1. INTRODUCTION

1.1. Following the Shipman Inquiry, the Government introduced strengthened monitoring and inspection arrangements for Controlled Drugs (CDs) to minimise the risk to patient safety of the inappropriate use of controlled drugs. These were incorporated into the Health Act 2006, and in England, the Controlled Drugs (Supervision of Management and Use) Regulations 2006 which came into force in January 2007.

1.2. Each NHS organisation is required to appoint an Accountable Officer (AO) with overall responsibility for the safe use and management of CDs within the organisation. The Accountable Officer for this Trust is the Chief Pharmacist. The AO is responsible for ensuring that there are standard operating procedures for the management of CDs within all areas of the Trust, and that these procedures are amended and updated as necessary, and reviewed regularly. The AO is ultimately accountable for all systems for the safe management of CDs.

1.3. This document reflects the above legislation and closely reflects interpretative guidance issued by the Department of Health in October 2007 (Safer Management of Controlled Drug: a guide to good practice in secondary care). It sets out the procedures which must be followed for the management of controlled drugs.

2. WHAT ARE CONTROLLED DRUGS?

2.1. Controlled Drugs (CDs) are any substance (medicinal or otherwise) which may be addictive and/or subject to misuse, as defined in the Misuse of Drugs Act 1971, which divides CDs into classes which will affect the culpability of the person in possession of them. The use of controlled drugs in medicines is permitted by the Misuse of Drugs Regulations 2001, which divides CD into five schedules according to their level of control.

2.2. Schedule 1 CDs have virtually no therapeutic uses, and can only legally be in the possession of a person who has a licence from the Home Office. Examples of Schedule 1 CDs include cannabis, LSD and magic mushrooms. A summary of the CD regulations as they apply to Schedules 2 - 5 can be found in Annex 1. This table gives details of the prescription-writing, storage and record-keeping requirements that apply to the drugs in each Schedule.

2.3. Within the regulations, Trusts are permitted to treat non-CD medicines as CDs if they are considered to carry a risk of dependency or misuse; this may apply on a Trust-wide basis, or at an individual Trust site, and may be a temporary or permanent measure. Similarly, certain CDs may be subject to more stringent controls than is required by their Schedule. Details of the
requirements as they apply to specific drugs within this Trust are included in the table in Annex 1.

2.4. Tables listing the most common CDs in Schedule 2, Schedule 3, and Schedule 4 Part I, can be found in Annex 2. Products are listed by generic name, with an indication of brand name(s) where these exist. Those CDs that are used most frequently within the Trust have been identified with an asterisk (*).

3. ACCOUNTABILITY AND RESPONSIBILITY

3.1. The Accountable Officer (AO) is responsible for ensuring that there are standard operating procedures for the management of CDs within all areas of the Trust, and that these procedures are amended and updated as necessary, and reviewed regularly. The AO is ultimately accountable for all the systems for the safe management of CDs. All incidents which relate to CDs must be reported via the Trust’s incident reporting process, which will result in the AO being notified.

3.2. The Appointed Nurse or Practitioner in Charge of a ward or unit is responsible for the safe and appropriate management of CDs in that area, by ensuring that all relevant procedures in this document are complied with. Where the person in charge is not a nurse, the responsibility for CDs rests with the most senior nurse/practitioner permanently employed on the ward or unit. She can delegate control of access to the CD cupboard (i.e. key-holding) and other CD-related tasks to another registered nurse/practitioner, but legal responsibility remains with the most senior nurse/practitioner. See also section 5.2.

3.3. All staff handling CDs shall comply with these procedures.

3.4. Where conditions arise in which staff are unable or have difficulty complying with these procedures, they shall notify the registered practitioner in charge and the Community Health Services Pharmacy Lead at the earliest opportunity.

4. CONTROLLED DRUG STOCKS

4.1. In most cases CDs will be ordered as required for individual patient care. However, where CDs are routinely held as stock on a ward/unit there should be a list detailing the quantities usually held. This list should be agreed between the pharmacist or pharmacy technician responsible for stock control for that ward/unit and the registered practitioner in charge, and should be reviewed at least annually.

4.2. Stocks of Schedule 2 and 3 Controlled Drugs (see Annex 1 and Annex 2) are not topped-up by the pharmacy service. They must be ordered from the pharmacy by the ward/unit, using a CD order book (see section 5).

4.3. Stock CDs should be kept to a minimum and unwanted or out of date stock items should be disposed of promptly (see sections 14 and 15).
5. REQUISITIONING CONTROLLED DRUGS STOCK

5.1. The registered nurse/practitioner in charge of a ward or unit is responsible for ordering Schedule 2 and 3 Controlled Drugs for use in that area. Where the person in charge is not a nurse, the responsibility for ordering CDs rests with the most senior nurse/practitioner permanently employed on the ward or unit. This responsibility can be delegated to another registered nurse/practitioner.

5.2. Practitioners who are authorised to order and handle CDs must provide a specimen signature to the supplying pharmacy department, using the form shown in Appendix 2 of CLPG13.

5.3. Schedule 2 and 3 CDs must be ordered from the pharmacy using a Controlled Drug Order Book with duplicate numbered pages. The order (requisition) must be signed by an authorised nurse.

5.4. Legislation requires that requisitions to another health body for the supply of CDs must be countersigned by a doctor or dentist employed by the Trust, as independent verification that the drugs ordered are required for use on the ward or unit.

The requisition must be countersigned by a doctor or dentist, because the Trust obtains its supplies of CDs from the pharmacy departments of other NHS trusts. The doctor/dentist who countersigns the CD order is not accountable for the management of CDs on the ward or unit; this responsibility remains with the Appointed Practitioner in Charge.

5.5. All CD orders (requisitions) must state:
   - Name of the Hospital or Organisation and Service
   - Name of the ward or unit
   - Drug name, form (e.g. tablets, capsules), strength and ampoule size (if applicable)
   - The quantity required (CDs should be ordered as whole packs – check with the pharmacy if unsure what pack sizes are available)
   - Signature and printed name of the registered nurse/practitioner
   - Date
   - Signature and GMC/GDC number of the countersigning doctor/dentist if ordering from another organisation

5.6. When writing an order in the CD Order Book it is important to ensure that the carbon paper is placed, the correct way up, between the order and paired duplicate page, that both copies of the order carry the same serial number, and that a clear copy of the order is visible on the second page.

5.7. Once the order has been completed and signed, the CD Order Book should be sent to the pharmacy by secure means.
A new CD Order Book can be obtained by sending a written order to the appropriate hospital pharmacy; this must be signed by a registered practitioner who is authorised to order CDs.

6. TRANSPORT OF CONTROLLED DRUGS STOCK

6.1. Controlled Drugs must be transported from the pharmacy to the ward or unit in a locked or sealed, tamper evident container carried by an appropriate messenger, who is responsible for ensuring that the box is delivered intact. The messenger may be a member of the ward/unit staff, a member of the local portering services, Trust transport service or supplying pharmacy’s transport service.

6.2. The messenger who collects the CD box from the pharmacy must carry a valid identification card; the pharmacy will not release CDs to messengers without appropriate ID.

6.3. The messenger shall sign the CD Order Book or a specific consignment record at the pharmacy. The top copy of the order will be removed and retained in the pharmacy, and the messenger will be given the CD Order Book to return to the ward/unit together with, or within, the locked or sealed, tamper evident container. The messenger may also be asked to sign the pharmacy CD Register to confirm collection.

6.4. On arrival at the Trust ward or unit, the messenger must give the locked or sealed, tamper evident container and CD Order Book to a registered nurse/practitioner, who then assumes responsibility for the container and its contents. On no account must the container be left unattended.

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

7. RECEIPT OF CONTROLLED DRUGS STOCKS

7.1. Deliveries of CDs must be accepted by an authorised practitioner whose name and signature have been notified to the pharmacy (see Appendix 2 of CLPG13).

7.2. The authorised nurse/practitioner must immediately:

- check that the container is locked/sealed and intact
- open the container and check the contents (drug, strength, quantity) against the duplicate order page in the CD Order Book. If a CD has been supplied in a manufacturer’s pack closed by an un-broken seal, the seal should not be broken in order to count the contents. If there is no tamper evident seal, or the seal is broken, the contents of the pack should be removed and counted.
- if the delivery is correct, sign the receipt section of the duplicate order page in the CD Order Book.
enter the details of the received item(s) in the ward/unit CD Record Book and confirm that the stock balance is correct (see section 9.2).

- place the received items in the CD cupboard

7.3. The receipt shall be witnessed by a second nurse/practitioner, who shall also sign the CD Record Book.

7.4. There is no need to record the receipt of Schedule 3 controlled drugs apart from buprenorphine and midazolam in the record book unless instructed by the Community Health Services Pharmacy Lead or Chief Pharmacist.

7.5. Discrepancies on receipt

7.5.1. If the delivery does not match the duplicate order page, or an item is missing, the details of the discrepancy must be reported to the supplying pharmacy immediately.

7.5.2. If the messenger who delivered the CD is able to return it to the pharmacy immediately, the receipt section of the duplicate order page should not be signed. The container and its contents should be re-locked/re-sealed and returned to the pharmacy together with the CD Order Book, to enable the pharmacy to rectify the problem.

7.5.3. If it is not possible to return the incorrect item to the pharmacy immediately, the duplicate order page should be endorsed with the details of what was actually received and the receipt section signed. The details of the received item should be entered into the CD Record Book and marked as ‘received in error’, and the item should then be stored in the CD cupboard pending resolution of the problem by pharmacy.

8. STORAGE OF CONTROLLED DRUGS

8.1. All controlled drugs (Schedule 2 and 3) must be stored in a locked controlled drug cupboard, which can only be opened by a person who can lawfully be in possession, such as the registered nurse in charge or a pharmacist, or a person working under their authority.

8.2. The Misuse of Drugs (Safe Custody) Regulations 1973 sets out standards for cabinets used to store controlled drugs. Any new cupboards must comply with these requirements, and it is recommended that all CD cupboards conform to these standards. Ward/unit CD cupboards should conform to BS2881 or be otherwise approved by the Chief Pharmacist or designated deputy as suitable for the storage of CDs.

8.3. Leave or discharge medication which includes CDs should be stored in the ward/unit CD cupboard in a sealed bag until the time of discharge. These items should be segregated from the stock CDs that are used on the ward/unit, and should be entered into the CD Record Book, unless the patient is leaving the ward immediately. If a patient awaiting leave/discharge
requires a dose of a CD before they leave the ward/unit, this should normally
be administered from stock and not from their discharge medication.

8.4. General measures for the storage of CDs include the following:

- The CD cupboard must be kept locked when not in use
- The lock must be unique (not the same as any other lock in the Trust)
- The keys for the CD cupboard must be kept separate from the other
  medicine keys and stay on the person of the keyholder all the time (not
  in a drawer or a key cupboard)
- Keys must only be available to authorised staff and the keyholder must
  be readily identifiable at all times; the keyholder for each shift should be
  named on the shift rota
- The CD cupboard must only be used for storing Schedule 2 and 3 CDs,
  plus any drug which the Trust requires to be treated as a Schedule 2 or
  3 CD (see section 2.3 and Annex 1 and Annex 2)
- CDs must be locked away in the CD cupboard when not in use
- There must be adequate arrangements for keeping the keys secure in
  units which are not staffed 24 hours a day; in such cases, a standard
  operating procedure for the keys must be agreed with the Accountable
  Officer

8.5. Responsibility for CD cupboard keys

8.5.1. The registered nurse/practitioner in charge of the ward or unit is
  responsible for the key to the CD cupboard.

8.5.2. Key-holding may be delegated to an authorised registered
  nurse/practitioner whose signature is held by the Community
  Health Services Pharmacy Lead and whose name is listed in the
  CD Record Book (see section 5.2), but legal responsibility rest
  with the Appointed Nurse or Practitioner in Charge.

8.5.3. The keyholder named on the shift rota may give the CD
  cupboard key to another authorised member of staff if necessary
  (for example, a nurse administering medicines, a pharmacist or a
  pharmacy technician) but it must be returned to her as soon as
  possible.

8.6. Missing CD cupboard keys

8.6.1. If the key to the CD cupboard cannot be found, urgent efforts
  must be made to retrieve it as soon as possible, e.g. by
  contacting the responsible staff who have recently gone off-duty
  or off-site.
8.6.2. The Appointed Nurse or Practitioner in Charge of the ward or unit must be informed immediately that the CD key is missing, and the Community Health Services Pharmacy Lead must be informed as soon as possible. If necessary, additional security measures must be implemented in order to preserve the security of the CD cupboard until the missing key has been found.

8.6.3. If a spare key is not available, and a patient is due to receive a dose of a CD, the doctor should be called to assess whether the dose may be omitted without harm to the patient. If administration is essential, the required dose of the CD may be obtained from another nearby ward or unit within the Trust (see section 17.2).

8.6.4. If no other nearby ward or unit has a stock of the required drug, a supply must be ordered from the pharmacy. The Community Health Services Pharmacy Lead will advise on the storage of such items until the CD key has been located.

8.6.5. If the keys cannot be found promptly, the Accountable Officer must be informed about missing CD keys during working hours. Out of hours, the on-call manager should be informed. Depending on the circumstances, it may also be appropriate to contact the Risk Management Department and the police.

8.6.6. An Adverse Incident Report must be submitted, and a copy must be sent to the Accountable Officer as well as the Risk Management Department.

9. RECORD KEEPING

9.1. Controlled Drug Record Book

9.1.1. Every ward or unit that holds Schedule 2 or 3 Controlled Drugs, (and any drug which has been designated within the Trust, or locally, to be treated as a controlled drug), must keep a record of all CDs received and administered in a Controlled Drug Record Book. The Appointed Nurse or Practitioner in Charge is responsible for keeping the CD Record Book up to date and in good order.

9.1.2. All entries in the CD Record Book must be legible, made in indelible ink, and should be made in chronological order.

9.1.3. It is good practice to create an index at the front of the CD Record Book that states which pages are currently in use for each product. It is important that this index is updated whenever the running balance is transferred to a new page in the record book.
9.1.4 All entries in the CD Record Book (receipts and administration) should be signed by a registered nurse/practitioner and should be witnessed by a second person, preferably another registered nurse/practitioner.

9.1.5 Each strength and form of a drug must be recorded on a separate page of the CD Record Book, e.g. morphine 10mg tablets, 20mg tablets and liquid require separate pages in the register. Every page in use in the CD Record Book must have a heading which clearly states:

- The **name** of the drug
- The **strength** of the drug
- The **form** of the drug, e.g. tablets, capsules. If the product is a special formulation, this should also be specified, together with the brand name, e.g. ‘Morphine sulphate tablets MR 10mg (MST Continus 10’).

9.1.6 A running balance of the quantity in stock should be kept for each drug and this balance should agree with the content of the CD cupboard. The running balance must be adjusted whenever a CD is received, administered or disposed of.

9.1.7 When all the available lines on a page have been used, the running balance must be transferred to the next available blank page in the CD Record Book (which will not necessarily be the next consecutively numbered page):

- **At the foot of the full page**: Write ‘Balance transferred to page **xx**’, giving the number of the new page. Date and sign the entry; obtain a witness signature if available.

- **On the new page**: Complete the heading (see section 9.1.5) and on the first line write ‘Balance transferred from page **xx**’, giving the number of the page containing the previous records for the drug. Write the running balance in the final column. Date and sign the entry; obtain a witness signature if available.

- **On the index page**: Cross out the previous page number and write in the new page number.

9.1.8 A new CD Record Book can be obtained by sending a written order to the appropriate hospital pharmacy; this must be signed by a nurse/practitioner who is authorised to order CDs.

9.2. **Recording receipt of stock CDs**

9.2.1. If the drug supplied by the pharmacy already has a page in the CD Record Book, the receipt should be recorded on the next
blank line. The entry in the record book must include (see sample below):

- Date of the entry in the record book
- **Quantity (number) or volume of drug received, in words**
- Name of the supplying pharmacy
- Serial number of the requisition (from the duplicate order page in the CD Order Book)
- Signature and printed name of the authorised person making the entry
- Signature and printed name of the witness
- New running balance of stock held

9.2.2. If the drug has not previously been used on the ward/unit, it will be necessary to create a new record page in the CD Record Book. This must be done on the next available blank page in the register. The new page should be given a heading as detailed in section 9.1.5, and the drug name and page number should be added to the index at the front of the Record Book.

The receipt should be entered on the first line of the newly created page, in the same format as shown below. The quantity supplied should be entered as the opening balance.

**Figure 1: Sample receipt entry (stock)**

<table>
<thead>
<tr>
<th>NAME, FORM OF PREPARATION AND STRENGTH</th>
<th>Morphine Sulphate Tablets MR 10mg (MST Continus 10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMOUNT(S) OBTAINED</td>
<td>AMOUNT(S) ADMINISTERED</td>
</tr>
<tr>
<td>Amount</td>
<td>Date Received</td>
</tr>
<tr>
<td>--------</td>
<td>---------------</td>
</tr>
<tr>
<td>Twenty</td>
<td>18/04/11</td>
</tr>
<tr>
<td></td>
<td>01/01/11</td>
</tr>
</tbody>
</table>

9.3. **Recording receipt of patients own CDs**

9.3.1. Patients will occasionally bring their own supply of CD medication with them when admitted or a supply of CDs dispensed for the individual patient (rather than a stock supply) may be received from the supplying Hospital Pharmacy. All CDs labelled with an individual patients name should be checked by two registered practitioners if available, or one registered practitioner and one other person, and then stored in the CD cupboard.

**In-Patient units holding stock CDs:** The details of a patient’s own CDs must be entered in the back of the CD Record Book, starting at page 100 and working forwards, using a new page to
record each CD for each patient. The patient’s name and the page number should be added to the index page of the register.

**In-patient units not holding stock CDs:** The records shall be entered from page 1 of the CD Record Book

9.3.2. The heading of the page should state the name of the drug, its form and strength, and the name of the patient. The quantity should be entered on the first line in the following style:

**Figure 2: Sample receipt entry (patient’s own drug)**

<table>
<thead>
<tr>
<th>NAME, FORM OF PREPARATION AND STRENGTH</th>
<th>Morphine sulphate tablets MR 10mg (MST Continus 10) – Fred BLOGGS</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMOUNT(S) OBTAINED</td>
<td>AMOUNT(S) ADMINISTERED</td>
</tr>
<tr>
<td>Amount</td>
<td>Date Received</td>
</tr>
<tr>
<td>Twenty</td>
<td>15/05/11</td>
</tr>
</tbody>
</table>

9.3.3. Once the CDs brought in by the patient have been booked in and stored securely, a decision must be taken about whether they are to be used on the ward/unit, returned home or disposed of – see section 13.

9.3.4. When a patient’s leave/discharge medication includes a CD, the medicines shall be stored in the CD cupboard until they are ready to be handed over to the patient, and shall be entered in the Patient’s Own Drug section in the ward’s CD Record Book, unless the patient will be leaving the ward immediately.

9.4. **Recording administration of CDs** – see section 12.7.

9.5. **Recording return or disposal of CDs** – see sections 14.4 (South East Essex only) for returns and 15.7.3 for disposal.

9.6. **Correcting errors**

9.6.1. If a mistake is made when making an entry in the record book, it must not be erased, crossed-out or obliterated; all entries must remain legible.

9.6.2. The incorrect entry should be bracketed, and ‘error’ written next to the brackets. An appropriate footnote should be written at the bottom of the page explaining the error – this should be signed, dated and witnessed by a second practitioner (see section 9.1.4).

9.6.3. A new entry should then be made on the next blank line, the correct running balance inserted, and the entry witnessed by a second practitioner.

9.6.4. If an addition/subtraction error has been made with the running balance, resulting in several lines of the register being incorrect,
a pharmacist should be contacted to investigate the error and make a correction to the register.

9.7. Archiving Controlled Drugs Records

9.7.1. Wards/units must retain all CD Order Books and CD Record Books for two years from the date of the last entry. All other CD-related documents, with the exception of CD denaturing/disposal records, should also be retained on the ward/unit for two years.

9.7.2. CD Record Books which contain records of the denaturing and disposal of CDs on the ward/unit (see section 15 and Annex 3) must be retained on the ward or unit for 7 years.

9.7.3. Completed CD Order Books and Record Books should be marked on the front cover with the date of the last entry and the date after which they can be destroyed (two years after the date of the last entry or seven years if the CD record book contains entries of destruction). CD Record Books contain patient-identifiable information and must be disposed of securely.

9.7.4. If a ward or unit closes, the CD records must be sent for archiving. The archived material must be clearly marked with the date of the last entry and the date after which it can be destroyed. The Accountable Officer must also be notified as soon as it is known that a ward/unit is planned to close (see section 16).

10. CONTROLLED DRUG BALANCE CHECKS

10.1. The running balance of all CDs entered in the CD Record Book should be checked against the contents of the CD cupboard by ward/unit staff on a weekly basis. If necessary, the Accountable Officer may require that a ward or unit carries out more frequent stock checks.

10.2. Ward/unit CD balance checks will also be carried out by pharmacy staff every three months.

10.3. CD balance checks by ward/unit staff

10.3.1. The appointed practitioner in charge of the ward or unit is responsible for ensuring that a **weekly CD balance check is carried out**. This check must be carried out even if no CDs are currently being administered to patients, in order to ensure that any stock is still present, correct and in date.

10.3.2. CDs that are unlikely to be used should be returned to an EPUT pharmacy or disposed of by supervised destruction (see section 15.7.3), in order to eliminate the need for CDs to be counted and recorded on a weekly basis.
10.3.3. Two authorised registered practitioners should carry out the balance check, unless only one is on duty. Where possible, the staff undertaking the CD check should be rotated periodically, so the same people are not responsible every time.

10.3.4. The weekly check should take account of the following points:

- The balance of each drug in the CD Record Book should be checked against the physical stock in the CD cupboard, not the reverse, to ensure that all balances are checked.
- The CD cupboard should be checked to ensure that it does not contain anything that is not entered in the record book.
- Packs with intact tamper-evident seals should not be opened for stock checking.

Balances of liquid medicines should be checked by visual inspection and estimation, in order to avoid contamination and loss through measuring, with an accurate check using a graduated measuring cylinder undertaken once a month. The balance in the record book and the physical quantity of liquid in stock must be reconciled when a bottle of liquid has been completed.

10.3.5. For each item checked, an entry must be made in the CD Record Book on the next line stating 'Stock checked and correct,' giving the date and time of the check. This entry must be signed by the two practitioners who performed the check.

10.3.6. If the balance in the record book and stock count do not agree, other entries for that preparation should be checked for accuracy. If the problem is not found entries for other preparations in the CD Record Book should be checked.

10.3.7. Any errors should be marked in the CD Record Book as described in section 9.6.

10.3.8. If a discrepancy is found between the balance in the CD Record Book and the physical stock in the cupboard, it must be investigated without delay. The supplying pharmacy must be notified as soon as possible (not out of hours), if the discrepancy cannot be promptly rectified by the ward/unit.

10.3.9. If this is necessary, a pharmacist should investigate the discrepancy and carefully check the transactions in the CD Record Book and the contents of the CD cupboard. If an error or omission is traced, the pharmacist must make an appropriate entry in the record book stating the reason for the error/omission.

*Note: Discrepancies often occur with liquid medicines as a result of manufacturer's overage, the measurement process or spillage. If the check shows that the stock exceeds the balance in the register, the excess must be disposed of by two authorised staff. If the check shows that the physical stock is less than the balance in the register, the supplying pharmacy should be contacted. If the discrepancy is large, the Accountable Officer should be contacted.*
and correcting the running balance. This entry should be dated and signed by the pharmacist, and witnessed by an authorised member of the nursing staff.

10.3.10. If no error or omission can be traced to explain the discrepancy, an Adverse Incident must be submitted immediately by the Appointed Nurse or Practitioner in Charge of the ward or unit. A copy should be sent to the Accountable Officer (automatic within Datix) as well as to the Risk Management Department, and both should be notified by telephone so that a decision can be taken on further investigative action.

10.4. **CD checks by pharmacy staff**

10.4.1. Pharmacy staff will carry out a balance check at 3-monthly intervals, and provide a summary report to the Appointed Nurse or Practitioner in Charge and to the Accountable Officer. The check will also cover other aspects of the requirements for the management and use of CDs on the ward/unit.

10.4.2. These balance checks should be carried out by a member of the pharmacy staff and an authorised member of the nursing staff/practitioner, and should follow the same criteria as in section 10.3.4.

10.4.3. In the case of liquid preparations, the amount will be physically measured rather than estimated. Wards/units that hold stocks of liquid CDs should obtain small and large size measuring cylinders, approved by the Pharmacy Lead, for this purpose, e.g. 25ml and 2 x 250ml. These should be kite-marked or equivalent to ensure accuracy.

10.4.4. For each item checked, an entry must be made in the CD Record Book on the next line stating ‘Quarterly balance check’, and giving the date and time of the check. This entry must be signed by the member of pharmacy staff and the authorised nurse who carried out the check.

10.5. **Stock checks at administration**

10.5.1. Whenever a CD is administered, the remaining quantity should be checked in order to confirm that the running balance in the CD Record Book is correct. Any discrepancy should be dealt with as in section 10.3.8.

11. **PRESCRIBING CONTROLLED DRUGS**

11.1. Prescribers must complete a signature form which includes their registration number – this form can be found at Appendix 1 of CLPG13.
11.2. Prescribing CDs for inpatients

11.2.1. CDs for inpatients should be prescribed on an authorised Medicine Prescription & Administration Chart.

11.2.2. There are no special prescription-writing requirements when CDs are prescribed for inpatients. CDs should be prescribed in the same way as other medicines (see section 7.8 of CLPG13):

11.2.3. Inpatient prescription charts for Controlled Drugs will be endorsed ‘CD’ by the pharmacy.

11.3. Prescribing CDs for leave, discharge and outpatients

11.3.1. Prescriptions for Controlled Drugs for leave, discharge and outpatients must be written in accordance with all the requirements of the Misuse of Drugs Regulations, as detailed below. The prescription-writing requirements for CDs can also be found in the introductory pages of the BNF.

11.3.2. Prescriptions must be written on a Trust or supplying hospital prescription form or a FP10 or FP10MDA prescription form. The prescription must be written so as to be indelible, i.e. handwritten in ink, typed or computer-generated. Prescriptions for all Schedule 2 and 3 CDs, including temazepam† (see Annex 2) must contain the following details:

- The prescriber’s address, i.e. the ward or unit, or the location of the clinic where the prescriber is based.
- The patient’s full name and address, plus their NHS number
- The name of the drug
- The form of the preparation, e.g. tablets, capsules, liquid, patches, even if only one form exists
- The strength of the preparation
- The dose to be taken
- The total quantity of the preparation to be supplied, in both words and figures, e.g. 'ten (10) tablets', 'one hundred ml (100ml)'.
- The signature of the prescriber. To aid identification, the prescriber should also print their name in block capitals, followed by their professional registration number.
- The date on which the prescription has been written
- Instructions for any instalments

† From 1st June 2015
11.3.3. **Handwriting:** CD prescriptions no longer have to be handwritten – typed or computer-generated prescriptions are acceptable, but the *prescriber’s signature must be in his/her own handwriting*. Any amendments to a CD prescription must be signed by the prescriber.

11.3.4. **Labels:** The use of pre-printed ‘addressograph’ labels containing patient details is not recommended for CD prescriptions. If the use of such labels is unavoidable, the prescriber should add a second signature, starting his/her signature on the label and extending it onto the prescription form, so that it is apparent at the time of dispensing if the label has been tampered with.

11.3.5. **Duration of supply:** Prescriptions for CDs should be for a maximum of 30 days supply. In exceptional circumstances a prescriber may issue a CD prescription for more than 30 days’ supply of medication, but if this is to be done, the risk must be assessed and the reasons for doing so must be documented in the patient’s healthcare record. CD prescriptions are only valid for 28 days from the date of writing.

11.3.6. **Leave/Discharge:** CDs MUST NOT be dispensed from stock for a period of home leave/discharge as this does not meet the legal requirements for the supply of CDs.

When authorising leave for a patient who is on regular treatment with a CD, medical and nursing staff must take into consideration the restrictions that apply to the prescribing and supply of CDs. If it is not feasible to obtain a supply of leave medication from the hospital pharmacy in time for a period of leave, the following options are permissible:

- If the clinical area is holding a supply of the patient’s own CDs, these can be returned to the patient when they go on leave provided the dosage instructions have remained unchanged and they are still in date. The complete pack must be returned to the patient (see section 13.5); they must not be re-dispensed
- If the patient (or a relative/carer) confirms that they still have a supply of the medication at home, they can be instructed to use this while on leave, provided the dose has remained unchanged.
- The patient can be instructed to return to the clinical area on each day of leave for a dose of the CD to be administered from stock
- If the pharmacy is able to supply the medication by the following day, the patient can be instructed to return to the clinical area to collect the item.
• If the clinical area has access to FP10 prescription forms, the CD can be prescribed on one of these for dispensing via a community pharmacy.

If none of the above options is feasible but the provision of a supply of a CD is clinically essential, the patient’s leave should be delayed until a supply can be obtained.

11.3.7. **Instalment prescriptions:** Community Drug and Alcohol Services may prescribe CDs for instalment dispensing using blue instalment prescription forms (FP10 MDA). The maximum supply permitted on these forms is 14 days.

11.4. **Non-medical prescribers**

11.4.1. Members of staff who train as non-medical prescribers to include prescribing of Controlled Drugs as part of their role shall confirm the circumstances in which they are able to prescribe within current legislation with the Community Health Services Pharmacy Lead.

11.5. **Patient Group Directions**

11.5.1. Members of staff who are considering using a PGD relating to CDs should contact the Community Health Services Pharmacy Lead or Accountable Officer as part of the PGD process.

11.6. **Clinical consideration when prescribing CDs**

11.6.1. The decision to prescribe a controlled drug should take into account the benefits and risk of treatment, including dependency, overdose and diversion, whether the patient is opiate naïve and other medicines which affect the central nervous system that they may be taking, including non-prescribed medicines.

11.6.2. Evidence-based sources such as the BNF, Opioids Aware and NICE guidance should be used to inform prescribing decisions. Local and national guidance should be taken into account about appropriate route, dose and formulation, including when dose conversions or dose equivalence is needed. Take into account the total opioid load when reviewing or changing opioid prescriptions and use a recognised dose conversion guide.

11.6.3. The indication for treatment with controlled drugs and details of the regimen should be clearly documented in the patient’s healthcare record. The arrangements for reviewing and monitoring treatment should be discussed with the patient, along with:

• how long the patient is expected to use the CD
• how long it will take to work
11.6.4. Dosage instructions should be included on the prescription (with the maximum daily amount, and/or frequency of doses, so that these are included on the label when the CD is dispensed. Expressions such as ‘as directed’ should not be used.

11.6.5. When determining the quantity to prescribe, ask about and take into account, any existing supplies of CDs that the patient already has.

11.6.6. Inform the patient’s GP of all prescribing decisions involving CDs, taking into account the normal rules for sharing information.

12. ADMINISTRATION OF CONTROLLED DRUGS

12.1. The administration of CDs must follow the Trust procedures for the administration of medicines, as detailed in procedural guideline CLPG13 (section 15), with the additional controls set out in this document. These principles apply in any clinical area where controlled drugs are used.

12.2. The CD must be administered by a registered practitioner, and the administration must be witnessed by a second person, who should usually be another registered practitioner (a nurse from a neighbouring ward/unit can act as the witness if a second nurse is not available). Alternatively, administration may be witnessed by a doctor, pharmacist or pharmacy technician.

12.3. Exceptionally, if there are routinely insufficient nursing staff /registered practitioners available on a ward/unit to act as CD administration witnesses, the ward/unit manager must assign this role, and provide appropriate training, to suitable unregistered members of staff. These staff must sign the specimen signature sheet (see section 5.2). Registered healthcare professionals should be used first.

12.4. The witness and the person administering the CD must be present for the whole of the procedure in order to confirm that:

- the prescription is complete and legible (in clinical areas where only a Medicines Administration Record is used for a dispensed Controlled Drug, check against the labelled instructions)
• the medicine has not already been administered
• the correct CD is selected from the cupboard and is in date
• the stock level is correct against the last entry in the CD Record Book. Balances are to be checked, ticked and initialled every time an entry is made
• the medicine is prepared and/or measured correctly
• the dose is administered to the right patient by the right route in the right form
• the patient has actually taken the medicine and cannot retrieve it later
• any excess medicine which cannot be reused (for example, part of the contents of an ampoule, a dropped or spat out tablet, a dose prepared but refused) is destroyed appropriately (see sections 12.8 - 12.10 and 15.8).

12.5. To minimise the risk of administration errors, staff should seek advice from other healthcare professionals (which may include by telephone or email) if they are at all unsure about dose calculations or the route of administration. Unless the circumstances prevent this, the person administering should advise the patient of the name and dose of the CD before it is administered.

12.6. If dose calculations are required it is recommended that staff obtain a second check from another healthcare professional.

12.7. **Recording the administration of CDs**

12.7.1. A record must be made in the CD Record Book whenever a CD is administered. The entry in the record book should contain the following details:
• date and time of administration
• name of the patient
• quantity administered (as the number of tablets or the volume of liquid administered, not as the number of mg)
• quantity wasted, if applicable (see section 12.8)
• form administered
• names / full signatures of the person administering and the person witnessing, for both administration and for the quantity wasted and destroyed, if applicable
• balance left in stock - to be checked, ticked and initiated every time an entry is made
12.8. Quantities wasted at administration

12.8.1. In the case of unit dose products (e.g. ampoules) for which the patient does not require the entire quantity in the ampoule, the entry in the register should show the amount given and the amount wasted. For example, if 2.5ml was given from a 5ml ampoule, the entry should read ‘2.5ml given, 2.5ml wasted’. The quantity wasted should be destroyed as detailed in section 15.8.

12.8.2. Where part of an infusion containing a CD, e.g. PCA device or syringe driver, has been discontinued before the entire drug has been delivered, it should be denatured on the ward. Details of the unused drug should be recorded on the first available blank page at the back of the ward CD record book. The following details must be recorded:

- Date and time
- Patient’s name
- Preparation (e.g. morphine 30mg in 8ml Water for Injection)
- Estimated volume remaining
- Names / full signatures of the person destroying and person witnessing

The quantity wasted should be destroyed as detailed in section 15.8.3.

12.9. Doses prepared but not administered

12.9.1. Doses prepared but not given, e.g. drug drawn up into a syringe but refused by the patient, should be destroyed as detailed in section 15.8. The reason for non-administration should be documented in the CD Record Book in the presence of the witness.

12.10. Dropped / broken / damaged items

12.10.1. If a tablet or capsule is dropped on the floor, liquid spilled or an ampoule broken, an appropriate entry must be made in the CD Record Book and witnessed by a second practitioner. The
Running balance should then be adjusted to reflect the quantity lost. The quantity wasted should be destroyed as detailed in section 15.8.

12.10.2. Broken ampoules should be disposed of in a bin for sharps contaminated with pharmaceutical waste. Liquid spills should be mopped up with a paper towel, which should then be disposed of in the ‘pharmaceutical waste’ bin.

13. MANAGEMENT OF PATIENT’S OWN CONTROLLED DRUGS WITHIN IN-PATIENT UNITS

13.1. A Controlled Drug brought into a ward or unit by a patient must be checked and entered onto a fresh page of the CD Record Book as detailed in section 9.3.

13.2. If the patient’s own CD is not labelled or boxed, it must be placed in a suitable container (clear plastic bag if available) and labelled with the name of the patient, the date of admission and the quantity of drug in the bag, in addition to making an entry in the record book.

13.3. If the patient’s CD is not required for their treatment whilst an inpatient, one of the following procedures should be followed:

- If the patient agrees, the CD may be disposed of on the ward/unit. The patient should be asked to give their consent to the disposal of the item (see CLPG13 section 9.4) using the form at Annex 3 of Appendix 11 to CLPG13. The item should be clearly marked ‘Awaiting disposal – consent obtained’ and an entry should be made on the appropriate page in the CD Record Book also stating ‘Awaiting disposal – consent obtained’. The consent form should be kept in the CD Record Book at the appropriate page until it can be removed to EPUT pharmacy or disposed of securely on the ward/unit.

- If the patient wishes, and if it is appropriate to do so, the CD may be returned home with an identified responsible adult. This person must sign and date an entry in the CD Record Book when he takes responsibility for the CD. The entry must show the quantity returned home, and the running balance must then be changed to zero. If the item is not fit for use, or is no longer clinically appropriate, the patient and the patient’s agent should be advised that the item should be taken to a community pharmacy for safe disposal.

- If the patient does not consent to disposal or to the item being returned home, it should be retained on the ward/unit until the patient is ready to be discharged (see section 13.5).

13.4. Use of a patient’s own CDs on the ward/unit

13.4.1. Ideally, a patient’s own CDs which have been brought in with them on admission should not be used for their treatment whilst an inpatient. Instead, a stock supply or item dispensed for the
individual patient of the required medication should be ordered from the pharmacy as detailed in section 5.

13.4.2. However, in some circumstances it may be necessary to use a patient’s own CDs until a stock supply can be obtained from the pharmacy, e.g. at weekends when the pharmacy is closed. If so, the item must be checked to ensure that it is fit for use (see Appendix 11 of CLPG13 for how to assess a patient’s own drugs). Provided the item is fit for use, it can be administered and recorded in the CD Record Book as detailed in section 12.7.

Where a patient is directly transferred from another NHS unit with their medication it is acceptable to use CDs which have been issued specifically for that patient. These should be recorded in the patient’s own section of the CD record book.

13.4.3. A patient’s own CDs must never be used to treat another patient.

13.5. Patients’ own CDs at discharge

13.5.1. If a patient continues to require treatment with a CD at discharge and has their own supply of medication in the CD cupboard, the item can be returned to them provided it is still suitable for use and the dosage instructions are still correct.

13.5.2. An entry must be made in the CD Record Book to indicate that the drugs were returned to the patient, and the register should be signed by the patient or their representative to confirm receipt. The running balance must then be changed to zero.

13.5.3. If a patient’s CD treatment has been discontinued or altered but there is still a supply of their original medication in the CD cupboard, the patient’s consent should be sought (see CLPG13 section 9.4) for the item to be removed to a EPUT pharmacy or disposed of securely on the ward/unit; see section 15.

13.5.4. A patient’s own CDs remain their personal property until they consent to disposal (see CLPG13 section 9.4). If a patient does not consent to the disposal of a CD item that they no longer require for treatment, this item must be returned to them, and an entry made in the CD Record Book as in section 13.5.2. However, the patient should be advised to take the item to a community pharmacy for secure disposal because it is not required for their current treatment. The giving of this advice should be documented in the patient’s healthcare record.
Figure 4: Sample entry (patient’s own drug)

<table>
<thead>
<tr>
<th>AMOUNT(S) OBTAINED</th>
<th>AMOUNT(S) ADMINISTERED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amount</td>
<td>DateReceived</td>
</tr>
<tr>
<td>Twenty</td>
<td>15/05/11</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

14. RETURN OF CONTROLLED DRUGS TO PHARMACY

14.1. Unused CD stock and unwanted Patient’s Own Drugs from wards or units may only be returned to the pharmacy where the pharmacy department is part of the same organisation.

14.2. The only exception is the very small quantities of CDs that are wasted at the time of administration, e.g. part-used ampoules or doses that have been spat out (see section 15.8).

14.3. Bedfordshire, West Essex: All unwanted CDs must be disposed of at ward / unit level (see section 15).

14.4. South-East Essex: All unwanted CDs should be returned to an EPUT pharmacy for safe destruction and onward disposal.

14.4.1. The ward or unit should keep a record of drugs returned to pharmacy. This should be in the form of a consignment note with duplicate pages so that both the pharmacy and ward / unit have a record of the transaction.

14.4.2. The following details should be recorded when CDs are returned to the pharmacy:

- Date
- Name, form, strength and quantity of drug being returned
- Name and signature of registered nurse

14.4.3. An entry should be made on the relevant page of the ward / unit CD Record Book showing:

- Date
- Reason for return
- The names and full signatures of the registered nurse responsible for the return and the pharmacist or pharmacy technician witnessing
- Quantity removed
CLPG13-CHS - SAFE & SECURE HANDLING OF MEDICINES – ALL STAFF CHS
APPENDIX 3 (April 2019)

- Name, form and strength of drug
- Balance remaining

14.4.4. The CDs should be transferred to the pharmacy in a safe and secure manner by approved pharmacy staff.

Figure 5: Sample return entry

<table>
<thead>
<tr>
<th>NAME, FORM OF PREPARATION AND STRENGTH</th>
<th>Morphine sulphate tablets MR 10mg (MST Continus 10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMOUNT(S) OBTAINED</td>
<td>AMOUNT(S) ADMINISTERED</td>
</tr>
<tr>
<td>Amount</td>
<td>Date Received</td>
</tr>
<tr>
<td>--------</td>
<td>---------------</td>
</tr>
<tr>
<td>Twenty</td>
<td>18/04/11</td>
</tr>
<tr>
<td></td>
<td>19/04/11</td>
</tr>
<tr>
<td></td>
<td>20/04/11</td>
</tr>
</tbody>
</table>

15. DISPOSAL OF CONTROLLED DRUGS

Sections 15.1 to 15.7 apply to Bedfordshire, West Essex only

15.1. Disposal of CDs that are no longer required may only be undertaken on the ward or unit in Bedfordshire, West Essex.

15.2. All Schedule 2, 3 and 4 (Part 1) Controlled Drugs that are no longer required by a ward or unit must be denatured (rendered irretrievable) before they can be disposed of. This denaturing process must be carried out on the ward or unit.

15.3. The denaturing of Schedule 2 and 3 CDs prior to their disposal must be witnessed by two people:

- An authorised practitioner who works on the ward / unit (see section 5.2)
- A person authorised by the Accountable Officer to witness the destruction of Controlled Drugs on wards/units

Contact the Community Health Services Pharmacy Lead if advice is required on authorised witnessed destruction.

15.4. Drugs in Schedule 4 (Part 1) need to be denatured before disposal not simply discarded into a pharmaceutical waste bin. There is no requirement for an authorised person to witness destruction and records of destruction do not need to be kept.

15.5. The Accountable Officer is not permitted to personally witness the destruction of CDs, and dispensary pharmacy staff who visit Trust sites cannot carry out this role if they are also involved in the supply and audit of CDs. Details of the
Trust’s ‘authorised witnesses’ can be found on the intranet (search for “witness”).

15.6. All staff who are authorised by the Accountable Officer to witness the destruction of CDs must have received appropriate training. They are accountable for this activity directly to the Accountable Officer, who will maintain a list of authorised ‘CD destruction witnesses’.

15.7. **Process for denaturing and disposal of CDs**

15.7.1. When a ward or unit has unwanted CDs requiring disposal, they should first contact a Trust ‘authorised witness’ to arrange a suitable date and time for the disposal process to be carried out (see section 15.5).

15.7.2. Prior to carrying out the denaturing process, the authorised registered practitioner and the witness should remove the unwanted CD (and any other stock of the same product) from the CD cupboard and check that the total quantity agrees with the running balance in the CD Record Book (if there is a discrepancy, refer to section 15.7.7).

15.7.3. An entry must then be made in the CD Record Book stating:
- The date and time of denaturing
- The quantity of drug denatured, e.g. ‘10 tablets’, ‘35ml’
- The reason for denaturing, e.g. ‘out of date’, ‘no longer required’
- In the case of a patient’s own CDs, ‘patient’s consent obtained’
- The signatures of the authorised nurse and the authorised witness
- The remaining balance in stock, or NIL if the entire stock has been denatured. In the case of a patient’s own CDs that have been denatured, the running balance should be zeroed and a line put through the remainder of the page.

15.7.4. A form for recording the denaturing and disposal of CDs must also be completed by the authorised registered practitioner and witness – see Annex 3. The completed CD denaturing/disposal form, together with any relevant patient consent sheets, must be retained on the ward or unit with other CD records for 7 years from the date of disposal. The authorised witness must also forward a copy of the completed CD denaturing/disposal form to the Accountable Officer.

15.7.5. Once the entries in the CD Record Book and the record sheet have been completed, the authorised witness should carry out the denaturing process in the presence of the authorised
nurse/practitioner. The authorised witness will bring a suitable CD denaturing kit to the ward/unit. Disposal will be undertaken by the authorised witness in accordance with the operational procedure in Annex 4.

15.7.6. When the contents of the denaturing kit have gelled, the container can be placed in the ‘pharmaceutical waste’ bin for disposal.

15.7.7. If there is a discrepancy between the running balance in the CD Record Book and the quantity in the CD cupboard, the actions detailed in sections 10.3.8 - 10.3.10 should be carried out before any stock is disposed of.

15.8. Disposal of very small amounts of CDs within in-patient units

15.8.1. If small amounts of CDs are wasted at the time of administration (see sections 12.8 - 12.10), these can be disposed of by two authorised members of the ward/unit staff, who should make an appropriately worded explanatory entry in the CD Record Book and ensure that the running balance is amended accordingly.

15.8.2. The wasted material, e.g. the remaining contents of an ampoule or vial, spat-out tablets, etc, should be placed in the pharmaceutical waste bin. Emptied ampoules and vials should be placed in a sharps bin suitable for the disposal of pharmaceutical waste.

15.8.3. Part-used syringe drivers or PCAs should be denatured and disposed of on the ward. The entire contents of the device should be drained into a pharmaceutical waste bin and mixed with one measure of Vernagel (or equivalent) and an appropriate amount of water if needed, to render the drug irretrievable.

15.8.4. Bottles containing irretrievable amounts of liquid CDs (i.e. empty bottles) should be handled as follows:

- rinse the bottle with a small volume of water and dispose of the rinsing water into a pharmaceutical waste bin
- remove/obliterate any identifiers from labels
- disposal of the clean, empty bottle into the recycling waste

15.8.5. If a pharmaceutical waste bin is not available a sharps bin (Yellow lid) should be used. If a sharps bin with an orange lid has to be used, when it is sent for destruction it must be labelled “contains mixed pharmaceutical waste and sharps – for incineration”.
15.9. Disposal of Controlled Drugs belonging to deceased patients within inpatient units

15.9.1. If a patient dies whilst an inpatient, any Controlled Drugs that were their personal property should be disposed of in accordance with section 15.7 of this procedure. These medications do not form part of the patient's estate and should not be returned to relatives or carers.

15.10. Disposal of Controlled Drugs in pharmacy

15.10.1. Controlled drugs returned to a Trust pharmacy for destruction will be denatured and disposed of in line with the relevant pharmacy standard operating procedure.

16. WARD UNIT CLOSURES AND TRANSFERS

16.1. If a ward or unit is planned to be closed, either short-term or permanently, or if a ward/unit is to be transferred to another location, the Accountable Officer should be notified at the earliest possible opportunity.

16.2. The Accountable Officer will prepare a procedure for the management of Controlled Drugs during the closure or transfer, in consultation with senior ward/unit staff.

17. OBTAINING CONTROLLED DRUGS FOR IN-PATIENT UNITS OUT OF HOURS

17.1. If a patient requires treatment with a Controlled Drug that is not available on the ward/unit, a supply should be ordered from the appropriate supplying pharmacy. If the pharmacy is closed, it is acceptable to use the patient's own supply of medication until the pharmacy is next open (see section 13.4).

17.2. If a Controlled Drug needs to be administered as a matter of urgency and the ward/unit does not have the drug in stock, a single dose may be obtained from another ward/unit that does have the drug in stock, provided it is authorised by the nurse in charge. In this situation, the CD Record Book of the ward/unit supplying the CD must be taken, together with the container of the required drug, to the ward/unit where the patient is located. This must be done by a member of the nursing staff of the ward/unit supplying the CD. The administration details must be entered into the CD Record Book of the supplying ward/unit and witnessed by nurses from both wards/units. The location of the patient must be recorded in the CD Record Book alongside the patient’s name, and an entry made in the patient’s healthcare record to indicate that the dose was supplied from another ward/unit. Any CD transfer must be notified to the pharmacy at the earliest opportunity.

17.3. If administration is essential but no nearby wards/units have any stock of the drug in question, the on-call pharmacist should be contacted for advice. Although there is no agreement between EPUT and the acute trusts covering West Essex for the on-call pharmacists to supply medications outside normal
hours, they may be willing to do this in very exceptional circumstances where a CD needs to be administered as a matter of clinical urgency. Alternatively, they may be able to arrange for the patient to be taken to A&E or one of the acute trust wards/units for a dose of the drug to be administered. See section 9.6 of CLPG13 for details of how to contact the on-call pharmacist.

In South-East Essex, no equivalent arrangements apply.

18. POSTING CONTROLLED DRUG PRESCRIPTIONS

18.1. Under normal circumstances CD prescriptions should not be posted to service users, due to the potential for misuse if they should fall into the wrong hands. Prescription forms should always be given directly to the patient, or, in the case of children, to their parent or guardian.

18.2. In circumstances where posting a CD prescription is unavoidable, the following precautions should be taken:

- The prescription form should be posted to a community pharmacy nominated by the patient, and not sent to the patient’s home address
- The prescription form should be sent to the nominated community pharmacy by recorded delivery. If the use of recorded delivery is not feasible, a system should be set up whereby the nominated pharmacy is notified when a prescription is being posted, with instructions to complete and fax back a form which confirms that the prescription has been received. Records of posted prescriptions must be maintained so that any losses in transit can be identified.

18.3. Any prescription forms that go missing in the post despite these precautions must be notified immediately to the Accountable Officer for CDs.

19. CONTROLLED DRUGS MANAGEMENT BY REGISTERED DOCTORS, NURSES/PRACTITIONERS AND HEALTH AND SOCIAL CARE WORKERS WORKING IN THE COMMUNITY

19.1. Registered doctors and nurses caring for patients in the community may be required as part of their duties to carry out activities involving Controlled Drugs (CDs).

19.2. Controlled Drugs prescribed for an individual patient are the patient’s property and this determines responsibility and what may or may not occur.

19.3. Where there is any doubt about the legal position, ability to, or appropriateness of, handling CDs, the registered doctor or nurse shall contact their line manager and/or the Community Health Services Pharmacy Lead (Monday – Friday 9am - 5pm). Out of hours contact the on-call manager.
19.4 Transporting CDs to Patients in the Community

19.4.1. Controlled Drugs prescribed by an appropriate prescriber for an individual patient may be lawfully transported by:

- Registered nurses
- Midwives
- Doctors
- Pharmacists
- Pharmacy Staff
- Healthcare professionals
- Formal carers
- The patient’s representative

19.4.2. Registered nurses should not normally transport CDs. Registered nurses may, in extra-ordinary circumstances, transport medication, including CDs, e.g. where patients, carers/representatives or a Pharmacy are unable to collect or deliver them. The registered nurse shall explore the options above prior to agreeing to transport and follow the steps below in the event that they need to transport CD's:

- Convey CDs directly to the patient for who the medicine has been prescribed.
- Keep CDs and other medicines out of sight during transportation.
- Once conveyed to the patient’s home, the name, form, strength and quantity of medicine must be recorded in the patient’s care record and the date

19.4.3. Transport should not be via mail, taxi service (unaccompanied) or equivalent, except in exceptional circumstances dictated by urgent clinical need.

19.4.4. Prescription forms for Schedule 2 CDs (eg. Morphine, Diamorphine, Fentanyl) should not be sent to the patient’s pharmacy via the postal system (unless for treatment of addiction, when this is accepted practice)

19.4.5. When collecting CDs from a Pharmacy, the registered nurse is likely to be asked to prove identity in the form of an EPUT photo identity badge and be asked to sign for receipt.

19.5 Storage of CDs in a Patient’s Home

19.5.1. Patients and relatives should be encouraged to store CDs in the original dispensed labelled boxes, keeping different strengths
physically separated, especially injectable morphine and
diamorphine, to minimise risk of accidental preparation and
administration of a wrong dose (see NPSA Safer Practice Notice
12)."

19.5.2. Keep all medicines in one location to avoid them being mislaid.

19.5.3. Store them in a location which is cool and dry – i.e. not adjacent
to a radiator or other source of heat, or in a location subject to
steam or moisture e.g. bathrooms.

19.6 **Administration of CDs in a Patient’s Home**

19.6.1. Registered nurses may lawfully administer CDs to patients in
their care, provided they are acting in accordance with the
directions of a doctor, dentist, supplementary prescriber acting
within a Clinical Management Plan, or a Nurse Independent
Prescriber (NIP) prescribing a Schedule 2,3,4 and 5 Controlled
Drugs (including Diamorphine, dipipanone and cocaine for the
treatment of organic disease but not addiction)( Refer to
appropriate Policies, Procedures and Standard Operating
Procedures in methods of preparation and Administration.

19.6.2. Registered nurses may delegate the administration of CDs to
unregistered staff e.g. Health and Social Care Workers, however
the registered nurse remains responsible for the activity he/she
delegates and for ensuring that staff delegated such tasks are
fully trained and compliant with the legal and Trust requirements
stated in this Appendix. Read the prescription/authority to
administer carefully and check:

- patient’s name and NHS number, if available
- age and weight if appropriate
- any allergies or hypersensitivities recorded
- name of medicine to be administered, dose and frequency
- date and time the dose is due to be administered
- route of administration specified
- time of previous dose, if any
- signature of prescriber

19.6.3. Doctors administering CD’s to patients in their own homes
as part of the out of hours service, should ensure that this
administration is recorded in the patients’ healthcare record.

19.7 **Patient Safety**

19.7.1. Try to work on a flat surface, free of clutter. Gather together all
required drugs and lay out ready for preparation.
19.7.2. Check that the quantity reconciles with that stated in the patient care record or latest entry on the Controlled Drug Record of Administration (see Appendix 2) i.e. that none is missing or that there is too much.

19.7.3. Check that the drugs and doses match the prescription / Medicine Administration Record Chart / Syringe Driver Chart / Authorisation to Administer. When checking the dose of the opioid, consider the following:

- Any recent opioid dose that has been given
- The formulation – modified release (m/r) forms, liquids
- Strength (there may be several)
- Method of prescribing dose – i.e. by strength or by formulation (capsules/tablets)
- Frequency of administration
- Other analgesic medication has been prescribed – these may be additive effects

19.7.4. Check that the calculated dose is safe for the patient (e.g. for oral morphine or oxycodone in adult patients, not normally more than 50% higher than the previous dose).

19.7.5. Check that the dose has not already been given the patient (e.g. for oral morphine or oxycodone in adult patients, not normally more than 50% higher than the previous dose).

19.7.6. Carry out any calculations required to ascertain the amount or volume to be administered.

19.7.7. Select the appropriate medicine, checking against the prescription/authority to administer and be aware of:

- name of medicine
- strength of medicine
- preparation and that it is intended to be administered by the route prescribed
- expiry date

All these should be recorded appropriately in the healthcare record.

19.7.8. Obtain a check from a second qualified authorised professional, if present i.e. a second Registered Nurse, a doctor or pharmacist. If no registered professional is available a Health care Assistant may carry out the second check. The person checking should make any calculations independently, i.e. requested to calculate...
without knowledge of the requestor’s result. The results of the independent calculations shall be agreed before administration. NB – having a second checker does not absolve responsibility from the first checker. Each person is responsible for their actions.

19.7.9. If another healthcare professional is not available consider inviting patients and/or carers to carry out a second check (reference 5). Document accordingly.

19.7.10. Prepare the correct dose to be administered.

19.7.11. Take the medicine and prescription/administration record to the patient. Explain appropriately to the patient/client, and ascertain their consent to, the intended administration.

19.7.12. Administer the medicine, witnessed by any second person if present. Observe the patient taking the dose where this is given to the patient to do so.

19.7.13. Medicines prescribed for an individual patient must only be administered to and used by that patient.

19.7.14. The contents of one ampoule must never be used for more than one patient.

19.7.15. Injections must never be prepared in advance to be administered at a later time.

19.7.16. Excess medicine must not be used for another patient and must be appropriately destroyed.

19.8 Record Keeping

19.8.1. Record the administration, and the identity of the person administering. Where a second person checks the administration of a medicine, the identity of the person shall also be recorded; however, the ultimate responsibility remains with the registered nurse or doctor administering.

19.8.2. For continuous administration (e.g. via syringe drivers) there should be a record of those involved in setting-up the medication and of those involved in monitoring the administration.

19.8.3. Dispose of any unused medicine in a sharps container; do not use the sink as this delivers chemicals into the environment. The Sharps container should then be labelled “contains mixed pharmaceutical waste and sharps – for incineration only”. Any medicine liable to diversion should be disposed of in a safe and secure manner.
19.8.4. Complete the CD Record/Administration Chart with details of the dose administered and any proportion destroyed. Signatures of both the person administering and any person witnessing and checking shall be recorded.

19.8.5. Maintain a running balance of the amount of CD remaining, on the appropriate document:

- **For injectables** this should be the number of ampoules/vials of each strength.
- **For transdermal patches** this should be the number of patches of each strength.
- **For oral liquids** this should be the number of mL (millilitres) remaining. Note: do not measure remaining volumes; this is not required.

19.8.6. Record any refused doses, along with the reason for refusal if possible.

19.8.7. Record any accidental breakage/spillage/wastage of medication, which should be witnessed if at all possible.

19.8.8. Record any breakages of ampoules discovered when opening sealed packages, which should be witnessed if at all possible.

19.8.9. Record the removal of any CDs for destruction, or the destruction of any CDs at the patient’s home.

19.8.10. Record the amount of any CD unrequired and disposed of as from dose units eg. If a 25mg dose is given from a 30mg ampoule, record both “25mg given” and “5mg wasted”.

19.9 **Disposal of Controlled Drugs**

19.9.1. All Community Healthcare Workers, as producers of healthcare waste and specifically infectious waste, are required to comply with waste regulations including the Hazardous Waste Regulations (Special Waste Regulations in Scotland) and therefore need to ensure that waste is segregated, described, classified and disposed of appropriately.

19.9.2. Sharps containers with YELLOW lids must be used for disposal of sharps contaminated with medicinal products which are not cytotoxic or cytostatic – either residue or partially discharged syringes.

19.9.3. Sharps containers with PURPLE lids must be used for disposal of sharps contaminated with cytotoxic or cytostatic medicines (NB Controlled Drugs commonly used in the community are not cytotoxic or cytostatic)
19.9.4. Fully administered CDs

- Dispose of sharps containing residual medicine in the appropriate sharps container (yellow or purple lidded).
- Ensure all ‘empty’ packets/boxes are actually empty before disposal.
- Do not dispose of packaging until the balance of the quantity left is checked and there are no discrepancies.
- Fold used transdermal patches in half so the entire adherent surface is occluded and dispose of in the appropriate sharps container.

19.9.5. Part-used or prepared but unwanted CDs

If the patient refuses a dose which has been removed from its packaging or prepared ready for administration, the dose must be destroyed by disposal in an appropriate pharmaceutical waste disposal bin. If this is not available, then a sharps bin may be used instead, ensuring that the correct (yellow or purple-lidded) sharps container is used if available. If a sharps bin with an orange lid is the only type available then it must be labelled “contains mixed pharmaceutical waste and sharps – for incineration” when sent for destruction. This is to ensure that it is incinerated as required by law, and not sent to an alternative treatment site by the Waste Contractor.

19.9.6. CDs previously dispensed for a specific patient and no longer required

- Controlled drugs prescribed for a specific patient are the property of that patient, even after death. It is the responsibility of the patient or patient’s family/carer to arrange for the disposal of unwanted CDs. Advise that they should be taken to a community pharmacy or dispensing doctor practice for safe destruction.
- Do not agree to transport patients’ unwanted CDs to a pharmacy/dispensing doctor practice except in exceptional circumstances – e.g. where not removing them would represent a risk to the patient or could result in diversion and potential abuse.
- Where it is deemed necessary to remove unwanted CDs from a patient’s home, they must be transported to a pharmacy/dispensing doctor practice directly, for destruction.
19.9.7. Any removal of CDs should be recorded in the patient’s healthcare record and should include:

- Name, form, strength and quantity of CD removed or destroyed
- Reason for removal or destruction
- Date and time
- Name of the nurse or doctor removing the unwanted CD,
- Signature and name of the patient, patient’s family, carer etc., giving their permission to remove, or other healthcare professional/social care worker acting as a witness.
- Where there is no second person available to witness or give permission, annotate the record with “no second person available” or “no person available to give permission”.

If CDs are removed and transported to a community pharmacy for destruction, written consent should be sought or witness signature if possible, using the Form “Consent To The Removal Of Medicines Including Controlled Drugs From Patients’ Homes For Safe Disposal (Community)” (see Annex 5) and this should also be filed in the patient’s healthcare record. Where there is no second person available to witness or give permission, annotate the record with “no second person available” or “no person available to give permission”.

19.10 Reporting Incidents with CDs in the Community

19.10.1. Incidents with CDs and/or breaches of this SOP shall be reported to the Team Leader for investigation and Community Health Services Pharmacy Lead. When this occurs out of hours, this should be the next working day.

19.10.2. Complete and submit a Clinical Incident Report Form within 24 hours of the incident occurring.

19.10.3. In the event of a discrepancy in the quantity balance of a Controlled Drug, the registered nurse or doctor must immediately investigate the reason for the discrepancy. If this is not found, the discrepancy must be reported as soon as possible AND NO LATER THAN THE END OF THE SHIFT, to the senior manager responsible for the ward/unit or team.
References


7. NICE: Controlled Drugs: safe use and management. April 2016 https://www.nice.org.uk/guidance/ng46
### Legal requirements for Controlled Drug Schedules

<table>
<thead>
<tr>
<th>Schedule:</th>
<th>Schedule 2</th>
<th>Schedule 3</th>
<th>Schedule 4</th>
<th>Schedule 4</th>
<th>Schedule 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Designation:</td>
<td>CD</td>
<td>CD No Reg</td>
<td>CD Benz</td>
<td>CD Anab</td>
<td>CD Inv</td>
</tr>
<tr>
<td>Brief description:</td>
<td>Drugs which carry a severe risk of addiction but which may be used medicinally.</td>
<td>Must be stored in a CD cupboard in an institutional setting</td>
<td>Benzodiazepines and related drugs; cannabis extract</td>
<td>Certain steroids and hormones liable to misuse</td>
<td>Low strength opiates</td>
</tr>
<tr>
<td>Examples:</td>
<td>Morphine and other strong opiates; methylphenidate and other major stimulants; ketamine; cannabis-based products</td>
<td>Most barbiturates; buprenorphine, temazepam, midazolam, tramadol, gabapentin &amp; pregabalin</td>
<td>Diazepam, oxazepam, chloral hydrate, and most other benzodiazepines, z-drugs; Sativex®</td>
<td>Anabolic steroids, growth hormone</td>
<td>Oramorph®&lt;sup&gt;™&lt;/sup&gt; (morphine oral solution 10mg/5ml)</td>
</tr>
<tr>
<td>Storage in CD cupboard:</td>
<td>Yes</td>
<td>Yes, except phenobarbitone, tramadol, gabapentin &amp; pregabalin</td>
<td>No</td>
<td>No</td>
<td>No but required in EPUT for Oramorph®</td>
</tr>
<tr>
<td>Prescription writing requirements:</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>CD Requisitions needed:</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Record in CD register:</td>
<td>Yes</td>
<td>No but required in EPUT for buprenorphine and midazolam</td>
<td>No</td>
<td>No</td>
<td>No but required in EPUT for Oramorph®</td>
</tr>
<tr>
<td>Pharmacist MUST ascertain the ID of the person collecting CD:</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Emergency supplies allowed:</td>
<td>No</td>
<td>No, except phenobarbitone for epilepsy</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Validity of prescription:</td>
<td>28 days</td>
<td>28 days</td>
<td>28 days</td>
<td>28 days</td>
<td>6 months (if POM)</td>
</tr>
<tr>
<td>Maximum duration that should be prescribed:</td>
<td>30 days</td>
<td>30 days</td>
<td>30 days</td>
<td>30 days as good practice</td>
<td>30 days as good practice</td>
</tr>
</tbody>
</table>

**Note:** Drugs in Schedule 1 (CD Lic) have no legitimate medical applications, and legal possession requires a licence from the Home Office. Examples include LSD and magic mushrooms.
Annex 2

List of Common Controlled Drugs in Schedules 2 and 3

**Ordering:** All Schedule 2 and Schedule 3 Controlled Drugs required for ward stock must be ordered using a CD Order Book.

**Storage:** All Schedule 2 CDs must be stored in a CD cupboard. Many Schedule 3 CDs are exempt from the legal requirement for storage in a CD cupboard, but within this Trust, **buprenorphine, temazepam, midazolam and morphine 10mg/5ml oral solution** must be stored in a CD cupboard. However, **phenobarbitone and tramadol** does not need to be stored in a CD cupboard.

**Recording:** All Schedule 2 CD must be fully recorded in a CD Record Book (receipts and administration). Schedule 3 CDs do not legally require recording in a record book, but within this Trust, receipts and administration of **buprenorphine, midazolam and morphine 10mg/5ml oral solution** must be fully recorded in a CD Record Book.

**Disposal:** All Schedule 2 and 3 CDs, plus buprenorphine and midazolam, must be denatured by an approved person in the presence of an authorised witness and booked out of the CD Record Book prior to disposal. Schedule 4 (Part 1) CDs (benzodiazepines and z-drugs) must be denatured prior to disposal but do not need to be witnessed and recorded.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Brand Name(s)</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alfentanil</td>
<td>Rapifen®</td>
<td>2</td>
</tr>
<tr>
<td>Amobarbital</td>
<td>Amytal®️ (named patient only)</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Tuinal®️️ (with secobarbital – named patient only)</td>
<td>3</td>
</tr>
<tr>
<td>Buprenorphine</td>
<td>BuTrans®, Subutex®, Temgesic®, Transte®, Suboxone®️ (with naloxone)</td>
<td>3</td>
</tr>
<tr>
<td>Butobarbital</td>
<td>Soneryl®️️ (named patient only)</td>
<td>3</td>
</tr>
<tr>
<td>Cannabis-based products for medicinal use</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Cocaine</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Codeine injection/powder</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Dexamfetamine</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Diamorphine</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Dihydrocodeine injection</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Dipipanone</td>
<td>Diconal®️️ (with cyclizine)</td>
<td>2</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>Abstral®, Effentora®, Actiq®, Instany®, PecFent®, Durogesic DTrans®, Sublimaze®️, Tilofyl®️</td>
<td>2</td>
</tr>
<tr>
<td>Gabapentin</td>
<td>Neurotin®️️</td>
<td>3</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>Palladone®, Palladone SR®️️</td>
<td>2</td>
</tr>
<tr>
<td>Ketamine</td>
<td>Ketalar®️️</td>
<td>2</td>
</tr>
<tr>
<td>Lisdexamfetamine</td>
<td>Elvanse®, Elvanse Adult®️️</td>
<td>2</td>
</tr>
<tr>
<td>Methadone</td>
<td>Methadose®, Physeptone®, Synastone®, Metharose®️️</td>
<td>2</td>
</tr>
<tr>
<td>Meprobamate</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Methylphenidate</td>
<td>Ritalin®, Concerta XL®, Equasym XL®, Medikinet XL®️️</td>
<td>2</td>
</tr>
</tbody>
</table>
## List of Controlled Drugs in Schedule 4 part 1

(brand names in brackets)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Midazolam</td>
<td>3</td>
</tr>
<tr>
<td>Morphine</td>
<td>2</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>2</td>
</tr>
<tr>
<td>Papaveretum</td>
<td>2</td>
</tr>
<tr>
<td>Pentazocine</td>
<td>3</td>
</tr>
<tr>
<td>Pethidine</td>
<td>2</td>
</tr>
<tr>
<td>Phenobarbital</td>
<td>3</td>
</tr>
<tr>
<td>Pregabalin</td>
<td>3</td>
</tr>
<tr>
<td>Remifentanil</td>
<td>2</td>
</tr>
<tr>
<td>Secobarbital</td>
<td>2</td>
</tr>
<tr>
<td>Sodium Amytal</td>
<td>3</td>
</tr>
<tr>
<td>Tapentadol</td>
<td>2</td>
</tr>
<tr>
<td>Tramadol</td>
<td>3</td>
</tr>
<tr>
<td>Temazepam</td>
<td>3</td>
</tr>
</tbody>
</table>

### Further information can be found at:
# RECORD OF THE DENATUREING AND DISPOSAL OF CONTROLLED DRUGS

and / or REPORTING OF CONTROLLED DRUG DISCREPANCIES

<table>
<thead>
<tr>
<th>Ward / Unit:</th>
<th>Tel.:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registered Nurse in Charge:</td>
<td>Date:</td>
</tr>
<tr>
<td>Name: Authorised person for denaturing and disposal of Controlled Drugs:</td>
<td>Signature:</td>
</tr>
<tr>
<td>Name: Nurse witnessing denaturing and disposal:</td>
<td>Signature:</td>
</tr>
</tbody>
</table>

## Drugs to be denatured:

<table>
<thead>
<tr>
<th>Name of drug</th>
<th>Form and strength</th>
<th>Quantity denatured</th>
<th>Balance remaining</th>
<th>Stock or patient's own drugs (if POD, state name of patient)</th>
<th>Reason for disposal</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Comments:

## Discrepancies:

Period over which discrepancy may have occurred:
From (date/time): To (date/time):

Adverse Incident Report no:
NOTE: All details must be written on the form

Nurse in Charge notified on (date/time):

Name of authorised pharmacist for follow-up:

Comments:

- Completed copies of this form must be retained on the ward/unit with other Controlled Drug records for 7 YEARS from the date on which the drugs were disposed of.
- A copy should also be sent or faxed to the Accountable Officer as soon as possible after the denaturing/disposal of Controlled Drugs.
OPERATIONAL PROCEDURE FOR THE DISPOSAL OF UNWANTED CONTROLLED DRUGS ON WARDS/UNITS
(for use only by authorised destruction witnesses - see section 15.4)

1. On arrival at the ward/unit, identify the nurse in charge who has responsibility for the Controlled Drug cupboard keys, and explain that you have come to witness disposal of their unwanted CDs (show ID).

2. Ward staff are responsible for the destruction in the presence of the authorised witness, and need to be present throughout the process.

3. What to take with you
   - Copy of Appendix 3 of the procedural guidelines for the safe and secure handling of medicines (this document)
   - CD denaturing kits (the number will depend on the quantity of drugs to be disposed of)
   - Pestle and mortar
   - Measuring cylinder (if ward has liquids to be disposed of)\(^3\)
   - Cat litter (if ward has a large quantity of liquid to be disposed of)
   - Blank forms for consent to disposal and record of disposal (see Annex 3 within Appendix 11 of CLPG13 and Annex 3 of this document)

4. Preparing the drugs for disposal
   4.1. Confirm with the member of staff which Controlled Drug(s) require disposal. This may include out of date ‘stock’ drugs and unwanted ‘patient’s own’ drugs.
   4.2. Deal with one drug at a time. Remove all stock of the drug requiring disposal from the CD cupboard and place it on a clear work bench. In some cases, only part of the stock may need to be disposed of, with the remainder being retained on the ward. However, the entire stock of the drug should be removed from the cupboard so that it can be counted.
   4.3. Check that the content of each pack matches the details on the outer carton, i.e. check that what is printed on a foil/blister strip of tablets is the same drug and strength as stated on the carton.
   4.4. Remove the CD Record Book from the CD cupboard and identify the current page in the record book corresponding to the drug being disposed of. Confirm with the nurse witness that you have identified the correct page – remember that different strengths of a drug will each have separate pages in the Record Book. Note that ‘patient’s own’ supplies of CD medication are recorded on pages at the back of the Record Book.
   4.5. Count the total stock of the drug (number of tablets, capsules, etc). In the case of liquids, measure the volume using a measuring cylinder (full bottles do not need to be measured – accept the volume stated on the container).

\(^3\) Wards are advised to purchase measuring cylinders, so this may not be necessary.
4.6. Confirm that the quantity in stock agrees with the quantity stated in the CD Record Book. If so, proceed with booking-out. If there is a discrepancy, refer to section 7.

4.7. Confirm whether the entire stock of the drug is to be disposed of, or whether part of the stock is to be retained, e.g. because it is still in date. If part of the stock is to be retained, separate this from the stock requiring disposal and place it to one side until the entry has been made in the Record Book. Count the number of tablets, capsules, etc. requiring disposal.

Note: Very occasionally a ward may be holding both ‘stock’ and ‘patients own’ supplies of the same drug, only one of which requires disposal. In this case there should be separate pages in the CD Record Book for the two supplies.

In this situation, both pages of the CD Record Book will need to be checked. The supply that does not require disposal should be counted and checked against the record book, and then returned to the CD cupboard.

4.8. If the drugs to be disposed of are a patient’s own, check that the patient has signed a consent form for their disposal (see Annex 3 within Appendix 11 of CLPG13).

NB – If not present, confirm with the nurse that the patient who the drugs belonged to has been discharged from the ward; if so, the drugs can be disposed of. If the patient is still present on the ward but no longer requires the drug, ask the nurse to get a consent form completed immediately.

5. Booking the drugs out of the Controlled Drug Record Book

5.1. Having identified the items requiring disposal and having established the quantity to be disposed of, double-check that you have the correct page in the CD Record Book for the product in question. Then make an entry on the next blank line in the book. This entry should include the following information:

- The date and time of denaturing
- The quantity of drug denatured, e.g. ‘Ten(10) tablets’, ‘thirty-five (35) ml’
- The reason for denaturing, e.g. ‘out of date’, ‘no longer required’
- In the case of a patient’s own CDs, ‘patient’s consent obtained’
- The signatures of the authorised nurse and the authorised witness
- The remaining balance in stock, or NIL if the entire stock has been denatured. In the case of a patient’s own CDs that have been denatured, the running balance should be zeroed and a line put through the remainder of the page.
- If part of the stock was retained for future use, check that the remaining quantity agrees with the new running balance in the Record Book and return it to the CD cupboard.

5.2. The style of the disposal entries in the CD Record Book should be similar to these examples:
6. Denaturing the unwanted items

6.1. Wear rubber gloves during the disposal process – these should be available on the ward.

6.2. With the exception of very large quantities of liquids (see section 6.6), all items should be disposed of using a CD denaturing kit. See sections 6.5 to 6.8 for how to prepare items prior to placing them in the kit.

6.3. The CD denaturing kit carries instructions for its use. It should be shaken well before use, and must not be filled beyond half-full (use a second kit if necessary). When all the drugs have been added, the kit should be filled with water and the lid replaced securely. It should then be shaken well – the contents will set to a gel within 5 minutes.

6.4. The entire kit should then be placed in the ‘pharmaceutical waste’ bin. If the ward does not have such a bin, the kit should be stored securely until a bin is available (contact Estates Dept).

6.5. Solid dose formulations – tablets, capsules

6.5.1. Put a small amount of water in a mortar. Add the tablets and grind/crush with the pestle to make a loose slurry – add more water if necessary. If there are capsules to be disposed of, pull them apart and let the powder and shell fall into the mortar before grinding. If the capsules cannot be pulled apart, crush them so that the shell is split.

6.5.2. Pour the slurry from the mortar into the kit, then rinse the mortar with a little more water to transfer any remaining debris.

6.6. Liquid formulations

6.6.1. Small volumes of liquid (up to 100ml) can be poured directly into the denaturing kit and mixed with any other items being disposed of at the same time. If necessary, a second kit can be used.
6.6.2. If the quantity of liquid to be disposed of is very large (>300ml), an alternative is to carefully mix it with an appropriate amount of cat litter in a bowl. The litter can then be disposed of in the ‘pharmaceutical waste’ bin.

6.6.3. Minor volume discrepancies are common with liquid preparations. If the quantity of liquid in stock exceeds the balance stated in the Record Book, the excess can be disposed of – in this case the entry should state the amount of the excess, e.g. ‘Forty-five ml (45ml) plus twenty ml (20ml) excess destroyed’.

6.6.4. If the quantity of liquid in stock is less than the amount stated in the CD Record Book, contact the Community Health Services Pharmacy Lead to investigate. Disposal should not proceed until this investigation has been completed. If there is a very large shortfall, the Accountable Officer should also be notified.

6.7. Injections

6.7.1. Ampoules containing liquids should be opened and the liquid tipped into the kit. The remains of the ampoule should be placed in a ‘sharps’ bin suitable for sharps contaminated with pharmaceutical waste.

6.7.2. Ampoules containing powder should be opened and water added to dissolve the powder. They should then be treated as above.

6.8. Patches

6.8.1. The backing paper should be removed from the patch, and the patch folded over on itself. It can then be placed into the kit. It is essential that gloves are worn whilst carrying out this process.

7. Completing the denaturing/disposal record / Discrepancies

7.1. Once the denaturing process has been completed, the authorised person and the witness should complete a record sheet which lists the items that have been disposed of (see Annex 3). Any patient consent forms should be attached to the record sheet.

7.2. The original of the completed record sheet must be retained on the ward for 7 years. A copy should be retained by the authorised destruction witness and a second copy should be sent or faxed to the Accountable Officer for CDs.

7.3. If a discrepancy is found between the content of the CD cupboard and the CD Record Book, this should be detailed on the denaturing/disposal form. Disposal of the drug in question must not proceed, although other drugs may be disposed of. The discrepancy must be reported and investigated as explained in sections 10.3.8 - 10.3.10 of this document.
CONSENT TO THE REMOVAL OF MEDICINES
INCLUDING CONTROLLED DRUGS FROM PATIENTS’ HOMES FOR SAFE
DISPOSAL (COMMUNITY)

Dear Patient/ Carer,
We would like to ask your permission to DISPOSE of the following excess/unwanted medicines, in line with guidelines and regulations by taking them for destruction to a community pharmacy. If you consent to these medicines being disposed of on your behalf, please sign the box below.

Thank you

<table>
<thead>
<tr>
<th>Name of Patient:</th>
<th>DOB</th>
<th>NHS No:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Team:</td>
<td>Date of removal</td>
<td>Time of removal</td>
</tr>
<tr>
<td>Reason for Removal:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Name of Registered Healthcare Professional Removing medication:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Signature:</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Medicines to be disposed of:</strong></td>
<td>Strength</td>
<td>Form</td>
</tr>
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<td><strong>Controlled Drugs to be disposed of:</strong></td>
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<td>Patient /carer /witness/signature for consent: (delete as appropriate)</td>
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<td>State Name if not the patient:</td>
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Nursing staff. Medicines may only be removed for disposal by EPUT staff under exceptional circumstances. (Refer to CLPG13-CHS) Any medicines removed from patient’s homes must have consent, either from the patient, their carer/family if they lack capacity, or in the case of deceased patients, where possible their family or another witness to the removal. This document should be scanned into the patient’s healthcare record.

Pharmacy details:
Please complete details below for the pharmacy to which the medicines have been taken for destruction:

<table>
<thead>
<tr>
<th>Name of Pharmacy:</th>
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<tr>
<td>Address:</td>
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<td>Tel no:</td>
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</tbody>
</table>

I confirm that I have received the medicines listed overleaf for destruction:

Signature of Pharmacist:………………………………………………………………………………

Date: ..................................................................................................................

Name of Pharmacist:.................................................................................................

Signature of Registered Nurse/Healthcare Assistant: ...................................................

Date: ..................................................................................................................

Name of Registered Nurse/ Healthcare assistant: ..........................................................