Barts Health NHS Trust

TRUST CLINICAL POLICY
CONTROLLED DRUG POLICY

APPROVING COMMITTEE(S)	Trust Policies Committee	Date approved:	15/09/16
EFFECTIVE FROM	Date of approval		
DISTRIBUTION	All Clinical areas		
RELATED DOCUMENTS	Medicines Management Policy Injectables Policy Incident Reporting Policy PCA/Epidural Policy Acute Pain Policy		
STANDARDS	Controlled Drugs (Supervision of management and use) Regulations 2013 DOH Regulations Statutory Instrument 2013/373 Misuse of Drugs Act 1971 Misuse of Drug Regulations 2001 Medicines, Ethics and Practice, Royal Pharmaceutical Society Medicines Management Standards, NMC		
OWNER	Chief Nurse		
AUTHOR/FURTHER INFORMATION	Lead Nurse Medicines Management		
SUPERCEDED DOCUMENTS	CLI/POL/147/2015-002		
REVIEW DUE	3 years after approval		
KEYWORDS	Controlled drugs, CD		
INTRANET LOCATION(S)	http://bartshealthintranet/Policies-and-Guidelines/Trust-wide-policies.aspx		

CONSULTATION	*Barts Health*	Site pharmacy departments Controlled Drug Accountable Officer Metropolitan Police CD Liaison Officer Site Directors of Nursing Medicines Governance Board
	External Partner(s)	*N/A*

SCOPE OF APPLICATION AND EXEMPTIONS	**Included in policy:** *For the groups listed below, failure to follow the policy may result in investigation and management action which may include formal action in line with the Trust's disciplinary or capability procedures for Trust employees, and other action in relation to organisations contracted to the Trust, which may result in the termination of a contract, assignment, placement, secondment or honorary arrangement.*
	This policy applies to all Trust staff. This policy does not apply to workers provided by independent contractors providing a contract for service to the Trust or any other workers. Those working for CHL and its Service Providers are not expected to comply with this policy
	Where the policy applies to individuals employed by other organisations the contractor will be specifically advised.

1 INTRODUCTION

1.1 This Controlled Drug (CD) policy applies either to drugs controlled under Schedule 2 of the Misuse of Drugs Act 1971, or to drugs from other schedules that senior nurses and pharmacists have agreed should be treated as Schedule 2 controlled drugs (CDs) in the Trust (See Appendix 7). The legal requirements pertaining to the main groups of CDs are summarised in *(Appendix 9).*

1.2 The Misuse of Drugs Act 1971 dictates how CDs are held and managed within a clinical area.

1.3 Additional statutory measures for the management of CDs are laid down in the Health Act 2006 and its associated regulations.

1.4 The Trust is accountable, through the Controlled Drug Accountable Officer (CDAO), who is the Chief Nurse, for ensuring the safe management of CDs.

1.5 A duty of collaboration is placed on the Trust to share intelligence with other local and national healthcare organisations, including professional regulatory bodies, police forces,the Care Quality Commission and MHRA on CD issues

2 SUMMARY OF THE POLICY

2.1 This policy lays down the rules for the safe and secure handling of CDs. It covers responsibilities, how CDs are supplied to clinical areas and patients, how they must be stored and who has the authority to prescribe. It details what needs to appear on a prescription and how they must be administered. It also covers the loss and disposal of CDs.

3 DUTIES AND RESPONSIBILITIES

All staff	Report any incidents related to CDs of which they become aware.
All staff who are involved in the prescribing, supplying, administering or disposing of CDs, or who manage such staff	Be familiar with the SOPs relevant to their work areas and work as set out in these. Escalate any concerns about related matters and report any incidents that occur. Maintain practice in line with the table overleaf, which details which categories of staff can undertake which roles within this policy.
The Controlled Drug Accountable Officer (CDAO)	The CDAO is the Chief Nurse within Barts Health NHS Trust. The CDAO is responsible for all aspects of the safe and secure management of CDs within the Trust. This includes ensuring that safe systems are in place for the management and use of CDs, monitoring and auditing the management systems and investigation of concerns and incidents related to CDs. The CDAO must ensure there are adequate and up-to-date

	SOPs in place in relation to the management and use of CDs. All SOPs must be formally approved by the CDAO or a nominated deputy, although the CDAO retains final responsibility. The regulatory requirements for CDAOs are set out in full in the Controlled Drugs (Supervision of Management and Use) Regulations DOH 2013; The CDAO must ensure that there are adequate and up-to-date SOPs in place in relation to the management and use of CDs.
Committees	The Medicines Safety Committee is responsible for monitoring incidents through Datix and to ensure appropriate escalation to the CDAO and relevant Central, Site and CAG governance teams.

Task	**Authority to undertake**	**Acceptable witness**	**Notes**
Ordering CDs for wards and departments (definition to include theatres through CD policy)	Registered nurse (RN), Registered midwife (RM), Registered Operating Department Practitioner (RODP) Must be a substantive member of staff.	n/a	In the absence of an approved signatory on the ward or department, signature must be obtained from site manager, matron or directorate senior nurse
Collecting/Delivering CDs for wards and departments from pharmacy	Authorised messenger may sign for sealed bag containing CD. This includes porters with specific validated training or RNs, RMs or RODPs authorised by the RN, RM or RODP in charge.	n/a	CDs can only be collected by a porter with validated specific training, RN, RM or RODP The person collecting the CD must be different to the person ordering the CD
Accepting delivery of CDs on wards and	RN, RM, RODP	n/a	The person accepting the CD must be a RN, RM, RODP different to the

departments			person ordering the CD
Task	**Authority to undertake**	**Acceptable witness**	**Notes**
Transferring CDs from one CD Register to another	RN, RM, RODP	RN,RM, RODP, 3rd year student nurse who has completed their medicines management training, pharmacist	
Administration of CDs	RN, RM, RODP, doctor	RN, RM, RODP, 3rd year student nurse who has completed their medicines management training, pharmacist, doctor, radiographer	Two members of staff must be involved in all stages of the administration of CDs i.e. preparation, administration and destruction of any surplus
Checking of ward and department CD stocks	RN, RM, RODP Must be a substantive member of staff	RN, RM, RODP, 3rd year student nurse who has completed their medicines management training,	Must be carried out at least once every 24 hours Staff undertaking should rotate periodically
Carrying out ward/ and department CD audit	Pharmacist, accredited pre-registration trainee pharmacist, accredited pharmacy technician	RN, RM, RODP/ 3rd year student nurse who has completed their medicines management training,	Must be carried out at least once every 3 months
Returning CDs to pharmacy from ward and department	RN, RM RODP	Pharmacist, pre-registration trainee pharmacist, accredited pharmacy technician	Acceptable for either RN, RM, RODP or pharmacy staff to make entries in CD Register, witness to countersign
Destroying CDs in pharmacy	Person authorised by the CDAO	Pharmacist, pre-registration trainee pharmacist,	For best practice, patients own CDs, morphine sulphate oral solution 10mg in 5 ml

		accredited pharmacy technician	and temazepam, ketamine, buprenorphine and phenobarbital recorded in CD Destruction Register
Destroying CDs in wards	Only part used vials can be destroyed or doses prepared and then refused by the patient.	Second checker must witness destruction.	Liquid doses to be destroyed should be pour onto a paper towel and then put in the yellow bin to denature them.

4 GENERAL MANAGEMENT OF CDS

Standard Operating Procedures (SOPs)

4.1 The CDAO is responsible for ensuring that each of the activities that relate to CDs within the Trust is described in a SOP *(for more information on SOPs see the Trust Policy on the Safe and Secure Handling of Medicines)*.

4.2 SOPs must be kept up-to-date, reflecting current legal and good practice requirements for CDs, and each one must be clearly marked with the date of issue and review date. All SOPs must be formally approved by the CDAO or a nominated deputy, although the CDAO retains final responsibility.

4.3 All staff who are involved in the prescribing, supplying, administering or disposing of CDs must be familiar with the SOPs.

4.4 The SOPs must cover the following:

- Who has access to the CDs
- Where the CDs are stored
- Security in relation to the storage and transportation of CDs as required by the misuse of drugs legislation.
- Disposal and destruction of CDs
- Who is to be alerted if complications arise
- Record keeping including:
  - Maintaining CD Registers
  - Maintaining a record of schedule 2 CDs that have been returned by patients.

CD Registers

4.5 All stationery which is used to order, return or distribute CDs must be stored securely and access to it must be restricted to authorised persons. On ward and departments these must be locked in CD cupboards. Once completed, CD Registers must be stored on wards or departments for 2 years since the last date of entry and then destroyed via confidental waste. Dispensary CD Registers recording return to the pharmacy department must be retained for 2 years from the last date of entry.

4.6 The order form for a new CD Register (found towards the end of the CD Register on page 96 and the Patient's own and To Take Away (TTA) CD Register) should be used for ordering a new CD Register. This must be signed by the RN, RM, or RODP in charge.

4.7 Any unused CD stationery returned to pharmacy will be recorded as a return, with the details above in the supply record. Loss or theft of any CD stationery which may be used to order CDs must be reported immediately to the Director of Pharmacy and Medicines Management and the CDAO.

4.8 Each ward or department that hold stocks of schedule 2 CDs must keep a record of CDs received and administered in the CD Register. Patients bringing in their own CD supplies must hand the CDs to a RN or RM who will record this in the Patient's own and TTA CD Register. The TTA CD Register will also be used to record CDs supplied by pharmacy for patients on discharge. The RN or RM in charge is responsible for keeping the CD Record and the Patient's own and TTA Register up to date and in good order.

4.9 When the total stock of a CD supplied on a requisition in the CD Register has been administered, the corner of the right-hand side of the page with the administration details must be torn off to show that the page is complete.

4.10 In the case of the Patient's own and TTA Register, once the patient has been discharged, transferred or the patient's own stock returned (either to pharmacy or to the patient) the corner of the page must be torn off to show that the page is complete.

4.11 All entries must be signed by a RN, RM, or RODP and witnessed preferably by a second RN, RM or RODP. If a second RN, RM or RODP is not available, the transaction can be witnessed by another registered practitioner e.g. doctor, pharmacist, or a third year student nurse who has completed their medicines management training.

4.12 If a mistake is made, it must not be obliterated, it can be crossed through with a simple line and error annoted and signed by two RNs, RMs or RODPs. The information underneath must be readable. It can also be bracketed [ ] in such a way that the original entry is still clearly legible. This must be signed, dated and witnessed by a second RN, RM or RODP, other registered professional e.g. doctor, pharmacist, or a third year student nurse who has completed their medicines management training. The witness must also sign the correction. The correct entry must be made on the next available line or as a footnote.

4.13 As with all other patient related documentation, CD orders/records must be made in chronological order in ink or be otherwise indelible to ensure that any photocopies, made at a later date for legal purposes, are legible.

4.14 All other documentation designed to track,monitor and audit CD usage must also be kept for 2 years after the last entry or date of use.

Transferring CDs from one CD Register to another

4.15 Only two CD Registers and Patient's own and TTA Register must be in use per ward or department. When a new CD Register is started, the balance of CDs in stock must be written into the new book promptly by a RN, RM or RODP. This

transfer must be witnessed by a RN, RM, RODP or authorised member of staff e.g. pharmacist, an accredited pharmacy technician, or a third year student nurse who has completed their medicines management training.

4.16 The transfer of CDs from an old to a new CD Register must always be undertaken promptly by a RN, RM or RODP who must sign and date both CD Registers.

4.17 This transfer should be witnessed by a RN,RM or RODP or authorised member of staff e.g. pharmacist, an accredited pharmacy technician, or third year student nurse who has completed their medicines management competency.

4.18 The new requisition number must be written in the old CD Register.

4.19 The name of the CD, form, strength and quantity must be recorded in the new CD Register with the old requisition number

4.20 The order number on the container should be altered to reflect the new number

4.21 The order slip should be voided and detached from the CD Register and kept in the CD cupboard until the three monthly pharmacy checks.

5 SECURITY OF CDS

5.1 CDs on wards and departments are ultimately the responsibility of the RN, RM or RODP in charge of the area. That person may decide to delegate some of his/her duties e.g. key holding, to another for ease of access. However the ultimate responsibility remains with the RN, RM or RODP in charge of the area

Keys

5.2 The RN, RM or RODP in charge is responsible for the CD keys, and must be aware of their location or who is in possession of them at all times.

5.3 The CD keys **MUST** be kept separate from the main drugs key ring which must be kept on the person of the nurse in charge of the ward. Spare keys may be stored in a suitably secure location in agreement with Risk Management, Pharmacy, the Senior Nurse and the CDAO.

5.4 Access to keys must be restricted to persons authorised under the Misuse of Drugs Act, i.e. a pharmacist, the RN, RM or RODP in charge. The legal responsibility rests with the RN, RM or RODP in charge

5.5 On occasions, for the purpose of stock checking, the CD key may be handed to an authorised member of the pharmacy staff e.g. the pharmacy technician responsible for stock control of medicines on the ward or pre-registration trainee pharmacist, on production of a valid Trust ID badge. The key must be returned immediately after use.

5.6 Key-holding may be delegated to other suitably-trained, registered healthcare professionals RN, RM, RODP on shift, but the legal responsibility rests with the RN, RM or RODP in charge who must be aware of where the keys are at all times.

5.7 When new locks are installed, or new cupboards purchased the keys for the locks must be restricted and unable to be copied without authorisation.

Missing CD keys

5.8 If the CD keys cannot be found then urgent efforts should be made to retrieve the keys as timely a manner as possible; e.g. by contacting nursing, midwifery or ODP staff who have just gone off duty.

5.9 The RN, RM or RODP in charge must ensure the security of the CDs held in the clinical area is maintained, and that patient care is not impeded.

5.10 In all instances the Senior nurse, midwife manager, Site Management Team and the ward pharmacist (or on-call pharmacist out of hours) must be informed as soon as possible. Their responsibility must be to follow the procedure for investigating and reporting missing keys.

5.11 If the keys cannot be found, the estates and facilities helpdesk must be contacted to open the cupboard and replace the lock as soon as possible.

5.12 The Chief Pharmacist, Director of Nursing, CDAO, Clinical Risk and the Medicines Safety Pharmacist or Lead Nurse Medicines Management must be informed of the missing keys.

5.13 If a spare key is available this can be used. However, there must be a full CD balance check performed at each shift handover until the lock is changed.

5.14 If no spare key is available CDs must be borrowed from adjacent wards until alternative arrangements can be made in consultation with pharmacy.

5.15 In all cases a Trust Datix incident report form must be completed together with a report of the actions taken and sent to the ward and department manager.

Checking stock of CDs

5.16 A stock balance check of CDs within a clinical area involves checking the balance in the CD Register and Patient Own and TTA CD Register against the contents of the CD cupboard, not the reverse, using the register as the primary source. This **MUST** be performed at least once every 24 hours; however the frequency of this check may be varied for local operational reasons e.g. five day wards by the senior nurse in charge of the clinical area in consultation with the nurse manager and senior pharmacist. Some clinical areas may choose, or be required for monitoring purposes, to check their stocks at every change of shift.

5.17 Two RNs, RMs, RODPs or registered health professionals such as Pharmacists should perform this check. Where possible the staff undertaking this check should be rotated periodically. Bank staff who work regularly in the ward or department who have completed their Trust medicines management training and third year student nurses who have completed their medicines management training may check CD stock provided that the other person checking is a substantive member of qualified nursing staff.

5.18 Providing that a manufacturer's seal on a container is intact, it is not necessary to open the pack for stock checks.

5.19 Stock balances of liquid medicines must be checked by visual inspection but there must also be periodic volume checks e.g. once a month. The balance must be confirmed to be correct on completion of a bottle. It is best practice that oral medications are drawn out of those bottles using medication syringes that are comptiable with the purple oral/enteral syringes.

5.20 A record of the daily CD stock check must be made in the CD Register on the left hand side of the page, entering date, time of check and whether the amount present is correct. Both members of staff must sign the record.

5.21 The RN, RM or RODP in charge is responsible for ensuring that the regular CD stock check is carried out by staff in the ward or department.

5.22 The security, stock levels and overall completion of CD records (including daily checks) must be checked by a pharmacist or pharmacy technician with a RN, RM or RODP, once every three months. Both must record that they have done this in ink in the CD Register by signing and dating the CD Register.

5.23 It is the responsibility of the Site/CAG Pharmacist to ensure that the pharmacy checks are organised and carried out to a minimum of three monthly. This should be organised and agreed to a mutually convenient time with the wardor department manager.

5.24 The pharmacy CD audit must cover the following: The audit will cover both the main Trust CD Register and the Patients Own and TTA CD Register where a ward or department has both.

- A check that the levels of drugs in stock tally with the balances recorded in the CD Register.
- Check that every page that has been completed has a zero balance.
- A check of a sample of CD orders to ensure that they have been entered correctly in the CD Register
- A check of a sample of recording of administration records on drug charts, comparing this to the record in the CD Register
- A review of the security and quality of record keeping
- Check the signature list and highlight to the ward manager any discrepancies.
- A check for exceptional usage of CDs
- A check of the physical security arrangement for the storage of CDs, CD stationery and the key-holding policy
- A check of the audit trail of CDs returned from the ward or department during the previous 6 month period
- Reconcile any voided requisition slips* and sign the bottom right of the page in the CD Register. The voided slip may then be destroyed. *generated when CDs are transferred from one page to another in a CD Register.
- A check of patient's own CDs held on the ward at the time.

- Check to ensure all pages are accounted for
- Check to ensure CDs needing return to pharmacy are not allowed to accumulate for excessive periods
- Ensure that CDs are only transferred from one page to another when that page is complete and that quantities are carried forward correctly.

5.25 The pharmacy will report audit results and any action needed back to the senior nurse and the clinical pharmacist who must agree and implement an action plan. A record of the audit and action plan must be recorded on the central pharmacy database.

5.26 Any ward or department that fails to achieve a an acceptable score on the CD audit check will be re-audited one month after the original audit when all problems must have been resolved. Monthly audits will continue until the area passes all aspects of the audit.

5.27 The CDAO and Chief Pharmacist must be regularly updated on the results of the CD audits and all action plans.

5.28 It is important to avoid large quantities of voided slips accumulating in ward or departments. The pharmacy department can be contacted in between the audits to reconcile these slips and destroy them if necessary.

Loss of CDs

5.29 Any discrepancy between the contents of the CD cupboard and the balance in the CD Register or loss of medicines from a clinical area must be investigated immediately by the RN, RM or RODP in charge, (Appendix 11). During the first 24 hours the nurse in charge in consultation with the ward pharmacist must attempt to track back the medication.

5.30 In the first instance the following should be carefully checked:

- All requisitions received have been entered into the correct page of the CD Register.
- All CDs administered have been entered into the CD Register.
- Items have not been accidentally put into the wrong place in the cupboard.
- Arithmetic to ensure that balances have been calculated correctly.

5.31 For morphine sulphate oral solution 10mg/5ml bottles of 100ml a variation of +/- 5ml of the stated volume is acceptable, and does not require reporting as an incident. Where there is a variation in the actual volume (within the 5% limit), pharmacy and the RN, RM or RODP in charge must both sign the page in the CD Register stating that there was a discrepancy of +/- x ml.

5.32 If the loss, error or omission is traced, the registered RN, RM or RODP in charge must make an entry in the CD Register, clearly stating the reason for the entry and the corrected balance. This entry must be witnessed by a second RN, RM, RODP, pharmacist, accredited pharmacy technician or doctor. Both persons must sign the CD Register. The nurse in charge must decide upon the most appropriate course of action e.g. staff education, supervision and revised protocols. An incident form must be completed, noting the local action. The

CAG Governance Lead must make further enquiries as per Trust incident management protcols.

5.33 In normal working hours: If a discrepancy is not resolved or if there is immediate cause for concern the Site or CAG pharmacist, the RN, RM or RODP in charge of the ward or departmentmust immediately report this to one of the following:

- CDAO
- Lead Nurse Medicines Management
- Chief Pharmacist
- Relevant Senior Nurse or Senior Midwife for the area.

5.34 The person contacted will contact the other staff on this list. A datix from must be completed. CDs loss are no longer classed as an SI in the 2015/2016 framework but it is good practice that these are followed through with a local meeting to ensure due diligence is followed. A decision must be made as to whether the police should be informed. Listed below are the circumstances when the police must be notified:

- A substantial amount of CDs were deemed as missing/stolen.
- A pattern had emerged in a specific area and which had been raised as a concern through audit and pharmacy practices.
- An area had been forced into and drugs stolen.

5.35 Outside Normal Working hours: If a discrepancy is identified the RN, RM or RODP in charge of the ward or department must contact the out of hours pharmacist and they must work together to try and account for the error. If the discrepancy cannot be rectified the site manager must be contacted via the switchboard. The site manager must then decide whether the incident must be escalated to the Silver On-call or wait until the next normal working day to alert the staff listed in point 5.35.

5.36 A RMs records related to the administration of medicines must be regularly audited by their named supervisor of midwives and any concerns must be reported to the CDAO and the Local Supervising Authority Midwifery Officer.

5.37 Staff in any supervisory position must be aware of the signs that may indicate abuse or diversion of medicines e.g. changes in an individual's behaviour such as; lack of concentration, regular unexplained absences from the work area, a change in character, odd behaviour, or other changes such as loss of stock, excessive ordering, and take appropriate action.

Safeguarding children issues

5.38 Parents who are substance misusers sometimes bring CDs on to hospital premises if their child is an inpatient and they are staying with them on the ward. On a parents request the CD may be stored in the CD cupboard. The CD must be recorded in the Patients Own and TTA CD Register. The parent should request a dose from the nurse when required. These CDs must be clearly labelled and kept separate from other CDs.

5.39 If ward staff become concerned about the safety and welfare of the children for any reason in these circumstances they must refer to the BH Safeguarding

Children Policy for advice and support or seek advice from the Safeguarding Children Team.

6 PRESCRIBING CDS

6.1 CDs can be prescribed or supplied by the following mechanisms.

6.2 Prescription by a medical doctor or dentist – schedule 2, 3, 4 and 5 drugs. Prescription by supplementary prescribers – when acting under, and in accordance with, the terms of a clinical management plan to administer, supply and /or give direction to administer CDs in schedules 2, 3, 4 and 5. Independent Nurse Prescribers may prescribe a range of CDs for specific conditions; see the current British National Formulary.

6.3 An accredited RN can supply or administer diamorphine under a Patient Group Directive (PGD) for the treatment of cardiac pain to a patient admitted to the coronary care unit or accident and emergency department.

6.4 RNs, RMs, pharmacists, paramedics, health visitors, chiropodists, orthoptists, physiotherapists, radiographers, dieticians, speech and language therapists and occupational therapists can supply or administer any schedule 4 or 5 CD in accordance with a PGD (except anabolic steroids in schedule 4, part 2 or injectable formulations for the purpose of treating a person who is addicted to a drug).

6.5 When prescribing 'when required' controlled drugs:

- Document clear instructions for when and how to take or use the drug in the person's Medical Record.
- Include dosage instructions on the prescription (with the maximum daily amount or frequency of doses) so that this can be included on the label when dispensed
- Ask about and take into account any existing supplies the person has of 'when required' controlled drugs.
- Use a recognised opioid dose conversion guide when prescribing, reviewing or changing opioid prescriptions to ensure that the total opioid load is considered.

Prescribing CDs for NHS outpatients and discharge medication

6.6 This information must be written so as to be indelible i.e. by hand or computer generated. Only the signature has to be in the prescriber's own handwriting.

6.7 The prescriptions for schedule 2 and 3 CDs (with the exception of those medication indicated by legislation) must include the following:

- The patient’s full name, address and where appropriate, age
- The drug name and form (e.g. tablets), even if only one form exists

- Dosage form release characteristics e.g. M.R
- Strength, dose and frequency
- Route
- State in **words and figures** either the **total quantity** of the CD or the **total number** of CD dose units to be supplied;
- If more than one strength of a medicine is to be supplied then each strength must be specified and the number of e.g. tablets must be stated in words and figures.
- For "when required" drugs a minimum interval for administration must be specified e.g. Every six hours and a maximum total quantity to be administered in 24 hours;
- The prescription must be signed (not just initialled) and dated by the person authorising the prescription with his/her usual signature. The date does not have to be handwritten;
- The prescriber must also clearly print name and bleep/contact number.
- CD TTA's require a hard copy signature.
- Document and give information to the person taking the controlled drug or the carer administering it, including:
- how long the person is expected to use the drug
- how long it will take to work
- what it has been prescribed for
- how to use controlled drugs when sustained-release and immediate-release
- formulations are prescribed together
- how it may affect the person's ability to drive (see the advice from the Department of Transport on drug driving and medicine: advice for healthcare professionals)
- that it is to be used only by the person it is prescribed for.

6.8 Medical doctors who have not achieved full registration with the GMC are permitted to prescribe CDs (and other Prescription Only Medicines - POMs) for inpatient use and on Trust discharge prescriptions so far as is necessary for the purposes of their employment as defined in the Medical Act 1983. **Pre-registration doctors (FY1) are not permitted to write outpatient prescriptions.**

6.9 Prescriptions for schedule 2, 3 and 4 CDs will be limited to a quantity necessary for up to 30 days clinical need for outpatients, and 14 days for discharge medication. In circumstances where the prescriber believes that a supply of more than 30 days is clinically indicated, and would not pose an unacceptable risk to patient safety, the prescriber must make a record of the reasons in the patient record and should be ready to justify this decision if required.

6.10 When a prescription for a CD does not comply with the CD prescription requirements, a pharmacist may amend a prescription in the following circumstances:

- Minor spelling mistakes
- Minor typographical mistakes
- Where the total quantity of the preparation of the CD or the number of dosage units as the case may be is specified in either words or figures but not both, i.e. either the words or the figures can be added to the CD prescription if one or the other has been omitted.

  (In the event of any such amendment, the pharmacist must ensure that the prescription is marked so that the amendment made is attributable to him or her, i.e. signed and dated)

6.11 In all other circumstances the doctor must be contacted and asked to amend and countersign any prescription for a CD that does not comply with legal requirements, before it is supplied. If the original prescriber is not available it is acceptable that another prescriber countersigns the changes, and that a note of the change is made in the patient's medical record or ETTA.

6.12 It is illegal for a prescriber to issue and for a pharmacist to dispense an incomplete or incorrectly written prescription for a CD.

6.13 If a hospital prescriber issues an FP10 (HNC) form for dispensing in a community pharmacy, the clinic code (printed on the prescription) is acceptable as an alternative to the prescriber's personal number, as hospital prescribers do not have personal numbers.

6.14 Authorised prescribers must not prescribe CDs for themselves or family members.

6.15 When prescribing controlled drugs outside general practice (for example in hospital or out of hours), inform the person's GP of all prescribing decisions and record this information in the person's care record so the GP has access to it. When sharing information take into account the account the following 5 rules

6.16 **Confidential information about service users or patients should be treated confidentially and respectfully.**

6.17 **Members of a care team should share confidential information when it is needed for the safe and effective care of an individual.**

6.18 **Information that is shared for the benefit of the community should be** anonymised.

6.19 An individual's right to object to the sharing of confidential information about them should be respected.

6.20 Organisations should put policies, procedures and systems in place to ensure the confidentiality rules are followed.

Prescribing CDs for inpatients

6.21 Inpatient medication charts and anaesthetic charts are an instruction to administer a medicine within the hospital.

6.22 When using these charts the handwritting requirements for CDs i.e in words and figures do not need to be satisfied, so these can be prescribed as for any other medication.

Prescribing intravenous bolus doses of opiates for inpatients

6.23 Whenever possible, intravenous bolus doses of opiates must be avoided.

6.24 Intravenous bolus doses of opiates must only be prescribed for the following patients within the Trust:

- Patients receiving an IV bolus opiate as part of a Patient Controlled Analgesia (PCA)/Nurse Controlled Analgesia Programme *(refer to PCA Policy)*
- Patients being treated for acute myocardial infarction or acute pulmonary oedema (refer to relevant IV Monograph)
- Patients during anaesthesia, and in the immediate post-operative period in Recovery where under close continuous supervision
- Patients with clotting deficiencies (e.g. thrombocytopenia, haemophilia) where an intramuscular injection, and sometimes a subcutaneous injection are inappropriate
- Patients receiving an intravenous bolus under the direct supervision of a doctor (e.g. in ITU, theatres and in monitored areas of A&E) or a member of the Pain Team
- Patients receiving intravenous bolus doses of pethidine to treat rigors associated with certain chemotherapy agents.

Prescribing equivalent parenteral morphine doses

6.25 As most opiates have differing bioavailability when administered by different routes, it is important to ensure that each route is separately prescribed where the dose varies. For example:

Intramuscular Injection	Subcutaneous Injection	Slow Intravenous Injection
10mg	10mg	2.5mg to 5mg

6.26 If non equivalent doses are prescribed, e.g. morphine 10mg i.v./s.c./i.m. the prescriber must be contacted and the i.v. bolus dose stopped or re-prescribed at a lower dose. If the prescriber is unavailable and the intravenous bolus dose inappropriate a pharmacist may stop the intravenous dose and countersign the chart “as per policy”, initial, add contact details and date in green ink.

6.27 If an intravenous bolus dose is prescribed as the only route and this is not appropriate the prescriber must be contacted to change to a safer route of *administration* and dose as appropriate. A pharmacist must annotate the chart after contacting the prescriber, countersign with their initials, add contact details and date in green ink.

6.28 When “when required” intravenous bolus doses are prescribed, limits on bolus size and the maximum ***total*** dose which may be given must be clearly stated as

well as a specified dosing interval (eg. morphine 5mg IV up to every two hours to a total maximum dose of 10mg).

Prescribing diamorphine, dipipanone or cocaine for addiction

6.29 Registered medical practitioners may prescribe diamorphine or dipipanone for patients (including addicts), for the relief of pain due to organic disease or injury, without a special licence.

6.30 Specialist licences are required for the prescribing of diamorphine, dipipanone or cocaine for the treatment of opiate addiction/dependence.

6.31 If a patient is admitted who is receiving such a prescription, this must be confirmed both verbally and in writing by the usual prescriber. It is then at the discretion of the hospital medical team as to whether or not they continue to prescribe it. If continuing to prescribe, the prescriber must inform the community pharmacist and community prescriber to stop the supply until notified otherwise. The time and date of the last dose supplied in the community must be determined and recorded in the patient's medical record.

6.32 Discharge arrangements must be as point 6.45 below and advice must be sought from Specialist addictions unit.

Specific CD management for RMs

6.33 In law, a RM may possess diamorphine, morphine, pethidine and pentazocine in her own right so far as is necessary for the practice of their profession. At the Trust RMs do not have a need to keep their own supplies of these drugs. The use of CDs in midwifery is therefore covered by the content of this policy.

6.34 An exemption in the Medicines Act 1998 enables RMs to supply and administer pethidine to patients in their care, without a prescription signed by a doctor. At the Trust the handling of pethidine by midwives is included in a local directive, akin to a PGD

Prescribing in Paediatric services

6.35 Often the dose required for paediatric patients is smaller than that contained in a single vial or ampoule and so when a dose is given, an amount is left to be discarded. In order to minimise the opportunities for diversion, when a dose is given, the nearest suitable dose unit containing the nearest suitable volume to the dose prescribed must be selected, so that the minimum has to be discarded.

6.36 In areas where large quantities of CDs are used and there are a high volume of part used vials, ampoules and syringes and infusion bags for destruction a denaturing kit may be used on the ward or department following a risk assessment.

Prescribing CDs for a new case or suspected case of addiction

6.37 Doctors must not initiate opiate treatment for patients during an acute admission without advice from the specialist addiction unit (SAU). Doctors can continue to prescribe for registered substance misusers. If a substance misuser is admitted to hospital, the prescriber must check the drug and dose routinely prescribed in the community with the community prescriber or pharmacist and

ascertain when the last supply was made. The prescriber must inform the community pharmacist and community prescriber to stop the supply until notified otherwise. The time and date of the last dose supplied in the community must be determined and recorded in the patient's medical record.

6.38 If a substance misuser is experiencing pain, the Pain Team should be consulted for advice on pain management or the on call anaesthetist.

6.39 On discharge, it is the prescriber's responsibility to liaise with the community prescriber or specialist addiction unit to arrange for community supplies of medication to be made or re-instated. The hospital prescriber must confirm with the community prescriber and community pharmacist when the last dose was administered to the patient in the hospital. The hospital will only supply sufficient medication to cover the period until community supplies resume. If this is for more than one day, the patient must return to the hospital for daily supplies until the community supply is re-instated. Administration must be witnessed and recorded on the in-patient drug administration chart. It may be more appropriate to supply the patient with max 2 day supply for weekends or a max 3 day supply for bank holidays.

7 CONTROLLED DRUGS PATHWAY

Ordering

7.1 A list of stock item CDs must be held in each ward or department. The contents of the list must reflect current patterns of usage of CDs in the ward or department and must be agreed between the pharmacist or pharmacy technician responsible for stock control of medicines on the ward and the RN, RM or RODP in charge. The list must be modified if practices change and must be reviewed six monthly

7.2 The RN, RM or RODP in charge of a ward or department is responsible for the requisitioning of CDs for use in that area. If the ward or department is managed by someone other than a nurse or midwife, the most senior RN or RM present is responsible for CDs under the present regulations.

7.3 The RN, RM or RODP in charge can delegate the task of preparing a requisition to another, such as a RN, RM of RODP. However, legal responsibility remains with the RN, RM or RODP in charge.

7.4 Only permanently employed (not bank or agency) RNs, RM or RODPs can order CDs on a requisition form in the CD Register. If none of these staff are available, the requisition must be signed by the site manager or matron, or senior RN or RM for the area.

7.5 Use a new page in the CD Register to order CDs. At the top of the right hand page enter the name form, strength and quantity of drug ordered. The RN, RM or RODP ordering the CD must also print and sign their name and add the date of the order.

7.6 On the requisition slip the following details must be completed:

- hospital name

- ward/department
- drug name, form and strength
- quantity to be ordered
- name of the person ordering the CD and date
- Signed by an authorised signatory.

7.7 Anyone ordering CDs must sign the order and then print their initials and surname. This is to assist both the pharmacy in identifying the person ordering and to facilitate any audit trail/queries thereafter.

7.8 Completed orders must be detached from the CD Register and taken to pharmacy by an RN, RM or RODP, sent to the pharmacy via the pharmacy porter with validated training, or given to a member of the pharmacy staff (e.g. pharmacy technician, pharmacy porter with validated training or pool pharmacy porter).

7.9 Orders for non-stock items on the ward and for CDs where different dose forms of the same strength are available, e.g. morphine sulphate immediate release and modified release tablets, must be accompanied by the prescription to the pharmacy unless the order is given to the clinical pharmacist on the ward. The clinical pharmacist must assess clinical appropriateness, and sign the order in the "Pharmacist screened" section.

7.10 In accordance with robust stock management, it is the responsibility of the RN, RM or RODP in charge of a clinical area to ensure that CD stocks are sufficient to cater for out-of-hours periods.

7.11 In some areas pharmacy may operate a top up scheme where a member of staff (usually a RN, RM, RODP, pharmacy technician or senior assistant technical officer) checks stock balances in the ward CD Register against the levels in the agreed stock list and prepares the CD requisition forms in order to replenish the stock. These requisition forms must be signed by the RN, RM or RODP in charge. The responsibility for CDs remains with the RN, RM or RODP in charge.

7.12 Pharmacy staff must not sign an order for CDs for a ward or department/area.

Transfer of CDs

7.13 Transfer of CDs is likely to involve the following situations:

- Collection by ward or department RN, RM or RODP from the pharmacy
- Delivery by pharmacy staff to wards or departments, and returns from these areas
- Collection by patient or representative for outpatient items only
- Delivery by Trust porter/driver
- Delivery by hospital contracted transport company (See SOP on the delivery of CDs between sites.)

7.14 CDs must always be transferred within the Trust in a sealed pharmacy bag or lockable trolley.

7.15 Duplicate keys for opening locked trolley or bags must be held by the RN, RM or RODP in charge on the ward or department.

7.16 CDs must not be transported in pneumatic tubes.

7.17 At each point where a CD moves from the authorised possession of one person to another, a signature for receipt should be obtained by the person handing over the drug and the person receiving it.

7.18 The person who conveys the CD, e.g. a member of portering staff who has validated training, acts as a messenger; that is to say he/she carries a sealed or locked container and is responsible for delivering the intact container. The person acting as the messenger must:

- Ensure destination is known
- Be aware of safe storage and security, the importance of handing over the item to an authorised person and obtaining a signature for delivery on the delivery document.
- Have a valid ID badge

7.19 CDs must only be handed to a RN, RM or RODP wearing a valid Trust ID badge, or Tranport Courier or Taxi staff who have undertaken validated training or clearance and with valid ID.

7.20 A member of the pharmacy staff will supply the CD and sign and fill in the amount supplied on the requisition slip; this may differ from the amount ordered. Pharmacy may make minor adjustments in the amount supplied – to the nearest original container or whole strip of medication for in-patient supplies. Any other changes to the amount supplied on a requisition can only be made after consultation with the ward pharmacist and the RN, RM or RODP in charge.

7.21 The pharmacy porter or authorised messenger with validated training must sign that he/she has accepted the sealed package for delivery and must then deliver to the ward or department.

7.22 A RN, RM or RODP must collect the CDs from pharmacy, on production of a valid Trust ID badge. In such cases, responsibility for the delegation of this task lies with the RN, RM or RODP in charge. The RN, RM or RODP must sign for receipt of the sealed package. This member of staff must be different to the RN, RM or RODP ordering the CDs.

7.23 If intending to supply dispensed controlled drugs to a person in police custody, first check whether the custody staff have adequate arrangements and handling facilities for controlled drugs. It is acceptable to hand controlled drugs to a police officer for a patient that is being taken into custody. Ensure that they sign the Green TTA book and record their shoulder number as well as their name in the book.

7.24 Community Nurses should not normally transport CDs. This must only be undertaken in circumstances where patients or their representatives are unable

to collect them, provided the nurse is conveying the CD to a patient for whom the medicine has been prescribed: e.g. from a pharmacy to a patient's home. CDs must be kept out of sight during transportation.

Receipt of CDs on wards

7.25 A RN, RM or RODP for the ward or department must receive the CD, checking the CD supplied including the quantity ordered and received against the requisition in the presence of the messenger. The delivery record must also be completed by the delivery person. The RN, RM or RODP must have a currently valid ID badge to be able to receive the CD. If correct, the CD requisition must be signed to indicate receipt while the porter or messenger is present. This signed requisition must then be returned to pharmacy. If the supply is incorrect, pharmacy must be contacted immediately.

7.26 The receiving person must not be the person who ordered the CDs.

7.27 The signed requisition must be returned to pharmacy. Pharmacy must check after each delivery that all CD delivery requisitions have been returned, and signed for receipt.

7.28 Once the supply has been checked, the RN, RM or RODP must enter the received CDs in the CD Register. This **must be witnessed** by a second person. Appropriate persons are:

- First or second level RN;
- Registered midwife;
- Third year student nurse who has completed their medicines management training.
- RODP or Operating Department Assistant (ODA) who has completed their medicines management training
- Doctor
- Pharmacist
- Accredited Pharmacy Technician
- Pre-registration trainee Pharmacist

7.29 The RN, RM or RODP must fill in the details at the top of the appropriate page in the Register that corresponds to the serial number on the order and lock the drugs away immediately in the CD cupboard. Details to be recorded are:

- Date of register entry.
- Quantity received
- Name/signature of RN, RM or RODP
- Name/signature of witness

7.30 When Schedule 2 CD discharge medications (TTAs) are collected from the pharmacy; the RN, Rm, RODP or porter with validated training collecting them must be asked to sign for receipt.

Storage of CDs

7.31 CDs must be kept locked in the CD cupboard when not in use. This cupboard must be used exclusively for the storage of CDs. No other medicines or items may be stored in the CD cupboard. The exception to this is wards that are not authorised to hold potassium injection as stock may store this in the CD cupboard on a temporary basis. Usually the cupboard is a locked cupboard inside the drug cupboard, but it can be a separate cupboard. The Misuse of Drugs (safe custody) regulations 1973 (SI1973 No 798) apply.

7.32 Epidural infusions containing CDs may be stored in a standard CD cupboard providing intravenous infusions containing CDs are not stored in the same cupboard. On wards where both epidural and intravenous CDs are stored a separate epidural cupboard must be used. If the two CD cupboards are located adjacent to each other one CD Register can be used for both cupboards. If they are geographically apart, the ward must use two CD Registers. When epidural infusions are delivered to or received on the ward they must be placed directly into the authorised epidural storage location in the clinical area.

7.33 CD cupboards must conform to the British Standard or be otherwise approved by pharmacy.

7.34 Cupboards must be kept locked when not in use. The lock must not be common to any other lock in the hospital.

7.35 Discharge medication containing CDs must be locked in the CD cupboard immediately until the patient is discharged. The medication must be segregated from the ward CD stock , be clearly marked and must remain in a sealed bag. Discharge medication containing CDs must be entered in to the Patient's Own and TTA CD Register under receipt and the following details entered:

- Date and time received
- Drug name and form
- Strength
- Quantity
- Where the drugs have been received from e.g. pharmacy
- Enter the words "discharge"
- Entered by (name and signature)
- Witnessed by (name and signature)

7.36 In CD cupboards separate storage locations such as different shelves in the CD cupboard must be designated e.g. for low strength products used for bolus administration and high strength products used to prepare infusions. This will help to avoid the wrong product being selected in error as the packaging of different strengths of one product can be similar. The use of high strength products on wards must be restricted to situations where no ready to use

infusions are available and the pharmacy dispensary must attach a High Strength Product sticker to these items.

Temporary ward /area closure

7.37 Day units, wards and clinical areas such as outpatients departments that are not open continuously e.g. five days a week, but need to stock CDs must perform a risk assessment, in consultation with Risk Management and pharmacy. The risk assessment must identify if the unit is sufficiently secure to hold CDs when closed, or whether the CDs must be returned for storage to pharmacy or another ward area. If the CDs are stored in pharmacy or another ward area they must be in a sealed container (for which the pharmacy or the other ward does not have access). The CD Register and keys must be kept in a secure place agreed with Risk Management, pharmacy and the CDAO. This may be in the sealed container.

7.38 The RN, RM or RODP in charge must place the CDs and CD Register/keys (if agreed for that area) in the container for storage and seal it.

7.39 A log sheet for receipt and issue of the sealed container must be completed. This must list the contents of the sealed container so the pharmacy or the ward storing it is aware from a risk management viewpoint of what it is storing. It must include details of the ward or department the container comes from.

7.40 When the sealed container is handed over to pharmacy or the ward they must sign for receipt and date the log sheet. They are signing for a sealed container and not that the contents of the container are correct. The log must be kept in the pharmacy or on the ward in the CD cupboard, and retained for at least 2 years.

7.41 When the sealed container is collected the RN, RM or RODP collecting it must have valid Trust ID badge. A record that identification was seen must be recorded on the log sheet, and the recipient sign the log for receipt of the sealed container.

7.42 If CD stationery/keys are to be stored in the sealed container this must also be documented on the log sheet.

7.43 If CDs are no longer required or the ward or department is closing for a prolonged period of time, the CDs must be returned to pharmacy and a full CD check should be performed by pharmacy..

7.44 .

Transfer of wards/areas arrangements

7.45 When a ward or department moves to another location the CDs and CD Register must be transferred to a new ward or department location. A CD balance check must be carried out by two RNs, RMs or RODPs prior to the CDs leaving the ward and once the CDs arrive at the new ward.

7.46 Two RNs, RMs or RODPs must place the CDs into a sealable pharmacy bag. The bag must then be sealed and transferred to the new ward or department location by the RN, RM or RODP in charge who must be accompanied by another member of hospital staff. On arrival at the new location, the sealed bag

must be opened and the CDs placed into the CD cupboard each one being checked against the CD Register. The CD Register must be transferred with the CDs.

7.47 The pharmacist or pharmacy technician responsible for stock control of medicines on the ward must ensure that the ward signatory lists and stock lists are updated to reflect the new ward location, name and number.

Obtaining CDs in an emergency out-of-hours

7.48 In an emergency out-of hours when CDs may be transferred from one ward to another. The site manager must be consulted, and also the out of hours pharmacist if advice is required.

7.49 The details of the transfer, including the ordernumbers must be entered out of the supplying ward or department CD Register and entered into the CD Register of the receiving ward or department. Both entries must be signed by two RNs, RMs or RODPs from each ward or department. The order number on the container must be altered. The order slip must be voided and detached from the CD Register and kept in the CD cupboard until the next three monthly pharmacy check.

7.50 The borrowing of single doses is discouraged but if a single dose is borrowed then the ward borrowing should take their register to the ward they are borrowing from and a nurse from that ward needs to countersign that one item into the register. This practice is not encouraged as the 24 hour pharmacy service should be utilised but in exceptional emergency siutations then this can be allowed. The site manager and 24 pharmaicst should be informed of this decision

7.51 CDs may occasionally be required at another site within the Trust from the pharmacy dispensary at the Royal London. The out of hours pharmacist must be called to ascertain if they have stock of the CD that is required. If they do then a CD requisition must be faxed to the dispensary at the Royal London Hospital and on receipt of this the pharmacist will commence to dispense the order. The ward or department sending the request must arrange for the original requisition to be sent by authorised taxi to the Royal London and asked to wait for the return journey with the medication. Only on receipt of the original order will the pharmacist release the medication to the authorised hospital transport or taxi company for onward transportation. It is illegal to dispense a CD on a fax order.

7.52 Authorised BH transport systems must be used i.e. hospital transport department or the contracted, validated taxi firm. The identification of the driver must be checked. As a matter of good practice the taxi registration number must also be recorded. The driver must be given the CDs in a plain sealed package and must sign and print their name on a courier delivery record sheet to accept the package for delivery. There must be no indication on the exterior of the package as to what it contains.

7.53 On receipt the package must be signed for by an RN, RM, RODP – again this signature is for receipt of a sealed package. This does not need to be opened or the contents inspected. Copies of receipts must be retained in the pharmacy department for at least the current legal minimum period of two years.

Lending or borrowing to or from other hospitals outside the Trust

7.54 If a quantity of CDs is required and there is no stock at any of the dispensaries within the Trust it may be possible to borrow CDs from another hospital outside of the Trust with their permission. In this instance the out of hours pharmacist **MUST** be contacted who will co-ordinate and organise the supply, and complete the appropriate paperwork (out-of-hours supply from other hospitals).

7.55 A requisition in writing must be provided to the external supplying hospital stating:

- The hospital name and address (ideally on headed notepaper)
- Signature, name and profession of the senior member of staff ordering the CD e.g. site-manager (or senior nurse on site if not a nurse), registrar or on-call pharmacist.
- Name and address of the supplying hospital
- Name, form, strength, and total quantity of CD required
- Purpose for which it is required
- Signature of recipient.

7.56 If the requisition is sent via a messenger (e.g. taxi), the messenger must have a statement in writing given by the professional ordering the CD to the effect that the messenger is empowered to receive the drug on his/her behalf.

7.57 Both records must be kept for a minimum period of 2 years.

7.58 Please note that GPs must not borrow or obtain CDs from the Trust, as they have their own access to emergency supplies.

Use of CDs for patients in transit

7.59 There are exceptional circumstances when it is necessary and acceptable to secure CDs for potential use by a patient who is in transit and is likely to be away from the ward or department for a prolonged period e.g. a patient who may require an IV bolus for sedation or analgesia whilst away for a CT scan.

The following principles must prevail:

7.60 The CD must be checked out of the ward stock and stock level reconciled in the normal way.

7.61 An entry must be made on the next available line in the CD Register that details what the CD has been secured for e.g. ‘10mg morphine has been secured for possible use with patient (name) away for CT scan, date and time.’ The entry must state that the CD has been secured for potential use rather than actual use.

7.62 The transaction must be signed for in the normal way. The person signing the administration column must be the custodian of the CD during this time. The witness must also sign in the normal way. One of these people must be a RN or RM.

7.63 The CD must be carried safely e.g. in a secure bag, that must be with the RN or RM at all times.

7.64 While away from the original clinical area, a record must be kept of any usage of the CD and if any of the CD was unused and disposed of. Two people must be involved in the administration and recording process, one of these people must be a RN or RM, and the other must be another healthcare professional ie. a doctor or pharmacist. This must be recorded in the patient's medical record and on the patient's prescription chart. The entry in the medical record must include the names, signatures and job title of both staff members.

7.65 The custodian of the CD must return to the original clinical area and attend to the following depending upon the circumstances:

CD has not been used

7.66 Return the CD to stock where appropriate e.g. ampoules. Document the return on the next available line of the CD record book and reconcile the stock levels once more. Two people must undertake this, one of whom must be a RN or RM.

CD has been used or part-used

7.67 Document the use on the next available line in the CD Register. The RN or RM who was custodian of the CD and who administered it must sign the Register, and enter the name of the witness as recorded in the patient's medical record, with an entry on the next line stating where the dose was administered, who witnessed the administration and that the signature is in the patient's medical record.

CD has been opened but unused

7.68 Discard any unused but opened CD in line with the guidance in the destruction of CDs section.

Destruction or return of CDs

7.69 Only CDs which are prepared but not administered or only partly administered (e.g. PCA intravenous preparations that are taken down) or part contents of ampoules that are wasted, must be destroyed on the ward or department in the presence of a second person. One person must be a RN/RM. The other must also be a RN/RM, RODP/ODA, a pharmacist, pharmacy technician, a doctor or a third year student nurse who has completed their medicines management training.

7.70 Broken ampoules should be recorded accurately in the CD register and signed by two HCP who have witnessed the breakage and the register balance shoud be updated to reflect the new balance. A datix form MUST be completed.

7.71 A record of the volume wasted and the reason for this must be made in the patients notes or on the PCA chart and signed by the two staff members. Wastage of part used PCA/Epidurals containing CDs must also be recorded (see 7.65).

7.72 It should be noted that PCA bags do contain a small amount of overage. Therefore all PCA bags or epidural bags containing a CD must be disconnected from the patient by two persons. Any remaining overage in the bag must be squeezed out onto paper towels to render this irretrievable.

7.73 For small amounts of CDs, the CD must be rendered irretrievable by emptying it onto a paper towel before placing in a sharps bin. The emptied vial or ampoule must then also be placed in the sharps bin. When the bin is sent for destruction it must be labelled "mixed pharmaceutical waste and sharps-for incineration". If only half a tablet is used or a tablet falls on the floor it must be crushed before being put into the waste system.

7.74 For part used bags of PCA's that are no longer required these must be destroyed on the ward or in the clinical area using a denaturing kit, e.g. DOOP kit (available through NHS Logistics)

7.75 In all other cases, unwanted or expired CDs must be returned to pharmacy in person with the ward CD Register – as the return must be recorded in there (in a sealed pharmacy bag), or the senior nurse must contact the pharmacy to arrange removal of CDs. These must be removed promptly and regularly to prevent crowding in the CD cupboard.

7.76 Unused CD stock from wards or departments can be reissued by the pharmacy provided it was initially issued by that pharmacy and has at all times been under the control of that hospital and is still fit for purpose.

7.77 Drugs that are time-expired or otherwise unfit for use (e.g. opened liquids) must also be returned to the pharmacy for safe destruction and onward disposal.

7.78 Any other CDs that are no longer needed on the ward or department must be returned to pharmacy as soon as practical.

7.79 The pharmacist, pharmacy technician or pre-registration trainee pharmacist and RN, RM or RODP must enter the transaction into the CD Register on the appropriate page with corresponding requisition number. The entry must state the date and quantity being removed, the balance remaining, and the reason for return with the name and signature of the RN, RM or RODP. The pharmacist, pharmacy technician or pre-registration trainee pharmacist and RN, RM or RODP must sign the entry. CDs must be returned to pharmacy in a sealed container. The *CD returned to pharmacy* form should be complete (Appendix 8)

7.80 The following details must be recorded in the pharmacy CD Register: date, ward or department name; name form strength and quantity of CD being returned, requisition number, reason for return, name and signature of the RN, RM or RODP.

7.81 For removal and destruction of unknown substances see the *'Procedure for the destruction of illicit substances thought to be CDs'* (Appendix 5)

7.82 Records of CDs returned to pharmacy must be audited at regular intervals, at least once every three months as part of the pharmacy CD audit confirming that the records in the ward CD Register and pharmacy CD Register correspond.

7.83 Community Nurses are not responsible for the destruction of CDs in the community. The patient or patient's representative should be advised that all CDs no longer required must be returned to a community pharmacy for safe destruction. However, there may be occasions where it is appropriate to facilitate the recovery or disposal of CDs. The following actions may be taken: the RN with another member of the nursing team acting as a witness disposes of the CD in an appropriate and safe manner, or the RN takes the CDs to a community pharmacy, who must be asked to countersign the patient nursing record.

8 ADMINISTRATION OF CDS TO PATIENTS

Responsibility for administering

8.1 Two members of staff must be involved in all stages of the administration of CDs; one of these must be a RN, RM, RODP or doctor. The second person may be a:

- First or second level RN
- RM
- Third year student nurse who has completed their medicines management competency
- RODP
- Doctor
- Pharmacist
- Radiographer

8.2 When adult community nurses are administering CDs in patient's homes, and a second healthcare professional is not available, consideration should be given to inviting patients and/or their representatives to carry out the second check.

8.3 The only exception to this is those wards or departments that have been agreed as suitable by the senior sister/ charge nurse who wish to implement single nurse checking of Morphine Sulphate Oral Solution 10mg/5ml.(Appendix 10)

8.4 Both practitioners must be present during the whole of the administration procedure. They must both witness:

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

8.5 Within an operating theatre setting, in an emergency situation, a doctor may request that a CD is drawn up if they are unable to do so due to the fact that they need to tend directly to the patient. In this instance, the CD must be checked with the doctor before opening and drawn up in the presence of the doctor.

8.6 Both staff members must complete the record of administration each time a dose of a CD is given in the ward or departmental CD Register, taking care to make the record on the correct page – the number of the page is printed on the container of the CD.

8.7 The following details must be recorded:

- Date and time administered
- Name of patient
- Amount given
- Amount wasted
- Balance in stock (physical stock checked)
- Name and signature of nurse/authorised person who administered the dose
- Name and signature of witness

8.8 The RN, RM, RODP or doctor who administers the CD must complete the 'given by' column in the CD Register and also the patient drug administration record. The second person must check all aspects of the administration, including entries made in the CD Register and sign the 'witnessed by' section in the CD Register.

8.9 In the case of morphine sulphate oral solution 10mg/5ml, single nurse administration and recording is permissible at the discretion of the senior nurse. Only permanently employed trained and accredited RN and RM staff are eligible to undertake single nurse administration and recording. The senior nurse must keep a record of all named nurses. (Appendix 10)

8.10 All aspects of the reconstitution and preparation of the CD must be under the direct supervision of the person who is going to administer the drug. The CD Register must always be taken to the patient's bedside, (unless for reasons of infection control this is not possible). Only once the patient has been administered the CD must the witnessed by and administered by boxes be signed in the CD Register.

8.11 Any entry found to be wrong or any actual or suspected CD loss must be reported immediately to the nurse in charge.

8.12 Any drug wasted, e.g. part of an ampoule must be recorded and emptied onto a paper towel and disposed of in a yellow sharps bin for destruction. A record of the wastage must be made in the CD Register "amount wasted" column and signed by the two members of staff.

8.13 If a mistake is made, it must not be obliterated, it can be crossed through with a simple line and error annoted and signed by two RN/RM/RODP/doctor or

pharmacist. The information underneath must be readable. It can also be bracketed [ ] in such a way that the original entry is still clearly legible. This must be signed, dated and witnessed by a second RN, RM or other registered professional. The witness must also sign the correction. The correct entry must be made on the next available line or as a footnote.

8.14 Oral liquids must be measured using an oral purple syringe rather than a measuring cup or spoon.

8.15 Ampoules must not be used for more than one patient.

8.16 Adult Community Nurses and the Palliative Care Team working in the community can undertake single nurse administration. This only applies to specified groups of patients receiving palliative and end of life care who must have care agreed and documented.

Patient's own CDs

8.17 As with other types of medicines, patient's own CDs remain the patient's own property. Patients own CDs must be locked in the CD cupboard and an entry made in the Patient's own and TTA Register by a RN or RM. This entry **MUST** include the patient's name, hospital number, date and time, Drug name and form, strength and quantity of the CDs received, and be witnessed by another RN or RM, or other second person i.e a doctor or a pharmacist.

8.18 Patient's own CDs may be used on the ward for that patient providing they meet the requirements specified in the *Patient's Own Drugs Procedure*.

8.19 Patients' own CDs must **NOT** be given to any other patient and **NOT** be added to ward stock.

8.20 Patients' own CDs that are not to be used for administration must not routinely be stored on the ward. If patients' own CDs are not required for use then one of the following actions must be undertaken: the CDs can be returned home via an identified adult (the patient's agent) or returned to the patient on discharge (responsibility for security is given to that adult) or returned to pharmacy for destruction.

8.21 If the medicines are not safe and/or appropriate for use, then the patient and/or patient's agent must be advised and they must be encouraged to send them to the pharmacy for safe destruction. A RN/RM and a second witness i.e a pharmacist must sign the CDs out of the Patient's own and TTA Register.When the drugs are released to the patient or patient's agent (with the patient's permission), a RN or RM a second witness i.e a pharmacist must sign the CDs out of the Patient's own and TTA Register. The witness must observe the CDs being handed over to the patient/patient's agent.

8.22 CDs can be taken to the pharmacy for destruction or given to the ward pharmacist. The patient/patient's agent's permission must be obtained to

destroy the CDs, and the consent for destruction section completed in the relevant section of the Patient's own and TTA CD Register. The pharmacist takes responsibility for the destruction. The RN or RM must sign the drugs out of the Patient's own and TTA Register. This must be witnessed by a second person i.e a pharmacist or pharmacy technician. If a patient is discharged and does not take their own CDs home with them, these must be retained for 24 hours, after which the CDs can be sent to pharmacy for destruction.

8.23 If a patient dies, their CDs must be returned to the pharmacy for destruction. The medicines are the property of the patient only, and cannot become the property of the next of kin. If the next of kin wishes to keep the medicines for analysis, they will be sealed, kept by pharmacy, and handed over to the legal advisor of the next of kin.

8.24 If a patient is transferred from one ward or department to another, the patient's own CDs must be transferred with them. The CDs must be transferred from one ward or department's Patient's own and TTA CD Register to the receiving ward or department's Patient's own and TTA Register by two RNs or RMs, one from each ward or department.

9 CLINICAL TRIALS

9.1 The procedures for the use of CDs in clinical trials must comply with the Misuse of Drugs Regulations (1971) and with local policies governing the management of clinical trial medicines, in addition to clinical trials legislation and MHRA guidance on clinical trials.

9.2 All clinical trial CDs must be stored separately from stock CDs. They do not necessarily need to be stored in a separate CD cupboard. A separate page in the CD Register must be used to record receipt and issues in addition to clinical trial documentation so that a running balance of trial stock can be kept.

9.3 If a discrepancy is identified then it must be reported on the Trust incident reporting system. A note to file should be stored with all the clinical trials documentation. The sponsor and investigator must be informed and also the Director of Pharmacy and Medicines Management and the CDAO.

9.4 For double blind trials in which only one arm involves a CD, pharmacy staff may be unaware which packs contain CDs. In this situation, all supplies must be treated as CDs until the end of the trial.

9.5 For trials that involve the use of Schedule 1 CDs, such as cannabinoids, a licence from the Home Office must be obtained before the item is received into stock or supplied. The licence must normally be held by the Chief Pharmacist and/or the CDAO. A copy must be kept with the trial protocol.

Labelling

9.6 All clinical trial CDs must be labelled and dispensed in accordance with the specific trial protocol in addition to the MDR requirements.

Disposal

9.7 Clinical trial CDs must be destroyed in the same way as other CDs. However, this destruction may need to be carried out following the monitoring instructions with the trial sponsor. For example, the sponsor may wish to carry out an independent reconciliation (in addition to the check and reconciliation carried out by the pharmacy department) prior to any destruction.

Clinical trial CDs returned by patients

9.8 CD clinical trial medicines returned by patients must be entered into the Clinical Trials CD Register. Clinical trial protocols must be followed and drug accountability records completed promptly.

Arrangements for research departments

9.9 If pharmacy supplies CDs to a research department, then the same governance arrangements for safe use must apply as for elsewhere in the organisation. All the activities must be covered by SOPs and the processes must be robust and auditable.

10 MANAGEMENT OF CDS WITHIN THE HOSPITAL PHARMACY

10.1 The Chief Pharmacist is legally responsible for the safe and appropriate management of CDs in the pharmacy. SOPs must be available covering all aspects of the safe management of CDs such as ordering, receipt, record keeping etc. SOPs must be kept up-to-date, reflecting current legal and good practice requirements for CDs, and each one must be clearly marked with the date of issue and review date.

10.2 SOPs must be approved by the CDAO or by the person to whom (s)he has delegated this task. The CDAO remains finally accountable for all the systems for the safe management of CDs.

10.3 Ward clerks and Health Care Support Workers are are not authorised to collect controlled drugs from the pharmacy.

10.4 Agency staff with appopriate ID can pick up controlled drugs from the dispensary.

Ordering and receipt

10.5 Ordering of CDs from wholesalers and manufacturers and receipt of CDs must follow the principles of good procurement. There must be a robust audit trail and the opportunities for diversion minimised.

10.6 Receipt when CDs are received into the pharmacy department: A pharmacist, pharmacy technician or appropriately trained assistant technical officer (ATO) can sign for receipt. The order details must be checked against the delivery note and the actual quantity delivered and appropriate stock control documentation completed. Any tamper-evident seals on packs must be left intact when they are received from the supplier. This simplifies and speeds up balance checks.

10.7 If when the tamper-evident seal is broken, the contents do not match the expected amount stated on the pack, the pharmacy must contact the supplier. If there is a discrepancy the delivery note should be signed for the actual goods and quantities received and the items passed to the senior buying officer to resolve. The items must be entered into the CD Register (see 10.6 below), and stored in the CD cupboard separated from normal stock, until the problem has been resolved.

10.8 Goods must be entered into the CD Register upon receipt, entering:

- Name, form and strength of drug (or using appropriate page)
- Date received
- Order number
- Supplier name and address
- Quantity received
- Signature of pharmacist/pharmacy technician/pre-registration pharmacist or ATO receiving the CDs
- Amended balance

10.9 The entry must be checked by a second member of pharmacy staff (pharmacist/pharmacy technician/pre-registration pharmacist or ATO). As a matter of good practice the balance in stock must be checked and recorded as correct by the person making the entry. The stock must be put away into the appropriate section of the CD cabinet promptly. A record of receipt of the order must be made on the pharmacy computer system

Storage

10.10 Pharmacy CD cabinets must comply with the Misuse of Drugs (Safe Custody Regulations) This is a minimum security standard which may not be sufficient for areas where there are large amounts of CDs in stock at a given time and/or there is not a 24-hour staff presence or easy control of access.

Issuing of CDs to wards and departments

10.11 Ward or department staff must fully complete a CD requisition form from the ward CD Register and send it to pharmacy dispensary.

10.12 All the following details must be completed:

- Hospital name
- Ward/department
- Drug name
- Form
- Strength
- Quantity
- Ordered by (signed, with printed initials, surname and qualification)

- Date of order

10.13 Orders for non stock items on the ward and for CDs where different dose forms of the same strength are available, e.g. morphine sulphate immediate release and modified release tablets, must be accompanied by the prescription to the pharmacy unless the order is given to the clinical pharmacist on the ward. The clinical pharmacist must assess clinical appropriateness.

10.14 Pharmacy must enusre that stock is appropriatley rotated to ensure that stock going to have the ward have an appropriate expiry date. Where short date expiry stock is issued this MUST be clearly highlighted to the ward that short expiry stock is being issued.

10.15 If there are any discrepancies the member of pharmacy staff must contact the person placing the order and clarify what was intended. The order can be annotated and signed by the member of pharmacy staff. The pharmacist must screen and sign the order for non stock CDs.

10.16 The details required on labels are:

- Drug name, form and strength
- Quantity
- “Store in CD cupboard”
- Requisition / serial number of signed order
- Department / ward name or number
- Date of issue
- Batch number and expiry date if dispensed from bulk. (NB: Certain preparations have a reduced expiry once opened, e.g., morphine sulphate oral solution)
- “Keep out of reach of children”
- Address of pharmacy

10.17 Each carton, syringe or bottle must be individually labelled.

Pharmacy CD Register

10.18 A CD Register of receipts and supplies of Schedule 2 CDs and drugs that are treated as full schedule 2 CDs must be kept by the pharmacy.

10.19 Each CD form, strength and pack size must be given a different page in the CD Register. The CD name, form, strength and pack size must be written at the top of the page. An index must be kept at the front of the CD Register. CD Register entries must be made in consecutive, chronological order. The entry must be made on the day when the CD is received or supplied. Entries must be in ink or be otherwise indelible.

10.20 If a mistake is made the entry must not be crossed out, deleted, obliterated or defaced; correction fluid must not be used. If an error is found, it must be

bracketed and accompanied by a clearly recognised signature; the balance shown must be accurate and easily read. A footnote must be added to explain the alteration

10.21 The following staff may complete the CD Register

- a registered pharmacist under their own authority
- a registered pharmacy technician
- a pre-registration trainee pharmacist
- a student pharmacy technician
- an assistant technical officer
- a trainee assistant technical officer undergoing NVQ2 training

10.22 All entries in the CD Register must be checked and countersigned by either a registered pharmacist or an accredited pharmacy technician.

10.23 The register entry must also include:

- Date of transaction
- Name and address of person/department supplied
- The name of the person ordering the drug
- Licence or authority of person/department supplied i.e. requisition number
- Amount supplied
- Form in which supplied
- Name of patient, if individually dispensed
- Prescriber's name, if individually dispensed

CD stock checks

10.24 The stock balance in the pharmacy CD Register must be checked every three months against both the quantity in the CD cabinet and the balance shown in the pharmacy stock control system. This check must be undertaken by any competent person approved by the pharmacist with operational responsibility for CDs, or by a trainee working under their direct supervision as described in the SOP.

10.25 Action plans drawn up by the pharmacy representative completeing the quartely check will highlight the ward or deprtment deficiences and will be doucumted and feedback to the senior sister charge nurse via the CD audit feedback form and it is their rsponsibiity to enusre that this action plan of improvement is implemented this action plan should agreed with the senior nurse for the area to make sure that it is appropriate and covers all measures highlighted in the audit. The senior nurses have responsibility to ensure that the wards are completing their action plans..

10.26 The check must be recorded in the CD Register by means of signature, date and an appropriate entry, for example, "Stock checked. Balance correct". If one or more of these levels does not tally, the discrepancy must be investigated and

resolved without delay. It is important to remember that a discrepancy may indicate misuse. The discrepancy must be reported to the responsible pharmacist for that area immediatelty.

10.27 There must be a careful check of transactions in the CD Register and in the stock control system to trace an error or omission. If an error is traced then a CD Register entry must be made, clearly stating the reason for the entry, the reference of the error or the omission, the date of the error or omission and the signature of both the person carrying out the amendment and the witness.

10.28 Stock that has not been used for 30 days or more should be returned to the pharmacy department to ensure that wards are not unneseccarily holding stock.

10.29 If no error or omission can be traced, the Chief Pharmacist and CDAO should be informed And they must decide on what action to take. In all cases the incident must be reported on the Trust incident reporting system together with the action taken.

11 RECEIPT OF CDS BY OUTPATIENTS

11.1 For outpatient CD prescriptions being given directly to the patient or their representative pharmacy staff must seek to establish whether the person collecting the medicine is the patient, their representative or a healthcare professional acting in his professional capacity on behalf of the patient.

11.2 Where the person is the patient or their representative, the dispenser:

- **May** request evidence of that person's identity and
- **May** refuse to supply the medicine if s/he is not satisfied as to the identity of the person

11.3 Where it is a healthcare professional acting in his professional capacity on behalf of the patient, the dispenser:

- **Must** obtain the person's name and address
- **Must**, unless he is acquainted with that person, request evidence of that person's identity; but may supply the medicine even if he is not satisfied as to the identity of the person. 'However, even if ID is not provided the pharmacist may still supply the CD. In order not to deny patients' access to the drugs they require, it will be not be a criminal offence to supply a Schedule 2 CD without proof of identity, even when the pharmacist does not know that person. This will be at the discretion of the pharmacist.

11.4 The dispenser has the discretion not to ask patients or patient representatives for proof of identity if, for example, they have concerns that to do so may compromise patient confidentiality or deter patients from having their medicines dispensed.

11.5 It is a requirement to record the following information in the CD Register for Schedule 2 CDs supplied on prescription:

- Whether the person who collected the CD was the patient, the patient's representative or a health care professional acting on behalf of the patient

- If the person who collected the CD was a health care professional acting on behalf of the patient, that person's name and address
- If the person who collected the CD was the patient or their representative, whether evidence of identity was requested (as a matter of good practice a note as to why the dispenser did not ask (may be included but this is not mandatory).
- Whether evidence of identity was provided by the person collecting the drug.

11.6 The person collecting schedule 2 or 3 CDs must sign for receipt of a specified number of doses using the *Controlled Drug Receipt for Outpatients* (Appendix 3) for collection for RLH and SBH Lloyds (Appendix 4) Pharmacy and this information must then be transferred into the main register within 24 hours.

11.7 Types of ID that may be considered suitable include:

- Professional registration number for a healthcare professional.
- Official photo I.D.
- Driving Licence (including photo card section).
- Passport.
- Cheque Guarantee, debit or credit card.
- Birth/marriage certificate.
- Cheque book.
- Utility bills (two different ones but not mobile telephone statement).
- Pension or benefit book.
- Council tax payment book.
- Recent bank or building society statement (Within previous six months).
- Bank or building society book.
- Store charge card (not a loyalty card).
- Council rent book.
- National Savings book.

CD discharge Medication

11.8 When schedule 2 CDs are collected from the pharmacy, the person collecting them (who must be a RN, RM , RODP or porter with validated training) must sign for receipt.

11.9 When the CDs arrive on the ward, the CDs must be booked into the Patient's own and TTA CD Register. If they are not being handed to the patient immediately they must be stored in the CD cupboard.

11.10 When schedule 2 or 3 CDs are handed to patients as part of their discharge medication, the patient or their representative must sign the Patient's own and TTA CD Register for receipt of the specific number of doses of CDs contained in the discharge medications. This must be countersigned by the nurse

discharging the patient. If the patient or their representative is unable to sign, two RNs or RMs must sign the CD Register.

Supplies to External Units

11.11 External trusts must follow the SOPs developed and agreed by BH. The CDAO of those Trusts must ensure that his/her organisation has up to date SOPs for the use and management of CDs.

11.12 Where CDs are used in satellite units managed by BH this CD policy must be followed. The Chief Pharmacist will agree arrangements for CD supply, return of supplies to pharmacy, and pharmacy audits.

11.13 At each point where a CD moves from the authorised possession of one person to another, the transfer must be recorded by means of the signatures of both parties. See Pharmacy SOP; *Transportation of Medication*. The CD must be transported in a secure, lockable container (using a sealed tamper proof pharmacy transport bags using a numbered seal) and a suitable delivery document completed to provide a full audit trail. Staff must record the number of the seal on the order slip.

12 PRODUCTION AND QUALITY CONTROL

12.1 When products that contain CDs are being prepared in the pharmacy production unit, then the same governance arrangements for safe use must apply as for elsewhere in the Trust. All the activities must be covered by SOPs and the processes must be robust and auditable.

12.2 If small amounts of CDs, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up, must be rendered irretrievable by emptying into a sharps bin. The emptied vial or ampoule must then also be placed in the sharps bin.

12.3 When the bin is sent for destruction it must be labelled “mixed pharmaceutical waste and sharps- for incineration”.

12.4 The CD will already have been issued to the extemporaneous or aseptic preparation areas. To maintain a full audit trail the worksheet must show the amount used and the amount wasted, for example “2.5ml used 0.5ml wasted”.

12.5 As a matter of good practice, the emptying of the part dose into the sharps bin must be witnessed and recorded on the worksheet. Both people must sign the worksheet.

12.6 *In the* event that a CD is sent to pharmacy quality control for analysis, the CD must be returned and booked out of the Pharmacy CD Register.

13 DISPOSAL DESTRUCTION WITHIN PHARMACY DEPARTMENT

13.1 Unwanted CDs must be disposed of in the pharmacy in such a way that the drug is denatured or rendered irretrievable so that it cannot be reconstituted or used again. See SOP; *Destruction of CDs*, that sets out the methods for denaturing and disposal of CDs.

13.2 Pharmacy held stock of obsolete, expired or unwanted Schedule 2 CDs not returned by patients that require destruction can only be destroyed in the presence of a person authorised by the CDAO this is an 8a nurse or above.

13.3 A pharmacy representative MUST always be involved in the return of unused, not required stock to the dispensary. This must always be done in a safe and secure manner and the pharmacy representative should fill in a returns to pharmacy form and a ward HCP should sign this that the pharmacy repreentative is taking responsibility for the safe return to the dispensary. The drug returned should be then entered into the detruction register, or if deemed approproate returned to stock.

13.4 The CDAO must not be authorised to witness destruction as they must be independent from day-to-day management of CDs.

13.5 Until they can be destroyed, obsolete, expired and unwanted stock CDs requiring safe custody, according to arrangements appropriate to their schedule, must be kept segregated and clearly marked from other CDs in the CD cupboard in order to minimise the risk of errors and inadvertent supply.

13.6 When stock Schedule 2 CDs are destroyed, the following details must be entered into the CD Destruction Register:

- Drug name
- Drug form
- Drug strength
- Quantity of drug being destroyed
- Date of destruction
- Signature of the person in whose presence the drug was destroyed
- Signature of the person carrying out the destruction

13.7 Destruction must be witnessed by a pharmacist, accredited pharmacy technician or pre-registration trainee pharmacist.

13.8 The record of destruction must be made in a CD Destruction Register. This must not be made in the CD Register. The following details must be recorded:

- Date of return of the CDs.
- Name, quantity, strength and form of the CDs.
- Role of the person who returned the CDs (if known).
- Name and signature of the person who received the CDs.
- Patient's name and address (if known).
- Names, positions and signatures of the person destroying the CDs and the witness.
- Date of destruction.
- Comments, for example, expiry date, name of patient and ward.

13.9 CDs awaiting destruction must be stored in the CD cabinet separately from pharmacy stock controlled drugs.

13.10 Destruction of CDs must occur with sufficient frequency (for example, monthly) to ensure that excessive quantities are not stored awaiting destruction.

13.11 CDs for destruction must be placed in suitable waste containers which are then sent for incineration and must not be disposed of in the sewerage system. The containers containing waste should be labelled “contains pharmaceutical waste – for incineration”.

13.12 All CDs in Schedule 2 and those CDs in Schedule 3 schedule 4 Part 1 (benzodiazepines) must be rendered irretrievable (e.g. by denaturing) before being placed into waste containers.

14 MONITORING THE EFFECTIVENESS OF THIS POLICY

Issue being monitored	Monitoring method	Responsibility	Frequency	Reviewed by and actions arising followed up by
Handling of CDs in the Trust	A CD audit will be completed. Compliance with carrying out the 3 monthly audits, this audit will also include an audit on the safe and security of medicines in general in the area audited.	Pharmacy Dept/ward departmental manager.	Minimum 3 monthly	Issues escalated locally to ward manager for immediate attention by pharmacy staff carrying out audit.
Handling of CDs in the Trust	The Trust Board receives an annual report	Chief Pharmacist	Annual	Trust Board
NHS England	Quarterly report is submitted to NHS England LIN (Local Intelligence Network)	Medicine Safety Committee prepares report with has to be signed off by the CDAO.	Quarterly	LIN Group

END

Barts Health NHS Trust

Appendix 1: Change Log

Change Log – Controlled Drug Policy		
Substantive changes since previous version	**Reason for Change**	**Author & Group(s) approving change(s)**
The Barts Health Controlled Drug Policy	Update policy to reflect changes following serious incidents	Pharmacy

Appendix 2: Impact assessments

Equalities impact checklist - must be completed for all new policies

equalities

Organisational impact checklist - must be completed for all new policies

Organisational impact assessment

Barts Health NHS
NHS Trust

Appendix 3: Controlled Drug Receipt for Outpatients

Outpatients Pharmacy Department (For use at WXUH and NUH Dispensaries)

CONTROLLED DRUG RECEIPT for OUTPATIENTS

Pharmacy: _____

Date dispensed: _____

Patient's Name: _____

Drug, Strength, Form & Quantity: _____
_____
_____

TO BE COMPLETED BY PATIENT/REPRESENTATIVE:

Date received: _____

Name (in block capitals): _____

Signature: _____

Circle as appropriate: PATIENT / REPRESENTATIVE / HEALTH CARE PROFESSIONAL

Address of Health care professional: _____
_____

Barts Health NHS
NHS Trust

_____

TO BE COMPLETED BY PHARMACY STAFF MAKING THE SUPPLY

Proof of identity seen: YES / NO If no, state reason: _____

Tick which form of proof was checked:
Professional registration no for health care professional
Driving license (including a photo card)
Passport
Cheque guarantee, debit or credit card
Birth, marriage certificate
Cheque book
2 different utility bills (no mobile phone)
Pension/ benefits book
Council tax payment book
Recent bank/building society statement/book from last 6 months book
Store card (not loyalty card)
Council rent book
National savings book

Signature of Pharmacy Staff _____

Barts Health NHS Trust

Appendix 4: For Use in Lloyds Outpatient Dispensaries

Outpatient Controlled Drug Prescription Receipt LloydsPharmacy

To be completed by person collecting the Controlled Drug(s)			
Name		Signature	
Relationship to patient		Address of collector (if different to patient's address)	
To be completed by LloydsPharmacy colleague			
Was ID Requested	Yes / No	Was ID provided?	Yes / No
If ID not requested why not?			
ID provided	☐ **Driving licence** ☐ **Credit/Debit card** ☐ **NHS ID Badge** ☐ **Passport** ☐ **Other** (please state):		
CD Register entry completed by (where required)			

Staple this form to the prescription

Version: 1.0
Author: [redacted]

Created: 16/02/2015

Outpatient Controlled Drug Prescription Receipt LloydsPharmacy

To be completed by person collecting the Controlled Drug(s)			
Name		Signature	
Relationship to patient		Address of collector (if different to patient's address)	
To be completed by LloydsPharmacy colleague			
Was ID Requested	Yes / No	Was ID provided?	Yes / No
If ID not requested why not?			
ID provided	☐ **Driving licence** ☐ **Credit/Debit card** ☐ **NHS ID Badge** ☐ **Passport** ☐ **Other** (please state):		
CD Register entry completed by (where required)			

Staple this form to the prescription

Version: 1.0
Author: [redacted]

Created: 16/02/2015

Appendix 5: The handling of illicit substances (thought to be Controlled Drugs)

1. It is known that some patients bring into hospital with them substances which are, or may be, illicit e.g. cannabis, crack cocaine, ecstasy. If these are small quantities sufficient for only a few (up to 5) doses for personal use, the medical and nursing staff may consider it is in the patient's best interest not to inform the police. The police concur with this as long as larger quantities e.g. for resale, are reported to them.

2. It is not acceptable for illicit substances to be kept or used by patients, so they should be removed from the patient by medical or nursing staff.

3. If the patient refuses to hand over a suspicious substance, security should be called immediately and the patient should be informed that they are suspected of possessing a suspicious substance which may cause them or others harm. If they are unwilling to hand over the substance, the police may be called.

4. If the patient is unconscious or otherwise unable to voluntarily hand over the item, it should be removed from the patient, a Datix completed and point 6 and 7 followed, substances which are thought to be illegal must never be handed back to the patient or relatives/carers.

5. Section 5 of the Misuse of Drugs Act provides a statutory defence for those persons who take possession of a drug for the purpose of preventing another from committing or continuing to commit an offence, provided that reasonable steps are taken to destroy the drugs promptly. Our solicitors advise that this part of the legislation would appear to provide protection in law for nurses, pharmacists and those responsible, to handle the drugs in order that they may be destroyed. The police have confirmed that they will not prosecute a nurse, pharmacist or doctor who holds an illicit substance for a short while until it is destroyed according to hospital procedure and is witnessed by an 'authorised person.'

6. Suspected illicit substances, whether being used or held, should be handed over to the Nurse in Charge of the ward, recorded in the Controlled Drugs' Register, and handed over to the ward pharmacist on his/her next visit or until the pharmacy is open.

7. The pharmacist removing the substance must sign in the ward's Controlled Drug's register that he/she has removed the substance for destruction, and carry it securely to the pharmacy. In the pharmacy it should be signed into the destruction register and put in the Controlled Drugs' Cupboard to await destruction by one of the senior nurses approved by the AO for destruction. The pharmacist must carry identification especially when the ward is not in the same hospital as the pharmacy base.

8. Occasionally the police may ask the nursing staff to collect a substance that may have been swallowed in a package (or packages). The police must collect this substance within a few days, otherwise it should be sent to the pharmacy as above for storage until it is collected. The police should be reminded to collect this substance if they have not collected it within one week.

Appendix 6: Controlled Drugs Delivery Record

Controlled Drugs Delivery Record

Dispensary:_____ **Date**_____

Ward	Requisition Number **OR** patient name (TTA)	Drug				Issued from pharmacy by (print & sign):	Collected/ Delivered by (print & sign):
		Drug name	Form	Strength	Quantity		

Appendix 7: Drugs liable to abuse that are treated as full CDs

By local policy, the following drugs which are not included in the Schedule, are treated as full schedule 2 CDs within Barts Health NHS Trust

- Ketamine
- Buprenorphine
- Phenobarbital
- Temazepam
- Morphine Sulphate Oral Solution 10mg/5ml
- Mifepristone (CD prescription writing requirements not needed)
- Misoprostol (CD prescription writing requirements not needed)
- Midazolam is not handled as a full schedule 2 CD. A signed requisition is required for any orders for Midazolam. CD prescription requirements apply for TTA and outpatient prescriptions.
- Tramadol is not handled as a full schedule 2 CD. A signed requisition is required for any orders for Tramadol. CD prescription requirements apply for TTA and outpatient prescriptions.

Appendix 8: Controlled Drugs (CDs) returned to pharmacy record form

A separate form must be used to record drugs to be returned into pharmacy stock & drugs for destruction

Destination of CD **Return to pharmacy stock / Destruction register** (delete where applicable)

Date …… Ward / Department …….

Drug	Form	Strength	Quantity	Ward CD Requisition no / patient name if Patient own CD	Removed by Name **Designation*** Signature (pharm. staff)	Witnessed by Name Designation Signature (ward staff)	Entered into Pharmacy CD register or Pharmacy destruction register by	End-user (if returning to stock) or Destruction number	Checked by Name **Designation*** Signature (tec/pharmacist)	Entered on computer by (Date & sign)

Note column 1 can be signed by a pharmacist, or alternatively a pre-registration pharmacist or pharmacy technician who has been trained and accredited under the BH procedure for checking CDs. The pharmacy technician must be on the professional register for pharmacy technicians. Retain completed form in pharmacy for 2 years.

Appendix 9: Summary of legal requirements that apply to controlled drugs in Schedules 2, 3, 4 and 5 of the Misuse of Drugs Regulations

Schedule (refers to schedules of the Misuse of Drugs Regulations See current BNF for up to date information.	**Schedule 2** Includes – Opioids, (e.g. diamorphine, morphine, methadone), major stimulants (eg amphetamines), remifentanil secobarbital, lisdexamfetamine	**Schedule 3** Includes minor stimulants, temazepam, midazolam, diethylpropion, buprenorphine, flunitrazepam, Barbiturates except secobarbital Phenobarbital/ Phenobarbitone Tramadol	**Schedule 4, pt I** Includes benzo-diazepines, zopiclone, zaleplon,	**Schedule 4, pt II Includes** anabolic steroids, clenbuterol, growth hormones	**Schedule 5** Includes low strength opioids
Designation	CD POM	CD No reg POM	CD Benz POM	CD Anab POM	CD Inv P or CD Inv POM
Safe custody	Yes, except quinalbarbitone	Yes with certain exemptions (see MEP)	No	No	No
Prescription requirements (including handwriting *) – apply to OP and discharge prescriptions	Yes	Yes	No	No	No
Requisitions necessary?	Yes	Yes	No	No	No
Records to be kept in CD register	Yes	No	No	No	No
Pharmacist must ascertain the identity of the person collecting CD	Yes	No	No	No	No
Emergency supplies allowed	No	No, except phenobarbital for epilepsy	Yes	Yes	Yes
Validity of prescription	28 days	28 days	28 days	28 days	6 mths (if POM)
Maximum duration that may be prescribed	Generally up to 30 days for outpatients, and 14 days for discharge medication	Generally up to 30 days for outpatients, and 14 days for discharge medication	Generally up to 30 days for outpatients, and 14 days for discharge medication	Generally up to 30 days for outpatients, and 14 days for discharge medication	Generally up to 30 days for outpatients, and 14 days for discharge medication

(Table adapted from the Medicines, Ethics and Practice Guide
Prescriptions for schedule 2 and 3 CDs may be typed or computer generated but must be signed by the prescriber.

Appendix 10: Single nurse administration of morphine sulphate oral solution (10mg/5ml)

Below sets the standards that should be followed prior to an area deciding that single nurse administration of Morphine Sulphate oral solution 10mg/5ml can be implemented in that area.

- Participation will be at the discretion of the ward manager
- Only nurses employed by the trust who permanently work on the participating ward may single nurse administer the morphine solution oral (10mg/5ml). Bank or agency nurses will continue to administer using the two nurse checking procedure.
- A log will be kept at ward level of nurses who are permitted to administer via a single check
- All nurses will be aware that they are free to administer the drug with another qualified member of staff if they prefer

Procedure:

- Morphine sulphate oral solution 10mg/5ml ordered from pharmacy on a CD requisition and will be stored in the CD cupboard
- Stock levels checked in the usual way; two registered nurses every 24hrs
- One registered nurse is required to sign in the CD book and administer the drug to the patient
- Two nurses required to confirm by signature in CD book if spillage occurs

NOTE: Morphine Sulphate Concentrated Solution 100mg/5ml is NOT COVERED by this protocol as this is a schedule 2 Controlled Drug and must by checked by two Registered Health Care Professionals.

Appendix 11: Single Nurse Administration of Morphine Sulphate oral solution10mg/5ml Signature List

Nursing staff eligible to use the single nurse check (morphine sulphate oral solution10mg/5ml) policy.

Ward: _____

Ward manager:_____

Name	Signature	Date

Appendix 12: Loss of Controlled Drugs from Ward or Department

Action to be taken in the event of the unaccountable loss of controlled drugs or a discrepancy between the contents of the CD cupboard and the balance in the CD register.

- The nurse/midwife/RODP in charge in association with the clinical pharmacist must establish the facts.
- What is missing? – dose, form, strength and quantity.
- Time since the balance was correct

Take steps to establish a reason for the discrepancy:
Checks should be made against:

1. Running balance
2. Calculations
3. Prescription details
4. Patient administration records (administered but not signed for)
5. Orders and supplies received
6. Checking entries are on the correct page
7. Checking other cupboards that items have not been placed in wrong place.

Ensure all staff who have had possession of the CD Keys, or were involved in the administration and second checks of the CD who were on duty since the loss have been contacted to see if they can assist with the whereabouts of the CD.

During normal working hours, if a discrepancy is not resolved or there is an immediate cause for concern, the clinical pharmacist and senior nurse should be contacted. They should report this loss immediately to either:

- The Accountable Officer for Controlled Drugs (Chief Nurse)
- Deputy Chief Nurse
- Relevant Head of Nursing/Senior Nurse if not already contacted.
- Lead Nurse for Medicines Management 14-60139 gary.caughey@bartshealth.nhs.uk
- Chief Pharmacist

The first person contacted will make contact with the rest of the people on the list and inform them of the loss.

Out of hours the police MUST NOT be contacted, unless there is a serious concern, this would be deemed as:

- An area has clear evidence of forced entry

Out of hours:

- On call pharmacist should be made aware
- Site manager should be made aware – they will make the decision on whether to inform the bronze on-call in most cases this can wait until morning.
- The police MUST not be called unless if falls into the category above.

All losses must be reported on the Trust datix system and escalation to one of the list should happen at the earliest possible opportunity. Please also use the Trust email system to inform the above people. Do not rely purely on the datix system for cascading information as many people get numerous datix and this could be missed so a direct email including datix is required.

The involvement of the police will be on the authority of the Chief or Deputy Chief Nurse in hours and out of hours by bronze on call. The CAD number should be forwarded to the Lead Nurse for Medicines Management so that the Controlled Drug Liaison Team can be informed for follow up.

Appendix 13: References

Department of Health (2013) The Controlled Drugs (Supervision of Management and Use) Regulations: Statutory Instrument 2013 No. 373. [Online]. Available at: http://www.legislation.gov.uk/uksi/2013/373/pdfs/uksi_20130373_en.pdf [accessed 14/10/2015].

The Stationery Office Limited (1971*) Misuse of Drugs Act*. [online]. Available at: http://www.legislation.gov.uk/ukpga/1971/38/contents [accessed 14/10/2015].

Her Majesty's Stationery Office (2001) *Misuse of Drug Regulations*. [online]. Available at: http://www.legislation.gov.uk/uksi/2001/3998/contents/made [accessed 14/10/2015].

Royal Pharmaceutical Society, (2015*) Medicines, Ethics and Practice: the professional guide for pharmacists,* 39, London: Royal Pharmaceutical Society

Nursing and Midwifery Council (2010). *Standards for Medicines Management*. [online]. Available at: http://www.nmc.org.uk/globalassets/siteDocuments/NMC-Publications/NMC-Standards-for-medicines-management.pdf [accessed 14/10/2015].