

ESSEX PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST

**PROCEDURES FOR THE SAFE MANAGEMENT AND USE OF
CONTROLLED DRUGS IN MENTAL HEALTH SERVICES**

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 on wards and other units.

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.
- 2.3. 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.
- 2.4. 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

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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](#).

- 2.5. 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 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 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, but legal responsibility remains with the most senior nurse. See also section [5.2](#).

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 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 and the registered nurse 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 or 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

- 5.1. The registered nurse 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 permanently employed on the ward or unit. This responsibility can be delegated to another registered nurse.
- 5.2. Nurses 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. In addition, a list of the names and specimen signatures of all nurses authorised to order and handle CDs should be kept in the front of the ward/unit CD Record Book. This list should be signed by the Ward Manager and updated at least annually.
- 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 employed by the Trust, as independent verification that the drugs ordered are required for use on the ward or unit.

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

- 5.5. All CD orders (requisitions) must state:
 - Name of the Hospital
 - 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
 - Date
 - Signature and GMC number of the countersigning doctor (*only where supply is to be made by 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 its 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.

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Once the order has been completed and signed, the CD Order Book should be sent to the pharmacy. **For Robin Pinto and Woodlea:** This should be accompanied by a lockable Controlled Drug box. This box must clearly state which ward or unit it belongs to.

In Essex: With the exception of wards where the pharmacy is located on the same site and the CD order book can be delivered in person, this should be sent directly to pharmacy, in a sealed tamper evident bag accompanied by a consignment note. Seals and consignment notes can be obtained from pharmacy.

- 5.7. A new CD Order Book can be obtained by sending a written order to the appropriate hospital pharmacy; this must be signed by a nurse who is authorised to order CDs. **In Essex** page 100 of each order book will be completed by pharmacy staff as the order for the next CD order book; this must be signed by a nurse who is authorised to order CDs.

6. TRANSPORT OF CONTROLLED DRUGS

- 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 or Trust 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 will be required to 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 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, 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

- 7.1. Deliveries of CDs must be accepted by an authorised nurse whose name and signature have been notified to the pharmacy (see Appendix 2 of CLPG13)
- 7.2. The authorised nurse 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, 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 requested in a special case to do so by a Matron/Team Manager or the pharmacy department.
- 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 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 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, 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, 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 [2.4](#) and [Annex 1](#) and [Annex 2](#))
 - The CD cupboard must not be used for storing other items such as money and valuables.
 - 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 in charge of the ward or unit is responsible for the key to the CD cupboard.

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- 8.5.2. Key-holding may be delegated to an authorised registered nurse whose signature is held by the pharmacy and whose name is listed in the CD Record Book (see section [5.2](#)), but legal responsibility rest with the Appointed Nurse 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 in Charge of the ward or unit must be informed immediately that the CD key is missing, and the pharmacy 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 cannot be located, 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 (by taking the patient to the other ward or unit and making an appropriate entry in their CD Record Book). The unit is responsible for arranging appropriate transport.
- 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 pharmacy 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/or any drugs which the Trust requires to be treated as a Schedule 2 or 3 CD must keep a record of all CDs received and administered in a Controlled Drug Record Book. The Appointed Nurse 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 and should be witnessed by a second person, preferably another registered nurse. If a second registered nurse is not available, the transaction can be witnessed by another registered practitioner, e.g. a doctor, pharmacist, pharmacy technician, or by an appropriately trained healthcare assistant.
- 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):

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- **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 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.

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Figure 1: Sample receipt entry (stock)

NAME, FORM OF PREPARATION AND STRENGTH <u>Morphine sulphate tablets MR 10mg (MST Continus 10)</u> 13									
AMOUNT(S) OBTAINED			AMOUNT(S) ADMINISTERED						
Amount	Date Received	Serial No of Requisition	Date	Time	Patient's Name	Amount given	Given by	Witnessed by	STOCK BALANCE
			01/01/11	19:15	Balance transferred from page 12		Signature & name	Signature & name	15 ✓ initial
Twenty	18/04/11	Req. 24	18/04/11	14:30	Received from Rochford Pharmacy		Signature & name	Signature & name	35 ✓ initial

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. Any CDs brought in by a patient must be checked by two nurses and then stored in the CD cupboard. 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.

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 brought in should be entered on the first line in the following style:

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

NAME, FORM OF PREPARATION AND STRENGTH <u>Morphine sulphate tablets MR 10mg (MST Continus 10) – Fred BLOGGS</u> 100									
AMOUNT(S) OBTAINED			AMOUNT(S) ADMINISTERED						
Amount	Date Received	Serial No of Requisition	Date	Time	Patient's Name	Amount given	Given by	Witnessed by	STOCK BALANCE
Twenty	15/05/11		15/05/11	09:00	Brought in by patient		Signature & name	Signature & name	20 ✓ initial

9.3.3. Once the patient's CDs have been booked in and stored securely, a decision must be taken about whether they are to be used on the ward, 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](#) (Essex only) for returns and [15.7.3](#) (Robin Pinto and Woodlea only) for disposal.

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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. 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. This includes CD Record Books if they contain a record of disposal and will particularly apply to Robin Pinto and Woodlea.
- 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 or seven years after the date of the last entry). 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 Nurse 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 pharmacy (Essex only) or disposed of (Robin Pinto and Woodlea only; see section [15.7.3](#)), in order to eliminate the need for CDs to be counted and recorded on at least a weekly basis.
- 10.3.3. Two registered nurses should carry out the balance check. 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*.

* 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.

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- 10.3.5. For each item checked, an entry must be made in the CD Record Book stating '*Stock checked and correct*', giving the date and time of the check. This entry must be signed by the two registered nurses 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 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 in Charge of the ward or unit. A copy should be sent to the Accountable Officer 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. Staff from the pharmacy that supplies a ward/unit with CDs will carry out a balance check at 3-monthly intervals, and provide a summary report to the Appointed Nurse 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, and should follow the same criteria as in section [10.3.4](#).
- 10.4.3. In the case of liquid preparations, the stock will be physically measured rather than estimated. Wards/units that hold stocks of

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liquid CDs should obtain small and large size measuring cylinders, approved by the pharmacy department, 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 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 a standard inpatient 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 prescription form or a FP10 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:

[†] From 1st June 2015

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- 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

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 ward 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

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hospital pharmacy in time for a period of leave, the following options are permissible:

- If the ward 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 ward on each day of leave for a dose of the CD to be administered from ward stock
- If the pharmacy is able to supply the medication by the following day, the patient can be instructed to return to the ward to collect the item.
- If the ward has access to FP10 prescription forms, the CD can be prescribed on one of these for dispensing via a community pharmacy (but note that most wards do not currently have access to FP10 forms).

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 from the hospital pharmacy.

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. Most non-medical independent prescribers are able to prescribe controlled drugs in Schedule 2 – 5 for any medical condition within their competence, except diamorphine, cocaine and dipipanone for the treatment of addiction. However, independent prescribers in some professions are restricted in the range of CDs that they are authorised to prescribe. Practitioners other than nurses and pharmacists should seek advice from the Accountable Officer on what they may legally prescribe.

11.4.2. Non-medical supplementary prescribers may, within their competence, prescribe any controlled drug for any medical

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condition in accordance with the terms of an individual clinical management plan agreed with an independent prescriber.

11.5. Patient Group Directions

- 11.5.1. There are very limited circumstances in which certain CDs may be administered or supplied under a patient group direction (PGD) by certain named health professionals.
- 11.5.2. Members of staff who are considering using a PGD relating to CDs must contact the Accountable Officer to discuss the circumstances in which this is allowable within current legislation.

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, and 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
 - what it has been prescribed for
 - how to use sustained release and immediate release formulations if prescribed together
 - how it may affect the patient's ability to drive and the legal situation
 - that it is only to be used by the person it was prescribed for
 - that the patient or carer may need to show identification when they collect CDs from a pharmacy

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- 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.
- 12.2. The CD must be administered by a registered nurse or a doctor, and the administration must be witnessed by a second person, who should usually be a registered nurse (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 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 unqualified members of staff. These staff must sign the specimen signature sheet at the front of the CD Record Book (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
 - 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

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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 initialled every time an entry is made

Figure 3: Sample administration entry

NAME, FORM OF PREPARATION AND STRENGTH <u>Morphine sulphate tablets MR 10mg (MST Continus 10)</u>										13
AMOUNT(S) OBTAINED			AMOUNT(S) ADMINISTERED							
Amount	Date Received	Serial No of Requisition	Date	Time	Patient's Name	Amount given	Given by	Witnessed by	STOCK BALANCE	
			01/01/11	19:15	Balance transferred from page 12				15	
Twenty	18/04/11	Req. 24	18/04/11	14:30	Received from Rochford Pharmacy		Signature & name	Signature & name	31 ✓ initial	
			19/04/11	16:15	John Smith	2 tablets	Signature & name	Signature & name	29 ✓ initial	

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

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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

13.1. A Controlled Drug brought into a ward or unit by a patient must be checked and entered onto a fresh page at the back 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

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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 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 pharmacy (Essex) or disposed of securely on the ward (Robin Pinto and Woodlea; see section [15](#)).
- 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 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 should not be used for their treatment whilst an inpatient. Instead, a stock supply 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 back of the CD Record Book as detailed in section [12.7](#).

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

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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 for the item to be removed to pharmacy (Essex) or disposed of securely on the ward (Robin Pinto and Woodlea).
- 13.5.4. A patient’s own CDs remain their personal property until they consent to disposal. 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)

NAME, FORM OF PREPARATION AND STRENGTH <u>Morphine sulphate tablets MR 10mg (MST Continus 10) – Fred BLOGGS</u> 100									
AMOUNT(S) OBTAINED			AMOUNT(S) ADMINISTERED						
Amount	Date Received	Serial No of Requisition	Date	Time	Patient’s Name	Amount given	Given by	Witnessed by	STOCK BALANCE
<i>Twenty</i>	<i>15/05/11</i>		<i>15/05/11</i>	<i>09:00</i>	<i>Brought in by patient</i>		<i>Signature & name</i>	<i>Signature & name</i>	<i>20 ✓ initial</i>
			<i>15/05/11</i>	<i>10:00</i>	<i>Fred Bloggs</i>	<i>1 tablet</i>	<i>Signature & name</i>	<i>Signature & name</i>	<i>19 ✓ initial</i>
			<i>15/05/11</i>	<i>16:00</i>	<i>Returned to patient Patient’s signature</i>	<i>19 tablets</i>	<i>Signature & name</i>	<i>Signature & name</i>	<i>NIL ✓ initial</i>

14. RETURN OF CONTROLLED DRUGS TO PHARMACY

- 14.1. Unused CD stock and unwanted patient’s own CDs from wards or units may only be returned to the pharmacy where the pharmacy department is part of the same organisation. Therefore, different processes apply in to Robin Pinto and Woodlea from Essex.
- 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. **Robin Pinto and Woodlea:** All unwanted CDs must be disposed of at ward / unit level (see section [15](#)).

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14.4. **Essex:** All unwanted CDs should be returned to the pharmacy for re-issue or safe destruction and onward disposal. This includes unused stock, CDs which are time-expired or otherwise unfit for use (e.g. opened liquids), and any other CDs no longer needed on the ward (i.e. patient's own CDs for disposal, CDs dispensed for discharge, or labelled for an individual patient, that are no longer required).

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
- 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

NAME, FORM OF PREPARATION AND STRENGTH <i>Morphine sulphate tablets MR 10mg (MST Continus 10)</i>										13
AMOUNT(S) OBTAINED			AMOUNT(S) ADMINISTERED							
Amount	Date Received	Serial No of Requisition	Date	Time	Patient's Name	Amount given	Given by	Witnessed by	STOCK BALANCE	
			01/01/11	19:15	Balance transferred from page 12				15 ✓ initial	
Twenty	18/04/11	Req. 24	18/04/11	14:30	Received from Rochford Pharmacy		Signature & name	Signature & name	31 ✓ initial	
			19/04/11	16:15	John Smith	2 tablets	Signature & name	Signature & name	29 ✓ initial	
			20/04/11	09:00	Returned to Pharmacy – no longer required		Signature & name	Signature & name	NIL ✓ initial	

15. DISPOSAL OF CONTROLLED DRUGS

15.1. Disposal of CDs that are no longer required may only be undertaken on the ward or unit in Robin Pinto and Woodlea. In Essex all CDs should be returned to the pharmacy for safe denaturing and disposal.

Sections 15.2 to 15.7 apply to Robin Pinto and Woodlea only

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 nurse 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 (“Authorised Witness”)

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 pharmacy staff who visit Trust sites cannot carry out this role as 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 the Trust’s 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 ward nurse 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](#))

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- 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 nurse 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. The authorised witness will bring a suitable CD denaturing kit to the ward. 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.

Sections 15.8 to 15.9 apply to Bedfordshire, Essex and Luton

15.8. Disposal of very small amounts of CDs

- 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 staff, who should make an

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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 patients

- 15.9.1. **Inpatients:** 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.
- 15.9.2. **Community:** If a patient dies in the community and has been in regular contact with community-based mental health services, the community staff have a responsibility to ensure that any dispensed medications (including CDs) are safely disposed of. CDs do not need to be treated any differently to other dispensed medications in this situation.

Ideally, the patient’s relatives or carers should be advised to return the medicines to the community pharmacy that supplied them, so that they can be safely disposed of.

If the circumstances of the patient’s death mean that this is not feasible, the community staff should remove the medications

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from the patient's home, recording in the patient's healthcare record the names and quantities of the drugs removed – this should be witnessed by a second person. The drugs should then be taken to a community pharmacy, and a receipt obtained to confirm that the drugs were handed to the pharmacy for disposal. This receipt should be filed in the healthcare record in case any questions are raised regarding the removal of the patient's medication.

- 15.9.3. Situations may arise where community staff may need to remove medications from a patient's home for disposal. In circumstances, where it is not feasible to advise the patient's relatives or carers to return medicines to the community pharmacy, community staff should obtain the written permission of the patient or carer to remove medicines for disposal, recording in the patient's healthcare record the names and quantities of the drugs removed – this should be witnessed by a second person. The drugs should then be taken to a community pharmacy, and a receipt obtained to confirm that the drugs were handed to the pharmacy for disposal. This receipt should be filed in the healthcare record in case any questions are raised regarding the removal of the patient's medication.

15.10. Disposal of Controlled Drugs in pharmacy

- 15.10.1. Controlled drugs returned to pharmacy for destruction will be denatured and disposed of in line with the relevant pharmacy standard operating procedure, and in the presence of an "Authorised Witness".

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 staff.

17. OBTAINING CONTROLLED DRUGS 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 hospital 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 the patient has not brought in a supply of their own CD medication, the doctor should be called to assess whether the dose may be omitted without harm to the patient.

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- 17.3. 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 supplying the CD must be taken, together with the container of the required drug, to the ward where the patient is located. This must be done by a member of the nursing staff of the ward supplying the CD. The administration details must be entered into the CD Record Book of the *supplying* ward and witnessed by nurses from *both* wards. 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.
- 17.4. 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. There is no agreement between EPUT and the acute trusts in Bedfordshire and Luton for the on-call pharmacists to supply medications outside normal hours. In very exceptional circumstances it may be possible to arrange for the patient to be taken to A&E for a single dose of the drug to be administered. See section 9.6 of CLPG13 for details of how to contact the on-call pharmacist.

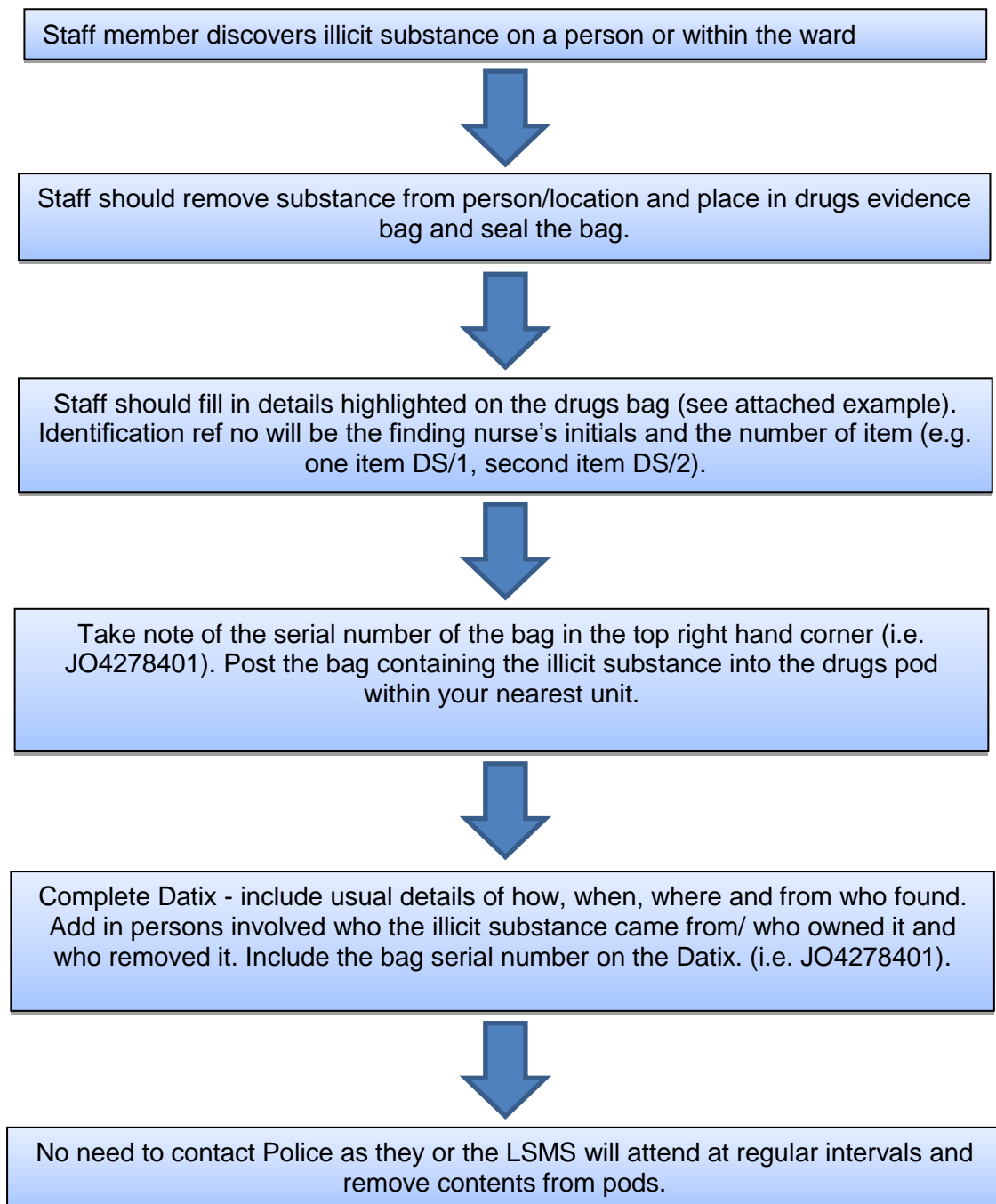
18. POSTING CONTROLLED DRUG PRESCRIPTIONS
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- 18.1. Under normal circumstances CD prescriptions should not be posted to service users, due to the potential for misuse if they should fall into the wrong hands. Prescription forms should always be given 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/email 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. SUSPECTED ILLICIT SUBSTANCES

- 19.1. Where a suspected illicit substance is brought onto Trust premises by a patient, as soon as it is discovered it shall be removed from the area in which it was found, placed in a drugs evidence bag, sealed and placed in the drugs 'pod' within the unit.
- 19.2. The process to be followed for the storage of suspected illicit substances is set out in the flowchart in Figure 6 and an example of how to complete the evidence bag in Figure 7.

Figure 6: storage of suspected illicit substances



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Figure 7: Example of an evidence bag

KEEP SAFE® KEEP SAFE® KEEP SAFE® KEEP SAFE® KEEP SAFE® KEEP SAFE® KEEP SAFE® KEEP SAFE® KEEP SAFE®

TO CLOSE, PEEL OFF WHITE TAPE TO EXPOSE GLUE AND PRESS ORANGE TAPE DOWN FIRMLY.

A9


EVIDENCE BAG DRUGS USE ONLY



J04278401

Authority Identification Ref. No. <u>DS/L</u> Court Exhibit No. R-V <u>JOE BLOGGS</u> Property Ref. No. Description <u>1x BAG OF WHITE UNKNOWN POWDER.</u> Time/Date Seized/Produced <u>10.33 24/5/2019</u> Where Seized/Produced <u>BASILDON MHU GRANGENATER WARD SEARCH ROOM</u> Seized/Produced By <u>DEBBY STOVENS</u> Signed <u>[Signature]</u> Incident/Crime No. <u>E126136</u> Property No. Laboratory ref.	(Continuity) Name/Rank/No. (Block Letters) Signed Date Name/Rank/No. (Block Letters) Signed Date Name/Rank/No. (Block Letters) Signed Date Name/Rank/No. (Block Letters) Signed Date Name/Rank/No. (Block Letters) Signed Date
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Annex 1

Legal requirements for Controlled Drug Schedules

Schedule:	Schedule 2	Schedule 3	Schedule 4 Part I	Schedule 4 Part II	Schedule 5
Designation:	CD	CD No Reg	CD Benz	CD Anab	CD Inv
Brief description:	Drugs which carry a severe risk of addiction but which may be used medicinally.	Must be stored in a CD cupboard in an institutional setting	Benzodiazepines and related drugs; cannabis extract	Certain steroids and hormones liable to misuse	Low strength opiates
Examples:	Morphine and other strong opiates; methylphenidate and other major stimulants; ketamine; cannabis-based products	Most barbiturates; buprenorphine, temazepam, midazolam, tramadol, gabapentin & pregabalin	Diazepam, oxazepam, chlordiazepoxide, and most other benzodiazepines; z-drugs; Sativex®	Anabolic steroids, growth hormone	Oramorph®
Storage in CD cupboard:	Yes	Yes, except phenobarbitone, tramadol, gabapentin & pregabalin	No	No	No
Prescription writing requirements: (See section 11)	Yes	Yes,	No	No	No
CD Requisitions needed:	Yes	Yes	No	No	No
Record in CD register:	Yes	No but required in EPUT for buprenorphine and midazolam	No	No	No but required in EPUT for Oramorph®
Pharmacist MUST ascertain the ID of the person collecting CD:	Yes	Yes	No	No	No
Emergency supplies allowed:	No	No, except phenobarbitone for epilepsy	Yes	Yes	Yes
Validity of prescription:	28 days	28 days	28 days	28 days	6 months (if POM)
Maximum duration that should be prescribed:	30 days	30 days	30 days	30 days as good practice	30 days as good practice

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.

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Annex 2

List of Common Controlled Drugs in Schedules 2 and 3

(The products most frequently used within the Trust are marked with an asterisk*)

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** and **midazolam** must be stored in a CD cupboard. However, **gabapentin**, **phenobarbitone**, **pregabalin** and **tramadol** do 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** and **midazolam** 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.

Drug	Brand Name(s) (generic version available for many)	Schedule
Alfentanil	Rapifen [®]	2
Amobarbital	Amytal [®] (named patient only) Tuinal [®] (with secobarbital – named patient only)	3
Buprenorphine*	BuTrans [®] , Subutex [®] , Temgesic [®] , Transtec [®] , Suboxone [®] (with naloxone)	3
Butobarbital	Soneryl [®] (named patient only)	3
Cannabis-based products for medicinal use		2
Cocaine		2
Codeine injection/powder		2
Dexamfetamine		2
Diamorphine		2
Dihydrocodeine injection		2
Dipipanone	Diconal [®] (with cyclizine)	2
Fentanyl	Abstral [®] , Effentora [®] , Actiq [®] , Instanyl [®] , PecFent [®] , Durogesic DTrans [®] , Sublimaze [®] , Tilofyl [®]	2
Gabapentin	Neurontin [®]	3
Hydromorphone	Palladone [®] , Palladone SR [®]	2
Ketamine	Ketalar [®]	2
Lisdexamfetamine	Elvanse [®] , Elvanse Adult [®]	2
Methadone*	Methadose [®] , Physeptone [®] , Synastone [®] , Metharose [®]	2
Meprobamate		3
Methylphenidate*	Ritalin [®] , Concerta XL [®] , Equasym XL [®] , Medikinet XL [®]	2

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Drug	Brand Name(s) (generic version available for many)	Schedule
Midazolam	Hypnoval [®]	3
Morphine	Filnarine [®] , Oramorph [®] , MST Continus [®] , Sevredol [®] , Morphgesic SR [®] , Zomorph [®] , MXL [®] , Morcap [®] , Cyclimorph [®] (with cyclizine)	2
Oxycodone	OxyNorm [®] , OxyContin [®] , Targinact [®] (with naloxone)	2
Papaveretum	Omnopon [®]	2
Pentazocine	Fortral [®]	3
Pethadine	Pamergan P100 [®] (with promethazine)	2
Phenobartibal		3
Pregabalin	Lyrica [®] , Alzain [®] , Axalid [®] , Lecaent [®]	3
Remifentanil	Ultiva [®]	2
Secobarbital	Seconal [®] (named patient only) Tuinal [®] (with amobarbital – named patient only)	2
Sodium Amytal		3
Tapentadol	Palexia [®]	2
Tramadol	Zydol [®] Tramacet [®] (with paracetamol)	3
Temazepam*		3

List of Controlled Drugs in Schedule 4 part 1
(brand names in brackets)

Alprazolam (Xanax [®]) Cannabis extract (Sativex [®]) Chlordiazepoxide (Librium [®]) Clonazepam (Rivotril [®])	Diazepam (Valium [®]) Flurazepam (Dalmane [®]) Loprazolam Lorazepam (Ativan [®])	Lormetazepam Nitrazepam (Mogadon [®]) Oxazepam Zaleplon (Sonata [®]) Zolpidem (Stilnoct [®]) Zopiclone (Zimovane [®])
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Further information can be found at:

<https://www.gov.uk/government/publications/controlled-drugs-list--2/list-of-most-commonly-encountered-drugs-currently-controlled-under-the-misuse-of-drugs-legislation>



Essex Partnership University
NHS Foundation Trust

RECORD OF THE DENATURING AND DISPOSAL OF CONTROLLED DRUGS
and / or REPORTING OF CONTROLLED DRUG DISCREPANCIES

Ward / Unit:				Tel.:	
Registered Nurse in Charge:				Date:	
Name: Authorised person for denaturing and disposal of Controlled Drugs:			Signature:		
Name: Nurse witnessing denaturing and disposal:			Signature:		
Drugs to be denatured:					
Name of drug	Form and strength	Quantity denatured	Balance remaining	Stock or patient's own drugs (if POD, state name of patient)	Reason for disposal
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 dispose of their unwanted CDs (show ID).
2. The nurse will need to be present as the witness throughout the booking-out and disposal 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

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- 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 Register for the two supplies. (The 'patient's own' medication should have been recorded on a page at the back of the CD Record Book, and the container will carry a community pharmacy label with the patient's name and dosage instructions).

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:

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NAME, FORM OF PREPARATION AND STRENGTH <u>Morphine sulphate tablets MR 10mg (MST Continus 10)</u>										13
AMOUNT(S) OBTAINED			AMOUNT(S) ADMINISTERED							
Amount	Date Received	Serial No of Requisition	Date	Time	Patient's Name	Amount given	Given by	Witnessed by	STOCK BALANCE	
			01/01/11	19:15	Balance transferred from page 12				15 ✓ initial	
			12/07/11	10:45	Seventeen (17) tablets destroyed (out of date stock)		Signature & name	Signature & name	NIL ✓ initial	

NAME, FORM OF PREPARATION AND STRENGTH <u>Methadone Liquid 1mg/ml (Physeptone) – James SMITH</u>										98
AMOUNT(S) OBTAINED			AMOUNT(S) ADMINISTERED							
Amount	Date Received	Serial No of Requisition	Date	Time	Patient's Name	Amount given	Given by	Witnessed by	STOCK BALANCE	
			19/08/10	12:30	Twenty ml (20ml) destroyed (patient's own, no longer required – consent obtained)		Signature & name	Signature & name	NIL ✓ initial	

If the ward has more than one CD requiring disposal, repeat the above preparation and booking-out processes for each drug in turn before proceeding to the denaturing stage.

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.

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- 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, the Lead Clinical Pharmacist for Bedfordshire and Luton should be contacted 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 emailed 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.