



Safe and Secure Handling of MEDICINES POLICY

Part B

Controlled Drugs

This procedural document supersedes: PAT/MM 1B V.7 Safe and Secure Handling of Medicines Pat B Controlled Drugs.



Did you print this document yourself?

The Trust discourages the retention of hard copies of policies and can only guarantee that the policy on the Trust website is the most up-to-date version. **If, for exceptional reasons, you need to print a policy off, it is only valid for 24 hours.**

Executive Sponsor(s):	Dr Tim Noble – Medical Director
Author/reviewer: (this version)	Rachel Wilson, Deputy Chief Pharmacist Liz Monaghan, Chief Pharmacy Technician
Date written/revised:	May 2021
Approved by:	Drug and Therapeutics Committee
Date of approval:	9 June 2021
Date issued:	5 November 2021
Next review date:	June 2024
Target audience:	Trust Wide

Amendment Form

Please record brief details of the changes made alongside the next version number. If the procedural document has been reviewed **without change**, this information will still need to be recorded although the version number will remain the same.

Version	Date Issued	Brief Summary of Changes	Author
8	June 2021	<ul style="list-style-type: none"> • Full review • Audit standards updated • Job titles of who receives audit reports updated and responsibilities • How to record audits updated • Job titles updated throughout • Updated to reflect divisions • Stock checks in pharmacy changed to pharmacy personnel • Student assistants added in as authorised to dispense and issue controlled drugs • Gabapentin and Pregabalin added to schedule 3 • Directions updated for destruction of CD's • Change of epidural bags from 500ml to 250ml • References updated • Summary of controlled drug requirements. 	Rachel Wilson Liz Monaghan
7	26 May 2017	<ul style="list-style-type: none"> • Corrected an error in the summary of CD requirements for wards – Ketamine (Now Schedule 2) 	John Bane
6	1 July 2015	<ul style="list-style-type: none"> • Updated to reflect care groups • CD requirements for individual products reviewed • Section 10 – rewritten to separate stock issues from discharge prescription. Stock supplies to third parties managed through separate Pharmacy procedure. 	Roger Hancocks
5	January 2014	<ul style="list-style-type: none"> • Allows more than one requisition book or record book in use - in exceptional circumstances and by application to the AO. 	D&T Committee

		<ul style="list-style-type: none"> • Ketamine preparations are to be treated as Schedule 2 CDs with respect to ordering, receipt, recording and storage. • Reference to disposable PCA device have been removed as they are no longer used • Section 7.13 now includes a section concerning the transfer of patient's own CDs. 	
4	December 2010	<ul style="list-style-type: none"> • The sections have been renumbered. • Section 7.14 Requirements for midazolam have been updated. • Sections 8 and 9 concerning PCA and Epidural Syringes updated to reflect ePrescribing and new and specific prescription charts. • Section 6.8 - The section concerning destruction of Pharmacy Stock CDs has been updated. 	Medicines Management Risk Group
3	June 2008	<ul style="list-style-type: none"> • Responsibilities of Accountable Officer. • Definition of audit requirements on ward departments and the pharmacies. • Changes records required for supply to outpatients. • Definition of CD destruction procedures. • Changes in requirements for handling midazolam. • Recommendation that discharge and outpatient prescription be limited to 30 days except in exceptional circumstances. • Recommendation that wards and departments have separate record books for their own stocks and patients' own medicines. • Detailed requirement for the management of PCA and epidural devices. <p>Definition of requirement for safe and auditable transport.</p>	Medicines Risk Management Sub Group

Contents

1	INTRODUCTION	6
2	PURPOSE	6
3	DUTIES AND RESPONSIBILITIES.....	6
4	PROCEDURE.....	8
4.1	THE HANDLING OF CONTROLLED DRUGS IN THE PHARMACY SERVICE	10
4.1.1	Responsibility	10
4.1.2	Security	10
4.1.3	Ordering.....	10
4.1.4	Receipt and Storage	10
4.1.5	Issues.....	12
4.1.6	Stock Checks	14
4.1.7	Controlled Drug Stationery.....	14
4.1.8	Destruction of Pharmacy Stock	15
4.1.9	Returns.....	17
4.1.10	Patient’s Own Medicines	17
4.2	THE HANDLING OF CONTROLLED DRUGS IN WARDS AND DEPARTMENTS INCLUDING THEATRES	19
4.2.1	Responsibility	19
4.2.2	Controlled Stationery.....	19
4.2.3	Stock Lists	20
4.2.4	Stock Checks	20
4.2.5	Requisitioning	21
4.2.6	Receipt	21
4.2.7	Storage and Security	23
4.2.8	Prescribing	24
4.2.9	Administration	25
4.2.10	Records.....	27
4.2.11	Returning Controlled Drugs.....	29
4.2.12	Transfers	30
4.2.13	Patients’ Own Medicines which are Controlled Drugs	30
4.2.14	Midazolam	32
4.2.15	Destruction of Controlled Drugs on Wards or Departments	33

4.3	AUDIT	34
4.3.1	Ward Stocks and Records	34
4.3.2	Pharmacy Stocks and Record	34
4.4	INVESTIGATION OF DISCREPANCIES	35
4.5	MANAGEMENT OF PATIENT CONTROLLED ANALGESIA DEVICES	35
4.5.1	Devices	36
4.5.2	Prescribing.....	36
4.5.3	Controlled Drug Record Book	36
4.5.4	Preparation and Record of Administration	36
4.5.5	Transfer from Theatres to Wards or between Wards	37
4.5.6	Disposal of Surplus Controlled Drugs from a PCA syringe	37
4.6	MANAGEMENT OF EPIDURAL INFUSION CONTAINING CONTROLLED DRUGS	38
4.6.1	Devices	38
4.6.2	Prescribing	38
4.6.3	Controlled Drug Record Book.....	39
4.6.4	Record of Administration	39
4.6.5	Transfer from Theatres to Wards or between Wards	39
4.6.6	Disposal of Surplus Controlled Drugs from an Epidural Infusion	39
4.7	TRANSPORT OF CONTROLLED DRUGS WITHIN DBH	40
4.7.1	Transport of Stock Controlled Drugs	40
4.7.2	Transport of Discharge Prescriptions.....	42
5	TRAINING/SUPPORT	46
6	MONITORING COMPLIANCE WITH THE PROCEDURAL DOCUMENT	46
7	DEFINITIONS	47
8	EQUALITY IMPACT ASSESSMENT.....	47
9	ASSOCIATED TRUST PROCEDURAL DOCUMENTS.....	48
10	DATA PROTECTION	48
11	REFERENCES	48
	APPENDIX 1 – SUMMARY OF CONTROLLED DRUG REQUIREMENTS FOR WARDS.....	49
	APPENDIX 2 - EQUALITY IMPACT ASSESSMENT PART 1 INITIAL SCREENING	51

1 INTRODUCTION

This policy is written to ensure the safe and secure handling of Controlled Drugs within the Trust. Controlled Drugs (CDs) are subjected to special legislative controls because there is a potential for them to be diverted or abused. This is written to ensure healthcare professionals within the Trust understand their roles and responsibilities in relation to Controlled Drugs.

PAT/MM 1 Part A - Safe and Secure Handling of Medicines Policy describes the general requirements for the safe and secure handling of medicines within the wards and departments of the Trust. This policy expands upon the detailed requirements concerning Controlled Drugs and must be read in conjunction with PAT/MM 1 Part A.

Sections 4.1 – 4.7 define the Standard Operational Procedures for the Pharmacy Service, Ward and Departments, the use of patient controlled analgesia devices, epidural infusions and Transport of Controlled Drugs.

2 PURPOSE

The purpose of this policy is to outline the roles and responsibilities of all staff involved in the handling of Controlled Drugs.

It provides details of both legal and good practice requirements for the safe and secure handling of Controlled Drugs within the Trust

3 DUTIES AND RESPONSIBILITIES

The Accountable Officer

The Accountable Officer is responsible to the Chief Executive for all aspect of the safe and secure management of Controlled Drugs within the Trust. This includes ensuring that there are safe systems in place for the management and use of CDs, including monitoring and auditing the management system and investigation of concerns and incidents related to CDs.

The Accountable Officer is the Chief Pharmacist.

Pharmacy Service Manager

The Principal Pharmacy Technician with day to day operational management responsibility for the dispensary. In their absence their responsibilities are delegated to the senior pharmacy technician in charge of the dispensary, or when the dispensary is closed the On Call Pharmacist.

Appointed Person

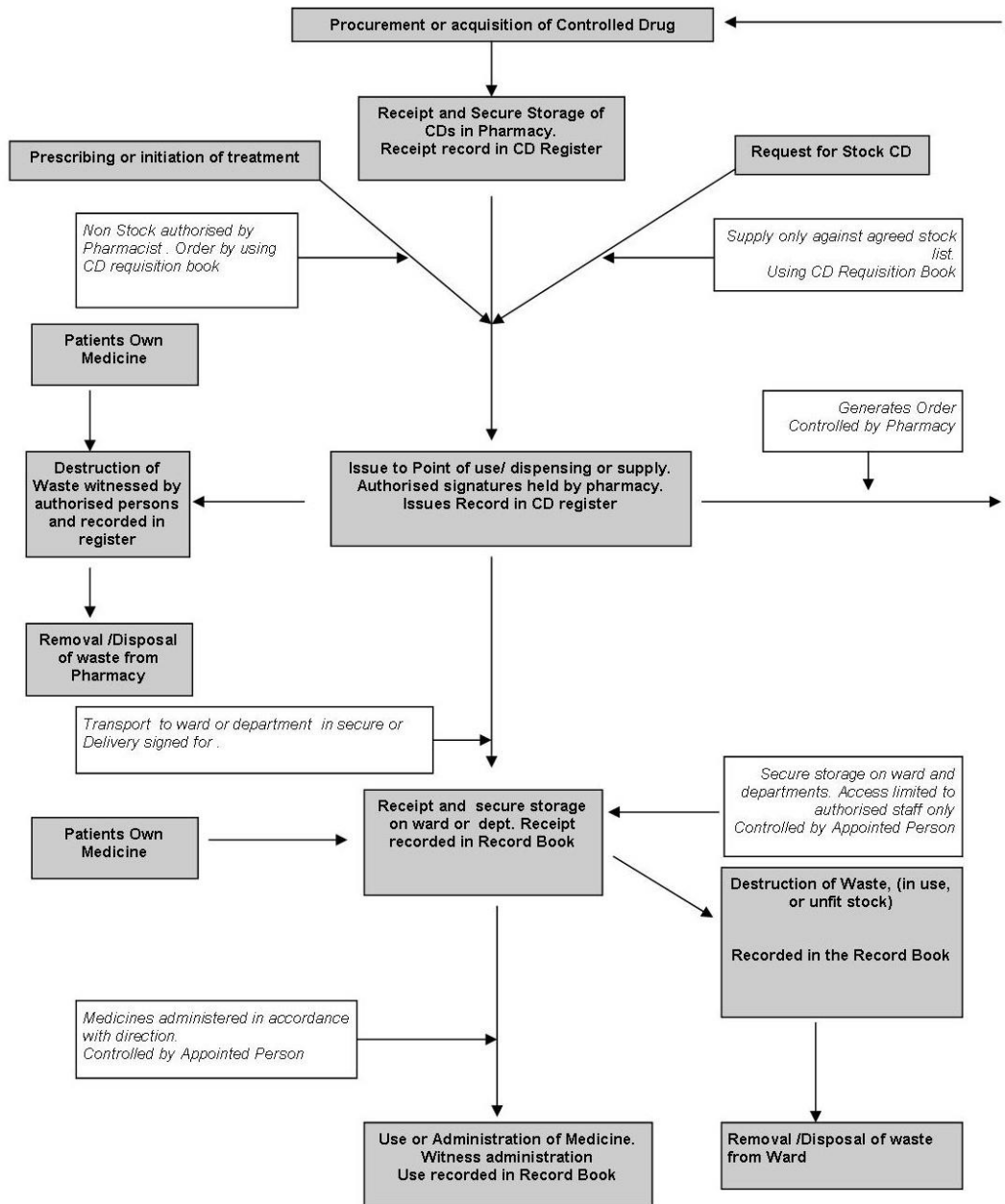
The Appointed Person in overall charge of a ward or department is responsible for the safe and appropriate management of Controlled Drugs in that area. Where the Appointed Person is not a registered nurse, midwife or operating department practitioner (ODP) then the most senior nurse, midwife or ODP in the department shall take that responsibility.

Assigned Person

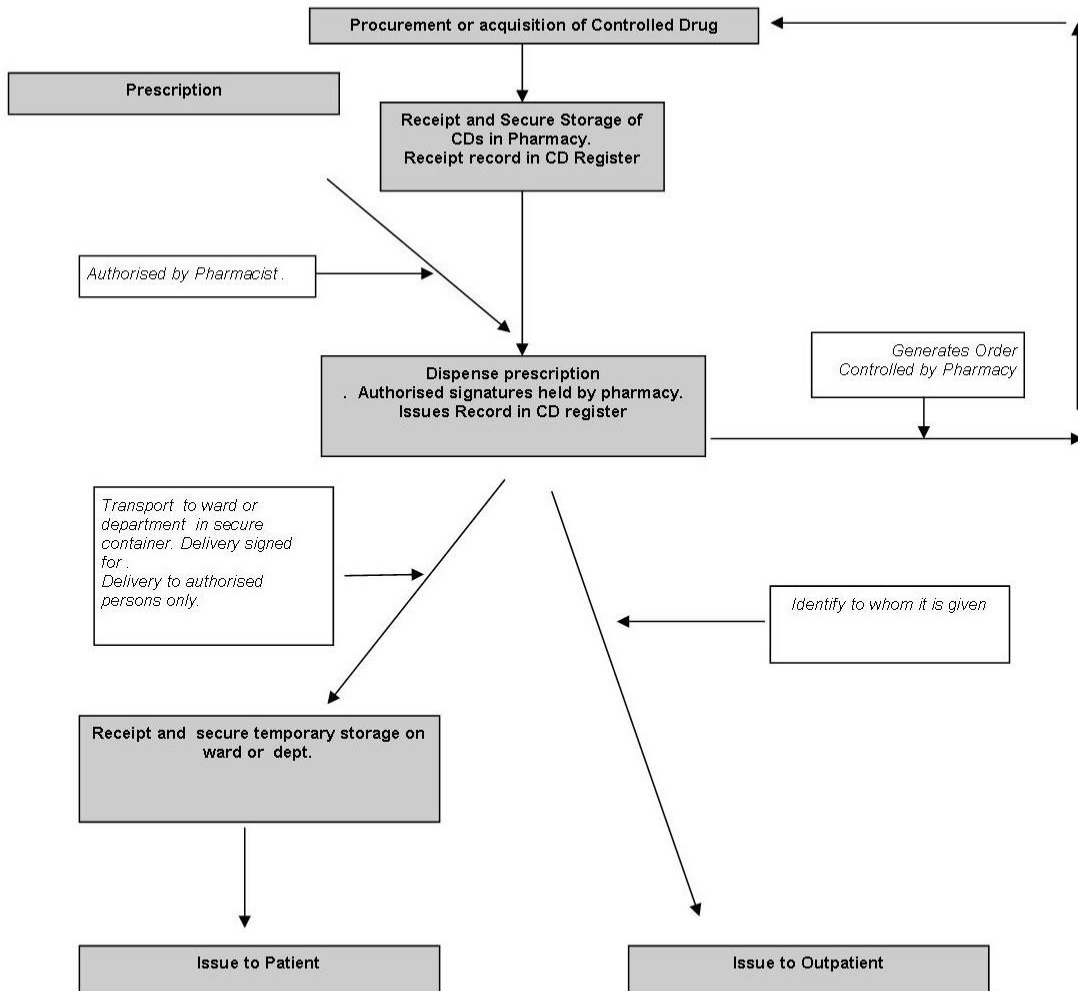
The registered nurse, midwife or ODP who is in charge of the shift in a ward or department.

4 PROCEDURE

The Medicines Trail for Ward and Departments



The Medicines Trail for Outpatients and Discharge Prescriptions



4.1 THE HANDLING OF CONTROLLED DRUGS IN THE PHARMACY SERVICE

4.1.1 Responsibility

The Chief Pharmacist is responsible for the safe and secure handling of Controlled Drugs. This procedure details how Controlled Drugs are handled within the Pharmacy Service which follows current applicable legislation. It describes to whom the day to day tasks are delegated. Whilst the tasks may be delegated the responsibility remains with the Chief Pharmacist.

4.1.2 Security

Controlled Drugs shall be stored within the dispensaries in the automated dispensing system (ADS) or cabinets that are approved by the Accountable Officer.

The Pharmacy Services Manager is responsible for the security of the Controlled Drugs Cabinet and ADS keys during daily use. They will be issued to the nominated technician, dispensing assistant, or student technician who is designated to dispense Controlled Drugs.

When the dispensary is closed the CD and ADS keys will be stored in a secure key cabinet within the alarmed area of the dispensary. Access is restricted to nominated pharmacists and technicians. The on call Pharmacist is responsible for ensuring the keys are replaced securely if used out of hours.

4.1.3 Ordering

The ordering of Controlled Drugs for Pharmacy stock is the responsibility of the Purchasing Managers. Controlled Drugs are ordered in accordance with normal procedures for the ordering of medicines.

The stock levels are determined in consultation with the Pharmacy Services Managers of the respective dispensaries.

Where it is necessary to transfer Controlled Drugs between the dispensaries of the Trust the relevant Pharmacy Services Manager is responsible for providing the requisition.

4.1.4 Receipt and Storage

Controlled Drugs are received in accordance with normal procedures for the receipt of medicines. If a delivery driver requires a specific signature to acknowledge the receipt of the CDs rather than the package then the person receiving the CDs must check the contents agree with the delivery note before signing. Tamper evident packs need not be opened to undertake this check. Unsealed tamper evident packs will not be accepted.

If there is a discrepancy the Purchasing Manager must be informed immediately; the Purchasing Manager is responsible for resolving the problem with the supplier.

Following receipt, the CDs must be transferred for secure storage without delay by informing the person holding the Controlled Drug Keys.

The Pharmacy Services Manager is responsible for entry into the CD Receipt Register and for secure storage. Entry into the register must be made as soon as possible after receipt and in any event within 24 hours.

Entry into the CD Registers may be delegated to a pharmacist, pharmacy technicians, NVQ2 qualified dispensing assistants, student pharmacy technicians or student dispensing assistants who have demonstrated they are competent to dispense Controlled Drugs. Tamper evident packs need not be opened.

The following record is made in the CD Receipt Register under the name of the ingredient:

- The date the supply was received
- The name of the person making the entry
- The order number
- The name of the supplier
- The address of the supplier
- The amount obtained
- The pharmaceutical form

A complementary entry is made in the CD Issues Register specifying the date, supplier, order number, quantity received, and the new running balance. The running balance is checked against stock held (where necessary by reference to the automated storage system inventory) and the pharmacy computer stock record. Any discrepancy must be reported to the Pharmacy Services Manager who will investigate.

High Strength Opioid Preparations

High strength injectable opioid preparations are defined as the following:

- Injectable Morphine preparation greater than 10mg/ml
- Injectable Diamorphine preparations greater than 10mg
- Injectable Alfentanyl preparations greater than 1mg/2ml

High strength opioid preparations are stored in a Controlled Drugs cupboard that is separate from the lower strength products.

High strength opioid preparation shall be labelled to distinguish them from lower strength products.

Where a warning is not printed on the original packaging by the manufacturer the following label shall applied to each box.

Warning

This is a HIGH STRENGTH OPIOID medicine.

When using any opioid beware of signs and symptoms of overdose especially respiratory depression.

Always ensure naloxone is available.

4.1.5 Issues

Controlled Drugs are issued to wards, departments or patients following the receipt of a valid prescription or CD requisition signed by an authorised person. The pharmacist clinically checking a prescription is responsible for ensuring the prescription is legally valid and signed by an authorised prescriber.

The technician checking the medicines will take appropriate and practical steps to ensure the person ordering the medicines is authorised to do so.

All dispensed Controlled Drugs are checked in accordance with the dispensing and checking procedures.

Controlled drugs may be dispensed and the register entries made by pharmacists, pharmacy technicians, NVQ2 qualified dispensing assistants, student pharmacy technicians and student dispensing assistants who have demonstrated they are competent to dispense Controlled Drugs.

The person dispensing must ensure that the requisition is complete with the name, strength, and form of the preparation together with the quantity to be supplied.

The following record is made in the CD Issues Register:

a) Completing the Controlled Drug Register

Column	Entry for a Requisition	Entry for a Prescription
Date	The date the supply was made	The date the supply was made
Name of person or department supplied	Name of person signing the order	Name of patient on prescription
Address	Ward or department and hospital, or full address of recipient	Address of patient
Authority to be in possession	Book/CD Req Nos	Name of prescribing doctor
Person making supply	Name or initials of person making supply	Name or initials of person making supply
Person Collecting	NA	Specify TTO or on the case of an Outpatient see below*
Request for identity	NA	For an Outpatient Yes or No
Proof of identity provided	NA	For an Outpatient Yes or No
Quantity Supplied	Quantity Supplied	Quantity Supplied
Balance	Running Balance	Running Balance

***For an Outpatient Supply** - The person collecting (patient, patient's representative or healthcare professional). In the case of a healthcare professional their name and address.

Entries into the register must be made in consecutive, chronological order. Entries must be made at the time of dispensing and must in ink or otherwise indelible.

Where a mistake is made the entry must not be crossed out, deleted, or obliterated; liquid paper must not be used. Errors must be bracketed and accompanied by a clearly recognisable signature; a foot note or margin note must be added to explain the alteration.

b) Completing the JAC Controlled Drugs Register

For all Controlled Drugs issued the electronic record must be completed as follows:-

Field	Entry
Initials	Users initials
Requestor Name	Name of the person signing the requisition or prescription
Req No.'s	The requisition book number followed by requisition number e.g.: 0101 0599

c) Stock Checks at Issue

Once per day for each product issued that day, the physical stock held in the CD cupboard and in the automated dispensing system (by reference to its stock inventory) shall be reconciled with the CD register and the Pharmacy Computer Stock record. This shall be undertaken at the first supply for each product each day.

Where all three match, the balance in the register shall be ticked, initialled, and dated to indicate the stock is correct. Where one of the balances does not match the dispenser shall inform the Pharmacy Services Manager who will undertake an investigation. In the event the error cannot be rectified within the working day the Pharmacy Services Manager shall inform the Deputy Chief Pharmacist, who will instigate further investigation. See Section 4.4 Investigation of Discrepancies.

d) Labelling

Controlled Drugs shall be labelled in accordance with the Pharmacy Labelling Standards. In addition Controlled Drugs issued as stock or as an inpatient supply will be labelled with:

The words 'Store in a Controlled Drugs Cupboard'

e) Receipt of Controlled Drugs by Outpatients

Prescriptions for Outpatients containing Controlled Drug shall be given out by the person checking the prescription or by a pharmacist.

The person handing over the prescription shall:

1. Establish the identity of the person receiving the Controlled Drug, who shall be either the patient, their representative or a health care professional acting on behalf of the patient.
2. Unless instructed otherwise by the verifying pharmacist, request evidence of their identity.
3. Ask the person to sign the prescription to acknowledge receipt of the Controlled Drug.

4.1.6 Stock Checks

Controlled Drugs are routinely stock checked at the first supply on each day of issue. For those CDs that are infrequently issued the following will apply.

Infrequently issued means – not issued, therefore not checked in the last month.

For these Controlled Drugs the stock will be checked during the first full week of the month by the physical stock held in the CD cupboard and in the automated dispensing system (by reference to its stock inventory) against the balances in the CD register and on the Pharmacy Computer Stock record. Where all three match an entry will be made in the register to record:

1. the date,
2. the words "Stock correct"
3. the signature of the person checking
4. the stock balance

Where one of the balances does not match the stock checker shall inform the Pharmacy Services Manager who will undertake an investigation. In the event the error cannot be found the Pharmacy Services Manager shall inform the Deputy Chief Pharmacist, who will instigate further investigation. See Section 4.4 Investigation of Discrepancies.

a) Liquid Preparations

Liquid preparation may be stock checked by visual inspection, but stock balance must be corrected at the end of each bottle. The stock correction must be witnessed by the Pharmacy Services Manager or a Pharmacist.

4.1.7 Controlled Drug Stationery

Controlled Drug Requisition Books and Controlled Drug Record Books shall be regarded as Controlled Stationery. As such only one book or record shall be in use on any ward or department at any time unless an area has been granted an exemption by the Accountable Officer

a) Supply of Registers

A register shall only be supplied following the receipt of a written requisition signed by the Assigned Person in Charge. A record of the supply shall be made. All registers issued shall bear the label:

‘This is controlled stationery and must be locked away when not in use’.

b) Supply of Requisition Book

Requisition books shall only be issued to wards and departments in response to a signed Controlled Drug requisition (usually number 100).

Before each requisition book is issued a label shall be affixed to requisition number 100 and its copy that shall say ‘Please supply one new Controlled Drug Requisition Book’. On receipt of this signed requisition a new Requisition Book shall be issued and a record of the issue shall be made in a separate (Controlled Drugs Requisition Book) Record Book.

All requisition books shall bear a label specifying:

Controlled Stationery

This requisition book must be locked away when not in use

Issued/..... /.....

Book Number

A new requisition book shall only be issued on receipt of a signed requisition from the Nurse in Charge.

Do not tear out cancelled requisitions from this book. Write ‘CANCELLED’ across the requisition and its copy.

The new book shall be marked with a book number which is the next number in the sequence following on from the book being replaced, (where a ward holds two books then one book shall be referenced with odd numbers and the other one with even numbers.) The book number shall be recorded in the remarks section of the issue record.

The record of the issue of the old (complete) book shall be located in the register and annotated in the ‘Remarks’ column ‘Replaced (date)’ to show it is out of use.

4.1.8 Destruction of Pharmacy Stock

Where Schedule 2 Controlled Drugs Pharmacy stock is identified for destruction it shall be destroyed in the presence of a person authorised by the Accountable Officer. The Accountable Officer shall ensure the person authorised to destroy Controlled Drugs is subject to a satisfactory CRB check, subject to a professional code of ethics and has received appropriate training for their duties.

As the Controlled Drug is identified as requiring destruction, for example it is expired, the dispenser will make an entry in the appropriate Controlled Drugs Register stating:

1. Date
2. The reason for destruction
3. Quantity for destruction

4. Signature of the person removing the stock
5. Countersignature of the Pharmacy Services Manager or dispensary pharmacist
6. The new balance

A complementary entry will be made in a Destruction Register stating:

1. A reference number
2. Date
3. The product form and strength
4. Quantity
5. The reason for destruction
6. Signature of the person making the entry
7. Countersignature of the Pharmacy Services Manager or dispensary pharmacist

The Controlled Drugs requiring destruction will be marked with the reference number and stored in a segregated section of the Controlled Drugs cupboard.

Other CD's do not require their destruction witnessed by an authorised person but should be disposed of using the same methods.

Procedure

The aim of this procedure is to render the Controlled Drug unrecoverable by dispersing the medicines in water and then setting them in a mass such as cat litter or wallpaper paste.

All items are added to a sealable waste disposal bin:

1. Remove any solid dose forms from their strip packaging or containers before adding to the waste disposal bin.
2. Decant any liquids into the waste disposal bin.
3. Fold patches in half upon themselves before adding to the waste disposal bin.
4. Open all ampoules before adding the contents and empty ampoule to the waste disposal bin.
5. Empty the contents of any vials in the waste disposal bin.
6. Remove creams, paste or ointments from the containers before adding to the bin (the empty containers should also be added).
7. Remove suppositories from their protective packing before adding to the waste disposal bin.
8. Aerosols should be expelled under water to prevent droplets entering the air, and the resultant liquid added to the bin.
9. Empty any prefilled syringes or infusion bags into the waste disposal bin.
10. Additional water may be added to bin so that the contents may be stirred to dissolve or disperse any solid doses and form a slurry.
11. Add the setting agent such as wallpaper paste or cat litter to form a solid mass.
12. Seal the disposal bin and place in the Pharmacy waste stream following waste disposal procedures.

4.1.9 Returns

The Pharmacy will normally only accept full boxes for return. In exceptional circumstances part boxes may be returned to Pharmacy stock for re-use, e.g. the medicine is required to fulfil a discharge prescription. A pharmacist or pharmacy technician will assess whether a product is fit for re-use. If a product is fit for re-use the CD will be returned in the following manner, otherwise unwanted medicines shall be destroyed on the ward in the presence of the Assigned Nurse in Charge.

The returns process is the reverse of the requisitioning process.

The nurse in charge shall record in the ward Controlled Drugs Record Book that the medicines have been returned and shall record a new balance. The authorised member of the Pharmacy staff shall counter sign the Record Book to confirm the balance. The Assigned Nurse in Charge shall write a CD requisition for each medicine being returned. In the space for 'Ordering by' the nurse shall write "Returned to Pharmacy". The nurse shall sign in the space 'Supplied by' and the authorised member of the Pharmacy shall sign the space below 'Accepted for delivery' such that on the pink copy the signature is in the space 'Received by'.

Those items suitable for re-use shall be returned on the computer using the returns program and shall be entered into the issues register as a receipt.

It is the responsibility of the member of the Pharmacy staff who returned the CDs to ensure that the CDs are returned to safe storage and the computer and register entries are made.

Staff authorised to return CDs are pharmacists or pharmacy technicians.

4.1.10 Patient's Own Medicines

Patient's own Controlled Drugs that are brought on a ward or department that stock CDs shall normally be destroyed in that ward or department following procedure in Section 4.2.15.

Where patient's own Controlled Drugs are presented to an Outpatient dispensary for destruction the following shall apply. The Dispensary shall maintain a Patient's Own Controlled Drug Receipt and Destruction Record Book. It shall record the following:

1. Date of Receipt and Destruction.
2. The name, form and strength of the Controlled Drug.
3. The quantity received and destroyed.
4. The name and address (if known) of the patient for whom the CDs were dispensed.
5. The role of the person returning the CD to the pharmacy.
6. The name and signature of the person receiving the CDs.
7. The names, positions, and signatures of the person destroying the CDs and the person witnessing the destruction.

Patient's own Controlled Drugs shall be received into the dispensary by the dispensary or Responsible Pharmacist who shall be responsible for their timely destruction.

Patient's own Controlled Drug shall be destroyed as soon as possible and before the pharmacist goes off duty.

Procedure for destruction

The purpose of this procedure is to render the Controlled Drugs irretrievable. Once the CD Denaturing Kit has been used it is disposed as Pharmaceutical Waste by the Pharmacy.

Solid Dose Forms

Solid dose forms must be removed from their strips or containers before destruction.

Unless otherwise directed by the denaturing kit they should be crushed or dissolved in warm soapy water before being added to the CD Denaturing Kit.

The CD Denaturing Kit should be topped up with water to form a solid mass.

Liquid Medicines

Liquid medicines may be added to the CD Denaturing Kit directly. The CD Denaturing Kit should be topped up with water to form a solid mass.

Ampoules and Vials

Liquid ampoules and vial must be opened and the contents added to the CD Denaturing Kit directly. The kit should be thoroughly shaken to ensure the contents are absorbed into the kit. The CD Denaturing Kit should be topped up with water to form a solid mass.

Patches

The backing should be removed and the patch folded over on itself before being added to the CD Denaturing Kit. The CD Denaturing Kit should be topped up with water to form a solid mass.

Aerosols

Aerosols should be expelled under water to prevent droplets entering the air, and the resultant liquid added to a CD Denaturing Kit.

4.2 THE HANDLING OF CONTROLLED DRUGS IN WARDS AND DEPARTMENTS INCLUDING THEATRES

4.2.1 Responsibility

This procedure details how Controlled Drugs are handled within a ward or department. It details to whom the day to day tasks may be delegated. Whilst the tasks may be delegated the responsibility remains with the Appointed Person.

The Appointed Person in overall charge of the ward or department is responsible for the safe and appropriate management of Controlled Drugs in that area.

Where the Appointed Person is not a registered nurse, midwife or operating department practitioner (ODP) then the most senior nurse, midwife, or ODP in the department shall undertake that responsibility. In all areas where Controlled Drugs are stocked the most senior nurse, midwife or ODP shall be identified as the person responsible for the overall management of Controlled Drugs.

The term Assigned Person in Charge is used to identify the person on duty who is a registered nurse, midwife, or ODP who is in charge of the shift.

4.2.2 Controlled Stationery

Controlled Drug Requisition Books and Controlled Drug Record Books (CDRB) are treated as controlled stationery. When they are not in use they must be locked away to prevent unauthorised access.

It is normal practice the only one requisition book and one record book for stock shall be in use in an area at any one time.

Wards and departments who may have patients own controlled drugs will keep an additional register to record patients own controlled drugs.

Exceptionally, the Accountable Officer may grant an exemption to allow more than one requisition book and record book to be in use at any one time, where the Appointed Person can demonstrate to the Accountable Officer an operational advantage that does not compromise security and good record keeping.

Replacement requisition books and registers shall be requisitioned by the Assigned Person in Charge using the Controlled Drugs Requisition Books.

Loss of Controlled Stationery

The suspected loss or theft of any controlled stationery that may be used to order Controlled Drugs must be investigated immediately by the Assigned Nurse in charge. If the loss cannot be accounted for the Assigned Person in Charge must report the loss to the Accountable Officer for further action.

4.2.3 Stock Lists

In conjunction with the Senior Clinical Pharmacist for the ward or department the Appointed Person will agree a range of Controlled Drugs and their quantities that may be held as stock. Stock Controlled Drugs will be supplied by the Pharmacy against a valid CD requisition without reference to a clinical pharmacist. Any amendments to the list can only be authorised by a member of the pharmacy senior management team.

Non Stock Controlled Drugs shall require the prior verification of the prescription by a pharmacist before supply.

4.2.4 Stock Checks

The stock balance of all CDs entered in the CDRB shall be checked and reconciled against the physical stock at least once every day when the ward/department is open. If a ward is not open 24 hours a day then it is recommended that the last stock check be undertaken immediately before planned closure and the next stock check be undertaken upon re-opening.

The Appointed Person in Charge is responsible for ensuring that the daily stock is undertaken.

The Appointed Person in Charge may delegate the stock check to another registered nurse, midwife or ODP and it shall be witnessed by a registered nurse, midwife or operating department practitioner working in the department.

The stock check shall be undertaken in the following manner:

1. Checking the balance in the register against the contents of the cupboard (not the reverse).
2. Tamper evident packs that are sealed need not be opened
3. Liquid medicines may be checked by visual inspection.
 - a. At the end of a bottle the balance should be corrected accounting for any overage. If there is an overage, the overage should be measured using an oral syringe and accounted for by adding to the total in the register. Any shortfall must be recorded before a new bottle is opened.
 - b. It is the responsibility of the Appointed Person in Charge to monitor any regular shortfall and determine whether it requires further investigation.
4. If the stock is found to be correct the stock check shall be recorded in chronological order working backwards from the end of the Controlled Drug Record Book. The entry shall state:
 - a. The date of the check.
 - b. The time.
 - c. The words 'Stock checked and correct'.
 - d. Signature of the person undertaking the check and the witness.
5. If the stock is found not to balance the Assigned Nurse in Charge will commence an investigation. See Section 4.4 Investigation of Discrepancies.

4.2.5 Requisitioning

For the purposes of requisitioning the following section applies to:

1. Schedule 2 CDs.
2. Schedule 3 CDs e.g. Barbiturates, Buprenorphine, Temazepam, Flunitrazepam, Tramadol, Gabapentin, Pregabalin and all Midazolam preparations.
3. Ketamine Preparations.
4. Morphine Sulphate 10mg/5ml Oral Solution.

The Appointed Person in Charge is responsible for the requisitioning of Controlled Drugs for use in that area. The Appointed Person may delegate that task to another registered nurse, midwife or ODP but the legal responsibility remains with the Appointed Person.

Controlled Drugs shall be requisitioned using the approved Controlled Drug Requisition Book in duplicate and signed by an authorised signatory.

The Controlled Drug Requisition will specify:

1. The name of the hospital
2. The ward or department being supplied
3. The drug name, form, strength – only one CD will be ordered on one requisition
4. The size of the ampoule or unit dose vial
5. The quantity to be supplied
6. Signature and printed name of the authorised requisitioner
7. The date

Where a Controlled Drug that is not stock for the area is required, the requisitioner will contact the Clinical Pharmacist for the area to obtain prior approval using the normal clinical pharmacy model and if approved the Clinical Pharmacist will countersign the requisition. If the dispensary receives a requisition for a non-stock item that is not countersigned the pharmacist will be contacted to confirm the supply is appropriate. Verbal authorisation is provided and the requisition endorsed with the pharmacist's name.

The completed Controlled Drug Requisition book shall be transported to the Pharmacy using a lockable transit box.

The Appointed Person is responsible for ensuring only authorised staff requisition Controlled Drugs. The Appointed Person will provide the Pharmacy Service with specimen signatures of nurses authorised to requisition Controlled Drugs every six months.

4.2.6 Receipt

For the purposes of receipt the following section applies to:

1. Schedule 2 CDs
2. Schedule 3 CDs e.g. Barbiturates, Buprenorphine, Temazepam, Flunitrazepam, diethylpropion, Tramadol, Gabapentin, and Pregabalin

3. Midazolam 5mg/ml (e.g. 10mg/2ml, 50mg/10ml) Injection (but not other midazolam preparations)
4. Ketamine Preparations
5. Morphine Sulphate 10mg/5ml Oral Solution

Controlled Drugs will be transported to the ward in lockable containers or numbered tamper evident transit pouches. The messenger will hand over the lockable container to the Assigned Person in charge of the shift on the receiving ward. The Assigned Person in Charge is identified by their valid identity badge and by the holding of the CD transport box keys.

Checking the receipt

A delivery note will identify which requisition numbers or patients TTOs are enclosed in the container.

- Tamper evident medicine packages need not be opened.
- Where an opened tamper evident package has been supplied check both the contents as well as the packaging.
- Where a CD has been supplied in a plain bottle or carton, check both the contents and the label.
- Check the CDs received (including both dispensing label and the original packaging) against the requisition; check the name, strength, form and quantity received. If these match sign the 'Received by' section on the copy requisition.
- Where the delivery is correct the delivery note need not be retained.
- Where there is any discrepancy contact the Pharmacy Services Manager of supplying dispensary immediately who will advise you of the action that needs taking.

Once in the possession of the Assigned Person it is the responsibility of the Assigned Person to ensure the contents are checked and stored in the CD cupboard as soon as possible.

Entering the Controlled Drugs in the Ward Controlled Drug Record Book

The Assigned Person shall enter the details of the receipt into the ward or department Controlled Drug Record Book and it shall be witnessed by a second registered nurse, midwife, or ODP.

The following details are recorded:

- The quantity received in words (TEN not 10).
- The date received.
- The requisition number.
- Across the administration section the words 'Received from Pharmacy'.
- The new running balance.
- The signature of the Assigned Person and the Witness.
- If the new balance and the physical balance do not match the Assigned Nurse in charge will record this in the register and will initiate an investigation.

4.2.7 Storage and Security

For the purposes of storage the following section applies to:

1. Schedule 2 CDs
2. Schedule 3 CDs e.g. Barbiturates, Temazepam, Flunitrazepam, diethylpropion
Tramadol, Gabapentin, and Pregabalin
3. Midazolam 10mg/2ml Injection (but not other midazolam preparations)
4. Ketamine Preparations
5. Morphine Sulphate 10mg/5ml Oral Solution

Ward Controlled Drugs cabinets must conform to BS2881 or be otherwise approved by the Accountable Officer.

The Appointed Person in Charge is responsible for the security of Controlled Drug Cupboard Keys. On a day to day basis the Assigned Person in Charge may delegate the key holding to another registered nurse, midwife or ODP but keys should be returned to the Assigned Person in Charge immediately after use. Cupboards are kept locked when not in use.

Keys are only passed to those who have authority to possess them and the Key holder is readily identifiable.

The Controlled Drug Cupboard is used only for the storage of Controlled Drugs. No other items are stored in there.

For units that do not operate 24 hours a day Controlled Drug cupboard keys are held securely when the unit is not open. It is the responsibility of the Appointed Person in Charge to obtain the approval of the Accountable Officer for such arrangements.

Authorised Key Holders

In the course of their duty the following groups of staff are authorised to hold the CD cupboard key:

- Registered Nurse or Midwife
- Operating Department Practitioners
- Pharmacists
- Pharmacy Technicians undertaking Controlled Drugs Audits
- Pharmacy Assistants undertaking topping up duties

Loss of the Keys

In the event that keys are unaccounted for then urgent efforts will be made to locate them as soon as possible.

1. The Assigned Nurse in Charge will initiate the investigation.
2. If a search of the immediate area does not locate the keys, the Matron and General Manager for the division will be informed. In addition the Divisional director or Deputy Chief Pharmacist will be informed.
3. Staff who have gone off duty will be contacted.
4. Consideration will be given to issuing a spare key.
5. Consideration will be given to moving Controlled Drugs if it is considered that by remaining in situ there is a risk of unauthorised access.
6. Consideration will be given to changing the locks.
7. Consideration will be given to informing the police.
8. If the keys are not found the Accountable Officer will be informed.

4.2.8 Prescribing

Prescribing shall follow the general procedures set out in PAT/MM 1 Part A - Safe and Secure Handling of Medicines Policy.

Prescribing for Inpatients

Prescriptions for inpatients do not need to meet Control Drug prescription requirements. They are prescribed on the Trust approved inpatient medicine charts, electronic prescribing system or anaesthetic records. As with other prescriptions they should specify:

1. Drug name, and form, including 'modified release' where applicable
2. Route
3. Dose
4. Frequency. For 'as required' prescriptions, the minimum interval between dose, and a maximum dose in 24hours; the indication such as 'for break through pain'.
5. Start date, and finish date if appropriate.
6. Signature of prescriber, their name and bleep number, or validated by the prescriber's password.

Prescribing for Discharge and to Outpatients

The following applies to all schedule 2 and 3 control drugs. Schedule 2 and 3 CDs include injectable and solid dose opiates, barbiturates, buprenorphine, temazepam, tramadol, gabapentin, pregabalin and midazolam.

These requirements do not apply to morphine sulphate oral solution 10mg/ml.

Prescriptions for Controlled Drugs to be supplied at discharge must comply with the prescription requirements of the Misuse of Drugs Regulations. These are:

1. Name and address of the patient, and where appropriate the age. The use of pre-printed labels is not recommended as these may not be permanent and may be tampered with.

2. The name of the Controlled Drug and form in which it is supplied including 'Modified Release' where necessary.
3. The strength of the preparation to be supplied.
4. The dose to be taken.
5. The total quantity of the preparation, or number of dose units, to be supplied in both word and figures.
6. The date and signature.

Medical doctors who have not achieved full registration with the GMC may prescribe discharge prescriptions but not prescriptions for outpatients.

The supply should be appropriate to the patient's clinical need and should not normally exceed 30 days. Where the prescriber believes it is in the clinical interest of the patient that longer than 30 days is necessary the prescriber, should contact the local dispensary and discuss this with the senior pharmacist present. If a prescription is required for longer than 30 days a record should be made in the patient's notes to detail the reasons.

Non-Medical Prescribing

Non-medical prescribers will follow the general principals set out in the policy albeit within the restrictions placed upon them by the Regulations applicable to Independent and Supplementary Non-medical Prescribing.

4.2.9 Administration

Administration shall follow the general procedures set out in Section 6 of PAT/MM 1 Part A - Safe and Secure Handling of Medicines Policy.

For the purpose of administration the following medicines require witnessed administration by another person authorised to administer medicines.

- Schedule 2 Controlled Drugs (including ketamine)
- Schedule 3 CDs e.g. Barbiturates, Temazepam
 - Including Midazolam 10mg/2ml injection (**but not** other midazolam preparations)
 - **But not Tramadol, Gabapentin or Pregabalin**

For the purpose of administration, single person administration is permitted for the following medicines:

- Tramadol, Gabapentin and Pregabalin
- Midazolam preparations except 10mg in 2ml injection
- Morphine Sulphate 10mg/5ml Oral Solution

For Controlled Drug administered the following details shall be recorded in the ward/department Controlled Drugs Record Book:

1. The date and time of administration
2. The name of the patient
3. The quantity administered
4. The name formulation and strength of the CD given

5. The name / signature of the person administering
6. The name/ signature of the witness
7. The stock balance

Checking the Administration of a Controlled Drug following the written directions of another person

The person administering the Controlled Drug will:

- Confirm the identity (including strength) of Controlled Drugs with the witness.
- Prepare the Controlled Drug for administration.
- Record in the Controlled Drug Register the amount administered to the patient and any wastage.
- Record and confirm the remaining stock balance and sign the register as given.

The witness will:

- Confirm the identity and strength of the CD given by the person administering the Controlled Drug.
- Witness the preparation of the Controlled.
- Witnessing the actual administration.
- Witness the destruction of any surplus Controlled Drug.
- Confirm the remaining stock balance and sign the register as witnessed.

Checking Administration of a Controlled Drug by a Prescriber or other Healthcare Professional who initiates and administers treatment themselves

There are circumstances where a healthcare professional initiates and administers (and titrate) a Controlled Drug to a patient, eg:

- a patient whose response is being titrated under the direct supervision of an anaesthetist in theatres.

These circumstances may compromise the validity of the checking process by a second person, as the person administering the medicines may be titrating the response of the patient to the medicines administered and the instruction may not be written in advance.

Where instructions can be written in advance then this should be done and the checking process should follow Section 7.9.2 above with the actual CD administration being witnessed.

The person administering the Controlled Drug will:

- Confirm the identity (including strength) of Controlled Drugs with the person in possession of the Controlled Drug Keys.
- Prepare the Controlled Drug for administration.

- Record in the Controlled Drug Register the amount administered to the patient and any wastage.
- Record and confirm the remaining stock balance and sign the register as given.

The witness will:

- Confirm the identity and strength of the CD given to the person administering the Controlled Drug.
- Witness the destruction of any surplus Controlled Drug.
- Confirm the remaining stock balance and sign the register as witnessed.

The responsibility for the correct administration remains with the person giving the medicine.

Waste

During Preparation

Where the dose required is part of an ampoule or vial the person administering the dose shall record both the amount given and the amount wasted, e.g. *x mg given y mg wasted*.

Where a dose is prepared but not given it must be destroyed (e.g. via the sharps bin or CD Denaturing Kit) and an entry made in the Controlled Drug Record Book which is signed by the person preparing the dose and by an appropriate witness, e.g. registered nurse, midwife, ODP.

After Administration

For detail regarding the handling of preparations for Patient Controlled Analgesia and epidural infusion see section 4.5 and 4.6.

In the event that there is a preparation containing a Controlled Drug left after administration has been completed, e.g. following the cessation of a syringe driver, the Assigned Person in charge shall record the preparation and volume wasted in a separate section of the ward Controlled Drug Record Book. The material shall be destroyed using a CD Denaturing Kit.

4.2.10 Records

For the purposes of recording the following section applies to:

1. Schedule 2 CDs
2. Schedule 3 CDs e.g. Barbiturates, temazepam, tramadol, pregabalin, gabapentin
 - Including Midazolam 10mg/2ml injection (**but not** other preparations)
3. Ketamine Preparations
4. Morphine Sulphate 10mg/5ml Oral Solution

Wards and departments that hold Controlled Drugs as stock shall maintain a Controlled Drug Record Book (CDRB) that records CDs received, administered, destroyed or returned to the Pharmacy. The Appointed Person in Charge is responsible for keeping the record book up to date and in good order.

The CDRB shall be a bound book with sequentially numbered pages. The CDRB shall be used in the following way:

- Entry will be made in ink or be otherwise indelible.
- Each preparation shall be entered on a separate page. The page title shall detail the drug name, form and strength.
- Entries shall be made in chronological order.
- A running balance shall be maintained.
- If a mistake is made it shall be bracketed in such a way as the original entry is still visible. Errors shall be initialled, dated and witnessed by registered nurse, midwife, or ODP or where appropriate doctor or pharmacist.
- On reaching the end of the page, the balance shall be transferred to new page. The new page number shall be added to the finished page and the index shall be updated. The transfer between pages shall be signed and witnessed.
- All entries shall be signed by the person undertaking the transaction and where necessary witnessed.
- Only one record book shall be in use in one area at any time (unless authorised by the accountable officer)

Transaction	Entered by	Witnessed by
Receipt	Registered Nurse, midwife, or ODP	Registered nurse, midwife, or ODP
Administration	Registered nurse, midwife Doctor Other person authorised to administer medicines e.g. ODP	Registered nurse, midwife, ODP
Return to Pharmacy	Registered Nurse, midwife, or ODP	Pharmacist Pharmacy Technician
Destruction in the course of administration	Registered Nurse, midwife Doctor Other person authorised to administer medicines e.g. ODP	Registered Nurse, midwife ODP
Destruction of Ward Stock	Registered Nurse, midwife, or ODP	Pharmacist Pharmacy Technician
Transfer of balance to new page	Registered Nurse, midwife, or ODP	Registered Nurse, midwife, or ODP
Transfer between Record Books	Registered Nurse, midwife, or ODP	Registered Nurse, midwife, or ODP
Daily stock check	Registered Nurse, midwife, or ODP	Registered Nurse, midwife, or ODP

Transferring record books

The Appointed Person in Charge is responsible for the timely and accurate transfer of stock between record books.

The transfer shall be undertaken by a registered nurse, midwife or ODP and shall be witnessed.

The stock balance shall be checked before transfer, checking the balance in the register against the physical stock.

Archiving Controlled Drug Record Books and Requisition Books

The Appointed Person in Charge is responsible for the safe storage of Controlled Drugs Record Books (CDRB) and Requisition Books once they are complete and no longer in use.

All CDRB and requisition books that are complete will be retained for a period on no less than two years from the date of the last entry.

4.2.11 Returning Controlled Drugs

Stock Controlled Drugs are not routinely returned to the Pharmacy except in exceptional circumstance, for example supply problems, CDs may be returned to the Pharmacy with prior agreement.

Returns

The Pharmacy will normally only accept full boxes for return. In exceptional circumstances part boxes may be returned to Pharmacy stock for re-use, e.g. the medicines is required to fulfil a TTO prescription. A pharmacist or pharmacy technician will assess whether a product is fit for re-use. If a product is fit for re-use the CD will be returned in the following manner, otherwise unwanted medicines shall be destroyed on the ward in the presence of the Assigned Nurse in Charge.

The returns process is the reverse of the requisitioning process.

The nurse in charge shall record in the ward CDRB that the medicines have been returned and shall record a new balance. The authorised member of the Pharmacy staff shall counter sign the register to confirm the balance. The Assigned Nurse in Charge shall write a CD requisition for each medicine being returned. In the space for 'Ordering by' the nurse shall write "Returned to Pharmacy". The nurse shall sign the in the space 'Supplied by' and the authorised member of the Pharmacy shall sign the space below 'Accepted for delivery' such that on the pink copy the signature is in the space 'Received by'.

Those items suitable for re-use shall be returned on the Pharmacy Computer using the returns program and shall be entered into the issues register as a receipt. It is the responsibility of the member of the Pharmacy staff who returns the CDs to ensure that the CDs are returned to safe storage and the computer and register entries are made.

Staff authorised to return CDs are pharmacists and pharmacy technicians.

Ward Closures

Temporary Closure

Where a ward is anticipated to be closed for greater than four days Controlled Drugs will be returned to the local pharmacy for storage. The Appointed Person will ensure a stock check is undertaken with a pharmacist or pharmacy technician who will remove the CD's and Controlled Drugs Record Book for temporary safe storage within the Pharmacy. On re-opening the Appointed Person will undertake a stock check with a pharmacist or pharmacy technician to confirm the correct return of the Controlled Drugs to the ward or department. All CD's will be returned to the ward.

Permanent Closure

Where a ward or department is permanently closed Controlled Drugs will either be destroyed on the unit, or if fit for reuse, be returned to the supplying pharmacy. The procedures in sections 4.2.11 and 4.2.15 must be followed.

4.2.12 Transfers

Ward stocks of Controlled Drugs must not be transferred between ward. In exceptional circumstances where an immediate supply is not available an individual dose for a specific patient may be issued from a nearby ward. The single record of administration must be made in the record book of the ward that holds the stock. A reference must be made in the entry to indicate which ward the patient was on at the time of administration.

4.2.13 Patients' Own Medicines which are Controlled Drugs

The use of Patient's Own Medicine shall follow the general procedures set out in MM1 Part 1- Safe and Secure Handling of Medicines Policy.

For the purposes of recording the following section applies to:

1. Schedule 2 CDs
2. Schedule 3 CDs e.g. Barbiturates, Buprenorphine, Temazepam, Flunitrazepam, Tramadol, Gabapentin, Pregabalin
3. Midazolam 10mg/2ml injection (but not other midazolam preparations)
4. Ketamine Preparations
5. Morphine Sulphate 10mg/5ml Oral Solution
6. TTO's that contain the above, that are intended to be used during the patient's stay.

Patient's own CDs should be clearly marked or segregated in the CD cupboard to distinguish them from ward stocks.

Records of Patients' Own Controlled Drugs

It is the responsibility of the Assigned Nurse in Charge to ensure that patients' own medicines that are Controlled Drugs that are received onto the ward are stored in the ward Controlled Drugs Cupboard and recorded in a Patient's Own Controlled Drug Record Book

(POCDRB). A separate record book is maintained for Patients' Own Controlled Drugs. Each patient and each preparation shall be assigned a single page in the POCDRB.

The record shall comprise of the following:

- The Patient Name and Hospital Number as the page header.
- Date received onto the ward
- Where the CDs were received from (whether from the patient on admission or by transfer from another ward)
- Drug name, form and strength.
- The Quantity received.
- Signature of the nurse receiving the patient's own Controlled Drug and the witness.

Use of Patients' Own Controlled Drugs

If the medicines are assessed as suitable for re-use they may be used for the patient to whom they belong. The method of administration and recording shall follow the standards detailed in sections 4.2.9 and 4.2.10 above.

Under no circumstance can medicines brought in by one patient be used for another.

Transfer of Patients' Own Controlled Drugs

Where a patient is transferred to another ward it is the responsibility of the nurse or ODP in charge of the transfer to ensure the Patients own CDs are transferred securely.

The medicines must be signed out of the transferring wards book and into the receiving wards book, and each record must be witnessed. Each record will record under each patient and medicine header the following:

- Date and time of the transfer
- The name of the receiving or transferring ward
- Quantity transferred or received
- The stock balance, which in the case of the transferring ward should be zero
- Signature of the practitioner in charge of the transfer
- Signature of a witness authorised to administer medicines

If the physical transfer of medicines cannot take place at the time of the patient transfer, the record book should be annotated to show the date and the ward to where the patient has been transferred, with the intention to the transfer of the patient's own CD at the earliest possible time

Return or Destruction of Patients' Own Controlled Drugs

Patient's own CDs not required for use on the ward or re-supply at discharge should either be destroyed (see section 4.2.15) or returned to the patient's home via a responsible adult representative of the patient. Where medicines are no longer clinically indicated the patient should be encouraged to have their Controlled Drugs destroyed.

- If the patient's own CD is to be destroyed the patient's permission must be gained.

- If the patient insists the medicines may be returned to their home via a responsible adult.

Where a patient's own Controlled Drug is returned to a patient or responsible adult a record shall be made comprising:

- Date and time of return.
- Quantity returned.
- Signature of nurse returning the CD and witness.

Discharge Prescriptions

Where there is no delay in discharge prescription being given to the patient following its receipt on the ward there is no requirement to make a record in the Patient's Own Controlled Drug Record Book.

Where discharge prescriptions are received in advance (and require holding on the ward greater than a shift), or where the discharge prescription needs to be administered as part of the patient's treatment, an entry shall be made in the POCDRB as detailed above (section 4.2.13), and those procedures shall be followed.

4.2.14 Midazolam

Midazolam is a Scheduled 3 Controlled Drug and the following restrictions apply to midazolam preparations.

Requisitioning Midazolam

Assigned Person in charge must provide a CD requisition for all preparations. In the case of ward stock supply, to the Pharmacy Store and in the case of non-stock supply, to the pharmacist authorising the supply.

Transport of Midazolam

Midazolam 10mg in 2ml injection shall be transported in accordance with the procedure described in section 4.7 of this policy.

All other preparations shall be transported in accordance with PAT MM1 Part A.

Receipt of Midazolam

Midazolam 10mg in 2ml Injection shall be received on the ward or department in accordance with section 4.2.6 of the policy.

All other midazolam preparations will be handled in accordance with PAT MM 1 Part A.

Record for Midazolam

Midazolam 10mg in 2ml Injection will be recorded in the Ward Controlled Drug Record Book in accordance with section 4.2.10 of this policy. This is not requirement for other preparations.

Destruction of Midazolam

Midazolam 10mg in 2ml Injection will be destroyed on wards and departments in accordance with section 4.2.15 of this policy. This is not requirement for other preparations.

4.2.15 Destruction of Controlled Drugs on Wards or Departments

The destruction of unwanted Controlled Drugs, including those brought in by patients, held by wards and departments require witnessing by an authorised member of the Pharmacy staff. Destruction shall be undertaken by the Appointed Person or nominated deputy in the presence of an authorised member of the pharmacy staff. The person destroying the medicines and the person witnessing the destruction shall record the destruction in the ward or department Controlled Drug Record Book or Patient's Own Controlled Drug Record Book. They shall record the date of destruction and quantity actually destroyed at that time, and the remaining balance. Both the person destroying the CD's and the person witnessing the destruction shall sign the record.

Staff authorised to witness the destruction of CDs on wards and departments are pharmacists and senior pharmacy technicians.

Procedure

The purpose of this procedure is to render the Controlled Drugs irretrievable. Once the CD Denaturing Kit has been used it is disposed of as Pharmaceutical Waste by the Pharmacy.

Solid Dose Forms

Solid dose forms must be removed from their strips or containers before destruction.

Unless otherwise directed by the denaturing kit they should be crushed or dissolved in warm soapy water before being added to the CD Denaturing Kit.

The CD Denaturing Kit should be topped up with water to form a solid mass.

Liquid Medicines

Liquid Medicines may be added to the CD Denaturing Kit directly. The CD Denaturing Kit should be topped up with water to form a solid mass. The bottle should be rinsed and the rinsings added to the CD denaturing kit.

Ampoules and Vials

Liquid ampoules and vial must be opened and the contents added to the CD Denaturing Kit directly. The kit should be thoroughly shaken to ensure the contents are absorbed into the kit. The CD Denaturing Kit should be topped up with water to form a solid mass. Powder ampoules should be reconstituted and the resulting mixture added to the CD denaturing kit.

Patches

The backing should be removed and the patch folded over on itself before being added to the CD Denaturing Kit. The CD Denaturing Kit should be topped up with water to form a solid mass.

Aerosols

Aerosols should be expelled under water to prevent droplets entering the air, and the resultant liquid added to a CD Denaturing Kit.

4.3 AUDIT

4.3.1 Ward Stocks and Records

Stocks and Record Books held on the ward shall be checked by an authorised member of the Pharmacy staff once every six months.

The check shall comprise of the following checks:

1. The area has only one register in use (unless authorised by the AO)
2. The controlled drug register is stored in a locked cupboard when not in use
3. Entries are made in chronological order
4. Alteration are clear and countersigned
5. Transactions that require witnessing are signed as witnessed.
6. That the arithmetic on a sample page has been undertaken correctly
7. The frequency of stock checking
8. That the physical stock balances with the stock in the record book.
9. The patient's own medicines are recorded separately
10. That record books completed within the last two years are available

The member of the Pharmacy Staff shall record in the register that the check was undertaken. This should be recorded where the daily check of CD's is recorded by the wards and state "CD check undertaken by pharmacy" and the date and signature of the auditor. A copy of the audit report will be provided to the ward manager.

Once all wards or departments within a division have been audited copies of all reports will be provided to the divisional directors of nursing who should seek reassurance from the ward managers that an action plan is in place to remedy any deviations from standards.

Copies of all reports will also be provided to the director of the division who should seek reassurance from the directors of Nursing.

Copies of all reports will also be provided to the Accountable Officer.

4.3.2 Pharmacy Stocks and Record

Stocks and Register Books held in the dispensaries shall be checked once every six months. The Accountable Officer shall authorise a suitable pharmacy professional to undertake this check.

The check shall comprise the following:

1. Entries are made in chronological order.
2. Alterations are clear and countersigned.
3. That the arithmetic on a sample page has been undertaken correctly.
4. That all CDs have had an in-use stock check or have been checked during the first week of the previous month.
5. That the combined physical balance and ADS inventory stock, of a sample of CDs match the CD register and Pharmacy computer stock balance.

The auditor shall provide to the Deputy Chief Pharmacist a copy of their reports. The auditor shall also provide a copy of the report to the Accountable Officer.

4.4 INVESTIGATION OF DISCREPANCIES

In the first instance any discrepancy found between the register or record book and physical stock shall be investigated without delay by the Pharmacy Services Manager for a dispensary or in the case of a ward or department the Assigned Person in charge. If the discrepancy is resolved immediately the Pharmacy Services Manager or Assigned Person in Charge shall correct the register or record book, annotating the register or record book with an explanation of the error. The explanation shall be witnessed by a pharmacist, senior pharmacy technician, registered nurse or operating department practitioner as appropriate.

Where the error cannot be resolved within the working day the discrepancy shall be recorded on Datixweb. Datixweb shall alert the Accountable Officers of all Controlled Drug incidents:

1. The Pharmacy Services Manager shall inform Deputy Chief Pharmacist who will agree the further investigation.
2. The Assigned Person In charge shall inform the divisional Director of Nursing who will agree the further investigation.
3. In all cases when the Pharmacy is closed the Pharmacy senior manager on-call shall be informed and will advise.

If the discrepancy cannot be resolved within a maximum of 48 hours the Accountable Officer shall be contacted who will decide whether further investigation is necessary.

4.5 MANAGEMENT OF PATIENT CONTROLLED ANALGESIA DEVICES

This section should be read in conjunction with Patient Controlled Analgesia (PCA) PAT/MM 7.

Because Patient Controlled Analgesia (PCA) Devices are moved between areas and used over a prolonged periods of time they present special circumstances that need to be addressed to ensure their safe and secure handling. This procedure is written to ensure devices are used safely and that the Controlled Drugs involved are properly accounted for.

4.5.1 Devices

The PCA pump is to be cleaned in accordance with Cleaning and Disinfection of Ward Based Equipment Policy PAT/IC 24.

PCA Pumps used must conform to the following specification:

PCA pump used shall be capable of locking the syringe onto the pump to prevent diversion. These pumps are pre-programmable and can only be changed by authorised personnel. They are locked once programmed for individual patients. They have audible alarms and indicators for dose administration. They have indicators for successful and unsuccessful administration. They store information that can only be accessed by authorised personnel.

4.5.2 Prescribing

The Trust uses a standard product for PCA devices; this is Morphine Sulphate 100mg/50ml presented as a 50ml vial. PCA devices are prescribed by anaesthetists or by other appropriate prescribers, using a standard label which is detailed as follows:

MORPHINE 100milligrams in 50ml 0.9% saline
1mg=0.5mls per I.V Bolus
P.C.A POLICY

Signature..... Date.....

The PCA syringe is prescribed on a PCA prescription and administration chart (WPR: 31320). This chart is used for the duration of the PCA syringe.

A PCA “check” is prescribed as a standard product on the ePrescribing system.

NB other Opiates e.g. Fentanyl may be used; this policy describes the use of the standard morphine product but the principals shall be applied to other preparation used.

4.5.3 Controlled Drug Record Book

The person setting up the PCA pump shall make a record of the issue in the ward/department Controlled Drug Record Book in the normal manner. In the case of Theatre Recovery the entry shall also specify the ward to which the patient is moving.

4.5.4 Preparation and Record of Administration

The PCA syringe is prepared by withdrawing 50ml of Morphine Sulphate 100mg/50ml from the 50ml vial into a 50ml luer lock syringe. The syringe shall be labelled as follows:

1. Name and hospital number of patient
2. Morphine sulphate 100mg/50ml
3. Route – Intravenous (IV)
4. Date and time prepared

5. Date and time of expiry (24 hours)
6. Signature of person preparing syringe
7. Signature of person checking preparation

The device will be connected to the patient by the person who sets up the device and before leaving the department regardless of whether it is administering medication or not.

As the administration of the solution is patient controlled the nurse or ODP caring for patient will, in addition to their clinical monitoring, monitor the syringe to ensure it is functioning correctly. This is done using the PCA prescription chart. The chart records the total mls infused.

4.5.5 Transfer from Theatres to Wards or between Wards

When a patient is transferred from Theatre Recovery to a ward (or between wards) the responsibility for the PCA syringe shall transfer to the Registered Nurse responsible for the patient on the receiving ward. This transfer shall be recorded on the Prescription Chart. This shall be done by means of a pre-printed sticker affixed to the administration record where the PCA solution is prescribed. It shall record the following:

1. Date and time of transfer
2. The ward/dept. the patient has been transferred to
3. The volume remaining in the syringe
4. The signature of the nurse receiving the patient
5. The signature of the nurse (ODP) handing over the patient

4.5.6 Disposal of Surplus Controlled Drugs from a PCA syringe

Any surplus morphine sulphate 2mg/ml solution, or any other opiate, remaining after the PCA has been disconnected shall be disposed of by directly adding the solution to an approved Controlled Drug Denaturing Kit.

When used these kit must be returned to the Pharmacy for disposal with the Pharmaceutical waste on a weekly basis.

A separate entry shall be made in the ward Controlled Drug Record Book under the heading e.g. "Morphine Sulphate 100mg/50ml as PCA syringes waste". The entry shall record:

1. Date and time of disposal
2. Patients name
3. The volume remaining in the syringe which is waste
4. The signature of the nurse disposing of the solution
5. The signature of the nurse witnessing the disposal

4.6 MANAGEMENT OF EPIDURAL INFUSION CONTAINING CONTROLLED DRUGS

Because epidural infusions are moved between areas and used over a prolonged periods of time they present special circumstance that need to be addressed to ensure their safe and secure handling. This procedure is written to ensure devices are used safely and that the Controlled Drugs involved are properly accounted for.

4.6.1 Devices

Epidural pumps are to be cleaned in accordance with the Cleaning and Disinfection of Ward Based Equipment Policy PAT/IC 24. The epidural pumps used are held by the recovery wards on all sites and are required to be returned to these areas as soon as they have been discontinued.

Epidural pumps used must conform to the following specification:

1. Epidural pump used shall be capable of locking the infusion bag inside the lock box.
2. Epidural pump shall be capable of locking the keypad to prevent diversion.
3. These pumps are pre-programmable and can only be changed by authorised personnel.
4. The lock box and keypad are locked once programmed for individual patients.
5. They have audible alarms and indicators for dose administration.
6. They have indicators for successful and unsuccessful administration (Patient Controlled Epidural Analgesia - PCEA).
7. They have indicators for total drug infused.
8. They store information that can only be accessed by authorised personnel.

4.6.2 Prescribing

The Trust uses one standard product for epidural infusions that contains a Controlled Drug;

Fentanyl 2microgram/ml with Bupivacaine 0.1% 250ml bags.

These are prescribed by anaesthetists or by other appropriate prescribers using a standard label which is detailed as follows:

250mls 0.9% saline containing 2micrograms/ml Fentanyl in 0.1% Bupivacaine 0-16mls/hr

Nurse controlled boluses 4-6mls (max boluses 2 in 3 hours)

The epidural infusion is prescribed on an Epidural Infusion and Administration Chart (WPR31270).

A "check" is prescribed as a standard product on the ePrescribing system.

4.6.3 Controlled Drug Record Book

The person setting up the epidural infusion that contains fentanyl shall make a record of the issue in the ward/department Controlled Drug Record Book in the normal manner. In the case of Theatre Recovery the entry shall also specify the ward to which the patient is moving.

4.6.4 Record of Administration

The device will be connected to the patient by the person who sets up the device and before leaving the department regardless of whether it is infusing.

As the administration of the solution is either patient controlled epidural analgesia (PCEA) or a continuous epidural infusion (CEA) without the patient controlled facility the nurse or ODP caring for patient will, in addition to their clinical monitoring, monitor the pump to ensure it is functioning correctly. This is done using the Epidural Infusion Chart (WPR 31270). The chart records the rate and the mls used.

4.6.5 Transfer from Theatres to Wards or between Wards

When a patient is transferred from Theatre Recovery to a ward (or between wards) the responsibility for the epidural infusion shall transfer to the Registered Nurse responsible for the patient on the receiving ward.

This transfer shall be recorded on the Prescription Chart. This shall be done by means of a pre-printed sticker affixed to the right hand side of the administration record where the epidural is prescribed. It shall record the following:

1. Date and time of transfer
2. The ward/dept the patient has been transferred to
3. The volume remaining in the bag or the total volume infused
4. The signature of the nurse receiving the patient
5. The signature of the nurse (ODP) handing over the patient.

4.6.6 Disposal of Surplus Controlled Drugs from an Epidural Infusion

Any surplus epidural infusion containing Fentanyl shall be disposed of by directly adding the solution to an approved Controlled Drug Denaturing Kit.

The disposal of the surplus solution shall be recorded on the controlled drug administration monitoring chart

The entry shall record:

1. Date and time of disposal.
2. The patient's name.
3. The presumed volume remaining in the bag which is waste. This can be deducted from the total "infused ml/hr" stated on the pump.
4. The signature of the nurse disposing of the solution.
5. The signature of the nurse witnessing the disposal.

When used these kits must be returned to the Pharmacy in the ward drug box for disposal with the Pharmaceutical waste.

4.7 TRANSPORT OF CONTROLLED DRUGS WITHIN DBH

This section deals with the transport of both stock Controlled Drugs and Controlled Drugs that form part of a discharge prescription (TTO). It relates to the transport of Controlled Drugs to wards and departments that are part of Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust and to Controlled Drugs dispensed to patients of other Trusts.

4.7.1 Transport of Stock Controlled Drugs

All Controlled Drugs shall be transported to the wards in lockable boxes or numbered tamper evident pouches.

The person checking the Controlled Drugs will assemble the CDs to be delivered into the ward transport box (or transit pouch). They will add to the container a delivery note that will inform the ward or department which CD requisition numbers they should expect to receive.

Carriage by Pharmacy Staff

- 1 The person assembling the delivery shall also record onto two part numbered delivery manifest:
 - a the delivery location
 - b the date of delivery
 - c the requisition numbers of the CD being supplied
 - d In the case of a pouch the unique seal number
- 2 The person assembling the delivery shall sign the delivery manifest to hand over the box or pouch to the courier
- 3 The pharmacy courier transporting the Controlled Drug shall sign the CD delivery manifest to accept delivery of the transport box(es) or pouches
- 4 The pharmacy courier will hand over the transport box or pouches to the Assigned Person in charge of the shift on the receiving ward. The Assigned Person in charge is identified by their name badge and possession of the CD transport box keys.
- 5 On delivering to the ward or department the Assigned Person in charge shall sign the CD delivery manifest to accept the delivery.
- 6 The signed CD delivery manifest shall be returned to the Pharmacy Services Manager by the Pharmacy Courier as proof of delivery.

- 7 For any deliveries not made the delivery manifest shall be marked 'Returned' and brought to the attention of the Pharmacy Services Manager who will arrange collection by the ward
- 8 Delivery manifest shall be filed in date order and retained for a minimum of 2 years.
- 9 On delivering to the ward or department the Assigned Person in charge shall check the delivery. If there is any discrepancy in the stock received this must be reported by the Assigned Person in charge to the Pharmacy Services Manager as soon as possible, otherwise once the delivery has been checked and received by the Assigned Person the delivery note may be discarded.

Carriage by Non Pharmacy DBTH Staff within the hospital

- 1 Controlled Drugs shall only be carried by Trust staff who can be identified by wearing a valid identity badge.
- 2 The ward or department member of staff, the messenger, transporting the Controlled Drug shall check the CDs supplied against the requisition. If this is correct the messenger shall, sign the section 'Accepted for delivery' on the white copy. The white copy shall be retained in the Pharmacy.
- 3 The Pharmacy Technician or Pharmacist handing over the Controlled Drug will ensure:
 - a The Controlled Drugs and requisition book are secured in a lockable CD transport box or numbered tamper evident pouch
 - b The messenger knows the destination of the CD transport box
 - c The messenger understands that they are personally responsible for the safe handling and security of the box; that the box must be delivered directly to the ward and not be left unattended
 - d The messenger understands to whom the box may be delivered, i.e. the Assigned Person in charge of the ward or department, identifiable by their valid name badge and possession of the transport box keys.
 - e The messenger understands that they must ensure the Assigned Person who receives the box must sign the pink duplicate copy to transfer responsibility to the Assigned person.
- 4 On delivering to the ward or department the Assigned Person in charge shall check the delivery. If there is any discrepancy in the stock received this must be reported by the Assigned Person in charge to the Pharmacy Services Manager as soon as possible, otherwise once the delivery has been checked and received by the Assigned Person the delivery note may be discarded.

Carriage by Third Party Transport Arrangements

These arrangements apply in circumstance where Controlled Drugs are delivered offsite by:

- Transport Drivers.
 - External taxi companies.
- 1 Controlled Drugs shall only be carried by transport staff who can be identified by wearing a valid means of identity such as a badge.
 - 2 Each dispensary supplying CDs to offsite locations shall maintain a transport delivery log that will detail the following:
 - a The date and time of collection.
 - b The destination.
 - c The number of the seal if applicable.
 - d The signature and name of the person handing over the container.
 - e The signature and name of the person acting as the messenger
 - 3 The Pharmacy Technician or Pharmacist handing over the Controlled Drug will ensure:
 - a The Controlled Drugs and requisition book are secured in a lockable CD transport box or numbered tamper evident pouch
 - b The messenger knows the destination of the CD transport box or pouch.
 - c The messenger understands that they are personally responsible for the safe handling and security of the box; that the box must be delivered directly and not be left unattended.
 - d The messenger understands to whom the box may be delivered.
 - e The messenger understands that if delivery is not possible they must return the package to the Pharmacy.
 - 4 The messenger shall sign transport delivery log to accept the responsibility for the safe delivery.
 - 5 On delivering to the ward or department the Assigned Person in charge shall check the delivery. If there is any discrepancy in the stock received this must be reported by the Assigned Person in charge to the Pharmacy Services Manager as soon as possible, otherwise once the delivery has been checked and received by the Assigned Person the delivery note may be discarded.

4.7.2 Transport of Discharge Prescriptions

Discharge Prescriptions for Controlled Drugs shall be supplied in sealed tamper evident Controlled Drug Discharge bags. They are transported to wards in lockable boxes or numbered tamper evident pouches.

Controlled Drugs for delivery to patients' homes shall be packaged carefully to maintain its integrity during transport; ideally the medicines will be packaged in an outer cardboard pack to resist crushing and be closely wrapped in plain brown paper wrapper. The package will shall bear the name and address of the patient, but be otherwise anonymous.

In all cases:

- 1 The person checking the Discharge Prescription shall ensure a delivery note is sent with the medicine that details the patient's name, the Controlled Drug medicine, and quantity supplied.
- 2 The delivery note together with the CD medicines are placed into the tamper evident Controlled Drug Discharge bag that is identified by a unique serial number. Each bag contains medicines for a single patient. The serial number of the bags is recorded on the discharge prescription.

Carriage by Pharmacy Staff

- 1 The person assembling the delivery shall record onto two part numbered delivery manifest:
 - a the delivery location
 - b the date of delivery
 - c Name of the patient
 - d The serial number of the CD discharge bag
 - e In the case of a pouch the unique seal number
- 2 The person assembling the delivery shall detach the collection slip and discard it
- 3 The person assembling the delivery shall sign the delivery manifest to hand over the box or pouch to the courier
- 4 The pharmacy courier transporting the Controlled Drug TTO shall sign the CD delivery manifest to accept delivery of the transport box(es) or pouches
- 5 The pharmacy courier will hand over transport box or pouches to the Assigned Person in charge of the shift on the receiving ward. The Assigned Person in charge is identified by their name badge and possession of the CD transport box keys.
- 6 On delivering to the ward or department the Assigned Person in charge shall sign the CD delivery manifest to accept the delivery.
- 7 The signed CD delivery manifest shall be returned to the Pharmacy Services Manager by the Pharmacy Courier as proof of delivery.

- 8 For any deliveries not made the delivery manifest shall be marked 'Returned' and brought to the attention of the Pharmacy Services Manager who will arrange collection by the ward
- 9 Delivery manifest shall be filed in date order and retained for a minimum of 2 years.
- 10 On delivering to the ward or department the Assigned Person in charge shall check the delivery. If there is any discrepancy in the Controlled Drug received this must be reported by the Assigned Person in charge to the Pharmacy Services Manager as soon as possible, otherwise once the delivery has been checked and received by the Assigned Person the delivery note may be discarded.

Carriage by Non-Pharmacy DBTH Staff

- 1 Controlled Drug shall only be carried by Trust staff who can be identified by wearing a valid identity badge.
- 2 The person assembling the delivery shall complete the supply details of the detachable receipt slip
- 3 The ward or department member of staff, the messenger, transporting the Controlled Drug shall check the bag is sealed
- 4 The messenger signs and dates the corresponding detachable collection slip.
- 5 The Pharmacy Technician, assistant or Pharmacist handing over the Controlled Drug will ensure:
 - a The receipt slip is attached to the prescription
 - b The CD Discharge bag is secured in a lockable CD transport box or number tamper evident pouch
 - c The messenger knows the destination of the CD transport box/ pouch
 - d The messenger understands that they are personally responsible for the safe handling and security of the box/pouch; that the box/pouch must be delivered directly to the ward and not be left unattended
 - e The messenger understands to whom the box may be delivered, i.e. the Assigned Person in charge of the ward or department, identifiable by their valid name badge and possession of the transport box keys.
- 6 On delivering to the ward or department the Assigned Person in charge shall check the delivery. If there is any discrepancy in the Controlled Drugs received this must be reported by the Assigned Person in charge to the Pharmacy Services Manager as soon as possible, otherwise once the delivery has been checked and received by the Assigned Person the delivery note may be discarded.

Carriage by Third Party Transport Arrangements

These arrangements apply in circumstance where Controlled Drugs Discharge Prescriptions are delivered offsite by:

- Transport Drivers.
 - External taxi companies.
- 1 Controlled Drug shall only be carried by transport staff who can be identified by wearing a valid means of identity such as a badge.
 - 2 The person assembling the CD discharge prescription shall detach the collection slip and discard it
 - 3 Each dispensary supplying CDs to offsite locations shall maintain a transport delivery log that will detail the following:
 - a The date and time of collection.
 - b The destination.
 - c The patients name
 - d The Serial number of the CD transit bag
 - e In the case of a pouch the number of the seal
 - f The signature and name of the person handing over the container.
 - g The signature and name of the person acting as the messenger
 - 4 The Pharmacy Technician or Pharmacist handing over the Controlled Drug will ensure:
 - a The detachable receipt slip is removed and discarded.
 - b The Controlled Drug discharge bag is secured in a lockable CD transport box or numbered tamper evident pouch, or in the case of a package for delivery to a patients home, the medicine is securely packaged
 - c The messenger knows the destination of the Controlled Drug.
 - d The messenger understands that they are personally responsible for the safe handling and security of the box; that the box must be delivered directly and not be left unattended.
 - e The messenger understands to whom the box may be delivered.
 - f The messenger understand that if delivery is not possible they must return the package to the Pharmacy.
 - 5 The messenger shall sign transport delivery log to accept the responsibility for the safe delivery.
 - 6 On delivering to the ward or department the Assigned Person in charge shall check the delivery. If there is any discrepancy in the medicines received this must be reported by the Assigned Person in charge to the Pharmacy Services Manager as soon as possible, otherwise once the delivery has been checked and received by the Assigned Person the delivery note may be discarded.

PATIENTS LACKING CAPACITY

Sometimes it will be necessary to provide care and treatment to patients who lack the capacity to make decisions related to the content of this policy. In these instances staff must treat the patient in accordance with the Mental Capacity Act 2005 (MCA 2005).

- A person lacking capacity should not be treated in a manner which can be seen as discriminatory.
- Any act done for, or any decision made on behalf of a patient who lacks capacity must be done, or made, in the persons Best Interest.
- Further information can be found in the MCA policy, and the Code of Practice, both available on the intranet.

There is no single definition of Best Interest. Best Interest is *determined on an individual basis. All factors relevant to the decision must be taken into account, family and friends should be consulted, and the decision should be in the Best interest of the individual. Please see S5 of the MCA code of practice for further information.*

5 TRAINING/SUPPORT

Please note: The Standard Training Needs Analysis (TNA) – The training requirements of staff will be identified through a training needs analysis. Role specific education will be delivered by the service lead.

6 MONITORING COMPLIANCE WITH THE PROCEDURAL DOCUMENT

What is being Monitored	Who will carry out the Monitoring	How often	How Reviewed/ Where Reported to
Controlled Drugs stock checks	Assigned nurse, midwife or ODP. Pharmacist or pharmacy technician.	Daily Monthly Six monthly	Monthly ward medicines management audit conducted by pharmacist or pharmacy technician and reported to assigned nurse and divisional leads. Full controlled drugs audit done by pharmacy technician and reported to ward/department

			managers, divisional leads and accountable officer.
Controlled Drugs stock and records	Pharmacy technician	Six monthly	Ward/department manager. Divisional teams. Accountable officer. Drug and Therapeutics Committee. Trust Clinical Governance Group.
Controlled Drugs Incidents	Accountable Officer	Monthly	Trust Clinical Governance Group 6 monthly report. CD LIN

7 DEFINITIONS

See also PAT/MM 1 Safe and Secure Handling of Medicines Policy Part A

Automated Dispensing System

An Automated Dispensing System (ADS) is a secure storage system that stores and delivers to the dispenser medication including Controlled Drug. It interface with the Pharmacy Stock Controls system but is managed by its own inventory software that accounts for its stock. The inventory only includes medicines held within the ADS.

Pharmacy Stock Control System

The system used to order, receipt, invoice and issue medicines including Controlled Drugs. The system accounts for all stock held both within the ADS and outside the ADS, for example within Secure Controlled Drug Cupboards.

8 EQUALITY IMPACT ASSESSMENT

The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are disadvantaged over others. Our objectives and responsibilities relating to equality and diversity are outlined within our equality schemes. When considering the needs and assessing the impact of a procedural document any discriminatory factors must be identified.

An Equality Impact Assessment (EIA) has been conducted on this procedural document in line with the principles of the Equality Analysis Policy (CORP/EMP 27) and the Fair Treatment Fo2r All Policy (CORP/EMP 4).

The purpose of the EIA is to minimise and if possible remove any disproportionate impact on employees on the grounds of race, sex, disability, age, sexual orientation or religious belief. No detriment was identified. (See Appendix 2).

9 ASSOCIATED TRUST PROCEDURAL DOCUMENTS

PAT/MM 1 A - Safe and Secure Handling of Medicines Policy – PART A
 PAT/MM 5 – Injectable Medicines Policy
 PAT/MM 7 - Patient Controlled Analgesia (PCA)
 PAT/PA 19 - Mental Capacity Act 2005 Policy and Guidance, including Deprivation of Liberty Safeguards (DoLS)
 PAT/PA 28 – Privacy and Dignity Policy
 CORP/EMP 4 – Fair Treatment for All Policy
 CORP/EMP 27 – Equality Analysis Policy

10 DATA PROTECTION

Any personal data processing associated with this policy will be carried out under ‘Current data protection legislation’ as in the Data Protection Act 2018 and the General Data Protection Regulation (GDPR) 2016).

For further information on data processing carried out by the trust, please refer to our Privacy Notices and other information which you can find on the trust website:

<https://www.dbth.nhs.uk/about-us/our-publications/uk-data-protection-legislation-eu-general-data-protection-regulation-gdpr/>

11 REFERENCES

Medicines, Ethics and Practice Edition 43 July 2019. Royal Pharmaceutical Society

Misuse of Drugs Act 1971 as amended

Professional Guidance on the Administration of Medicines in Healthcare Settings (2019)
 Royal Pharmaceutical Society

Professional Guidance on the Safe and Secure Handling of Medicines (2018) Royal
 Pharmaceutical Society

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

The Health Act 2006 as amended

The Misuse of Drugs Regulations 2001 as amended

The Misuse of Drug (Safe Custody) Regulations as amended

Department of Constitutional Affairs

Mental Capacity Act (2005): Code of Practice, 2007 www.dca.gov.uk

APPENDIX 1 – SUMMARY OF CONTROLLED DRUG REQUIREMENTS FOR WARDS

	Ordering	Receipt	Storage	Recording in CD Register	Single/Two person Authorised Administration	Storage of Patients' Own	Prescription Requirements for outpatients and TTOs
Schedule 2 CD POM							
E.g. Diamorphine Inj. Pethidine Tablets, MST Tablets, Ketamine	Signed Requisition	Signed Receipt	CD Cupboard	Yes	Two Persons	CD Cupboard	Yes
Schedule 3 CD No Register POM							
E.g. Barbiturates, Buprenorphine, and including Temazepam , unless specified below	Signed Requisition	Signed Receipt	CD Cupboard	Yes	Two Persons	CD Cupboard	Yes
Exceptions to S3 requirements above							
Tramadol preparations	Signed Requisition	Signed Receipt	CD Cupboard	Yes	One Person	CD Cupboard	Yes
Gabapentin preparations	Signed Requisition	Signed Receipt	CD Cupboard	Yes	One Person	CD Cupboard	Yes
Pregabalin preparations	Signed Requisition	Signed Receipt	CD Cupboard	Yes	One Person	CD Cupboard	Yes
Midazolam 10mg/2ml Injection	Signed Requisition	Signed Receipt	CD Cupboard	Yes	Two Persons	CD Cupboard	Yes

	Ordering	Receipt	Storage	Recording in CD Register	Single/Two person Authorised Administration	Storage of Patients' Own	Prescription Requirements for outpatients and TTOs
Other Midazolam Preparations including buccal preparations	Signed Requisition	No	Locked Medicines Cupboard	No	In accordance with general policy	Locked Medicines Cupboard or Patients' Individual Patient Cabinet	Yes
Schedule 4 CD Benz POM and CD Anab POM							
E.g. diazepam, zopiclone	No signed requisition	No	Locked medicine cupboard	No	No	Locked medicine cupboard	No
CD Schedule 5 Inv POM and CD Inv P							
Morphine Sulphate Oral Solution 10mg/5ml	Signed Requisition	Signed Receipt	CD Cupboard	Yes	Single Person	CD Cupboard	No
Other Requirements							
Strong Potassium Injections, e.g. Strong Potassium Chloride Solution 15%	Signed Requisition	Signed Receipt	CD Cupboard	Yes	Two Persons	NA	No

APPENDIX 2 - EQUALITY IMPACT ASSESSMENT PART 1 INITIAL SCREENING

Service/Function/Policy/Project/Strategy	Division	Assessor (s)	New or Existing Service or Policy?	Date of Assessment
Safe and Secure Handling of Medicines Policy Part B: Controlled Drugs	Trust Wide	Liz Monaghan	Existing	June 2021
1) Who is responsible for this policy? Drug and Therapeutics Committee				
2) Describe the purpose of the service / function / policy / project/ strategy? To ensure the safe and secure handling of Controlled Drugs				
3) Are there any associated objectives? Ensure compliance with national legislation, CQC standards and national best practice guidelines				
4) What factors contribute or detract from achieving intended outcomes? Non-compliance with policy				
5) Does the policy have an impact in terms of age, race, disability, gender, gender reassignment, sexual orientation, marriage/civil partnership, maternity/pregnancy and religion/belief? No				
<ul style="list-style-type: none"> If yes, please describe current or planned activities to address the impact [e.g. Monitoring, consultation] – 				
6) Is there any scope for new measures which would promote equality? N/A				
7) Are any of the following groups adversely affected by the policy?				
Protected Characteristics	Affected?	Impact		
a) Age	No			
b) Disability	No			
c) Gender	No			
d) Gender Reassignment	No			
e) Marriage/Civil Partnership	No			
f) Maternity/Pregnancy	No			
g) Race	No			
h) Religion/Belief	No			
i) Sexual Orientation	No			
8) Provide the Equality Rating of the service / function /policy / project / strategy – tick (✓) outcome box				
Outcome 1 ✓	Outcome 2	Outcome 3	Outcome 4	
<i>*If you have rated the policy as having an outcome of 2, 3 or 4, it is necessary to carry out a detailed assessment and complete a Detailed Equality Analysis form – see CORP/EMP 27.</i>				
Date for next review:				
Checked by: Rachel Wilson			Date: June 2021	