.

Medicines labelled for a specific named patient must NOT be used to treat another patient, and should be segregated from stock medicines within the CD cupboard, wherever possible.

If these require safe custody (schedule 2 and some schedule 3 CDs as per table 1) then they must be stored in a CD cupboard and register entries made in the Patient's Own CD record book (see CDSOP5). The only exception is PODs which have been approved for self-administration by the appointed practitioner in charge of the area as per 5.7.1.

Discharge TTOs containing CDs with safe custody requirements must be recorded in the Patient's Own CD register, unless the patient is leaving imminently.

5.3.6 Supply of Discharge (TTO) Controlled Drugs

CDs that may be taken home by the patient must be supplied against a valid discharge prescription (TTO) or outpatient prescription (Section 5.6 Prescribing CDs).
These items **must include full dosage instructions on the label.**

Patient Own CD items can be supplied from the ward providing the two registered practitioners ensure the administration details on the label match the prescription exactly.

These two practitioners should sign these items out of the Patient Own CD register.

Other CD items should be ordered from Pharmacy against a discharge prescription / form meeting prescribing requirements for controlled drugs.

Stock CDs or those issued 'for inpatient use only' (i.e. temporary stock) must NEVER be given to patients on discharge (NOTE: labels 'for inpatient use only' may include a patient name but never include directions for administration).

Where a patient is given their CDs directly at the point of discharge and is able to manage these safely and securely, then these may be placed with other medicines in a standard discharge medicines bag.

Where the patient lacks capacity, use a tamper-proof CD Discharge / Despatch Bag (Appendix C). The patients name and address need to be clearly visible so that the ambulance crew or patient representative can deliver the bag with an intact seal.

5.4 Transfer & Transportation of Controlled Drugs

5.4.1 Safe custody of CDs when collecting or transferring

All staff should transport CDs in a sealed bag. Non-registered staff may be trained to collect or transfer CDs Controlled Drugs, but this must always be handed to them in a tamper-proof bag, with serial number, which has been sealed by a registered staff member trained in controlled drug management.

A record of transport must always be used (CDSOP6&7 and Pharmacy SOPs).

The non-registered staff (acting as 'messenger / courier') therefore remain responsible for transferring an intact bag on to a registered practitioner in the destination area.

The person acting as the messenger should be aware of the following prior to taking receipt of the bag:

- The intended destination of the bag
- Aware of the safe storage and security and requirement to hand this over ONLY to a registered staff member who should sign the accompanying paperwork
- In the case of transfer from a pharmacy location, the delivery paperwork must be returned to the Pharmacy immediately
- All staff members involved in transfer must carry and show their valid trust ID badge.

5.4.2 Transfer of Controlled Drugs from a UHDB Pharmacy

Detailed procedures for Pharmacy transport / delivery is covered separately in Pharmacy Controlled Drug SOPs.

5.4.3 Transfer of Controlled Drugs from a UHDB clinical area

5.4.3.1 Stock CDs and CDs used 'for inpatient use only':

Stock should not be transferred between wards when patients are transferred. The destination ward should be informed to place an order with the pharmacy. This allows a full audit trail for the security of medicines and to protect staff.
If the patient transfer is due to take place when the pharmacy is closed, either the destination ward should follow Appendix CDSOP10 to obtain a single dose or contact the on-call pharmacist for advice prior to transfer.

Temporary Stock ('for inpatient use only') may be transferred ONLY if that medication has been ordered from the hospital pharmacy, for the same named individual during the current patient admission. If in any doubt, the duty pharmacist must be contacted.
A securely sealed CD transfer bag (Appendix C) must be used and register entries made on both the transfer and destination wards as per CD SOP 6.

5.4.3.2 Patient's Own Drugs

A securely sealed CD transfer bag must be used to transport patient's own controlled drugs in the following scenarios following CDSOP6:

- At any-time between UHDB wards (all sites)
- When a patient is transferred to another hospital

5.4.3.3 Palliative Care Syringes

RDH Nightingale Macmillan Unit (ONLY) may initiate the transfer of pre-filled palliative care syringes using CDSOP7 when a patient is transferred to NMU.

5.4.3.4 Transfer of Patients receiving CDs by infusion devices

Controlled Drug Infusions will require transfer in the following situations:

- When a patient is receiving a CD by means of a syringe pump (Critical care sedation or Patient Controlled Analgesia – PCA)
- When a patient is receiving a CD by means of a syringe driver (usually palliative care syringes with opioids or midazolam)
- When a patient is receiving a CD by means of an infusion (epidural infusions, etc.).

The ability to lock infusion devices, when used specifically for PCA or epidural, should be considered during the procurement / tender process for new equipment.

Where the device allows, these pumps must be locked during transfer of a patient and when the pump is unattended in-use (in practice, this would be whenever the syringe is loaded and in-use outside of 1:1 care e.g. ICU or theatre care)

Wards and departments who regularly transfer these patients with infusions running must ensure documentation of the following upon transfer. These wards and departments should consider having an SOP in place to facilitate these requirements. If no SOP in place, transfer or handover paperwork must be in place, be up to date and subject to regular review):

- An active prescription is in place on the transferring ward/department for the syringe/infusion
- The syringe / infusion are clearly and accurately labelled and the label details are clearly visible. For syringes / infusions prepared in the clinical area, the labelling must clearly state what has been added. Where an original manufacturer's container is in use without additives e.g. epidural infusions, the manufacturers labelling must be clearly visible.
- Ensure that the prescription can be used by the destination area to check the infusion upon receipt. If the destination ward is using a different prescribing system / paperwork then check there is provision for this to be prescribed upon transfer.
- Check and document the volume of the infusion at the point of transfer, ideally with a practitioner from both the sending and receiving department. Most pumps will indicate the volume remaining and / or infused to facilitate this. Where possible, for syringes or graduated infusion bags, ensure this value is consistent with the volume remaining indicator on the pump. This may not be possible for some cartridges or infusion bags.

5.5 Returns & Destruction

5.5.1 Controlled Drugs requiring Safe Custody

An entry must be made in the ward or department CD register for all returns or destruction of schedule 2 CDs (and schedule 3 when requiring safe custody) in the appropriate section. The balance must be amended and the entry witnessed and signed by a second registered practitioner at the time of the return or destruction. [CDs returned to pharmacy from a ward or department must be documented and transported to the pharmacy in accordance with Pharmacy SOPs].

In the interests of safety and environmental pollution, CD's in this Trust should (as far as practicable) be returned to Pharmacy for safe denaturing and destruction in the Pharmacy. Exceptions to this are outlined in table 2.

CD's should be destroyed in a way that renders the drug irretrievable so that it cannot be reconstituted or re-used.

In the case of schedule 2 CDs (and those schedule 3 CDs requiring safe custody as per table 1), denaturing at ward / department level may only be carried out:

a) By pharmacy practitioners (see table 2) in accordance with Pharmacy SOPs.

OR

b) by the department and/or pharmacy staff identified in table 2 who MUST strictly follow the provisions and restrictions within that table as part of this policy.

NB/ Table 2 is a policy and/or legal requirement and not an SOP or procedural aid.

Security of CDs requiring Safe Custody whilst awaiting return/destruction

Unwanted Schedule 2 CDs (and those schedule 3 CDs requiring safe custody) should be labelled as unsuitable (e.g. 'expired', 'soiled', 'damaged') and segregated in to a separate area of the CD cupboard where possible until the defined staff are available to perform a returns or destruction procedure as per table 2.

These quarantined items should never be placed in Pharmacy return boxes / bins as these do not meet CD storage requirements.

These medicines must still be included in the daily checks of the CD stocks (CDSOP9).

Table 2- Return and Disposal of Controlled Drugs

Note that there are legal restrictions on which items can be destroyed in clinical departments.

Table 2a shows the items which need to be removed by Pharmacy for destruction. These include some items which can be removed from clinical areas by Pharmacy but which require specific witnesses (as per legislation) to be present if destruction takes place within UHDB Pharmacy

Table 2b shows scenarios where the ward and department can legitimately destroy CDs.

Table 2- Return and Disposal of Controlled Drugs

Note that there are legal restrictions on which items can be destroyed in clinical departments.

Table 2a shows the items which need to be removed by pharmacy for destruction. These include some items which can be removed from clinical areas by pharmacy but which require specific witnesses (as per legislation) to be present if destruction takes place within UHDB pharmacy

Table 2b shows scenarios where the ward and department can legitimately destroy CDs.

Table 2a – Situations where pharmacy must be contacted to facilitate return/destruction of controlled drugs [requiring safe custody]

CD type and clinical location	Where destruction should take place	Person permitted to destroy drug	Person who must witness destruction	Relevant Register	Notes
Patient's own (POD)– unsuitable for use or no longer required (including deceased patient) [Note: PODs have both patient name AND directions for administration]	Pharmacy or on the ward following pharmacy approved procedure.	Pharmacist or CD-trained Pharmacy Technician	Pharmacist or CD-trained Pharmacy Technician or practitioner (nurse/ODP /midwife)	Patients own CD register	Deceased patient' CDs will be destroyed with or without consent of the estate/relative at UHDB.
Temporary Stock labelled with patient name for inpatient use only [Note: patient name but NO directions]	Pharmacy or on the ward following pharmacy approved procedure.	Pharmacist or CD-trained Pharmacy Technician	Pharmacist or CD-trained Pharmacy Technician or practitioner (nurse/ODP /midwife)	Ward CD register	
Ward stock – unfit for use or no longer required	Pharmacy only	Pharmacist or CD-trained Pharmacy Technician	Authorised Witness as designated by the CDAO	Ward CD Register(+ Pharmacy CD destruction register **when** returned to pharmacy)	
Transdermal Patches if unopened (including expired) [see table 2b for opened/damaged patches]	See above depending whether it is • POD • Stock • 'Temporary stock' with patient name	Pharmacist or CD-trained Pharmacy Technician.	See above depending whether it is • POD • Stock • 'Temporary stock' with patient name	Ward CD Register (+ Pharmacy CD destruction register **if** returned to pharmacy)	
Solid dosage forms (capsules, tablets) if still sealed in blister or in bottle/box (including expired) [see table 2b for damaged or removed from pack]	See above depending whether it is • POD • Stock • 'Temporary stock' with patient name	Pharmacist or CD-trained Pharmacy Technician.	See above depending whether it is • POD • Stock • 'Temporary stock' with patient name	Ward CD Register (+ Pharmacy CD destruction register **if** returned to pharmacy)	

Table 2b – Situations where the ward or department can destroy Controlled Drugs [requiring safe custody]

CD type and clinical location	Where destruction should take place	Person permitted to destroy drug and method	Person who must witness destruction	Relevant Register	Notes
Wards (and other non-anaesthetic departments) Liquid/injectable wastage from doses drawn up for individual patient	On the ward or department (but for anaesthetists and theatres, see below)	Nurse/ midwife **Empty into sharps bin containing superabsorbent mat***	Nurse, midwife, doctor, pharmacist	Ward CD Register	Ward register should show name of patient and details of dose/wastage e.g. 5mg given/5mg wasted OR reason not administered (e.g. refused)
Theatre (or anaesthetic practice elsewhere) Liquid/injectable wastage from doses drawn up for an individual patient, (including excess volume for the dose required AND whole doses which have been drawn up but not administered)	In theatre or other area of anaesthetic practice.	Nurse, midwife ODP or Doctor. **Empty into sharps bin containing superabsorbent mat***	Nurse, midwife, ODP, doctor or pharmacist (see section 5.10.2 for responsibilities of second check in the context of anaesthetic practice)	Theatre or ED CD Register (or other stock register used in the department of anaesthetic activity – e.g. anaesthetic activity in recovery, radiology etc.	The register should show name of patient and details of dose/wastage e.g. 5mg given/5mg wasted OR reason not administered (e.g. refused)
Liquid/injectable - Ampoules/vials/bottles found broken or accidentally dropped or spilled during procedures	Consider whether the damage was witnessed (see notes column) before deciding on local destruction. Follow procedure for the relevant ward/department OR theatre from one of the two rows above. **Complete an incident form**	Follow procedure for the relevant ward/department OR theatre from one of the two rows above.	Follow procedure for the relevant ward/department OR theatre from one of the two rows above.	Relevant register for the department and product (could include any of ward, theatre, ED or Patient own registers)	Where two registered practitioners witness a breakage, these can be destroyed in the clinical area and are recorded in the register by both practitioners. Where breakages are unwitnessed or found damaged in the packaging, the products should be quarantined in the CD cupboard for inspection by pharmacy whenever it is safe to do so (enter these on to a new page in your register to help segregate and quarantine from any stock which remains fit for clinical use).
Table 2b continued on next page					

Table 2b – Continued from previous page					
CD type and clinical location	**Where destruction should take place**	**Person permitted to destroy drug and metho**	**Person who must witness destruction**	**Relevant Register**	**Notes**
Wastage from discontinued parenteral infusion (e.g. PCAs, palliative care syringes, epidurals)	On ward, department or Theatre	Nurse, midwife or ODP **Empty into sharps bin containing 1 x additional superabsorbent mat per 200ml destroyed***	Nurse, ODP, midwife, doctor, pharmacist or CD-trained technician	A page of the ward or theatre CD register should be designated for the destruction of infusions. The quantity remaining when disconnected should be confirmed by both practitioners before immediate destruction and documentation. The volume recorded should match the clinical and administration records.	Details of amount administered should be recorded in the administration records / infusion checklist or other patient record to complete an accurate clinical record which aligns with the volume documented as destroyed in the register.
Transdermal Patches	Clinical Department if used, damaged or unwanted after opening individual seals. (see table 2a for unused patches)	Nurse/ODP /midwife or pharmacist	Nurse/ODP /midwife or pharmacist	Ward CD Register or Patient own drug register Register entry needs to include reason wasted	Used CD patches (e.g. Fentanyl, Buprenorphine) must be rendered irretrievable by folding the patch over upon itself with the adhesive surfaces facing inwards, so the release membrane is not exposed. The folded patch must be placed directly in the sharps bin. Complete incident report for unwitnessed damage
Solid dosage forms (capsules, tablets).	Clinical Department if damaged or unwanted after removing from pack. (see table 2a for unused still sealed / usable)	Nurse/ODP /midwife or pharmacist	Nurse/ODP /midwife or pharmacist	Ward CD Register or Patient own drug register Register entry needs to include reason wasted	Place directly in sharps bin Complete incident report for unwitnessed damage.

* Liquid CD waste must NOT be flushed down the drain , sink, sluice . Liquid or injectable CDs may be emptied into a sharps bin after a Sharpak HYDRI Mat (or other superabsorbent mat approved by pharmacy) has been added to ensure the contents cannot be retrieved. The empty vial or ampoule should then also be placed in the sharps bin.

One Sharpak HYDRI Mat of 150mmx150mm is sufficient to absorb up to 200ml of liquid. Therefore local SOPs may need to be established to ensure multiple mats are placed in sharps bins for areas with particularly high frequency of small volume wastage (e.g. theatres) or in areas who regularly dispose of infusions (e.g. areas caring for patients on PCA or epidural infusions). Sharpak HYDRI Mats are obtained via NHS Supplies.

Sharps bins used for disposal of liquid CD waste should be stored securely until these are ready for collection.

5.5.2 Controlled Drugs NOT requiring Safe Custody

Unwanted Schedule 3 CDs (if not requiring safe custody as per table 1) and Schedule 4 or 5 CDs should be returned from wards or departments in the Pharmacy return boxes / bins (which MUST always be stored in a locked clinic room).

The pharmacy department have SOPs to manage this stock upon return.

5.6 Prescribing Controlled Drugs

Medication prescribed for administration **within** the hospital (inpatient, clinic, theatre & daycase) can be prescribed in the same way as any other prescription medicine. This is a Patient Specific Direction (PSD) and does not constitute an instruction to supply to the patient. This is an authority to administer doses during the hospital visit only.

TTO, out-patient and daycase-discharge prescriptions are instructions to supply and therefore MUST conform to all the requirements of the Misuse of Drugs Regulations (regulation 15). Such prescriptions require:

- Use of official prescription forms including locally approved Trust forms
- Prescriptions for all Schedule 2 and 3 CDs to be written/printed indelibly (by hand, typed or computer generated), to include:
    - **Patient's full name, address and, where appropriate, age** (e.g. Children) - Pre-printed addressograph labels can be used but the prescriber must ensure that any duplicate copies of the prescription have the same addressograph and that the label cannot easily be removed. It is good practice to sign over the sticky label to safeguard it being tampered with
    - **Generic name *and* form (tablet, capsule, ampoule etc) of the drug** (legally required, even if only one form exists) - Where fast acting and slow release forms exist, it is important to make this explicit and also include the brand name on the prescription
    - **Strength** of the preparation, where more than one exists (almost all CDs)
    - **Dose** to be taken
    - **Frequency**
    - **Total quantity of the preparation, or the number of dose units, to be supplied in both words *and* figures -** TTO, outpatient and daycase prescriptions are usually limited to a maximum of 30 days' supply, unless authorised by the CD Accountable Officer.

The prescription *MUST be indelibly signed and dated by the prescriber*, who takes full responsibility for the contents of the prescription. Electronic signatures are <u>not</u> allowed.

Inpatients - Prescriptions for CDs should be recorded on the Trust electronic prescribing and medicines administration (ePMA) systems. If working in an area not currently covered by EPMA (or if the EPMA system is down), official Trust prescription stationery should be used e.g. inpatient medicines chart / downtime chart, anaesthetic chart (theatres) or integrated care pathway (daycase)

Discharge - Prescriptions should be written on the Trust ePMA systems or using the Trust TTO discharge form where these are still in use. Burton sites should refer to CDSOP11 relating to use of paper requisitions alongside ePMA (MediTech) discharges. Electronically generated prescriptions used for discharge must be signed and dated by hand.

Daycase - Prescriptions to be administered whilst on-site should be written on official Trust prescription stationery (e.g. day case medicines chart) or using the Trust electronic prescribing and medicines administration (ePMA) system. For discharge supplies, daycase areas should follow detail for outpatients as below.

Outpatients (NHS) - Prescriptions should be written on a Trust outpatient prescription form, an FP10HNC (where this has been authorised for your department) or using the Trust electronic prescribing and medicines administration (ePMA) system. Electronically generated prescriptions must be signed and dated by hand.

Medical doctors who have not achieved full registration with the GMC (Foundation Year 1) are NOT permitted to prescribe CDs on outpatient prescriptions but can prescribe for in-patients and daycase patients, including discharge /TTO prescriptions.

Supplementary prescribers can prescribe any Schedule 2, 3, 4 or 5 CDs (except diamorphine, cocaine and dipipanone for the treatment of addiction), providing it is in accordance with the patient's clinical management plan.

Nurse & Pharmacist Independent prescribers can prescribe any Schedule 2, 3, 4 or 5 CDs (except diamorphine, cocaine and dipipanone for the treatment of addiction).

Restrictions apply to the prescribing of Schedule 2, 3, 4 or 5 CDs for all other independent prescribers including Physiotherapists, Radiographers, Chiropodists / Podiatrists, Dentists, Dieticians, Paramedics, Optometrists.[3] These professions can only prescribe CDs as permitted by legislation **AND** when declared as part of their scope of practice following the trust Non-Medical Prescribing registration process (see Non-Medical Prescribing Policy on Koha)

Controlled Drugs must **NOT** be prescribed for use by Trust staff or their families unless they are being treated as part of official NHS activity (refer to Trust Self-Prescribing Policy).

Outpatients (Private) – Only CD prescriptions generated as part of a private consultation, within the UHDB legal entity, can be dispensed via the hospital Pharmacy.

Note on Managing prescriptions that do not meet CD prescription requirements:

Where a prescription for a schedule 2 or 3 CD contains a minor typographical error or spelling mistake, or where either the words or figures (but not both) of the total quantity has been omitted, a pharmacist can amend the prescription indelibly so that it becomes compliant with legislation. The Pharmacist needs to have exercised due diligence, be satisfied that the prescription is genuine and that the supply is in accordance with the intention of the prescriber. The prescription must also be marked to show that the amendments are attributable to the pharmacist (name / initials, date, signature, and GPhC registration number). Pharmacists cannot correct other amendments or omissions (e.g. missing date, incorrect dose, form or strength). These should ideally be corrected by

[3] https://psnc.org.uk/dispensing-supply/receiving-a-prescription/who-can-prescribe-what/

the original prescriber or, if not possible, another prescriber authorised to prescribe CD's. Amendments cannot be made by covering letter from the prescriber.

5.7 Preparing & Administering Controlled Drugs

Administration of CDs must follow the general principles laid out in the Medicines Policy for Administration of Medicines.

In addition, for all CDs requiring safe custody (see table 1) there must be two members of staff involved in the administration of a CD (any authorised exceptions to this will be listed in section 5.10 of this policy)

- The individual who is administering the CD must be a registered practitioner (but NOT a Nursing Associate)

- The second person (the witness) can be a registered practitioner, or a Nursing Associate who has completed the required additional training. The witness provides a second independent check and should follow the principles for independent check as outlined in the Trust Medicines Policy

Note: Student nurses / midwives are encouraged to shadow and observe the CD processes; however, they are not permitted to be a substitute for the roles of either of the registered practitioners who must both be involved as above

The second registered practitioner MUST directly witness the preparation, administration AND disposal of any residual dose of all schedule 2 Controlled Drugs, with the following exceptions:

- In Critical Care, Theatre areas and Emergency Departments it may not always be possible to directly witness administration, where doses are administered incrementally by medical staff. However, the total cumulative dose administered must be documented on the administration record / prescription and the disposal of any remaining dose or the syringe, vial or ampoule MUST be witnessed and countersigned in the register

- In community settings it is recognised that a second registered practitioner is unlikely to be present to witness preparation, administration or disposal of CDs. Where appropriate this can be checked with the patient, a carer or another responsible adult

- The registered practitioner administering the CD must have the administration witnessed by the second practitioner and must record the administration in the CD register and sign that the drug has been administered, this must be counter-signed by the witness and if any excess or waste, that this has been destroyed as per section 5.5 of this policy (Table 2)

- When removing CD's from the CD cupboard for administration it is important that the stock balances for that drug formulation are checked at the same time. Discrepancies must be reported immediately to the designated practitioner in charge of the shift to be investigated

- The reason for any doses prepared but not given must be recorded in the controlled drug register

- Failure to witness the administration and/or disposal of Controlled Drugs is considered a breach of procedure and could result in disciplinary action or criminal prosecution if evidence of theft or diversion occurs. Such incidents may be reported to the professional regulator.

Administration of CDs on a verbal order must only take place in emergency situations and under the direct supervision of the prescriber. The registered practitioner administering the medication must confirm the instruction with the prescriber. A prescription, record of administration and CD register entry should be completed as soon as possible following the event.

5.7.1 Self-Administration of CDs

Self-administration is only possible where Patient's Own CDs are available. Patient's own CDs are defined as those which are either brought in from home or dispensed from pharmacy against a discharge/outpatient prescription with **full administration directions.** As with all patients' own drugs (PODs), CD PODs must be treated as the patient's own property.

Patient's own CD's should never be used to treat other patients. Further detail on handling Patient's Own CDs is included in CDSOP5 & CDSOP6.

The appointed practitioner in overall charge of a ward or department must take the decision to authorise a patient to self-administer controlled drugs which have safe custody requirements (See Table 1). Considerations prior to taking this decision include any security risks or concerns posed by patients or staff present elsewhere on the ward. Additionally, the following criteria must be fulfilled:

- Patient has been fully assessed for self-administration of medicines under UHDB self-administration policy (including any CD specific requirements)

- A lockable bedside medicines locker is available and an individual locker key can be provided to the patient (the key must be unique to that one patient's locker on the ward/department). The patient must understand the need for safe and secure storage of medicines at all times

- Minimum daily reconciliation of the quantity in the patient locker in order to maintain accurate administration records and CD register records (which must still be maintained – see CDSOP5)

- Ensure all registered staff on the ward are aware of CDSOP5 and agree minimum time intervals for recording administration and update the medical team (including documentation in the medical notes) so they are aware of any lag time that may occur between administration and documentation of doses

- The ward pharmacist (or senior pharmacist in the BU / Division) must be informed during working hours. This is so any prescription annotations needed to support the safe SAM of CDs can be made in a timely fashion and taken into consideration should there be any prescription alterations or other clinical changes.

5.8 Suspected Abuse of Medicines (staff and patient concerns)

In addition to abuse with Controlled Drugs, a number of other prescription only medicines are sometimes subject to misuse, abuse or diversion, including common analgesics, some anaesthetic agents or products which may be used either recreationally or cosmetically. A list of some of these agents is included in Appendix B.

The appointed practitioner in overall charge of a department needs to be familiar with the abusable list and proactively notify the pharmacy department (Divisional Pharmacist) of any change in clinical practice for these agents so that stock levels can be reviewed.

Pharmacy have processes for monitoring deviations in stock issue patterns and/or for comparing prescribed doses versus usage (administered doses). Any concerns arising from this process will be presented by Divisional Pharmacists (or Deputies) to senior clinical staff within the wards, departments, business units or divisions.

If there are any unjustified deviations from expected use, these must be documented on a Datix Incident form e.g. if the deviation cannot be explained by clinical change in practice OR an assessment of administration records OR evidenced waste / expiry / breakage.

Concerns about Patients:
Ensure that you contact a member of the medical team directly responsible for the care of a patient if you suspect they may be abusing medicines (either prescription medicines or illicit medicines). If you have to contact an out of hours doctor, ensure this is documented in the medical notes / patients EMR for the attention of the parent team. If you suspect someone may be selling or supplying medicines in your area, follow section 5.9 for illicit substances.

Concerns about Staff and looking out for one another:
It is recognised nationally that increasing numbers of healthcare workers are abusing medicines. The CQC regularly flag this issue in their annual CD report.

Staff should be aware of the signs that might indicate abuse or diversion of medicines by colleagues (e.g. changes in an individual's behaviour such as lack of concentration, agitation, sweating, tremor, regular unexplained absences from the work area, a change in character, or other 'odd' behaviour).

It is important for that staff member's wellbeing, as well as for the safety of their patients and/or colleagues, that any concerns are reported. This could be to your own line manager or to a line manager of the staff member you are concerned about. Advice and support is available from the Occupational Health and Wellbeing service. Alternatively, if you feel uncomfortable approaching staff from your area directly, consider following the Freedom to Speak up Policy (Raising concerns at work) or visit the Freedom to Speak Up pages on Net-i.

5.9 Illicit Substances

Patients and visitors will sometimes bring medicines to abuse, suspected illicit / unknown substances into hospital. Staff are reminded to be vigilant and report any suspicion to the designated practitioner in charge of a shift.

Where these represent a small quantity 'for personal use', then the patient should be asked to surrender these for destruction. Staff have no automatic right to search a

patient's belongings and if considered necessary, consent must be obtained. In the case of an unconscious patient, a search of belongings may be necessary as part of a collateral history in the patients' best interests and it is accepted that consent is not possible in this scenario. Document in the nursing records that this has taken place and record if any substances have been removed.

The full procedures to follow when taking illicit or unknown substances in to custody are outlined in CDSOP12. Full documentation in a CD register is required.

Where the quantity is large or there is evidence of a criminal act taking place e.g. dealing on UHDB premises, then the Police will ONLY be called to investigate following agreement by **both**:

- The Consultant/clinician in charge of the patient's care
- The Trust Accountable Officer for Controlled Drugs (Chief Pharmacist).

If a patient refuses to give up any quantity of suspected illicit substance, then staff should refer to Trust Security. If security are met with continued refusal, and possession is suspected, they should consult with the accountable officer for CDs and the treating consultant **before** contacting the police, as above.

Illicit substances must NEVER be given back to a patient or their carer once removed. This constitutes an act of criminal supply and may be prosecuted under the Misuse of Drugs Act.

5.10 Authorised Exceptions or Variations to the Controlled Drug Policy

5.10.1 Midwives

Midwives can legally operate under midwives exemptions. This exemption in law is covered by clinical guidelines / procedure approved by the Division of Women and Children at UHDB (with approval from the Accountable Officer for AOCD

Some controlled drugs (including some schedule 2 CDs) are included in midwives exemptions for supply and/or administration depending on the drug. This means that a midwife working within their knowledge and competency may provide certain medications without a prescription providing they are following the agreed maternity procedure / guideline. In the case of controlled drugs, these should still be independently checked by a registered practitioner following all other policy requirements for Preparing and Administering Controlled Drugs (Section 5.7).

5.10.2 Theatres and Anaesthetic Practice

In Theatre areas, CDs are routinely issued to anaesthetists who document and administer these. In this environment the anaesthetist has responsibility for the security & destruction of those CDs.

A Theatre specific CD register is available from pharmacy to record such issues and helps to clearly identify accountability of staff involved and document return or destruction of remaining CDs.

The theatre nurse or Operating Department Practitioner (ODP) must document the name of the Doctor / Anaesthetist and the patient name/identifier, in the relevant section of the CD register when these are handed over. At this point the anaesthetist assumes responsibility for the security, use and disposal of the CDs within the theatre complex or

other area of anaesthetic practice. In most circumstances the easiest way for the anaesthetist to ensure the security of CDs will be to keep them with the patient.

Second checking is considered good practice wherever possible. However, it is recognised that anaesthetic administration is not routinely witnessed by a second practitioner in Theatres. A record of administration (anaesthetic chart in theatres, or drug chart / pathway chart in other areas) must be recorded by the anaesthetist and compared with the quantity remaining at the end of each patient procedure.

In the event that anaesthetic staff change over during a procedure, the anaesthetist should agree **one of the following approaches**:

- Inbound anaesthetist reconciles remaining controlled drugs against the administration records for the current case. Both anaesthetists must confirm concentration and labelling of the syringes. Inbound anaesthetist then agrees to document any wastage at the end of the case.

  OR

- Outbound anaesthetist completes reconciliation/destruction and register entries before leaving and informs ODP/Nurse and remaining anaesthetist so that they can arrange any additional supplies immediately.

CDs must only be issued for use in ONE patient. Vial sharing is not permitted at UHDB.

At the end of each procedure, a Nurse or ODP MUST witness the anaesthetist's destruction of a part-used ampoule or syringe, and sign for this in the relevant section of the register. When witnessing destruction there is no expectation that the witness needs to accurately measure the volume being destroyed (beyond a simple visual check). The witness does not need to check the anaesthetic record for evidence of the doses administered. Unused ampoules may be returned back to stock and documented fully in the CD register. Part-used quantities must be rendered irretrievable in accordance with the *Returns and Destruction* section of this Policy.

Disposal of ampoules that are found broken, or are accidentally dropped or spilled during a procedure must be documented in the register and countersigned by a second registered practitioner. A Datix incident should be completed. Where two registered practitioners witness a breakage, these can be destroyed in the clinical area and are recorded in the register by both practitioners. Where breakages are unwitnessed or found damaged in the packaging, the products should be quarantined in the CD cupboard for inspection by pharmacy whenever it is safe to do so (enter these on to a new page in your register to help segregate and quarantine from any stock which remains fit for clinical use).

5.10.3 Emergency Department

In most cases, controlled drugs are prescribed and then administered in ED in accordance with the main body of this policy, including requisite second checks on preparation, administration and record-keeping against that prescription.

However, within a resuscitation emergency or intubation, it may be necessary for a registered practitioner to issue controlled drugs to an ED doctor or anaesthetist in advance of a prescription/administration record being documented by that doctor in the medical record or medication chart / ePMA.

In these circumstances, the registered practitioners in ED must follow the process outlined above in 5.10.2 for Theatres and Anaesthetic Practice. There is a dedicated ED CD Register (which replicates the theatre format) which is available to help alignment with the process for issuing CDs directly to a medical practitioner and for reconciling and witnessing any wastage.

5.10.4 Enhanced monitoring requirements or CD processes

On occasion, clinical areas are found to be experiencing unexplained loss or diversion of controlled drugs (including medicines from the lower schedules 4/5 which may be subject to abuse). These may be identified by clinical staff or by remote monitoring processes performed by the pharmacy department (Pharmacy SOP – Monitoring drugs with a potential for abuse or diversion). During investigation (or following an unsuccessful investigation) it may be necessary to safeguard staff and/or patients by initiating enhanced controls for that specific area, over and above this policy. When enhanced controls are used they will be recorded on the *Temporary Exceptions to CD Policy Register*, which is uploaded to the Pharmacy Controlled Drugs page of the intranet when approved by the Chief Pharmacist or the Medicines Safety Officer.

5.10.5 De-regulation or reductions in policy requirements

At the point of policy publication, there are no other concessions to policy requirement than those already outlined in Section 5.10.

De-regulation: If the Home Office instruct any deregulation or de-escalation in CD schedule, these will be reviewed immediately by the Accountable Officer for CDs and the Medicines Safety Group. An update to policy may be warranted but any formal relaxation will be communicated to wards after an entry is made on the *Temporary Exceptions to CD Policy Register* (as per 5.10.5).

If any local areas identify changes required to ensure patient safety or business continuity, they should liaise with the CDAO and MSO. Minimum legislation must still be met, however a local deviation from policy may be authorised providing this is agreed by the CDAO, the MSO and a risk assessment is written and accepted by the divisional management team making the case for change. Any agreed changes will be written in to policy as soon as practicable and will be recorded in the *Temporary Exceptions to CD Policy Register* on the intranet.

6. Monitoring Compliance and Effectiveness

The key requirements will be monitored in a composite report presented on the Trusts Monitoring Report Template:

Monitoring Requirement :	Audit questions against key policy criteria as outlined in appendices CDSOPs 13-16
Monitoring Method:	Audit submissions using an internet based eForm (no patient or staff data submitted)
Report Prepared by:	Controlled Drug Accountable Officer
Monitoring Report presented to:	Annual CDAO report (incorporating a summary of the interim reports 1-3 below) – Quality Improvement Group
Frequency of Report	Annual.

In addition the following interim / operational reports will be provided and will inform the above composite report:

1. Annual Trust CD Audit (yearly during Q2, coordinated by MSG but data collection and area specific action plans led by matrons/equivalent) – reviewed at Trust Medicines Safety Group. Changes to education and communication of broad themes will be coordinated at MSG.

2. Pharmacy-led CD Audits (clinical areas) in Q1, Q3, and Q4 – reviewed at Pharmacy CD management meetings. Datix reports are used to inform business units of non-compliance.

3. Pharmacy-led CD Audits (pharmacy areas) – reviewed at Pharmacy CD management meetings. Action plans and education planned.

7. References

Controlled Drugs (Supervision of Management and Use) Regulations 2013.

https://www.cqc.org.uk/sites/default/files/20190114_controlleddrugs_selfassessment-secondary.xlsx

The Misuse of Drugs Act (1971) as amended
https://www.legislation.gov.uk/ukpga/1971/38/data.pdf

The Misuse of Drugs Act Regulations 2001 as amended
https://www.legislation.gov.uk/uksi/2001/3998/made

The Misuse of Drugs (Safe Custody) Regulations 1973 as amended 2007
https://www.legislation.gov.uk/uksi/1973/798/made
https://www.legislation.gov.uk/uksi/2007/2154/made

The Health Act (2006)
https://www.legislation.gov.uk/ukpga/2006/28/contents

Safer management of CDs – a guide to good practice in secondary care (England) 2007

https://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_074511.pdf

Safe drug management in Anaesthetic practice RCOA 2020

https://rcoa.ac.uk/sites/default/files/documents/2020-09/Safe%20Drug%20Management%20in%20Anaesthetic%20Practice%20v2.0.pdf

Appendix A – CD SOPs

Appendix CDSOP 1 - Ordering and receipt of stock or inpatient controlled drugs from pharmacy

1. This SOP applies to ordering Controlled Drugs from Pharmacy during their opening hours, or by arrangement with the on call pharmacist. See separate procedure for obtaining doses of Controlled Drugs when Pharmacy is closed CDSOP10.

2. The nurse, midwife or ODP in charge of the ward is responsible for ordering CD's for use in that area, but may delegate the task of preparing an order to another nurse, midwife or OPD.

3. CD's must be ordered in the CD order book (or Form CD3NP/CD3ST for schedule 3 CDs that do not require safe custody - table 1) specific to that ward or department. If the ward has more than one CD cabinet, then separate CD registers and CD order book should be used for each. CDs should be routinely ordered Monday to Friday 9am – 5pm, and should only be ordered at the evening/weekend if it is an urgent supply.

5. The CD order book or requisitions should be kept in the CD cupboard where possible (or another locked medicine cupboard if necessary). Should an order book go missing, the nurse, midwife or ODP in charge must immediately inform the manager of that area and the duty pharmacist. An incident report must be completed.

6. A list of authorised nurse / midwife / ODP signatures is maintained in Pharmacy and the validity of a signature will be checked before dispensing can begin. Only an authorised signatory noted as working in that specific area will be able to sign for CDs (although a pharmacist or pharmacy technician may prepare the order before obtaining an authorised signature).

7. All orders must be prepared as follows:

a) Ensure the carbon paper is inserted between the duplicate pages, with the carbon facing down

b) A separate page must be used for ordering each different drug, strength or formulation

c) Refer to the stocklist for your area. If a medication you are ordering is not on your stocklist then add the name and hospital number of the inpatient requiring the prescription (Note: TTOs and outpatient supplies are never ordered using a CD requisition book)

d) Indelible black ink should be used

e) Must be signed by a nurse, midwife or ODP, authorised to order CDs in that area.

8. If an error is made when writing an order / requisition then it must be cancelled by striking across the page with the words 'cancelled' or 'void' signed and dated.

9. When the CD's are ready in Pharmacy they will either be delivered by porter/courier or Pharmacy will telephone the ward to collect.

10. If the ward sends a messenger (member of staff or trust volunteer) to collect the CDs, they must have their trust identity badge. The badge must be on display when receiving the CDs from Pharmacy.

11. CDs will always be placed in sealed bags (a bag seal security tag or the bag itself will have a unique code which will match with the *Pharmacy Controlled Drug Delivery Sheet)*.

12. The messenger or porter with a member of the Pharmacy staff, checks that the delivery bag is sealed.

13. The messenger or porter confirms the destination ward/department, checks that the bag seal number on the *Pharmacy Controlled Drug Delivery Sheet* corresponds to the unique number on the bag/tag. The messenger or porter then signs and dates the *Pharmacy Controlled Drug Delivery Sheet*.

14. The CDs must be taken directly to the ward or department by the messenger or porter in the sealed bag.

15. On arrival at the ward, a non-registered messenger or porter must hand the goods to a registered practitioner.

16. The registered practitioner receiving the CD's must immediately check that the seal on the bag is intact and that unique number on the bag/tag matches the entry on the *Pharmacy Controlled Drug Delivery Sheet*. They can then sign the *Pharmacy Controlled Drug Delivery Sheet* and return this via the porter or messenger to Pharmacy to be filed.

17. Out of hours, where CDs are required urgently, it may be necessary for the Trust contract taxi service to collect CDs and deliver to outlying wards or to patient's own home. In this circumstance a Taxi book must be completed and signed by the taxi driver. The taxi driver must provide identification before the CD's are released for transportation. The registration number of the taxi driver should be recorded. This can be made on the *Pharmacy Controlled Drug Delivery Sheet*.

DERBY ONLY – Ordering of pharmacy-prepared Palliative Care Syringes containing Controlled Drugs [requiring safe custody]

The following points must be followed when preparing a handwritten requisition for palliative care syringes containing a controlled drug. This guidance is provided to ensure that handwritten requisitions are prepared clearly and accurately in order to prevent risk of error due to lack of clarity.

✓Write the required information in the designated sections of the requisition i.e. dose must be written in the 'Strength' box and quantity required in the box marked 'Quantity' (see example below)

✓Use capital letters to clearly state the drugs included in the palliative care syringes ('Syringe Driver')

✓Ensure that the dose of drug required is written clearly in the section titled 'Strength' and clearly mark the decimal point for doses that require this.

✓Use one line per drug and strength

✓If an error/change is made whilst writing the order, strike through the requisition (marking as 'void') and start a new requisition – do not amend an existing requisition order, as this can increase risk of error and misinterpretation.

Example of a clearly written order for a syringe required for a continuous subcutaneous infusion in a ward CD order book:

Name of preparation	Strength	Quantity
DIAMORPHINE **CYCLIZINE**	**7.5mg** **150mg**	**1 x 15ml SYRINGE**

- ✓ Stop moment prior to signing (due to previous UHDB errors in these areas):
- ✓ Check the dose ('strength') is correctly aligned to the ingredients.
- ✓ Check decimal points are clear

Appendix CDSOP 2 - Storage and entry of controlled drugs [requiring safe custody] into the controlled drug register (record book)

1. Each ward or department that holds CD stocks must keep a record of CDs received and administered in the CD register. The nurse, midwife or ODP in charge is responsible for keeping the register in good order and up to date.

2. Each CD cabinet must have a CD register specific to that cabinet. Most ward areas will require both a ward stock register and a patient's own drug register (for CD medicines which have been legally issued to a patient in the community or against a hospital outpatient or discharge prescription. See appendix CDSOP5 for detail on patient's own CD register entries). Some areas who regularly use palliative care syringes may also keep a separate register for this purpose.

3. Once the CD's have reached the ward or department they become the ultimate responsibility of the senior nurse / midwife / ODP who at that time is in charge of the ward or department.

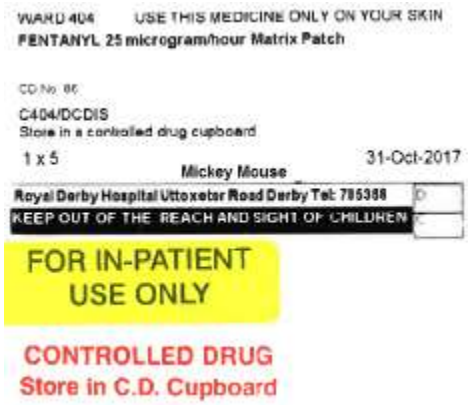
4. On receipt, CDs subject to the safe custody requirements MUST be immediately entered into the ward CD register and secured in the CD cupboard. This includes all schedule 2 CDs and some schedule 3 CDs (such as temazepam, buprenorphine and midazolam; refer to Table 1).

5. The nurse, midwife or ODP receiving the CD's must inspect each individual item, check there is the correct quantity and sign the receipt section on the pink copy of each order sheet.

6. Supplies should be checked on receipt to ensure that these have not been tampered with and correspond exactly with the requisition and pack label. Any discrepancy should immediately be reported to Pharmacy.

7. Stock items or temporary stock items (labelled 'For Inpatient Use Only') should be entered on the appropriate page for that drug, form and strength, in the ward stock register.

Tip: temporarystock items may have a patient name but are distinguishable from Patient's own medicines as they will be labelled 'For Inpatient Use Only' and will never have directions for administration. Example:



[NOTE: medicines received as TTOs or against an outpatient prescription are patient's own and are distinguishable by having printed directions for administration e.g. take *** tablets *** times daily. Follow Appendix CDSOP5 for patient's own medicines]

8. Each different type of CD should be entered on a separate page, taking care to clearly distinguish between different strengths of controlled drugs and different formulations.

Palliative Care Syringes, that have been received pre-prepared by pharmacy, should be booked in to a specific register if one is available. Or otherwise, in areas that rarely administer these pre-filled syringes, they may be booked in to a page in the stock register that reflects the exact combination of ingredients and doses.

9. Full details of the drug identification must be written at the top of each page. These details should include:

a. Approved name of controlled drug

b. Strength of preparation – It is best practice to annotate with "HIGH STRENGTH" next to any products listed in 13 below or for those which would not routinely be administered as a single dose (e.g. for products held as stock for the purposes of preparing palliative care syringes)

c. Formulation (e.g. liquid, tablet, patch)

d. Brand (where appropriate).

10. All new entries should be made in black ink and be otherwise indelible, and must be in chronological order with a running balance kept.

11. The register entry must include:

a. The date the CD was received

b. Order requisition number

c. Quantity received

d. Name / Signature of receiver (nurse, midwife or ODP)

e. Name / Signature of the witness (Registered practitioner or NA with additional CD training and assessment)

f. New stock level

g. Confirmation of correct balance in register.

12. No cancellation, obliteration or alteration of any entry may be made. Errors in the register are to be bracketed and endorsed "error", signed, dated and countersigned by a witness. Corrections must be made by way of marginal notes or footnotes.

13. All high strength opiates must be stored in a separate section of the CD cupboard to low strength opiates and the section labelled clearly as "high strength opiates".

High strength opiates have been identified as:

a. Morphine 30mg/ml (60mg/2ml)

b. Diamorphine Injection 30mg / 100mg / 500mg

c. Alfentanil 5mg/ml

d. Oxycodone 50mg/ml Injection.

Appendix CDSOP 3 - Administration of controlled drugs [requiring safe custody]

1. When an authorised prescriber has prescribed a CD for a patient, an entry must be made in the CD register against the item each time a dose is administered.

2. Administration of Controlled drugs must follow the general principles laid out in the Medicines Policy (Administration section) and also to the principals in section 5.7 of this Controlled Drug policy.

3. Administration of CD's must involve two registered members of staff (exceptions as per 5.7 of the CD policy). Administration must be undertaken by a registered practitioner. A second independent check (witness) can be a registered practitioner or an assessed and competent Nursing Associate.

   Note: Student nurses/midwives are encouraged to shadow and observe the CD processes, however, they are not permitted to be a substitute for the roles of either of the registered practitioners who must both be involved as above.

4. All aspects of the reconstitution and preparation of the CD must be under the direct supervision of the person who is going to administer the drug.

5. A second person must check all aspects of the administration (but see exceptions in CD Policy 5.7), including:

   a. Preparation of the CDs to be administered

   b. Entry in the CD register (the balance must be checked before administration to the patient)

   c. The administration of the CD to the patient

   d. Documentation of the medicine on the prescription or administration record

   e. The destruction of any surplus drug

6. The following should be recorded in the CD register:

   a. Date and time of administration of the dose

   b. Name of the patient

   c. Quantity administered* (and wasted / destroyed if applicable)

      **Or used in the preparation of a palliative care syringe – annotate clearly if the CD is being used for this purpose.*

   d. Drug name, form & strength (e.g. oxycodone liquid 5mg/5ml) – It is acceptable for this to be clearly documented once at the top of each register page for stock controlled drugs.

   e. Name / signature of registered practitioner who administered the dose

   f. Name / signature of independent second check (witness)

   g. Balance in stock.

7. If the dose prescribed is made up of two presentations then two entries are required in the CD Register, e.g. a dose of morphine sulphate m/r 40mg requiring one 30mg and one 10mg capsule.

8. CD's must not be administered if the prescription is unclear, illegible, ambiguous or illegal or there is any reason to doubt its clinical appropriateness.

9. Before administration confirm any recent opioid dose, formulation, frequency of administration and any other medicines prescribed for the patient.

10. Ensure where a dose increase is intended, that the calculated dose is safe for the patient (e.g. for oral morphine or Oxycodone in adult patients, not normally more than 50% higher than the previous dose).

11. Ensure familiarity with the following characteristics of the medicine and formulation; usual starting dose, frequency of administration, standard dosing increments, symptoms of overdose, common side effects.

12. Liquid medicines must only be administered by using a spoon, oral measure or purple EnFit syringe. If part of a vial is administered to the patient, the registered practitioner should record the amount given and the amount wasted in the CD register. E.g. "2.5mg given and 2.5mg wasted". This must be witnessed by a second person as above.

13. Individual doses of CDs which have been prepared but not administered should be destroyed and witnessed by a registered practitioner on the ward or department in accordance with the policy requirements outlined in Table 2 in section 5.5. of CD Policy. The reason should be documented in the register.

14. No cancellation, obliteration or alteration of any entry may be made. Errors in the register are to be bracketed and endorsed "error", signed, dated and countersigned by a witness. Corrections must be made by way of marginal notes or footnotes.

15. In the event of a CD being administered to the wrong patient, medical staff must be informed immediately. The designated practitioner in charge of the shift must be informed and an incident report must be submitted using the Trust drug incident form (Datix), the Accountable Officer must be informed of all incidents relating to CD's.

Appendix CDSOP 4 - Recording and administering of patients' own Controlled drugs [requiring safe custody]

It should be noted that CDs belonging to patients should, as with other patient's own medicines, be treated as the patient's own property. Patient's own CD's should never be used to treat other patients.

1. Two registered practitioners must be involved with the handling and administration of patient own CDs at all times.

2. All patients' own drugs brought into the Trust MUST be recorded in the Patient's Own Controlled drug record book. Record on a new page the details of the patient name, drug, strength and quantity of the CD.

3. Patients own CD's are ordinarily stored in the ward CD cupboard. On occasions, a patient who has been fully assessed for self-administration of controlled drugs may have been authorised by the appointed practitioner to have these in a locked bedside medicines locker where an individual locker key can be provided to that patient (policy 5.7.1).

4. Record the administration in the Patient's Own Drug register and record any wastage.
For patients who are self-administering and have custody of their own CDs, it is necessary to reconcile and document the quantities regularly with the patient to update the administration records and the CD register (each drug round is recommended and minimum daily is policy requirement).

5. During daily checks ensure that the drug quantity & strength is checked with another registered practitioner and that balance is correct. This must be done at least every 24 hours as with other CDs and documented on the daily CD check record.

6. Patients own drug no longer required - Where the medicine is no longer required, and if the patient or their representative agrees, a referral may be made to pharmacy to facilitate safe destruction. They should be stored in the ward/department CD cupboard, and remain subject to daily checks, until a pharmacist is able to remove or destroy this. If a patient refuses to allow discontinued medication to be destroyed, and where returning the medicine may present a risk to the patient or others, the ward staff or pharmacist should escalate to the accountable officer for CDs for advice.

7. If a patient is transferred to another ward then their patient's own CDs must be transferred with them (CDSOP6). A record of the transfer must be made in the patient's own drug book.

Appendix CDSOP 6 - Transfer of Patient's Own Controlled Drugs [requiring safe custody] when moving between inpatient locations (UHDB & external)

A securely sealed CD transfer bag must be used to transport controlled drugs in the following scenarios:

- Patient's Own Controlled Drugs
- Hospital supplies which have been dispensed the same admission to meet the needs of an individual patient as outlined in CD policy 5.4.2

This SOP must **NOT be used for transfer of ward stock CDs**

This SOP details the transfer process:

1. Obtain a CD transfer bag (these are disposable bags with serial number and tamper evident seals)

2. All CDs must be checked by two registered practitioners and signed out of the Patient's Own CD register recording the serial number of the bag to confirm both practitioners have sealed the contents

3. The patient's name, ward (both current and future for transfers), hospital number, and date of transfer should be completed on the tear-off section and signed by the Registered practitioner issuing the CDs for transfer

4. The hospital porter or ambulance crew must sign for receiving the sealed bag and transport this intact to the receiving ward

5. It is then best practice for the supplying ward to contact the destination ward to advise them a CD bag is in transit and will need signing for on receipt

6. The recipient Registered Practitioner accepting care of the patient should check the bag is intact and signs the tear-off record on the CD transfer bag

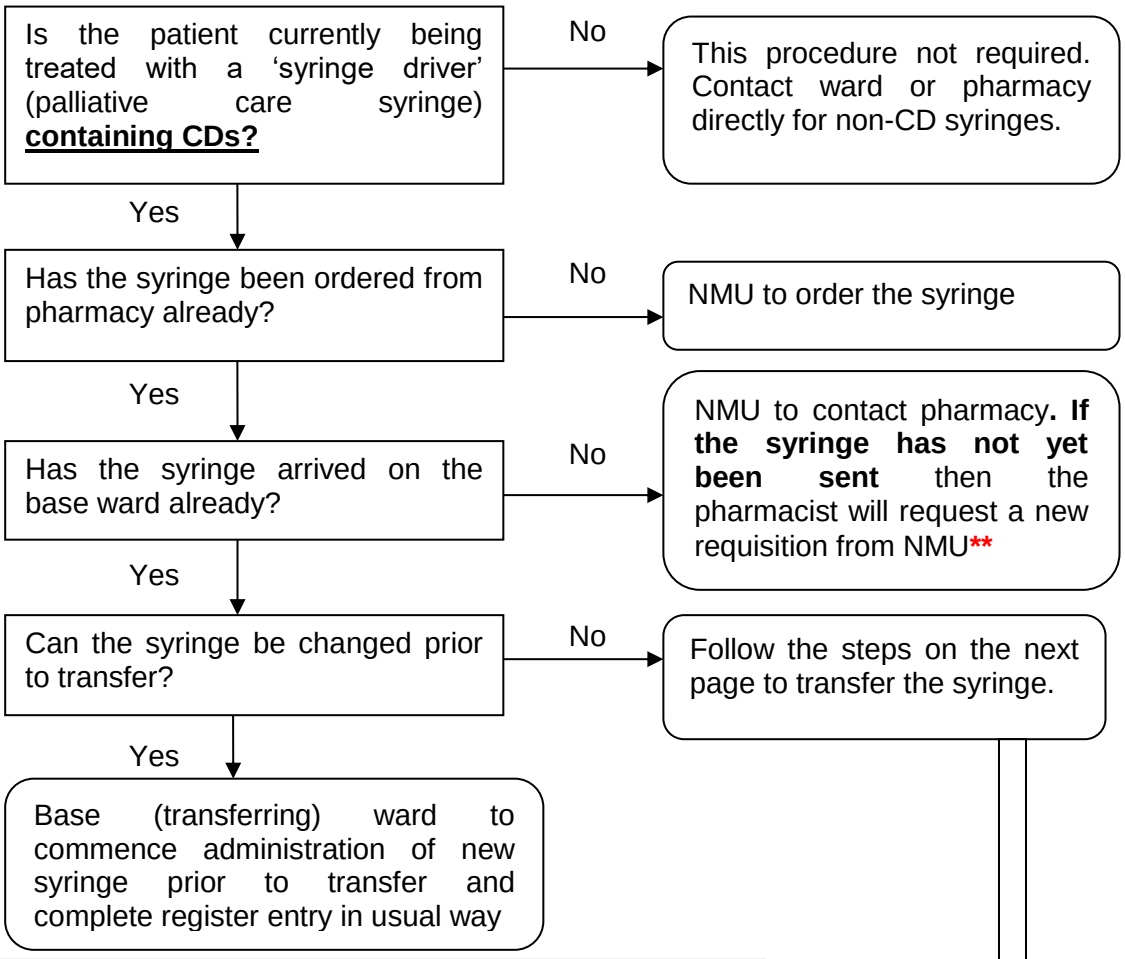
7. The tear-off record is retained by the person transporting the patient, as proof of delivery

8. For UHDB transfers: The recipient ward then opens the sealed bag, records the CDs and serial number in the ward patients own CD register by two registered practitioners.

Appendix CDSOP 7 DERBY ONLY - Transfer of palliative care syringes for patients transferred to Nightingale Macmillan Unit

Transfer of palliative care syringes for patients transferred to Nightingale Macmillan Unit

NMU nursing staff will establish if patients are on palliative syringes and help direct base (transferring) wards on appropriate action:



****NOTES FOR PHARMACIST:**

Clinically screen the new requisition from NMU against ePMA.

- **If the syringe has <u>not</u> yet been prepared:**
  - Cross through (void) base ward requisition
  - Prepare and supply against NMU requisition
- **If the syringe has been prepared already:**
  - Aseptic Check and release against base ward requisition
  - Annotate the base ward req *'despatched to NMU' &* include *'NMU req number XXX'*
  - Check the syringe against NMU req and prepare delivery/collection paperwork for NMU
  - Staple both white requisition copies together
  - Despatch syringe to NMU

PTO

Transfer of CD containing pre-filled syringe:

- Ensure the syringe has already been entered in to base/transferring ward Syringe Driver CD register (or Stock register for wards who do not hold a dedicated syringe driver register)
- Book out of base ward register and include the words 'Unused syringe transferred to NMU'. The register should be signed by two **registered practitioners** as usual, and those same practitioners sign for step 1 / 2 below.

Patient Name:	Syringe contents:	Quantity:

Process	Step	Who? (all must be registered practitioners)	Name	Signature	Date/Time
Booked-out from base ward register **Ward**…….	1	*Base ward practitioner*			
	2	*Transferring practitioner*[*]			

- The transferring practitioner transports the medicine and this form to NMU and must also take part in entering this in the NMU register as per step 3 / 4 below:

Received/entered into NMU register	3	*Transferring practitioner*[*]	Must be same staff member as step 2 above		
	4	*NMU practitioner*			

[*] The registered practitioner that transports the medicine must complete both step 2 & step 3. This practitioner can be from either the base ward or NMU.

Appendix CDSOP 8 - Management of Controlled Drugs on temporary Ward closure and transfer of Wards

This SOP will help senior staff make an informed decision about the security of CDs during a clinical department's closure or relocation.

When a ward is closing, this SOP describes the process for removal/quarantine of CDs [requiring safe custody] to minimise the risk of theft or diversion. There is also a process option for transferring the medicines to a new destination (providing the destination has an empty controlled drug cabinet).

Note: although not explicitly covered in this SOP, consideration should also be given by the staff managing this process to the security of any other medicines liable to abuse or theft (including medicines in schedules 4 and 5 – See Appendix B)

Ward Closures

All non-routine closures should be discussed with a divisional pharmacist or the pharmacy management team at the earliest opportunity.

A balance of risks should be considered to determine whether the CD's should be returned to Pharmacy. The appointed practitioner in charge of the department and a senior pharmacist should make this decision and inform the Divisional Nurse Director and the Chief Pharmacist (or their nominated deputies) in any case where the CD stock will be left in the clinical area during a non-routine closure.

The decision to secure or remove stock during a non-routine closure should be based on the risks to security which may include, but are not exclusive to:

- Whether the treatment room (or other medicines storage areas) can/will be accessed during the closure
- Any requirement for building works and whether these are by UHDB staff or contractors
- Level of supervision for any building works
- Presence of CCTV / swipe access and other monitoring / deterrents.

In general, if the ward will not have a nurse on duty who can monitor and fulfil daily check requirements then CDs requiring safe custody should be returned to Pharmacy

Short-term closures (or agreement to quarantine stock in pharmacy):

If the ward is closed for a short period of up to one week (or longer if authorised by the Accountable Officer for CDs) then the following quarantine process can be followed:

1. I**n advance of the ward closure:** Identify any patient's own medications which are no longer required and contact your pharmacist to facilitate return/destruction (See Pharmacy SOPs)
2. **In advance of the ward closure:** Identify any temporary stock items which had been ordered for patients no longer in the department and contact your pharmacist to facilitate return/destruction (See Pharmacy SOPs)
3. **On the day of the closure:** identify any patient's own medication for patient's still on the ward or department and prepare these for transfer to the destination ward or department as per CDSOP6

4. Contact the Ward Pharmacist or pharmacy technician to coordinate the removal of stock CDs for quarantine in the Pharmacy

5. The Pharmacist / Technician and a second registered practitioner (ideally from the ward but can be a second pharmacist/technician) in charge of a shift will perform a full stock check (see CDSOP9) but will also annotate each active page of the register with 'quarantined in pharmacy' and then complete signatures and balance check in CD register. [Any discrepancies at this stage will need to be reported and actioned as per CDSOP9 before continuing with the returns process]

6. The CD stock, requisition book(s) and register(s) must be placed in to a tamper-proof serial numbered pharmacy bag(s) and sealed. This must be done by the two practitioners who completed step 5 above who will then complete Form CD-QUARANTINE (available from pharmacy) which provides written confirmation that the CD checks were complete and the contents are complete and accurate

7. Form CD-QUARANTINE is taken to pharmacy by the pharmacist/technician where a second pharmacist or pharmacy technician will sign for receipt of the sealed bag(s) and attach the form to the outside of the bag

8. If the ward is closed for a short period of up to one week (or longer if authorised by the Accountable Officer for CDs) then the sealed bags will remain stored in the Pharmacy controlled drug room or cabinets. However, If the agreed time for storage passes then the divisional pharmacist will be informed. If no extension is agreed with the AOCD then stock will need to be returned for re-use or destruction as per See Pharmacy SOPs and the divisional pharmacist will plan a process for re-stocking once the department reopens

9. When the ward reopens after a short period the pharmacist/technician will return the bags to the ward and the practitioner in charge of the shift will check the bag is sealed, check the serial number, and sign for receipt on form CD-QUARANTINE

10. The bag(s) can then be opened and the contents will be checked by two registered practitioners in the clinical department. They must annotate each active page of the register with 'returned from quarantine' and complete signatures and balance check, which fulfils the requirement for the daily check on that day.

Longer closures:
If the ward or department is to be closed for periods longer than one week, the stock should be returned to pharmacy for re-use or destruction following the procedure for return of CD's. (See Pharmacy SOPs).

1. I**n advance of the ward closure:** Identify any patient's own medications which are no longer required and contact your pharmacist to facilitate return/destruction (See Pharmacy SOPs)
2. **In advance of the ward closure:** Identify any temporary stock items which had been ordered for patients no longer in the department and contact your pharmacist to facilitate return/destruction (See Pharmacy SOPs)
3. **On the day of the closure:** identify any patient's own medication for patients still on the ward or department and prepare these for transfer to the destination ward or department as per CDSOP6

4. Contact the Ward Pharmacist or pharmacy technician to coordinate the return of stock CDs to Pharmacy

5. The Pharmacist/technician and a second registered practitioner (ideally from the ward but can be a second pharmacist/technician) in charge of a shift will perform a full stock check (as per CDSOP9) but will also annotate each active page of the register with 'returned to pharmacy' and then complete signatures and balance check in CD register. [Any discrepancies at this stage will need to be reported and actioned as per CDSOP9 before continuing with the returns process

6. Form CD-RETURN (available from pharmacy) will be used to fully document the Drug / Form / Strength / Quantity of each medicine returned. Pharmacy staff will consider the appearance, integrity and expiry of each CD and identify on the form whether this is for stock return or destruction

7. The CD stock must be placed in to a tamper-proof serial numbered pharmacy bag(s) and sealed. This must be witnessed by the two practitioners who completed step 5 above who will then sign Form CD-RETURN and attach to the outer bag

8. The CD requisition books and registers should be moved to a CD cupboard elsewhere within the clinical department/specialty or within pharmacy

9. Pharmacy staff will transfer the sealed CD returns bag to the pharmacy CD room and follow pharmacy procedures for the prompt return or destruction.

Transfer of Wards

When a ward / department moves to another location it may be appropriate to transfer the CDs rather than return to pharmacy.

1. Ensure the destination department has a CD cabinet which available which meets minimum standards. If in doubt contact the CD Accountable Officer via pharmacy

2. I**n advance of the ward move:** Identify any patient's own medications which are no longer required and contact your pharmacist to facilitate return/destruction (See Pharmacy SOPs)

3. **In advance of the ward move:** Identify any temporary stock items which had been ordered for patients no longer in the department and contact your pharmacist to facilitate return/destruction (See Pharmacy SOPs)

4. Two registered practitioners (ideally one from the ward and a second pharmacist / technician) must perform a full stock check but will also annotate each active page of the register with 'Transferred to [enter new department]' and then complete signatures and balance check in CD register. Any discrepancies at this stage will need to be reported to the Ward Manager and actioned before continuing with the transfer

5. It is recommended that a tamper-proof serial numbered pharmacy bag(s) is obtained from pharmacy and the two practitioners use form CD-QUARANTINE to securely transfer the contents and deliver to the CD cupboard at the destination location. If this is not possible (e.g. urgent transfer out of hours without pharmacy support), then the full stock check and reconciliation will need to be repeated and

documented on each active page of the CD register by two registered practitioners when placing the CDs in the cupboard at the destination location

6. Ensure the front of CD registers and requisition books are updated with new department name

7. The divisional lead pharmacist should be informed at the earliest opportunity. They can ensure that the stock lists and the authorised signature lists reflect the new ward location. The divisional pharmacist will ensure new department number/name matches pharmacy stock management system.

Appendix CDSOP 9 - Checking Controlled Drug [requiring safe custody] stock and handling discrepancies:

1. The stock balance of all CDs entered in the CD register should be checked and reconciled with the amounts in the cupboard

2. These checks **MUST** be carried out at least once a day and preferably at each handover of keys at shift change. Theatres / radiology / endoscopy who are performing lists must complete sessional checks after each list. In addition, a line should be drawn on the relevant pages of the Theatre or Imaging department CD register at the end of each list to indicate the total entries for the operating list (to prevent further fraudulent entries being made)

3. The nurse, midwife or ODP in charge is responsible for ensuring that the regular CD stock check is carried out by staff on the ward or department

4. The balance in the register must be checked against the quantity of each CD by two nurses/ midwives/ ODPs or registered health professionals. **It is important to work sequentially through the register pages** rather than relying on the contents / index or the physical stock to prompt each check. This will ensure that if any stock is completely missing it will be identified

5. It is not necessary to open packs with intact tamper-evident seals for stock checking purposes

6. Stock balances of liquid medicines should generally be checked by visual inspection but periodic volume checks are helpful and the balance must be confirmed to be correct on completion of a bottle

7. A daily CD check record indicating time and date of the CD check should be signed by two registered practitioners and is to be held in the ward or department for at least 2 years as per other CD stationery

8. A balance check must also be made for any specific formulation each time it is issued, transferred or returned

9. If a discrepancy is found it should be investigated without delay.
For liquid medicines with discrepancy under 10%, the appointed practitioner in overall charge should discuss with a divisional lead pharmacist (or deputy) Monday – Friday to consider:

- Number of doses administered
- Method of measuring / preparing dose
- Other previous CD related datix reports in this department
- Changes in staffing / temporary staffing.

10. On discovering a discrepancy, action should include:

- Inform the most senior nurse, midwife or ODP for that shift (designated practitioner)
- Recount balance again including by a second individual authorised to do so

- Check arithmetic to ensure that balances have been calculated correctly since the last documented correct daily stock balance (& prior to that if appropriate)
- Check all CDs administered have been entered into the appropriate section of the appropriate ward or department CD register
- Check all requisitions received have been entered into the correct page of the appropriate ward or department CD register
- Check items have not been accidentally put into the wrong place or wrong packet in the cupboard.

If the error or omission is traced and rectified, the designated nurse, midwife or ODP in charge of the shift MUST make an entry in the ward register, stating the reason for the entry and the corrected balance. This entry should be witnessed by a second nurse, midwife, ODP, pharmacist, pharmacy technician or doctor, who will sign the ward or department CD register.

11. If the discrepancy cannot be resolved, the designated practitioner must:

- complete a Datix form (ensuring that it is logged as a medication incident and that YES is selected when prompted 'Does the Incident Involve a Controlled Drug')
- Inform the duty pharmacist (ward pharmacist or on-call pharmacist)
- Where diversion or misuse of a controlled drug is suspected this MUST be reported to the CDAO (or in their absence, the Deputy Chief Pharmacist or MSO) immediately. The Police should only be called on the instruction of the Accountable Officer (or in their absence the deputy chief pharmacist or Medicines Safety Officer who will consult with a trust executive).

12. On receipt of the Datix notification, the Appointed Practitioner in charge should investigate and resolve the discrepancy, and document this on the Datix report. The Divisional Pharmacist or deputy can be contacted to support this process.

13. The divisional pharmacist or deputy will brief the CDAO on possible unaccounted losses or suspicious activity at the earliest opportunity.

14. A report of discrepancies and subsequent investigations will be made by the CDAO to the CD local intelligence network (CD LIN) in line with statutory requirements of the Health Act 2006.

Appendix CDSOP 10 Obtaining controlled drugs when the Pharmacy is closed (all sites EXCEPT Royal Derby Hospital)

NB/ Royal Derby Hospital should always contact the on-call pharmacist if they do not have a CD required for administration.

For all other sites where the pharmacy dispensary closes:

1. Check whether the CD you need to administer is on your CD stocklist and available in your CD cabinet

2. It is acceptable to obtain ONE dose only for the patient, from another ward/ clinical area, without calling the on-call Pharmacist for authorisation. Details on how to access the CD stocklists are on the CD Pages of the Pharmacy Business Unit section of the hospital intranet

   Staff who plan to administer the dose must check that the dose is either an appropriate starting dose under BNF/local guidelines OR that the dose is consistent (equivalent) to existing opioid use on admission. Dosing and patient parameter checks are always a part of the administration process (Medicines Policy) but are especially important when accessing non-stock CDs which may be particularly potent opioids or uncommon formulations

   If in any doubt, or if patient has acute kidney injury (renal decline), speak with the prescriber and / or on-call pharmacist before obtaining from another ward

3. Telephone the stock-holding ward to ensure they have the drug and are willing to supply

4. Review the patient's medication record and note the patient details (after performing positive patient identification and the medication, strength and form required.Take your ward stock CD register with you to obtain the dose

5. TRANSFER Process: Review the patient medication record with the donor ward registered practitioner to ensure correct medication, strength and form are identified. Make an entry in the donor ward's CD register to state "transferred to ward xx [location] for administration to xx [patient's name]"

   Enter the dose into the receiving ward's CD register to state "Obtained from ward xx [location] for administration to xx [patient's name]"

   Two registered practitioners (one from the donor ward and one from the receiving ward) should sign both registers

6. ADMINISTRATION Process: Once back on the ward, two registered practitioners on the receiving ward may then document in the register and administer the dose following the usual procedure for administration of a Controlled Drug If further doses of the CD are required for the same patient before the pharmacy opens, then bleep the on call Pharmacist

7. Discuss with the Pharmacist whether it is appropriate to obtain a further dose of the CD from another ward (pharmacist should call that ward to authorise) or whether they will attend the hospital to open the Pharmacy to dispense. If several doses are required prior to the next Pharmacy opening time, a supply from Pharmacy will usually be appropriate.

Appendix CDSOP 11 Discharge Prescriptions (QHB/SRP/SJH)

Prescribing for discharge patients (Meditech ePMA)

Prescriptions for discharge medicines must be written on the Prescription for Controlled Drug Discharge Medication form (Pharmacy CD pages on Net-i). This prescription complies with the Misuse of Drugs Regulations and its amendments in 2001 for a controlled drugs prescription.

An entry on the electronic discharge summary (included in 'TTO review' on Meditech ePMA) must also be made to ensure that the patient's GP is informed of all discharge medication including controlled drugs.

Legal requirements (as per CD Policy Section 5.6):

- Prescriptions for all Schedule 2 and 3 CDs to be written/printed indelibly (by hand, typed or computer generated), to include:
    - **Patient's full name, address and, where appropriate, age** (e.g. Children) - The use of pre-printed addressograph labels can be used but the prescriber must ensure that any duplicate copies of the prescription have the same addressograph and that the label cannot easily be removed. It is good practice to sign over the sticky label to safeguard it being tampered with.
    - **Generic name *and* form (tablet, capsule, ampoule etc) of the drug** (legally required, even if only one form exists). Where fast acting and slow release forms exist, it is important to make this explicit and also include the brand name on the prescription
    - **Strength** of the preparation, where more than one exists (almost all CDs)
    - **Dose** to be taken

      Frequency
    - **Total quantity of the preparation, or the number of dose units, to be supplied in both words *and* figures.**

TTO, outpatient and daycase prescriptions are usually limited to a maximum of 30 days' supply, unless authorised by the CD Accountable Officer.

The prescription *MUST be indelibly signed and dated by the prescriber*, who takes full responsibility for the contents of the prescription.

Appendix CDSOP 12 Removal of Illegal or suspected illicit substances from patients

1. If a patient is in possession or suspected of being in possession of a drug illegally, he/she should be advised that possession is unlawful and asked to hand it over voluntarily to a member of staff. Staff have no automatic right to search a patient's belongings and if considered necessary, consent must be obtained.

Do not put your own safety at risk whilst removing such substances from patients.

If a patient refuses to give up any quantity of such a drug/substance , then staff should refer to Trust Security. If security are met with continued refusal, and possession is suspected, they should consult with the accountable officer for CDs and the treating consultant. The police are only to be contacted with the authority of those individuals.

2. If a patient is unconscious or is unable to voluntarily hand over a suspicious or illegal substance then it should be removed in the patient's best interests. Document in the nursing records that this search has taken place and record if any substances have been removed.

3. Illegal drugs that have been handed over voluntarily or removed from an unconscious patient should be recorded in the stock CD register on its own page using a suitable description of the substance or packaging (there is no need to open packaging to describe the contents). Enter the patient's hospital number (not name), the date and the time in the register and have this witnessed by a second registered practitioner. The substance should then be placed in a sealed bag or container. The sealed container should be placed immediately in the CD cupboard as per the register entry.

4. Make a record in the nursing notes that a substance has been retained. This should be countersigned by the nurse-in-charge.

5. The designated practitioner in charge of the shift should ensure that the medical staff directly responsible for the patient's care are informed. Out of hours, the designated practitioner may need to inform an on-call doctor. In these circumstances the designated practitioner must also make an entry in the medical notes to ensure this message is received by the medical staff directly responsible for the admission.

6. **Under no circumstances** should any quantity of illegal or suspected illicit substance be returned to the patient. This would constitute unlawful supply of a controlled drug.

7. Where the quantity is large or there is evidence of a criminal act taking place e.g. dealing on premises, then the Police may ONLY be called to investigate following agreement by both:

- The Consultant/clinician in charge of the patient's care
- The Trust Accountable Officer for Controlled Drugs (Chief Pharmacist).

8. Contact the ward pharmacist during normal working hours. The sealed container will be removed by a pharmacist following their standard returns procedures ensuring that the second signature is provided by a registered practitioner from the clinical department.

ACTIONS WITHIN PHARMACY

9. The Pharmacist must enter the item in the Pharmacy CD destruction register as per routine returns procedure. The entry should include a description of the product and number of dose units where appropriate. Do not remove the product from packaging or risk exposure.

10. If personal use has been assumed, the items will be scheduled for destruction as for any other CD

11. If the item is suspected as being used for dealing illegal substances, the item will be labelled as such in the destruction register and the CDAO must confirm if this should be scheduled for destruction or held quarantined in the CD Room to await transfer to safe custody of a police officer with warrant or authority.

Appendix CDSOP 13 Annual Audit Questions (Clinical Areas)

Access online at https://neti.uhdb.nhs.uk/az-c-pharmacy-controlled-drugs

Intranet > Pharmacy Pages > Controlled Drugs Search through links and documents.

Appendix CDSOP 14 Annual Audit Action Plan (Clinical Areas)

These will be generated via from the online audit submission and areas of non-compliance will be distributed to departmental / BU leads for comment and action plan submissions.

Appendix CDSOP 15 Pharmacy-led Quarterly Audit Questions (Clinical Areas)

Access online at https://neti.uhdb.nhs.uk/az-c-pharmacy-controlled-drugs

Intranet > Pharmacy Pages > Controlled Drugs Search through links and documents.

Appendix CDSOP 16 Pharmacy-led Quarterly Audit Questions (pharmacy areas)

Access online at https://neti.uhdb.nhs.uk/az-c-pharmacy-controlled-drugs

Intranet > Pharmacy Pages > Controlled Drugs Search through links and documents.

Appendix B – Examples of Drugs of Abuse

ALFENTANIL
BOTULINUM TOXIN TYPE A (BOTOX/Dysport)
BUPRENORPHINE
CLOBAZAM
CLONAZEPAM
COCAINE
CODEINE PHOSPHATE
CYCLIZINE
DEXAMFETAMINE
DIAMORPHINE
DIAZEPAM
DIHYDROCODEINE
FENTANYL
GABAPENTIN
HYDROMORPHONE
KETAMINE
LORAZEPAM
METHADONE
METHYLPHENIDATE
MIDAZOLAM
MIFEPRISTONE
MORPHINE
NEFOPAM
NITRAZEPAM
OXAZEPAM
OXYCODONE
PETHIDINE
PHENOBARBITAL
PHOLCODINE
PREGABALIN
PROCYCLIDINE
PROPOFOL
REMIFENTANIL
SILDENAFIL
TADALAFIL
TAPENTADOL
TEMAZEPAM
TESTOSTERONE
THIOPENTAL
TRAMADOL
ZOPICLONE

Appendix C – Examples of CD transfer or despatch bags in use across UHDB

Envopak: Various colours in use across UHDB – Security tag will always have a unique identification number if the EnvoPak contains controlled drugs [requiring safe custody]

Transfer Bag

(Within UHDB and to external healthcare)

Despatch/Discharge bag

(To patient residence)