Controlled Drugs Policy

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12	August 2021	Veena Shivnath	Lead Pharmacist BCHS & Clinical Lead Pharmacist Newham Centre	3.5 Amended to audit every 3 months by ward manager and Pharmacist 6.2.6 Old CD books to be destroyed on site after 2 years as from last entry date. This is the ward manager's responsibility. 7.2.2 Prescribers can add their electronic signatures to CD prescriptions 8.0 RNs can order CDs added 8.7 CD requisitions can be given to Pharmacy technicians by ward staff 8.10 For CD collection out of hours on a Saturday/Bank Holiday, the staff collecting must not be the one who wrote the CD requisition 8.12 Amended to reflect that Pharmacy staff must not write CD requests for wards 13.1.3 No CDs kept in EDR in EHCC 13.4.13 Amended- on call pharmacist does not organise transport out of hours for ward CD requests 14.9 Added any ward CD discrepancy must be reported to the ward Pharmacist 15.3 If patient is no longer on a CD brought to the ward, then it must be returned to a relative and not given to the patient or consent sought from patient to destroy the CD 17.7 CD Audit by snap surveys removed and added audit link sent by quality assurance every 3 months 17.8.3 Removed, as oramorph is not a CD 18.7.11 Removed presence of pharmacy staff to witness any CD spillage on the ward 20.0 CD audits to be completed 21.01 Added information relating to use of when required CDs 21.02 New section added regarding Opioid Thermometer Appendix 3- removed link to the previously used audit tool: https://www.snapsurveys.com/wh/s.asp?k=140844390193
12.1	Feb 2022	Veena Shivnath	Lead Pharmacist BCHS & Clinical Lead Pharmacist Newham Centre	3.4 Added qualified pharmacy technicians to assist with quarterly audit

12.2	Sept 2023	Susana Fontelo	Lead Pharmacist City and Hackney and Forensic Services	13.1.1 Out of hours emergency stock list updated for all sites

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Legislative Framework for Controlled Drugs

1.0 The management of Controlled Drugs (CDs) is governed by the Misuse of Drugs Act (1971) and the associated Regulations (in England, Wales and Scotland).

1.1 Additionally, statutory measures for the management of CDs are laid down in the Health Act (2006) and the associated Regulations. The relevant legislation and guidance is summarised briefly in Appendix 1.

1.2 The legal requirements pertaining to the main classes of CDs are summarised in Table 1 (overleaf). Schedule 1 drugs have been omitted from the table as drugs in this group have virtually no therapeutic indication in common practice.

Introduction

2.0 CDs are drugs with restrictions on their use including administration, prescribing, ordering, manufacturing, record keeping, storage, destruction and are subject to the Misuse of Drugs Act 1971 and the associated regulations. CDs are important for the management of a variety of clinical conditions and are subject to special legislative controls because of the potential for them to be abused or diverted and cause harm.

2.1 This policy is subject to review and audit and is accessible via the Trust Intranet. Various amendments exist and alterations are made occasionally. All relevant changes are notified to all those involved with CDs by the pharmacy staff.

Governance Arrangements

3.0 The Trust is accountable through the Accountable Officer for ensuring the safe use and management of CDs within the Trust. The Accountable Officer (AO) is the Chief Pharmacist for the Trust and has the responsibility for the safe and effective use and management of controlled drugs 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 investigating concerns and incidents relating to CDs.

See Appendix 2 for further details about role of the AO.

3.1 The Trust is required to complete an annual self-assessment on use of CDs using the Care Quality Commission audit tool. This is kept on record by the Trust Assurance Committee.

3.2 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 and the Care Quality Commission. A report will be sent to the Local Intelligence Network (LIN) every 3 months, prepared by the pharmacy team and approved by the Accountable Officer. The AO links with the Trust Medication Officer for list of incidents and completes a report for each directorate with input from Lead pharmacists (Lead Nurses from each directorate).

3.3 A report on the handling of Controlled Drugs in the Trust will be included in the Trust's annual Medicines Management Report to the Board.

3.4 A CD audit will be completed by a qualified nursing staff member and the ward pharmacist or pharmacy technician every 3 months as set by the assurance department. Audit results will be fed back via the Trust Audit Department to the Lead pharmacists and local directorate management team (DMT) for review. Where there are concerns, these will be reported via the local Medicines Safety Group and DMT where action plans for improvement will be presented and monitored. In addition, regular audits must be carried out to ensure compliance with CD management.

Refer to Appendix 4 for the audit tool which is here for educational and training purposes but not to be used for the quarterly audit.

Safer Management of Controlled Drugs: a guide to good practice in secondary care (England)

Table 1: 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)	**Schedule 2** Includes – opioids, (e.g. diamorphine, morphine, methadone), major stimulants (eg amphetamines, lisdexamphetamine), remifentanil secobarbital,	**Schedule 3** Includes minor stimulants, temazepam, tramadol diethylpropion, buprenorphine, flunitrazepam, barbiturates except secobarbital. Pregabalin and Gabapentin	**Schedule 4, Pt I** Includes benzodiazepines zopiclone, zaleplon	**Schedule 4, Pt II** **Includes** Anabolic and androgenic steroids, clenbuterol, growth hormones	**Schedule 5** Includes low strength opioids e.g. codeine, morphine 10mg/5ml
Designation	CD POM	CD No register POM	CD Benz POM	CD Anab POM	CD Inv POM CD Inv P
Safe custody	Yes, except quinalbarbitone	Yes, (with certain exemptions, including tramadol, pregabalin, gabapentin and midazolam -see MEP)	No	No	No
Prescription requirements (including handwriting*) – apply to Out Patient and discharge prescriptions	Yes	Yes	No	No	No
Prescription is repeatable*	No	No	Yes	Yes	Yes
	i.e instances of an added instruction on the main prescription to be repeated e.g. repeat x 3				
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 phenobarbitone for epilepsy	Yes	Yes	Yes

Validity of prescription	28 days	28 days	28 days	28 days	6 months (if POM)
Maximum duration that may be prescribed	30 days as good practice	30 days as good practice	30 days as good practice	30 days as good practice	30 days as good practice

Standard Operating Procedures (SOPs)

4.0 Each of the activities that relate to CDs, regardless of where in the organisation they occur, must be described in a standard operating procedure (SOP) approved by the AO. This is particularly important if tasks are delegated to others. For example, issue and receipt of Controlled Drugs in the pharmacy may be delegated to a pharmacy technician. However, final responsibility lies with the Chief Pharmacist.

4.1 The SOPs relating to CD activity in ELFT are housed within this Policy. They are up-to-date and reflect current legal and good practice requirements for CDs.

4.2 All staff involved in the prescribing, supplying, administering or disposing of CDs needs to be familiar with the SOPs.

4.3 Whilst the below sets out the standard operating procedures and policy for the organisation individual wards or services may be subject to additional requirements if there is a cause for concern after discussion with the lead pharmacist and the AO.

SOP for Schedule 3 Controlled Drugs and Other Drugs Liable to Misuse

5.0 Schedule 3 CDs are those that are not thought so likely to be misused or as harmful as those in schedule 2.

5.1 They therefore have different requirements for safe handling and storage under the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001 which must be followed.

5.2 Storage: They must be kept under safe custody unless exempted under the Misuse of Drugs (safe custody) Regulations 1973. Common Exemption include midazolam, tramadol, pregabalin and gabapentin.
Common schedule 3 CDs which MUST be kept under safe custody include temazepam and buprenorphine

5.3 Common Schedule 3 Controlled Drugs used within ELFT

Drug (Schedule 3)	Safe Storage in CD cabinet?	Order via ELFT CD requisition slip for inpatient supply (appendix 5)	Recorded in the CD register	Full prescription requirements apply (outpatient and discharge medication see section 7.2 of this policy)
Tramadol	No	Yes	No	Yes
Pregabalin	No	Yes	No	Yes
Gabapentin	No	Yes	No	Yes
Midazolam	No	Yes	No	Yes
Temazepam	**Yes**	Yes	No	Yes
Buprenorphine	**Yes**	Yes	No	Yes

SOP for Controlled Drug Stationery

General Principles

6.1.1 CD stationary used within ELFT comprises of specific pharmacy and ward CD registers, ward CD return books and pharmacy CD destruction registers. The ward CD register contains integral order slips that are linked to every page to enable ward staff to order CDs.

6.1.2 This stationery must be stored securely and access to it must be restricted to prevent unauthorised use of the stationary to obtain CDs for inappropriate uses.

6.1.3 On wards, these must be kept in a locked cupboard or drawer. In the pharmacy department these must also be kept in a locked cupboard.

Ordering Controlled Drugs Stationery

6.2.1 When a new ward CD register is required the nurse in charge at that time should complete the 'Please supply a new CD register' form that is located 5 sheets before the end of the CD register. They should contact a member of their ward pharmacy team and give this to them. The clinical pharmacy team member will take this to the pharmacy dispensary where replacement ward CD registers are stored. In the event that there is no such request form in the CD register, then staff must inform the pharmacy team about logistics of supplying the CD register.

6.2.2 The member of dispensary staff issuing the new CD register to the ward must check that the member of nursing staff requesting the new CD register on the 'Please supply a new CD register' form is an authorised CD signatory.

6.2.3 When issuing the new register, the dispensary member of staff should record the following in the 'Issue form for CD registers'.

- Date issued
- Starting and ending requisition numbers for CD register
- Name of member of staff issuing the CD register
- Name of ward staff member receiving the CD register.

6.2.4 For wards with an on-site dispensary, all CD registers should be collected from the dispensary. The member of staff collecting the new CD register should be a registered nurse, with a valid ID badge, and must not be the same member of staff who ordered the CD register. The nurse will sign the 'received by' column on the 'Issue form for CD registers'. The nurse will also sign and date for receipt on the 'Please supply a new CD register' form before taking the new CD book to their respective ward.

6.2.5 For wards that are off site from the dispensary, the new CD register will be delivered to the ward via the existing delivery system. The CD register along with a copy of the 'Please supply a new CD register' form will be placed in a sealed pharmacy delivery bag. The porter or authorised messenger will be required to sign the 'received by' column on the 'Issue form for CD registers' when collecting the bag for delivery. The pharmacy bag delivery sheet will be marked to indicate that the bag contains CD stationary. When the porter delivers the bag containing the CD register to the ward the bag must be handed to an appropriate member of staff. On no account must they be left unattended (see section 9.0; Transfer of Controlled Drugs). A local procedure must define the appropriate persons who are permitted to receive CDs/CD stationary and the way in which porters/messengers identify them. The appropriate member of staff will sign for receipt on the pharmacy bag delivery sheet. A registered nurse on the authorised signatory list must receive the CD register and sign and date for receipt on the 'Please supply a new CD register' form. This signed form must then be returned to pharmacy.

6.2.6 Completed CD registers must be stored for a minimum period of two years from the date of last entry, in line with legal requirements and the Trust's Records Retention and Disposal policy. Completed CD registers must be sealed with a sticky label stating the last entry date and the destruction date. All expired CD registers must be destroyed on site via confidential waste disposal. The ward manager is responsible for destroying the CD register once the period of 2 years is reached.

6.2.7 Any unused stationery returned to Pharmacy will be recorded as a return, with the details above in the supply record.

6.2.8 Loss or theft of any controlled stationery which may be used to order CDs must be reported immediately to the Chief Pharmacist of the Trust.

Controlled Drug Register

6.3.1 Each ward that holds stocks of schedule 2 CDs must keep a record of CDs received and administered in a CD register. The Modern Matron (MM)/Senior Nurse (SN) are responsible for ensuring that the CD Record book is kept up to date and in good order.

6.3.2 When the total stock of a CD supplied on a requisition has been administered, the top right-hand corner of the page must be torn off to show that the page is complete.

6.3.3 All entries must be signed by a registered nurse, and witnessed preferably by a second registered nurse. If a second registered nurse is unavailable, the transaction can be witnessed by another registered practitioner (a doctor, pharmacy technician or pharmacist).

6.3.4 If a mistake is made in the pharmacy CD register, it must not be obliterated or crossed through but bracketed [ ] in such a way that the original entry is still clearly legible. This must be signed, dated and witnessed by a second member of pharmacy staff who must also sign the correction. The correct entry must be made on the next available line or as a footnote.

6.3.5 If a mistake is made in the ward CD register, nursing staff may, in line with NMC guidance cross through the original entry with a single line or bracket the incorrect entry. This must be done in such a way that the original entry is still clearly legible. This entry should be signed and dated by the nurse and in addition a second nurse should also sign the change.

6.3.6 The CD register must be kept for a minimum of 2 years within the Trust from the day the last entry in the CD register was made.

6.3.7 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.

6.3.8 The CD register must be kept in a locked cupboard, where it must be accessible to staff authorised in this policy (See below).

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

Use of Controlled Drug stationery

6.4.1 Only one CD register per ward or department must normally be in use.

6.4.2 CD return books should only be kept by those wards in the Trust that are offsite to the nearest pharmacy dispensary.

6.4.3 When a new CD register is started, the balance of CDs in stock must be written into the new book promptly by a registered nurse. This transfer must be witnessed by a registered nurse or authorised member of staff e.g. pharmacist, or an accredited pharmacy technician.

6.4.4 If the transfer of CDs within a register is necessary i.e. from one page to a new page (e.g. when the balance is greater than 0 by the end of the current page), then both requisition numbers, the name of the drug, strength, form and quantity transferred must be recorded on both pages. Two registered nurses must sign both pages.

The order part/slip of the new page must be scored through, with the word "void" written across it. The slip must remain attached in the CD register. The order/CD req number on the container must be changed to correlate with new CD page.

SOP for Prescribing Controlled Drugs

7.0 Controlled drugs can be prescribed or supplied by the following mechanisms:

7.1.1 Prescription by a medical doctor or dentist – schedule 2, 3, 4 and 5 drugs.
7.1.2 Prescription by supplementary prescribers – when acting under, and in accordance with, the terms of a clinical management plan, CDs in schedules 2, 3, 4 and 5.

7.1.3 Pharmacist and Nurse Independent Prescribers may prescribe, administer and give directions for the administration of Schedule 2, 3, 4 and 5 Controlled Drugs. They are not permitted to prescribe diamorphine, dipipanone or cocaine for treating addiction but may prescribe these items for treating organic disease or injury. Prescribers must ensure that they are familiar with the various drug schedules, details of which can be found in the British National Formulary. Optometrist independent prescribers cannot prescribe controlled drugs.

7.1.4 The quantity of any CD prescribed must not exceed 30 days' supply per prescription (excluding schedule 5 drugs). This is not a legal restriction, but prescriber should be able to justify (on a clinical basis) if supply greater than 30 days is requested.

Prescribing Controlled Drugs for outpatients and discharge medication

7.2.1 Prescriptions for schedule 2 and 3 CDs must be prescribed on a separate CD form- see appendix 6 and 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 drug or the **total number** of dose units to be supplied;
- Doses prescribed in micrograms should be written fully as 'micrograms' and not abbreviated to 'mcg'
- For "when required" drugs a minimum interval for administration must be specified eg. 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.
- RiO/NHS number (good practice to include this);

7.2.2 This information must be written so as to be indelible i.e. by hand or computer generated and the signature can be an electronic signatures.

7.2.3 When prescribing controlled drugs, best practice guidance should be followed as outlined in NG46 including a documented discussion with the patient/carer outlining prescribing decision and rationale.
https://www.nice.org.uk/guidance/NG46/chapter/Recommendations#prescribing-controlled-drugs

7.2.4 Medical doctors who have not achieved full registration with the General Medical Council (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. FY1 doctors are not permitted to write outpatient prescriptions.

7.2.5 If sticky labels are used, prescribers must also sign on the sticky label or at least start their signature on the sticky label. This is a safeguard to ensure sticky labels are not tampered with or another sticky label is not placed on top of the one that the prescribers sign for.

7.2.6 Prescriptions for schedule 2, 3, and 4 CDs will be valid for 28 days from the date they are written.

7.2.7 Discharge TTAs for schedule 2, 3 and 4 controlled drugs will usually be limited to a quantity necessary for 14 days' supply and outpatient prescriptions for schedule 2, 3 and 4 CDs will usually be limited to a maximum quantity of 30 days' supply. 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 must be ready to justify this decision if required. Short term leave prescriptions for schedule 2,3 and 4 CD's will usually be limited to a quantity of less than 14 days' supply depending on the leave period.

7.2.8 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, so that the prescription is legally compliant.

7.2.9 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.

7.2.10 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 notes.

7.2.11 It is illegal for a prescriber to issue and for a pharmacist to dispense an incomplete or incorrectly written prescription for a controlled drug.

7.2.12 Oral morphine, oxycodone, fentanyl and buprenorphine patches can also be prescribed by brand name to reduce risk. E.g. morphine sulphate tablets 10mg (Sevredol). However, the majority of products are now available as generic preparations.

7.2.13 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.

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

Prescribing Controlled Drugs for Inpatients

7.3.1 Inpatient medication charts are an instruction to administer a medicine within the hospital. When using these charts, CDs do not need to be written up as full CDs, so can be prescribed as any other medication. The patients address does not need to be added to the medication chart as CD's will be administered in a hospital.

7.3.1 When ordering CD's for short term leave or discharge, the pharmacist should use the pre-printed CD prescription form to ensure all legal requirements for the prescription are met (see Appendix 6).

8.0 SOP for Ordering Controlled Drugs

8.0 The Modern Matron (MM)/Senior Nurse (SN) is responsible for the requisitioning of controlled drugs for use on the ward.

8.1 The ward manger can delegate the task of preparing a requisition to another, such as a registered nurse. However, legal responsibility remains with the MM/SN.

8.2 Only permanently employed (not bank or agency) registered nurses, who have successfully completed their preceptorship and Safe Administration of Medicines e-learning, can order controlled drugs on a requisition form in the controlled drug register. If none of these staff are available, the requisition must be signed by the Duty Senior Nurse.

8.3 The nurse must use a new page in the CD register to order CDs. At the top of the right hand page they should enter the name form and strength of drug ordered. Enter the quantity of drug ordered - pending CD register changes.

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

Hospital name
Ward
Drug name, dose form, strength and size
Quantity to be ordered
Printed name and signature of authorised registered nurse writing requisition.
Date

8.6 It is the responsibility of the Modern Matron and the ward manager to ensure that those ordering controlled drugs are registered and authorised staff members.

8.7 Completed order requisition slips must be detached from the register and given to the ward Pharmacist or Pharmacy Technician it can also be taken to the Pharmacy by ward staff or sent via the porter. Orders must be accompanied by an in-patient drug chart to demonstrate that it has been prescribed for patients on your wards are still using paper charts.

8.8 Before the requisition can be dispensed or issued by dispensary a clinical pharmacist must also sign the CD requisition slip to indicate that they have clinically screened the prescription. Before signing the slip, the clinical pharmacist should be assured that a prescription exists for the drug being requested and that a supply is genuinely required. They must also ensure that the ordering nursing staff are authorised to order controlled drugs and that the name is clearly printed and signed. The screening pharmacist can make the following minor amendments to requisition slip:

- Include brand name (where applicable)

- Change formulation to reflect the inpatient chart
- Amend quantity ordered

Any amendments made to the requisition slip must also be reflected in the CD register to ensure the received controlled drug corresponds with the requested order.

8.9 For clinical services off site to the dispensary, the CD requisition slip may be faxed or scanned by pharmacy staff to the relevant dispensary. The dispensary may dispense from this copy of the CD requisition slip, so long as local pharmacy staff are in possession of the original requisition slip. When the CD is then delivered to the relevant ward, the ward must retain the paperwork. The nurse receiving the CD **must sign** the copy of the requisition slip which will be collected by the local pharmacy staff on the next working day and this copy of the CD requisition slip will be matched with the original for audit trail purposes.

8.10 At weekends, only one dispensary is open in the Trust (Mile End Hospital Pharmacy) between the hours of 10am-1pm. If CDs need to be ordered from wards that are off site to this dispensary during this time, a member of ward staff or authorised messenger will need to bring the original requisition slip to pharmacy to enable a supply of the CD. The member of staff bringing this CD requisition must not be the same staff who wrote the CD requisition. This is because pharmacy must be in possession of the original slip in order to make a legal supply. This service should only be used in an emergency to avoid unnecessary disruption to staffing. This requirement is applicable to CD schedule 2 & 3.

8.11 In accordance with robust stock management, it is the responsibility of the MM/SN to ensure that adequate CD stock is ordered, especially before weekends or bank holidays when pharmacy may not be open.

Pharmacy staff must not write CDs for wards except for their locality EDRs whereby if the pharmacy technician is writing the CD requisition another pharmacist must countersign this requisition.

SOP for the Transfer of Controlled Drugs

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

- Collection by ward staff from the pharmacy
- Delivery by pharmacy staff to wards
- Collection by patient or representative for outpatient items only
- Delivery by Trust porter/driver
- Delivery by commercial courier (for example, taxi out-of-hours)

9.1.1 CDs must always be transferred within the Trust in a sealed pharmacy bag.

9.1.2 At each point where a CD moves from the authorised possession of one person to another, a signature for receipt must be obtained by the person handing over the drug and the person receiving it. This must be recorded in the controlled drug register or using auditable delivery paperwork.

9.1.3 The definition and role of ‘messengers’ is outlined below.

9.1.4 The person who conveys the CD, e.g. a member of portering staff, acts as a messenger; that is to say he/she carries a sealed or locked container and is responsible for delivering the intact container. Numbered seals are placed on Pharmacy bags, staff signing for receipt of CDs must confirm the number matches that on the delivery paperwork.

9.1.5 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

9.1.6 CDs will only be handed to members of staff who are wearing valid ID badges.

Supply, delivery or collection of Controlled Drugs from Pharmacy

9.2.1 A member of 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 nurse.

9.2.2 CDs at ELFT will either be collected or delivered from pharmacy depending on whether the clinical service ordering the CDs is on or off site in relation to the dispensary.

9.2.3 For clinical services with an onsite dispensary (Tower Hamlets Centre for Mental Health), a registered nurse, with a valid ID badge, must collect the CDs from pharmacy. The member of nursing staff must be different to the nurse ordering the CDs and the member of pharmacy staff issuing the controlled drug must check that the names and signatures are different. The nurse will check that the CD they are receiving matches that ordered on the CD slip and print, sign and date the CD slip in the 'received by section'. They should also print and sign their name on the pharmacy 'CD Collection Record'. The CD slip will then be retained by pharmacy and the nurse will transport the CD in a sealed bag to their respective ward.

For clinical services that do not have an on-site dispensary (City & Hackney Centre for Mental Health, John Howard Centre, East Ham Care Centre, Newham Centre for Mental Health, Wolfson House and Bedfordshire and Luton), the CD will be delivered by porter/authorised messenger. This situation may also apply to those sites with an on-site dispensary during weekends or out of hours, when only one dispensary site may be open in the Trust. The porter/authorised messenger will sign, print and date the 'delivered by' section of a photocopy of the completed CD requisition slip and this will be placed in a security sealed bag together with the CD. The porter/authorised messenger will also sign in the 'collected by' column of the pharmacy 'CD Collection Record'. Pharmacy staff will annotate the pharmacy bag delivery sheet (taken with bags by porter) to indicate that the bag contains a CD. This annotation will include writing the CD requisition number on the delivery sheet. The pharmacy porter/authorised messenger will then deliver the CD to the ward. The original CD requisition slip will be retained in pharmacy as a record of dispensing and will later be combined with the returned photocopy of the same slip from the ward for audit trail purposes.

SOP for the Receipt of Controlled Drugs on the Ward

10.0 **Receipt of controlled drugs from an on-site dispensary**

10.1.1 When CDs have been received from an on-site dispensary, the registered nurse who picked up the CDs from pharmacy must enter the received CDs in the CD register. This must be witnessed and countersigned by a second member of staff who can be:

A registered nurse
Doctor
Pharmacist
Pharmacy Technician

10.1.2 The nurse 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 and time of register entry
Quantity received
Drug name, form, strength
Name/signature of nurse/authorised person making entry
Name/signature of witness
Balance in stock

10.1.3 All TTAs containing schedule 2 CDs collected from pharmacy must be received into the ward CD book before being issued to the patient. This is to ensure that an audit trail exists for the transfer of CDs.

Receipt of Controlled Drugs from an off-site dispensary

10.2.1 When CDs are delivered to award from an off-site dispensary by the porter/authorised messenger they must be handed to a registered nurse wearing an identification badge. This member of staff will sign for receipt on the pharmacy bag delivery sheet. The bag must not be left unattended. (See section 9.0 Transfer of CDs). As a matter of good practice the receiving person must not be the same person who ordered the CD and where there is no other nurse, then the DSN must be contacted to receive this CD.

10.2.2 A registered nurse for the clinical area must receive the CD checking the drug supplied including the quantity ordered and received against the requisition in the presence of the messenger. If there is not an authorised nurse available, the duty senior nurse must receive the CD. The registered nurse must have a currently valid ID badge to be able to receive the CD. If correct, the CD requisition slip must be signed to indicate receipt while the porter or messenger is present. This signed requisition slip must be returned to pharmacy. If the supply is incorrect, a pharmacist must be contacted immediately.

10.2.3 The signed requisition slip will be collected by pharmacy staff on the next working day Pharmacy must check after each delivery that all CD delivery requisitions have been returned, and signed for receipt by an authorised nurse on the ward. This nurse must be different to the nurse who ordered the CD. Pharmacy must keep the returned CD delivery slip and reconciliate it with the original order

10.2.4 Once the supply has been checked, the registered nurse must enter the received CDs in the CD register. This must be witnessed and countersigned by a second member who can be:

A registered nurse
Doctor
Pharmacist
Accredited Pharmacy Technician

10.2.5 The nurse 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 and time of register entry
Quantity received
Drug name, form, strength
Name/signature of nurse/authorised person making entry
Name/signature of witness
Balance in stock

10.2.6 All TTAs containing schedule 2 CDs received from pharmacy must be received into the ward CD book before being issued to the patient. This is to ensure that an audit trail exists for the transfer of CDs.

SOP for the Storage of Controlled Drugs on the Ward

11.0 CDs must be kept locked in the controlled drugs cupboard when not in use and The Misuse of Drugs (safe custody) regulations 1973 (SI1973 No 798) apply. Access to this cupboard is restricted to authorised staff only. This cupboard must be used exclusively for the storage of CDs. No other medicines or items may be stored in the CD cupboard. Usually the cupboard is a locked cupboard inside the drug cupboard.

11.1 CD cupboards must conform to the British Standard reference BS2881 or be otherwise approved by pharmacy. This is a minimum security standard and may not be sufficient for areas where there are large amounts of drugs in stock at a given time, and/or there is not a 24-hour staff presence, or easy control of access. In this case a security cabinet that has been evaluated against the SOLD SECURE standard SS304 (See www.soldsecure.com) must be used.

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

11.3 Discharge medication containing CDs must be stored in the CD cupboard until the patient is discharged. The medication must be separated from the ward CD stock and clearly marked and must remain in a sealed bag.

11.4 Patient' own CDs stored in the CD cupboard must be clearly separated and marked in a sealed back to separate from normal stock. This must be not used for other patients. Please see section 'SOP for Patient's Own Controlled Drugs'.

11.5 Expired Controlled Drugs stored in the CD cupboard must be clearly separated and marked in a sealed back to separate from normal stock. This must be not used for administration to patients. Pharmacy must be informed, so that removal and destruction can be co-ordinated.

11.5 In the event of any problem with the CD cupboard, arrangements must be made to sort the problem as soon as possible and the ward pharmacist must be informed and the modern matron. Alternative arrangements may need to be made for safe storage

SOP for the Responsibility for Controlled Drugs Keys

12.0 Access to keys must be restricted to persons authorised under the Misuse of Drugs Act, i.e. a pharmacist, registered nurse. The legal responsibility rests with the registered nurse in charge, who must be aware of the key location or who is in possession at all times.

12.1 The controlled drugs keys must be kept separate from the main drugs key ring. The controlled drugs keys should be held by one designated senior nurse per shift (where possible) to avoid transfer of the controlled drug keys to multiple staff.

12.2 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 to a registered nurse after use.

12.3 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 Controlled Drugs Keys

12.7.1 If the CD keys cannot be found then the Modern Matron (MM)/Senior Nurse (SN) should be informed immediately and urgent efforts must be made to retrieve the keys as speedily as possible; e.g. by contacting nursing staff who have just gone off duty.

12.7.2 If the keys cannot be found then the pharmacist/on-call pharmacist (out of hours) must be informed. Depending on the circumstances, it may also be appropriate to inform the police. The pharmacist, will able to advise on continued access to relevant CDs prescribed to patients, so that patient care is not compromised (this may include borrowing from other wards).

12.7.3 A spare key (if available) can be used until the original is returned/found.

12.7.4 If the original key cannot be found, the estates and facilities helpdesk must be contacted to open the cupboard and replace the lock as soon as possible. The MM/SN must be present to supervise when this is undertaken to ensure continued safe storage. A balance check must be undertaken immediately after.

12.7.5 The Chief Pharmacist (as CD Accountable Officer), Lead Pharmacist and Borough Lead Nurse must be informed as soon as possible and a DATIX form completed.

12.7.6 A full CD balance check must be completed once the issue has resolved and normal access to the CD cupboard has resumed.

SOP for Obtaining Controlled Drugs in an Emergency out-of-hours

13.0 **Out of hours emergency stock Controlled Drugs**

13.1.1 The following CDs are kept as **out of hour's emergency stock** at the following locations within the Trust. There is information further below in reference to CD balance checks and the process of authorised supply out of hours.

Out of hours Emergency Stock Controlled Drugs:

Location	**CDs Available**
Tower Hamlets: Globe ward Ward CD Cupboard	1x500ml bottle Methadone 1mg/1ml 7x2mg Buprenorphine SL tabs 7x8mg Buprenorphine SL tabs 28x25mg Pregabalin capsules 28x100mg Pregabalin capsules 30x100mg Gabapentin capsules
City & Hackney: Ruth Seifert Ward Ward CD Cupboard Forensic services do not hold any CD on their emergency cupboard	1x 500ml x 1mg/1ml Methadone liquid SF 7x 2mg Buprenorphine SL tabs 7 x 8mg Buprenorphine SL tabs 28 x 25mg Pregabalin caps 30 x 100mg Pregabalin caps 10 x 10mg/2ml Midazolam solution for inj

Newham: Ruby Triage Ward EDR Emergency Drug Cupboard	1 x 500ml x 1mg/1ml Methadone liquid SF 7 x 2mg Buprenorphine SL tabs 7 X 8mg Buprenorphine SL tabs 28 x 100mg Gabapentin caps 10 x 10mg/2ml Midazolam solution for inj 28 x 25mg Pregabalin caps 28 x 100mg Pregabalin caps
Luton: Onyx Ward (Key with DSN) EDR Emergency Drug Cupboard	30 x 100mg Gabapentin caps 10 x 10mg/2ml Midazolam solution for inj 28 x 25mg Pregabalin caps 28 x 10mg Temazepam tabs 28 x 20mg Lisdexamfetamine tabs 28 x 30mg Lisdexamfetamine tabs 2 x 500ml x 1mg/1mL Methadone Oral Solution SF 30 x 5mg Methylphenidate tabs 30 x 18mg Methylphenidate XL tabs (Concerta) 30 x 27mg Methylphenidate XL tabs (Concerta) 100ml x 10mg/5ml Morphine sulphate oral solution 10 x 10mg/ml Morphine sulphate amp 51 x 10mg Morphine sulphate MR tabs 250ml x 250mg/5ml Oxycodone Liquid (Shortec) 28 x 5mg Oxycodone I/R caps 42 x 10mg Oxycodone MR tabs 50 x 50mg Tramadol caps 4 x 5mcg/hr Buprenorphine patches 7 x 0.4mg Buprenorphine S/L tablets 7 x 2mg Buprenorphine S/L tablets 7 x 8mg Buprenorphine S/L tablets

Issue of out of hours emergency stock controlled drugs

The DSN must be contacted for supply of any of the emergency CD stock listed above. The DSN must inform the on-call pharmacist if accessing supply for use out of hours.

The on call pharmacist will inform the relevant pharmacy department of the supply the following day.

The receiving ward will sign any CD received into their own CD register and store it in their CD cupboard.

Buprenorphine should be kept in the CD cupboard. The requisition slip in the tamper evident bag should be completed and must be given to the ward pharmacy team.

Storage and balance checks of Emergency Out of Hours CDs stock

a) **Tower Hamlets**, **City & Hackney**

Emergency out of hours CDs will be stored in the ward CD cupboard in tamper evident bags.

Methadone (500ml of 1mg/ml)
- Entered in the CD register of the ward and must be balance checked each day by ward staff.
- If the tamper evident bag remains unbroken, there is no need to physically count or measure the contents, they can be assumed ok.

Buprenorphine
- Although safe storage is required, there are no CD register requirements
- There will be a requisition present in the tamper evident bag that must be completed by the receiving ward and given to pharmacy as soon as possible.

b) Newham

Emergency out of hours CDs will be stored in the EDR CD cupboard on Ruby Triage ward.

CD checks will be performed by pharmacy staff Monday to Friday and by the DSN on weekends and bank holidays.

c) Luton

Emergency out of hours CDs will be stored in the EDR on Calnwood Court, Crystal ward.

CD checks will be performed by pharmacy staff Monday to Friday and by the DSN on weekends and bank holidays.

Re-order of Out of Hours CDs

a) **City and Hackney, John Howard Centre, Tower Hamlets**

A note should be made in the pharmacy order book in the ward to replenish what has been used out of hours. The pharmacy team will also have been additionally informed by the on call pharmacist prompting a re-supply.

b) **Newham**

The pharmacy team will re-order the CD during their daily EDR top up by completing a new requisition and ordering via Mile End Pharmacy. CDs in the EDR are to be requisitioned by Pharmacy Medicines Management Technicians and Pharmacist only. The on call pharmacist will also have informed them of the supply.

Eastham Health Care Centre

No CDs are stocked in the EDR cupboard as all wards hold a stock of frequently used CDs.

c) **Luton**
The pharmacy team will re-order the CD during their daily EDR balance check by completing the order slip in the CD book. CDs in the EDR are to be requisitioned by Pharmacy Medicines Management Technicians and Pharmacist only. The on call pharmacist will also have informed them of the supply.

Transfer of CDs between wards and CD register entry

13.2.1 In an emergency, out of hours when the pharmacy is closed, CDs may be transferred from one ward to another. The Duty Senior Nurse must be consulted, and also the on-call pharmacist if advice is required.

13.2.2 If only one dose is needed the details must be entered out of the supplying ward CD register (including the patient's ward) and the dose can then be administered to the patient on their ward. This should be undertaken by two registered nurses; one nurse from each ward involved.

13.2.3 If several doses are transferred e.g. a strip of tablets, the CD must be transferred from one CD register to the other (no loose tablets, or some amount of liquid decanted)

- Details of wards involved and page numbers must be entered in each register
- Both registers signed by a registered nurse from each ward,
- The number of the page in the new register must be written on the CD container.
- The order slip of the new page in the CD register being transferred to must be crossed through and marked void and left attached in the register for checking as part of the three monthly nursing audit.

Transfer of CDs between sites

13.3.1 CDs may occasionally be required at another site within the Trust and can be transferred from one site to another in the same way as transfers between wards. The Duty Senior Nurse and on-call pharmacist must be consulted when a transfer is taking place between sites.

13.3.2 The CD must be transferred from one CD register to the other, recording details of wards/areas and sites involved and page numbers in each register; two signatures will be required at each end. The number of the page in the new register must be written on the container. The order part of the new page must be crossed through and marked void. The order slip must either be left attached in the register for checking or placed in a designated area of the CD cupboard, until it is reviewed and collected as part of the three monthly CD audit check.

13.3.3 Authorised Trust transport systems must be used i.e. hospital transport department or the contracted taxi firm. The identification of the driver must be checked. As a matter of good practice the taxi registration number may also be recorded. The driver must be given the controlled drugs 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.

13.3.4 On receipt the package must be signed for and this signature is for receipt of a sealed package. Copies of receipts must be retained in the pharmacy department for at least the current legal minimum period of two years.

Lending/borrowing to/from other hospitals outside the Trust arrangements.

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

13.4.2 A written requisition must be provided to the external supplying Hospital. The requisition will be completed by the on-call pharmacist and can be found in the electronic pharmacy on-call folder on the shared drive and must comply with the legal requirements.

13.4.3 The ward staff requesting the CD must organize transport to collect the CD from the relevant Hospital by linking with the pharmacy department. Procurement must be informed of this action on the next working day by the on-call pharmacist.

13.4.4 The on-call pharmacist should refer to their own internal on-call procedure and also the most recent version of the MEP (Medicines, Ethics and Practice).

13.4.5 Records must be kept for a minimum period of 2 years.

13.4.6 Conversely, if another hospital wants to order controlled drugs from ELFT, it must be the on-call pharmacist that authorises and co-ordinates this supply, ensuring legal requirements are met and that the provision of supply is appropriate.

13.4.7 Please note that GPs may not borrow or obtain controlled drugs from the Trust, as they have their own access to emergency supplies.

SOP for the Administration of Controlled Drugs

14.1 Two members of staff must be involved in all stages of the administration of CDs; staff members may be a registered nurse, doctor, accredited pharmacy technician or pharmacist.

14.2 Both practitioners must be present during the whole of the administration process.

14.3 Both staff members must complete the record of administration each time a dose of a CD is given in the ward/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. Note: CD register entries are only required for schedule 2 CDs (e.g. methadone, oxycodone) and not Schedule 3 CDs (e.g. tramadol, buprenorphine, pregbabalin, gabapentin).

14.4 The following details must be recorded:

- Date and time administered.
- Name of patient.
- Amount given.
- Amount wasted.
- Signature of nurse/authorised person who administered the dose.
- Signature of witness.
- Balance in stock.

(The details of the drug name, strength and formulation are stated at the top of the page.)

14.5 Nursing staff administering controlled drugs should follow best practice outlined in NICE NG46 https://www.nice.org.uk/guidance/NG46/chapter/Recommendations#administering-controlled-drugs

14.6 The stock balance must be confirmed to be correct physically and in the register.

14.7 The registered nurse who administers the CD must sign 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 record book and sign the ‘witnessed by’ section in the register.

14.8 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.

14.9 Any entry found to be wrong or any actual or suspected drug loss must be reported immediately to the nurse in charge and the pharmacist.

14.9 Any drug wasted, e.g. part of an ampoule must be recorded and emptied out into a special waste container (usually a yellow sharps bin) for destruction. A record of the wastage must be made in the CD record book “amount wasted” column and signed by the two members of staff. Under no circumstances must an error in an entry in the controlled drugs register be altered or deleted. Such an entry must be rewritten. Errors must be bracketed and annotated ‘entered in error’ or may be crossed through in such a way that the original text still remains legible. Oral liquids must be measured using a bung and oral syringe rather than a measuring cup or spoon.

14. 10 Ampoules must not be used for more than one patient.

14. 11 Under no circumstances must controlled drugs be left unattended, including filled syringes or tablet administration pots.

SOP for Patient’s Own Controlled Drugs

15.0 As with other types of medicines, these remain the patient’s own property. They must be locked in the CD cupboard in a sealed bag and an entry made on the next empty page in the register under the heading ‘Patient’s own property’ by a registered nurse. This entry **MUST** include the Patient’s name, the date, and name, strength, form of drugs (tablets, ampoules etc) and quantity, and be witnessed by another nurse, or other second person (see 15.2). The sealed bag must be labelled with the CD register page number and patient name.

15.2 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. Please contact pharmacy if in doubt.

15.3 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 to the patient. Responsibility for security is given to that adult. In this scenario a registered nurse and a second witness must sign the CDs out of the register. The witness must observe the CDs being handed over to the patient/patient’s representative. The person receiving the CDs must countersign the entry in the CD register confirming receipt of the specified quantity of drugs.

- If the medicines are not safe and/or appropriate for use, then the patient and/or patient’s representative must be advised and they must be encouraged to send them to the pharmacy for safe destruction. The patient/patient’s representative’s permission must be obtained to destroy the CDs, and the consent for destruction signed on the designated section of the in-patient drug chart. The pharmacist takes responsibility for the destruction. The registered nurse must sign the drugs out of the CD register marking the entry “sent to pharmacy for destruction”, and the pharmacist must also sign the CD register. The drugs must be placed in a sealed bag, labelled with the CD requisition number. On arrival at dispensary, the pharmacist will enter the CD PODs into the appropriate section of the pharmacy department CD destruction register and this will be countersigned and witnessed by another member of pharmacy staff. The CD PODs will be held in a special section of the pharmacy CD cabinet until such a time that they can be destroyed.

15.4 Patient’s own CDs must **NOT** be given to any other patient and they must **NOT** be added to ward stock.

15.5 If a patient is transferred from one ward to another, the patient’s own CDs may be transferred with

them. The CDs must be transferred from one ward's register to a transfer page in the receiving ward register by two registered nurses one from each area.

SOP for the Disposal or Removal of Controlled Drugs on the Ward

16.0 Individual doses of CDs, which are prepared, but not administered, must be destroyed on the ward by the two people preparing and witnessing the drug. An entry must be made in the ward CD register, including the names and signatures of the two people involved in the destruction.

16.1 Small amounts of CDs, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or when a dose is drawn up but not used, must be rendered irretrievable by emptying into 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 "contains mixed pharmaceutical waste and sharps – for incineration". If there is any uncertainty about how to dispose of a particular item then a pharmacist must be consulted

16.2 **Expired or unsuitable Controlled Drugs, unknown substances or Patient's Own Controlled Drugs for Destruction**

Wards or teams with an onsite dispensary: These must be returned to pharmacy in a sealed bag under the supervision of a pharmacist or accredited technician. An entry will be made in the ward CD register, being signed by a qualified nurse and pharmacist/accredited technician. The CD will be entered into the relevant section of the pharmacy department CD destruction register by the Pharmacist/ Pharmacy technician and countersigned by another pharmacist or pharmacy technician. The CD will then be stored in the CD cabinet until such a time when it can be destroyed. For further information on dealing with unknown or suspected illicit drugs, please refer to ELFT Policy for Dealing with and the Disposal of Suspected Illicit Substances and Alcohol.

Wards or teams with an offsite dispensary: These will be signed out of the ward CD register, by a qualified Nurse and Pharmacist/Pharmacy technician. Simultaneously the ward 'Controlled Drugs Returns Book' will also be completed and the top non-carbonated white sheet of the entry placed in the pharmacy delivery bag along with the CDs or unknown substance to be returned to pharmacy. The bag will then be security sealed and sent back to pharmacy via the normal hospital delivery system-this process will include dispensary staff signing for receipt of the sealed pharmacy bag via the pharmacy bag delivery sheet. On arrival at pharmacy the CDs or unknown substance will be checked against the white controlled drugs return book form to ensure that they match. The CD will be entered into the relevant section of the pharmacy department CD destruction register by the pharmacist/accredited technician and countersigned by another pharmacist or pharmacy technician. The CD will then be stored in the CD cabinet until a time when it can be destroyed. For further information on dealing with unknown or suspected illicit drugs, please refer to ELFT Policy for Dealing with and the Disposal of Suspected Illicit Substances and Alcohol.

Wards or teams in Luton: Expired or unsuitable Controlled Drugs or Patient's Own Controlled Drugs for Destruction will be signed out of the ward CD register by a qualified nurse & pharmacist and destroyed on the ward using the appropriate destruction kit available within pharmacy. A record of the destruction will be made on appendix 5 by the ward nurse/technician and pharmacist and stored within the local pharmacy with a copy being sent to the ward manager for record. Unknown substance to be returned to pharmacy by a member of the pharmacy team and stored for collection by the Controlled Drugs Liaison Officer. For further information on dealing with unknown or suspected illicit drugs, please refer to ELFT Policy for Dealing with and the Disposal of Suspected Illicit Substances and Alcohol.

Controlled Drugs suitable for use that are no longer required

Wards or teams with an onsite dispensary: These must be returned to pharmacy by a pharmacist

or pharmacy technician. An entry will be made in the ward CD register, being signed by a qualified nurse and pharmacist/pharmacy technician. On arrival at pharmacy all CD stock returns must be approved by the Dispensary Manager or the Operations Manager. The quantity of returned CDs is checked and entered in the pharmacy CD register by the pharmacist/pharmacy technician and countersigned by a Pharmacist or accredited checking pharmacy technician. The stock must be returned on the JAC computer system, a total balance stock check must then be completed to ensure the physical stock, the computer stock levels and register all match, this must be ticked and initialled in the CD register by the person completing the checks.

Wards or teams with an offsite dispensary: These will be signed out of the ward CD register, by a qualified nurse and pharmacist/pharmacy technician. Simultaneously the ward 'Controlled Drugs Returns Book' will also be completed and the top non-carbonated white sheet of the entry placed in the pharmacy delivery bag along with the CDs to be returned to pharmacy. The bag will then be security sealed and sent back to pharmacy via the normal hospital delivery system-this process will include dispensary staff signing for receipt of the sealed pharmacy bag via the pharmacy bag delivery sheet. On arrival at pharmacy the CDs will be checked against the white controlled drugs return book form to ensure that they match. All CD stock returns must be approved by the Dispensary Manager or the Operations Manager. The quantity of returned CDs is checked and entered in the pharmacy CD register by the pharmacist/pharmacy technician and countersigned by a Pharmacist or accredited checking pharmacy technician. The stock must be returned on the JAC computer system, a total balance stock check must then be completed to ensure the physical stock, the computer stock levels and register all match, this must be ticked and initialled in the CD register by the person completing the checks.

16.4 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 register and pharmacy register correspond.

SOP for Checking Stock of Controlled Drugs

17.0 A stock balance check of CDs within a clinical area involves checking the balance in the CD register against the contents of the CD cupboard. This **MUST** be performed at least once every 24 hours.

17.2 Two registered nurses or health professionals must perform this check. Where possible the staff undertaking this check must be rotated periodically. Agency and locum staff, and accredited nursing assistants may check CD stock provided that the other person checking is a substantive member of nursing staff. It is not acceptable for two members of agency staff to check CD stock.

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

17.4 Stock balances of liquid medicines must be checked by visual inspection. Periodic volume checks e.g. once a month must be undertaken – consult the ward pharmacist for recommended frequency. The balance must be confirmed to be correct on completion of a bottle.

17.5 A record of the daily CD stock check must be made in the CD record book on the left hand side of the page, entering date, time of check and amount present and both members of staff must sign the record.

17.6 The MM/SN is responsible for ensuring that the regular CD stock check is carried out by staff in the ward.

Controlled Drugs Audits

17.7.1 The ward CD audit must be carried using the on-line CD link sent by the assurance department.

17.7.2 The security, stock levels and overall completion of CD records (including daily checks) must be checked by nursing staff regularly and audited every 3 months. They must also be checked when overall responsibility for drugs changes e.g. at change of appointment of the senior nurse or responsible pharmacist for that clinical area and at other times when requested by the ward or department manager. Both must record that they have done this in ink in the CD register by signing and dating the register.

17.7.3 It is the responsibility of the modern matron and ward manager to organise the 3-month check.

17.7.4 The pharmacy team will report and present the CD audit results quarterly at the Locality Medicines Safety Group and Clinical Governance meetings where all must agree and implement an action plan in case of any failures.

17.7.5 The Accountable Officer (Chief Pharmacist) must be regularly updated on the results of the CD audits and all action plans.

17.7.6 The CD register has been designed to minimise the generation of voided CD requisition slips. It is important to avoid large quantities of voided slips accumulating in ward. The pharmacy department can be contacted in between the 3 monthly audits to reconcile these slips and destroy them if necessary.

Loss of Controlled Drugs

17.8.1 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 without delay by the nurse in charge. During the first 24 hours the nurse in charge in consultation with the ward pharmacist must attempt to track back the medication. This must also be reported via the DATIX incident reporting system.

17.8.2 In the first instance the following must be carefully checked:

- All requisitions received have been entered into the correct page of the 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.

17.8.3 For liquid CD formulations; +/- 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 nurse in charge must both sign the page in the CD register stating that there was a discrepancy of +/- x ml.

17.8.4 If the loss, error or omission is traced, the registered nurse 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 nurse, pharmacist, accredited pharmacy technician or doctor. Both persons will 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. A DATIX incident form must be completed, noting the local action, and this will be reviewed by the Modern Matron / Senior Nurse who can make further enquiries if this is thought to be appropriate or indeed escalate to SUI status.

17.8.5 In normal working hours: If a discrepancy is not resolved or if there is immediate cause for concern the Lead Pharmacist and Modern Matron / Senior Nurse must immediately report this to one of the

following:

- Chief Pharmacist (Accountable Officer for the Trust).
- Senior Nurse.
- Relevant Head of Nursing.
- Trust Security Officer.

Outside Normal Working hours

17.9.1 If a discrepancy is identified the nurse in charge of the ward at that time must contact the Duty Senior Nurse and they must work together to try and account for the error. If the discrepancy cannot be rectified the on call pharmacist must be contacted. The on call pharmacist will advise on the relevant course of action and who should be informed.

17.9.2 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.

SOP for Management of Controlled Drugs Within The Hospital Pharmacy

18.0 **Accountability and Responsibility**

18.1.1 The Chief Pharmacist is responsible for the safe and appropriate management of CDs in the pharmacy. Day-to-day management of CDs (for example, receipt into and issue from dispensary stock) in the pharmacy will normally be delegated to a suitably-trained, competent registered pharmacy technician or pharmacist. However, legal responsibility for CDs remains with the Chief Pharmacist.

18.2 **SOP for the Security and Storage of Controlled Drugs**

18.2.1 Pharmacy CD cabinets must comply with the Misuse of Drugs (Safe Custody Regulations)
This is a minimum security standard and 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. In this case a security cabinet that has been evaluated against the SOLD SECURE standard SS304 (See www.soldsecure.com) should be used.

18.2.2 Access to the CD cabinet is restricted to the Dispensary Manager/Lead Pharmacist, and any other staff working in the dispensary that they allow access to. The staff include Pharmacy Assistants, Trainee Pre-Registration Pharmacy Technicians, Trainee Pre-Registration Pharmacists, Pharmacy Technicians and Pharmacists.

18.2.3 Responsibility for the safekeeping of the CDs rests with the Dispensary Manager/Lead Pharmacist. They are responsible for controlling access to the CD cabinet and must retain the keys on their person. The responsibility remains with the Dispensary Manager/Lead Pharmacist if he/she decides to delegate the duty.

SOP for the Ordering and Receipt of Controlled Drugs

18.3.1 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.

18.3.2 Routine orders to wholesalers and manufacturers for CDs for stock are usually placed electronically. Some health care organisations may, following a risk assessment, make a decision to store paper records.

18.3.3 Stock levels must be determined by need and kept to a minimum, but must not be so low that there is a danger of running out at busy periods. This will normally be calculated by the pharmacy stock management system. It may be necessary to increase stock levels temporarily when it is anticipated that there may be a greater demand, for example, during long holiday breaks

18.3.4 There is a local procedure for the receipt of CDs into the pharmacy department. The procedure must ensure the security of CDs and must be auditable. When CDs are received into the pharmacy department, a pharmacist, pharmacy technician or appropriately trained assistant technical officer (ATO) can sign for receipt

18.3.5 The order details must be checked against the delivery note and the actual quantity delivered and appropriate stock control documentation completed.

18.3.6 Any tamper-evident seals on packs must be left intact when they are received from the supplier. This simplifies and speeds up balance checks.

18.3.7 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.

18.3.8 If there is a discrepancy the delivery note must 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 below), and stored in the CD cupboard separated from normal stock, until the problem has been resolved.

18.3.9 Goods must be entered into the CD register immediately on 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

18.3.10 The entry must be checked by a second member of pharmacy staff (pharmacist/pharmacy technician).

18.3.11 As a matter of good practice the balance in stock must be checked and recorded as correct by the person making the entry.

18.3.12 The stock must be put away into the robot or the appropriate section of the CD cabinet promptly.

18.3.13 A record of receipt of the order must be made on the pharmacy computer System

SOP for the Issue of Controlled Drugs as stock items

18.4.1 The ward/department staff must fully complete a CD requisition form from the ward CD register.

18.4.2 All the following details on the CD requisition slip must be completed:

Hospital name;
Ward
Drug name, dose form, strength and size;
Quantity to be ordered
Printed name and signature of authorised registered nurse writing requisition
Date
Signature of clinical pharmacist to indicate that prescription is clinically screened.

18.4.3 The screening Pharmacist must check that the person ordering the CD is an authorised signatory.

18.4.4 If there are any discrepancies the screening Pharmacist must contact the person placing the order and clarify what was intended. The order can be annotated and signed by Pharmacist.

18.4.5 The details required on pharmacy 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.

18.4.6 Each carton or bottle must be individually labelled.

18.4.7 On issuing the CD, the pharmacy member of staff will endorse the following information on the CD requisition slip:

- Quantity supplied
- Printed name and signature
- Date

18.4.8 The following information must be recorded in the Pharmacy CD register:

- Date of transaction
- Name of authorised nurse who completed the requisition
- Name of ward/department supplied
- Serial number of ward CD requisition slip
- Amount supplied
- Initials of dispenser and checker
- Amended balance

18.4.9 For the transfer of CDs from pharmacy to the ward, staff should refer to section 10.2 of this policy.

SOP for the Issue of Controlled Drugs as TTAs

18.5.1 CD TTA prescriptions must comply with full CD prescription requirements in order to be issued by pharmacy. The pre-printed CD form should be completed to ensure adherence to full CD prescription requirements (see Appendix 6)

18.5.2 Labelling requirements for CD TTAs are identical to those of standard TTA and outpatient labels.

18.5.3 The following information must be recorded in the Pharmacy CD register:

- Date of transaction
- Name of prescriber who wrote the TTA prescription
- Name of ward/department that patient is on
- Patient's RIO/NHS number
- Patient's address
- Amount supplied
- Initials of dispenser and checker
- Amended balance

18.5.4 The TTA prescription should be endorsed by the dispenser with what was supplied. The original TTA prescription will be retained by pharmacy and a copy sent with the TTA back to the ward.

18.5.5 CD TTA prescriptions will be delivered to the ward as set out in section 9.0 of this policy and must be received on the ward according to section 10.0 of this policy.

SOP for the Issue of Controlled Drugs as Outpatient Prescriptions

18.6.1 For outpatient 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 their professional capacity on behalf of the patient.

18.6.2 Where the person is the patient or their representative, dispensary staff:

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

18.6.3 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 (professional work address is sufficient).
- **Must,** unless they are acquainted with that person, request evidence of that person's identity.

18.6.4 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.

18.6.5 The following information is required in the CD register for Schedule 2 CDs supplied on prescription:

- Whether the person who collected the drug was the patient,
- The patient's representative
- Or a health care professional acting on behalf of the patient, that person's name and address.
- If the person who collected the drug 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.

18.6.6 The person collecting schedule 2 or 3 CDs must sign for receipt of a specified number of doses as set in the standing operating procedure for receipt of CDs by outpatients.

18.6.7 Types of ID that may be considered suitable include:

- Professional registration number for a healthcare professional.
- Official photo id.
- Driving Licence (including photocard 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.

18.6.8 CD OP prescriptions must comply with section 7.2 of this policy in order to be issued by pharmacy.

18.6.9 Labelling requirements for CD OPs are identical to those of standard OPs and outpatient labels.

18.6.10 The following information must be recorded in the Pharmacy CD register:

- Date of transaction
- Name of prescriber who wrote the OP prescription
- Name of ward/department that patient is on
- Patient's RIO/NHS number
- Patient's address
- Amount supplied
- Initials of dispenser and checker
- Amended balance

18.6.11 The OP prescription should be endorsed by the dispenser with what was supplied.

18.7 SOP for Record Keeping

18.7.1 Pharmacy CD register

A register of receipts and supplies of Schedule 2 CDs and drugs that are treated as full schedule 2 CDs (see section 6) must be kept by the pharmacy.

18.7.2 Each drug form and strength must be given a different page in the register. The drug name, form and strength must be written at the top of the page and an index must be kept at the front of the register.

18.7.3 Register entries must be made in consecutive, chronological order. The entry must be made on the day when the drug is received or supplied, or on the next day. Entries must be in ink or be otherwise indelible.

18.7.4 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

18.7.5 The following staff may complete the CD register:

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

18.7.6 All entries in the register must be checked and countersigned by either a registered pharmacist or an accredited checking pharmacy technician.

18.7.7 The register entry must also include:

- Date of transaction
- Name and address of person/department supplied
- Licence or authority of person/department supplied i.e. requisition number
- Amount supplied
- Form in which supplied
- Name of patient, if individually dispensed

18.7.8 Liquid preparations arrangements are shown below.

18.7.9 Discrepancies can arise with liquid CDs as a result of manufacturer's overage, the measurement process or spillage. Such overage or losses of liquid preparations must be recorded in the CD register and the running balance adjusted with a note being made of the reason on the page.

18.7.10 Balances must be checked visually, and confirmed to be correct on completion of the bottle.

18.7.11 If a spillage occurs a second person must verify that the spillage has occurred, and both must record and initial an entry in the CD register. Both must be registered nursing staff.

SOP for Pharmacy Controlled Drug Audits performed by pharmacy staff

18.8.1 A Pharmacy CD audit must be carried out every 3 months.

18.8.2 The stock balance in the pharmacy CD register must be checked against both the quantity in the CD cabinet and the balance shown in the pharmacy stock control system every 3 months.

18.8.3 This check may 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 this SOP.

18.8.4 The check must be recorded in the register by means of signature, date and an appropriate entry, for example, "Stock checked. Balance correct".

18.8.5 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 within one working day.

18.8.6 There must be a careful check of transactions in the register and in the stock control system to trace an error or omission.

18.8.7 If an error is traced then a 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.

18.8.8 If no error or omission can be traced the Chief Pharmacist (Accountable Officer) must be informed. 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.

SOP for Archiving of records

18.9.1 Every requisition, order or private prescription on which a CD is supplied must be preserved by the Pharmacy department for a minimum period of two years from the date on which the last delivery under it was made. Although the mandatory period for keeping requisitions is two years, a longer period can be considered in the light of cases which often come to court at a much later date.

The time periods for archiving CD documentation are:

Requisitions	2 years
Registers and CDRBs	2 years from last entry
External orders and delivery notes	2 years
Prescriptions (inpatients)	2 years
Prescriptions (outpatients)	2 years
Destruction of CDs	7 years

18.10 SOP for the transfer of Controlled Drugs

18.10.1 At each point where a controlled drug 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 Standard Operating Procedure for Transportation of Medication.

18.10.2 The drug 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 to reduce tamper risk in transit.

18.11 SOP for returning Controlled Drugs back into stock

18.11.1 CDs no longer required by a ward that can be classified as suitable for use may be returned back into the general pharmacy stock.

18.11.2 For how pharmacists or ward accredited technicians should remove CDs from wards and return these to pharmacy staff should follow sections 16 and 17 of this policy.

18.11.3 When returning CDs into stock the pharmacist or pharmacy technician must confirm the goods are suitable for return with the Dispensary Manager or the Operations Manager they should then enter the following information in the pharmacy CD register:

- Name, form and strength of drug (or using appropriate page)
- Date received
- Original requisition number of CD when dispensed
- Ward that CD came from
- Quantity received
- Signature of pharmacist/pharmacy technician returning CDs.

18.11.4 This entry should be checked and countersigned by Pharmacist or accredited checking pharmacy technician, the CD placed in the robot or CD cabinet whichever is appropriate.

18.11.5 Stock must be returned on the Pharmacy Computer System (JAC) and then a final stock check must be performed, checking the Physical, computer and register levels all tally.

18.12 SOP for the Disposal/Destruction of Controlled Drugs in Pharmacy

18.12.1 All schedule 2 and 3 CDs that require disposal or destruction should be entered in the relevant section of the pharmacy CD destruction register according to whether they are A) Expired Stock, B)Unknown substances, C) Methadone D) Patient's own drugs.

18.12.2 All sites that denature and/or destroy CDs are required to register for a T28 exemption form. The MM/SN and lead pharmacist should ensure that this is completed.

https://www.gov.uk/government/publications/denaturing-of-controlled-drugs

18.12.3 For how pharmacists or ward technicians should remove expired or unknown substances from wards and return these to pharmacy, staff should follow sections 16 and 17 of this policy.

18.12.4 When any CD is entered into the pharmacy destruction register, this should be checked by another member of pharmacy staff who will countersign the entry. The following information must be recorded when entering a CD for destruction in the pharmacy CD destruction register:

- Drug name
- Drug form
- Drug strength
- Quantity of drug being destroyed

18.12.5 Until they can be destroyed, all CDs requiring destruction must be stored in the pharmacy CD cupboard but must be kept segregated and clearly marked from other CDs in order to minimise the risk of errors and inadvertent supply.

18.12.6 Each entry in the destruction register will need to be allocated the next consecutive number in the record book; prefixed by the relevant Letter (see 18.12.1), then placed into a re-sealable plastic bag with a label on the outside clearly stating this letter & number. There are boxes clearly labelled for this purpose on the bottom shelves of the CD cabinet.

18.12.7 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 Standard Operating Procedure for Destruction of Controlled Drugs that sets out the methods for denaturing and disposal of CDs.

18.12.8 A Pharmacist (Band 8a and above and not based at the site of destruction) and a registered pharmacy technician (Band 4 or above) will destroy the expired, unsuitable or unwanted controlled drugs and/or unknown substances in the pharmacy department.

18.12.9 The Accountable Officer must not be involved in destruction as they must be independent from day-to-day management of controlled drugs.

18.12.10 When Schedule 2, 3 CDs and unknown substances are destroyed, the following details must be entered into the CD destruction register:

- Date of destruction
- Signature of the authorised person in whose presence the drug was destroyed
- Signature of the person carrying out the destruction.

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

Staff Training for Management of Controlled Drugs

19.0 The Accountable Officer is responsible for ensuring that members of staff who are involved in prescribing, supplying, administering or disposing of CDs receive appropriate training to enable them carry out their duties.

19.1 Staff must receive appropriate training on local standard operating procedures for controlled drugs when they first become involved in prescribing, supplying, administering or disposing of controlled drugs and then regularly thereafter.

19.2 Staff must be informed and, if necessary receive additional training when SOPs are revised or amended and when new CD products or systems are introduced. The handling of CDs is included in the induction program for new staff handling CDs and is also included in the Risk Management Prospectus for medicine risk update sessions.

Audit

The CD Policy is audited via the following:

- The safe and secure handling of medicines audit
- The quarterly audits by wards and teams
- Care Quality Commission self- assessment

21.0 Provision of Information To Patients and Carers

The following information should be provided to patients and carers in accordance with recent NICE NG46 Guidelines recommendations;

- Need and duration of treatment
- Onset of action of the CD
- How to use the CD when provided as different formulations; modified release and normal release
- Driving restrictions and ability to drive – Refer to Dept of Transport:Drug Driving and medicine advice for healthcare professionals
- Storage of CD safely in a locked cupboard out of the reach of children
- Use only for self and not to distribute to others
- Safe disposal at a local Community Chemist in case it is not needed anymore
- Ensure that all provided information is clearly understood
- Documenting discussion

21.01 When Prescribing When Required CDs;

- Document clear instructions for when and how to take or use the drug in the patient's care record
- Include dosage instructions on the prescription (with 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

21.02 The Opioid Thermometer

- Opioids are useful for pain management; however their use can lead to harm and use of 'The Opioid Thermometer' can guide with optimum doses and prevent harmful effects. Refer to link below regarding optimal doses and harmful effects;

https://livewellwithpain.co.uk/wp-content/uploads/opioid-thermometer-for-patients.pdf

References;

1. NICE Guidelines CG46 available at; https://www.nice.org.uk/guidance/ng46/chapter/Recommendations#developing-and-establishing-systems-and-processes-for-organisations; accessed 06.08.2021

Useful Websites;

1. www.doh.gov.uk
2. www.poci.co.uk
3. www.nice.org.uk
4. www.homeoffice.org.uk
5. www.mhra.gov.uk
6. www.rpsgb.org.uk/pdfs/MEP30s1-2a.pdf

Appendix 1

Legislation for the management of Controlled Drugs

Misuse of Drugs Act 1971

The Misuse of Drugs Act (MDA) 1971 and its Regulations provide the statutory framework for the control and regulation of controlled drugs. The primary purpose of the MDA is to prevent misuse of CDs. The MDA 1971 makes it unlawful to possess or supply a controlled drug unless an exception or exemption applies. A controlled drug is defined as any drug listed in Schedule 2 to the Act.

Misuse of Drugs Regulations 2001 (MDR)

The use of CDs in medicine is permitted by the Misuse of Drug Regulations (MDR). The MDR classify the drugs in five schedules according to the different levels of control required (see below). Schedule 1 CDs are subject to the highest level of control, whereas Schedule 5 CDs are subject to a much lower level of control.

For practical purposes, health care staff needs to be aware of the current Regulations.
The MDR are periodically amended and revised. The MDR currently in force and its amendments can be found at the website for the Office of Public Information (www.opsi.gov.uk)

Schedule 1 (CD Licence)

Schedule 1 drugs include hallucinogenic drugs such as coca leaf, lysergide and mescaline. Production, possession and supply of drugs in this Schedule are limited, in the public interest, to research or other special purposes. Only certain persons can be licensed by the Home Office to possess them for research purposes. Practitioners (e.g. doctors, dentists and veterinary surgeons) and pharmacists may not lawfully possess Schedule 1 drugs except under licence from the Home Office.

The drugs listed in Schedule 1 have no recognised medicinal use although Sativex© (a cannabis based product) is currently being supplied on a named-patient basis.

Schedule 2 (CD POM)

Schedule 2 includes more than 100 drugs such as the opioids, the major stimulants, secobarbital and amphetamine.

Safe custody

Schedule 2 CDs (except secobarbital) are subject to safe custody requirements (under the Misuse of Drugs Safe Custody Regulations 1973, (see below)). They must be stored in a locked receptacle, such as an appropriate CD cabinet or approved safe, which can only be opened by the person in lawful possession of the CD or a person authorised by them**.**

Schedule 2 CDs may be manufactured or compounded by a licence holder, a practitioner, a pharmacist or a person lawfully conducting a retail pharmacy business acting in their capacity as such.

A pharmacist may supply schedule 2 CDs to a patient only on the authority of a prescription in the required form issued by an appropriate clinician.

Schedule 2 CDs may be administered to a patient by a doctor or dentist, or by any person acting in accordance with the directions of an appropriately qualified prescriber who is authorised to prescribe Schedule 2 CDs (DN - not all prescribers can prescribe Schedule 2 CDs).
Nurse Independent Prescribers are permitted to prescribe, administer, or direct anyone to administer some

CDs for specific conditions and routes of administration.

Record-keeping

There is a statutory requirement for pharmacy departments to keep a register for Schedule 2 CDs and this register must comply with the requirements of the Misuse of Drugs Regulations 2001.

As a matter of good practice wards and departments must also keep a register for Schedule 2 CDs

Destruction

The destruction of Schedule 2 CD stock must only take place in the presence of an appropriately authorised person. (For further information on appropriately authorised persons)

Schedule 3 (CD No Register)

Schedule 3 includes a small number of minor stimulant drugs and other drugs, which are less likely to be misused than drugs in Schedule 2, or are less harmful if misused.

Safe custody

Schedule 3 CDs are exempt from safe custody requirements and can be stored on the open dispensary shelf. Exceptions are flunitrazepam, temazepam, buprenorphine and diethylpropion, which must be stored in a locked CD receptacle within a secure environment.

Record keeping

There is no legal requirement to record transactions involving Schedule 3 CDs in a CD register. Invoices must be retained for a minimum of two years.
Schedule 3 CDs are subject to full import and export control.

Destruction

The requirements for destruction do not apply unless the CDs are manufactured by the individual.

Schedule 4 (CD Benzodiazepines and CD Anabolic steroids)

Schedule 4 is split into two parts.

Part 1 (CD Benzodiazepines) contains most of the benzodiazepines, plus eight other substances including zolpidem, fencamfamin and mesocarb.

Part 2 (CD Anabolic steroids) contains most of the anabolic and androgenic steroids such as testosterone, together with clenbuterol (adrenoreceptor stimulant) and growth hormones (5 polypeptide hormones).

There is no restriction on the possession of a Schedule 4 Part 2 (CD Anabolic steroids) drug when it is part of a medicinal product. However, possession of a drug from Schedule 4 Part 1 (CD Benzodiazepines) is an offence without the authority of a prescription in the required form. Possession by practitioners and pharmacists acting in their professional capacities is authorised.

Drugs in Part 1 (CD Benzodiazepines) are subject to full import and export control and a Home Office licence is also required for the importation and exportation of substances in Part 2 (CD Anabolic steroids) unless the substance is in the form of a medicinal product and is for administration by a person to themselves.
All substances in Schedule 4 are exempt from safe custody requirements, with destruction requirements only applying to importers, exporters and manufacturers.

Prescription-writing requirements for these CDs do not apply, except those requirements laid out in the Medicines Act 1968. CD registers do not need to be kept for Schedule 4 drugs, although records must be kept if such CDs are compounded, or if a licensed person imports or exports such drugs (see Regulation 22 of the Misuse of Drugs Regulations 2001).

Schedule 5 (CD Invoice)

Schedule 5 contains preparations of certain CDs (e.g. codeine, pholcodine)

There is no legal requirement to record transactions involving Schedule 3 CDs in a Schedule 5 contains preparations of certain CDs (e.g. codeine, pholcodine, morphine), which are exempt from full control when present in medicinal products of low strengths, as their risk of misuse is reduced.

There is no restriction on the import, export, possession, administration or destruction of these preparations and safe custody Regulations do not apply.

Preparations containing not more than 0.1% cocaine are no longer exempt from prohibitions on import, export and possession.

A practitioner or pharmacist acting in his capacity as such, or a person holding an appropriate licence, may manufacture or compound any CD in Schedule 5.
Invoices must be retained for a minimum of two years.

Misuse of Drugs (Safe Custody) Regulations 1973

The Safe Custody Regulations 1973 impose controls on the storage of controlled drugs. The degree of control depends on the premises within which the drugs are being stored.

All schedule 2 and some schedule 3 CDs must be stored securely in accordance with the Misuse of Drugs (Safe Custody) Regulations. These Regulations state that such CDs must be stored in a cabinet or safe, locked with a key. It must be made of metal, with suitable hinges and fixed to a wall or the floor with rag bolts that are not accessible from outside the cabinet

Misuse of Drugs (Supply to Addicts) Regulations 1997

These Regulations prohibit doctors from prescribing, administering or supplying diamorphine, cocaine or dipipanone for the treatment of addiction or suspected addiction except under Home Office licence. A licence is not required with such drugs for the treatment of organic disease or injury.

Medicines Act 1968

This Act, and Regulations made under the Act, sets out the requirements for the legal sale, supply and administration of medicines. It also allows certain exemptions from the general restrictions on the sale, supply and administration of medicines which, for example, enable midwives to supply and/or administer diamorphine, morphine, pethidine or pentazocine. A number of health care professionals are permitted to supply and/or administer medicines generally in accordance with a Patient Group Direction (PGD). Some of these professional groups, but not all, are permitted to possess, supply or administer CDs in accordance with a PGD under Misuse of Drugs legislation

Health Act 2006

The Key provisions of the Act are:

- All designated bodies such as healthcare organisations and independent hospitals are required to appoint an Accountable Officer
- A duty of collaboration placed on responsible bodies, healthcare organisations and other local and national agencies including professional regulatory bodies, police forces, the Healthcare Commission

and the Commission for Social Care inspection to share intelligence on controlled drug issues

- A power of entry and inspection for the police and other nominated people to enter premises to inspect stocks and records of controlled drugs

Controlled Drugs (Supervision of Management and Use) Regulations 2006

The Controlled Drug (supervision of Management and Use Regulations) 2006 came into effect in England on the 1S January 2007.

These set out the requirements for certain NHS bodies and independent hospitals to appoint an Accountable Officer and describe the duties and responsibilities of Accountable Officers to improve the management and use of controlled drugs.

The Regulations also require specified bodies to co-operate with each other, including with regard to sharing of information, about concerns about the use and management of controlled drugs, and set out arrangements relating to powers of entry and inspection.

Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007

This Regulation amends the Misuse of Drugs Regulations 2001 and the Misuse of Drugs (Safe Custody) Regulations to:

Give authority to Accountable Officers, within their organisation, to nominate persons or groups of persons to witness the destruction of CDs.

Allow ODPs to order, possess and supply CDs.

Remove the requirement to maintain a Controlled Drugs Register in a prescribed format. Change the record keeping requirements for CDs.

Reschedule Midazolam from Schedule 4 to Schedule 3 of the 2001 Regulations. All schedule 2 and some schedule 3 CDs must be stored securely in accordance with the Misuse of Drugs (Safe Custody) Regulations. These Regulations state that such CDs must be stored in a cabinet or safe, locked with a key. It must be made of metal, with suitable hinges and fixed to a wall or the floor with rag bolts that are not accessible from outside the cabinet

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Responsibilities of the Accountable Officer

The regulatory requirements for Accountable Officers are set out in full in the Controlled Drugs (Supervision and Management of Use) Regulations 2006; www.opsi.gov.uk. (hyperlink to www.opsi.gov.uk/si/si2006/uksi_20063148_en.pdf). Further detail is also given in Safer Management of Controlled Drugs: Guidance on Strengthened Governance Arrangements. January 2007 (www.dh.gov.uk)
[http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4141666&chk=AtnhRu]

Responsibilities of the Accountable Officer

In discharging his responsibilities, an Accountable Officer must have regard to best practice in relation to the management and use of controlled drugs.

The Accountable Officer must:

- Secure the safe and effective use and management of controlled drugs within local organisations subject to his/her oversight (i.e. the organisation and those with which it contracts).
- Appropriate systems for the safe management of controlled drugs must be established, operated and reviewed periodically.
- All arrangements must comply with relevant statutory requirements.
- Adequate and up-to-date standard operating procedures must be in place for the management and use of controlled drugs.
- Ensure that adequate destruction and disposal arrangements are made for controlled drugs.
- Appropriate arrangements for securing the safe destruction and disposal of controlled drugs must be established and operated.
- Ensure monitoring and auditing of the management and use of controlled drugs within the organisation and take action where necessary. The following must be in place:
- Systems to alert the Accountable Officer to complaints or concerns involving the management of controlled drugs.
- An incident reporting system to capture untoward incidents involving the management or use of controlled drugs.
- Arrangements for analysing and responding to untoward incidents involving the management or use of controlled drugs.
- Ensure that individuals involved in prescribing, supplying, administering or disposing of controlled drugs receive appropriate training. Arrangements must be in place for relevant individuals:
- To receive information and, where appropriate, training on local standard operating procedures for controlled drugs when they first become involved in prescribing, supplying, administering or disposing of controlled drugs
- To be informed when any local standard operating procedures for controlled drugs are subsequently reviewed and amended.
- Monitor and audit the management and use of controlled drugs by relevant individuals, and to monitor and assess their performance.

The Accountable Officer must, where appropriate, provide for the following:

- Recording concerns raised in relation to the management or use of controlled drugs by a relevant individual.
- Assessing and investigating concerns raised regarding the management or use of controlled drugs by a relevant individual.
- Determining whether there are concerns in relation to the management or use of controlled drugs by a relevant individual which the designated body reasonably considers must be shared with a responsible body.
- The Accountable Officer must be aware that unusually high usage of some CDs or unusually high numbers of breakages could indicate misuse.
- Maintain a record of concerns regarding relevant individuals. Such records may be paper-based or electronic. The Accountable officer must:

- Establish and operate appropriate arrangements for recording concerns:

  - expressed about incidents that involved, or may have involved, improper management or use of controlled drugs by a relevant individual. This must include a system to ensure that access to such records is limited to the Accountable Officer, her/his staff and others who need to have access for the purposes of ensuring the safe management or use of controlled drugs.

- Ensure that adequate records are compiled, which must include (but not be limited to), as appropriate:
- the date on which the concern was made known to the accountable officer;
- dates on which the matters that led to the concern took place;
- details regarding the nature of the concern;
- details of the relevant individual in relation to whom the concern was expressed;
- details of the person who, or body which, made known the concern;
- details of any action taken by the designated body in relation to the concern;
- the assessment of whether information in relation to the concern must be disclosed to another responsible body
- If information regarding the concern is disclosed to another responsible body, the details of any such disclosure, including the name of the responsible body to which the disclosure was made and the nature of the information disclosed to the body.
- Assess and investigate concerns
- Establish and operate appropriate arrangements for assessing and investigating concerns about incidents that involved, or may have involved, improper management or use of controlled drugs by a person who is, as regards his designated body, a relevant individual.
- Take appropriate action if there are well-founded concerns.
- Establish and operate appropriate arrangements for ensuring that appropriate action is taken for the purposes of protecting patients or members of the public in cases where concerns in relation to the management or use of controlled drugs by a person who is, as regards designated body, a relevant individual, appear to be well-founded.
- Establish arrangements for sharing information.
- Establish and operate appropriate arrangements for ensuring the proper sharing of information, by his designated body with other responsible bodies regarding the management and use of controlled drugs
- Provide a quarterly report to the PCT Accountable Officer lead for the Local Intelligence Network.
- Cooperate with other organisations including the Healthcare Commission, the Commission for Social Care Inspection, the NHS Business Service Authority and the police as circumstances require.
- Participate in the Local Intelligence Network

NHS East London NHS Foundation Trust

Appendix 3

Controlled Drugs Returned to Pharmacy Form

CONTROLLED DRUGS RETURNED TO PHARMACY

WARD	COST CODE			DATE RETURNED/ENTERED (TICK ONE)			
DRUG NAME (& REQ NO)	FORM	STRENGTH	QTY	CD REG	OPEN STOCK	D/REG*	GRIFF BIN*
RETURNED BY: CHECKED BY:			RETURNED ON COMPUTER BY: * *Do not return removals onto computer - (Destruction register & griff bins)*				
Use one form for each Cost code/ward State total quantity of each item if there is more than one requisition number							

Schedule 3 Requisition Sheet (for buprenorphine, midazolam, temazepam and tramadol, pregabalin, gabapentin)

Ward:	**Requested by Nurse(print and Sign):**	**Countersigned by (Pharmacist/pharmacy technician):**	**Date:**

Item	Strength	Form	Qty	Disp	Check

Issued By	**Received By**

Appendix 5 Controlled Drug Prescription

The Misuse of Drugs Act 1971 and Regulations under the Act authorises Pharmacists to dispense "Control Drugs (CDs) prescriptions" that contain **ALL** the information listed below.

This form **MUST BE SIGNED IN INK BY THE PRESCRIBER.** The prescription must be generated on this form and the name and dose of the prescribed CD(s) should also be documented on the TTO to provide a complete medication record. Any prescription not conforming to the requirement of the requisition will be referred back to the prescriber and not issued.

Patient Details

Patient Name		DOB	
Patient Address		Hospital number	
		Ward/ Dept	

1st Medication Details

Drug Name		Total quantity required **in figures**		
Drug Form				
Drug strength		Total quantity required **in words**		
Directions				
Prescriber signature		Print full name		
		Pharmacy Use only		
Date		Screening pharmacist:	Dispenser	Checker

2nd Medication Details

Drug Name		Total quantity required **in figures**		
Drug Form				
Drug strength		Total quantity required **in words**		
Directions				
Prescriber signature		Print full name		
		Pharmacy Use only		
		Screening pharmacist:	Dispenser	Checker

Appendix 6

Update: Recent schedule change to CDs

1) Pregabalin and Gabapentin

From April 2019, pregabalin and gabapentin were classed as schedule 3 controlled drugs. This means from 1st April 2019:
- Prescription for gabapentin/pregabalin must meet full prescription requirements for schedule 3 CDS as detailed under section 'Prescribing Controlled Drugs for outpatients and discharge medication' of this policy.
- Aligned to other 2,3 and 4 CDs, there is a strong recommendation from the Department of Health that the maximum quantity does not exceed 30 days.
- Pregabalin and gabapentin are exempt from safe custody requirements and there is no legal requirement for them to be recorded in the CD register.
- Pregabalin and gabapentin should not be kept as ward stock. Supplies for inpatients must be requested and supplied via the internal Schedule 3 CD Requsition Sheet (see Appendix 5)

2) Cannabis based products for medicinal use

- From the **1st November 2018**.changes to the Misuse of Drugs Regulations 2001 means that cannabis-based products for medicinal use have been reclassified from Schedule 1 to Schedule 2 Controlled Drugs.

- There is now a legal route for cannabis-based products for medicinal use to be prescribed by doctors on the General Medical Council (GMC) **specialist register** in the strictly controlled circumstances required by the 2001 Regulations without the requirement for a Home Office licence.

- The government has defined "**a cannabis-based product for medicinal use in humans**" as:
  "cannabis-based product for medicinal use in humans" means a preparation or other product, other than one to which paragraph 5 of part 1 of Schedule 4 applies, which—
  (a) is or contains cannabis, cannabis resin, cannabinol or a cannabinol derivative (not being dronabinol or its stereoisomers);
  (b) is produced for medicinal use in humans; and—
  (c) is—
  (i) a medicinal product, or
  (ii) a substance or preparation for use as an ingredient of, or in the production of an ingredient of, a medicinal product;";

- If the above criteria is met, then the preparation or product is considered as a 'cannabis-based products for medicinal use in humans' and a Schedule 2 drug under the 2001 Regulations. Products not meeting the above definition will remain in Schedule 1 and will be kept under strict controls and only available for use under a Home Office licence.

- Existing Schedule 2 requirements under the 2001 Regulations will apply, including; safe custody, prescription requirements, mandatory requisition forms, record keeping and destruction.

- Additionally, cannabis-based products for medicinal use in humans for administration are subject to specific access restrictions (new Regulation 16A of the 2001 Regulations) over and above the requirements applicable to other Schedule 2 drugs.

- There are three access routes available for the order and supply of these products for administration (to humans or animals):
  • a special medicinal product that is for use in accordance with a prescription or direction of a specialist medical practitioner;

• an investigational medicinal product without a marketing authorisation that is for use in a clinical trial; or
• a medicinal product with a marketing authorisation

These access restrictions do not apply to orders or supplies which are not for the purposes of administration (which will be treated as other Schedule 2 drugs).

In the UK, all cannabis-based products for medicinal use apart from Sativex (listed in Schedule 4) are currently unlicensed medicines (special medicinal products). Due to the limited evidence base and their unlicensed nature, the government has chosen to restrict prescribing of such products to only those clinicians listed on the specialist register of the General Medical Council. This restriction has been set out in regulations.

Smoking of cannabis and cannabis-based products for medicinal use in humans continues to be prohibited.

In the rare circumstance, a prescription is required for a cannabis based product for a specific patient, please contact the pharmacy for further advice.

- For further information, from the Department of Health and Social Care, please visit: https://www.gov.uk/government/collections/medicinal-cannabis-information-and-resources