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Author/Contact: (Asset Administrator)	Alison Felton, Head of Pharmacy		
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Approval Group / Committee(s):	MEHT Medicines Optimisation and Safety Group (MO&MSG) (virtual)	**Date:**	10th June 2019
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Consulted With:	Post/ Approval Committee/ Group:	Date:
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Related Trust Policies (to be read in conjunction with)	Management of Medicines and Guidelines for the Management of Medication errors, 09100 Incident Policy, 06021 Reporting Medication Errors & Near Misses 09060 Injectable Medicines Policy 09014 Intrathecal Chemotherapy 18030 Risk Management Strategy 07049 Non-medical Prescribing Policy 10004 Sharps Policy 08092 Mandatory Training Policy 13024 Illicit or Unknown Substances belonging to Patients

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1.1	Saiqa Mughal		August 2009
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3.0	Lesley Stuart	Appendix 4 added	December 2013
3.1	Lesley Stuart	Appendix 4 amended	May 2014
3.2	Lesley Stuart	Table 1 amended	June 2014
3.3	Jane Giles	Section 24.2 Clarification of role of non UK registered nurses Section 29.1 updated policy information Section 33.6 Minor formatting issues addressed	February 2016
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5.0	Alison Felton	Full Review	13th June 2019
5.1	Alison Felton	Updated section 11.1 & 11.2 Added 11.5,11.6,11.7	14th October 2019
5.2	Alison Felton	Clarification to points 17.1, 24.1 & 24.2	12th November 2019
5.3	Alison Felton	Addition of points to sections 18 and 27	17th January 2020
5.4	Richard Ketley	Amendment to implement Medicines Management Briefings during COVID19 Pandemic	30 April 2020
5.5	Richard Ketley	Amendment: Medicines Management Briefings during COVID19 Pandemic revoked	3 June 2020

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1. Purpose

1.1 Ensure the Trust complies with the legal requirements of the Misuse of Drugs Regulations (1971), all other relevant Controlled Drugs Legislation and NHS Guidance including Patient Safety Alerts (PSA).

1.2 Provide clear, standards and procedures for staff carrying out their duties involving Controlled Drugs.

1.3 CDs are subject to special legislative controls because there is a potential for them to be abused or diverted, causing possible harm. These procedures seek to set out robust systems for managing the risk posed by CDs whilst at the same time helping to ensure appropriate and convenient access for patients that require them.

2. Aims

2.1 To ensure that the Trust complies with relevant legislation governing the storage, supply and use of controlled drugs.

2.2 To ensure that all Trust staff is aware of the procedures regarding controlled drugs.

3. Scope

3.1 This policy applies to all healthcare staff employed by the Trust on a substantive or temporary basis who is involved in the prescribing, supply and storage, preparation, administration and monitoring of controlled drugs. This includes locum doctors, nurses and pharmacists/technicians.

3.2 These procedures apply to drugs listed on schedules 2 and 3 of the Misuse of Drugs Regulation 2001. These drugs are marked with the symbol **CD** in the British National Formulary (BNF) and will be endorsed “CD” by pharmacy. A current list of the drugs contained in Schedules 2, 3, 4 and 5 is provided in section 7.

4. Training

4.1 Staff should act within their professional codes of practice. It is the expectation that substantive Trust nurses will have undertaken the mandatory Medicines Management training.

4.2 Authorised pharmacy staff are those registered with the GPhC and are deemed competent to undertake the destruction of CDs following local training

5. Equality Impact Assessment

5.1 Mid Essex Hospital Services NHS Trust is committed to the provision of a service that is fair, accessible and meets the need of all individuals.
(Refer to Appendix 6)

6. Introduction and General Principles

6.1 The management of CDs is governed by the Misuse of Drugs Act (1971) and it's associated Regulations (in England, Wales and Scotland). Additional statutory measures for the management of CDs are laid down in the Health Act (2006) and it's associated Regulations.

6.2 The Government has introduced new monitoring and inspection arrangements for CDs in the Health Act 2006. Updated regulations relating to wards and departments were detailed in the document "Safer Management of CDs: a guide to good practice in secondary care (England)" [DofH Jan 2007-archived], Misuse of drugs regulations 2001, Controlled drugs (supervision of management and use 2013).

6.4 The convention adopted in this section of the policy is consistent with the "Safer Management of CDs" document above: the term **"must"** relates to statements governed by legal requirements; whereas **"should"** relates to best practice guidance, some agreed nationally and others agreed locally. However, Trust employees working to these procedures are expected to comply with all statements whether legally binding or not. Any employee who thinks they cannot comply with a specific aspect should bring the matter to the attention of their manager.

6.5 The Accountable Officer for the Trust is ultimately responsible for all aspects of the safe and effective use of CDs within the Trust. Any staff concerns about individuals or processes in the handling of CDs should be reported to the Accountable Officer. Their contact details are:

The Accountable Officer (AO) for Controlled Drugs

Mrs Alison Felton
Head of Department/Deputy Chief Pharmacist
Mid Essex Hospital Services NHS Trust, Pharmacy Department, Broomfield Hospital, Chelmsford, Essex, CM1 7ET.
Tel: 01245 513528 (Direct Line)
Pager: 07623954416

7. Controlled Drug List

7.1 There follows a list of the most commonly encountered controlled drugs in practice (from schedules 2, 3, 4 and 5 of the regulations). This list is not exhaustive or definitive, and some of the products listed are non-formulary (marked *), so are not recommended for prescribing locally. The brand names of the drugs are also mentioned where appropriate. All controlled drugs in schedules 2 and 3 are marked **CD** in the current BNF. If you are in doubt whether a product is a Controlled Drug or not; if it is in its original manufacturer's pack it should state "CD POM" on the packaging.

7.2 Prescriptions issued to patients for drugs from **schedules 2, 3, 4** are **only valid for 28 days** from the date of prescribing and there is a strong recommendation from the Department of Health that prescriptions should be for a maximum of 30 days (longer supplies must be justified in the clinical notes).

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

7.4 **Schedule 2 (CD POM)** – Includes – Opioids, major stimulants

- Alfentanil Injection;
- Cocaine (e.g. solution 10%);
- Codeine Injection 60mg in 1ml;
- Dexamphetamine tablets;
- Diamorphine Injection;
- Diamorphine 0.05% and Bupivacaine 0.15% Epidural;
- Fentanyl;
- Fentanyl 2mcg/ml and Bupivacaine 0.1% Epidural;
- Methadone (liquid 1mg in 1ml);
- Methylphenidate (Concerta XL®);
- Morphine *(except oral solution 10mg / 5ml)* (e.g. Oramorph conc®, *MST®, Zomorph®);
- Oxycodone (Oxynorm®, Oxycontin®, Longtec®);
- Pethidine;
- Dexamphetamine tablets 5mg;
- Ketamine;
- Tapentadol (Palexia).

The AO or Chief Pharmacist may request that certain agents be treated as Schedule 2 CDs even though they may not appear in the regulations as such, for clinical or governance reasons.

7.5 **Schedule 3** – Includes minor stimulants

- Buprenorphine (Temgesic®, Subutex®, BuTrans®, Transtec®);
- Midazolam (Injection, Syrup, Buccal Liquid);
- Temazepam;
- Phenobarbitone;
- Tramadol;
- Pregabalin;
- Gabapentin;

7.6 **Schedule 4 Part I -** Includes benzodiazepines

- Chlordiazepoxide;
- Clobazam;
- Clonazepam;
- Diazepam;
- Lorazepam;
- Nitrazepam
- Oxazepam*;
- Zolpidem*.

7.7 **Schedule 4 Part 2** - Includes anabolic steroids, clenbuterol, growth hormones Anabolic steroids e.g. Nandrolone, Somatropin

7.8 **Schedule 5**

- Codeine Phosphate;
- Dihydrocodeine Tartrate;
- Co-codamol;
- Co-dydramol;
- Morphine sulphate oral solution 10mg / 5ml (Oramorph®).

8. Controlled Drug Requirements

8.1 Table 1 outlines the requirements that the Trust follows for the storage, ordering, prescribing and destruction of the different classes of CDs.

8.2 **The AO and Head of Department has requested that ALL Schedule 2, 3 CDs are treated in the same way for clinical and governance reasons, see Table 1.**

8.3 Special Prescription Requirements detailed further in 11.3.

Table 1

	Schedule 2	**Schedule 3**	**Schedule 4, pt I** Includes benzo-diazepines	**Schedule 4, pt II Includes**	**Schedule 5** Includes low strength opioids
Prescribed as a CD on Discharge letter (TTA)	Yes, 28 day validity	Yes, 28 day validity. Includes Phenobarbitone, Midazolam and Temazepam	28 day validity	28 day validity	n/a
Safe Custody Requirements (Does it need to be stored in a CD cupboard?)	Yes (In inner CD cupboard)	Yes. (Can be kept in outer CD cupboard if no room in inner CD cupboard) except for the following:- Temazepam, buprenorphine safe custody is required in inner CD cupboard. Pregabalin and Gabapentin are exempt from safe custody requirements and can be stored in locked drug trolleys, drug cupboard and bedside lockers	n/a	n/a	n/a
Records	CD Register	CD Register except Pregabalin and Gabapentin where no records in CD register are required	n/a	n/a	n/a
Requisition	CEDAR or CD book	CEDAR or CD book	n/a	n/a	n/a
Destruction	Must be appropriately authorised and the person witnessing the destruction must be authorised to do so. Schedule 2 controlled drugs must be denatured before being placed into waste containers.	Must be appropriately authorised and the person witnessing the destruction must be authorised to do so. Schedule 3 controlled drugs must be denatured before being placed into waste containers.	No specific requirements.	No specific requirements.	No specific requirements.

9. Management of Stock Controlled Drugs

9.1 Ordering of Stock Controlled Drugs for onsite wards and departments

9.1.1 The ordering of CDs on a ward or department is the responsibility of the Nurse in Charge/Midwife in charge/ODP in charge or Assigned Nurse/Midwife/ODP in Charge. Even if the ward or department is managed by someone other than a nurse, the most senior Registered Nurse/Midwife/ODP present assumes this responsibility. This duty may be delegated to another Registered Nurse/Midwife/ODP, referred to below as a "Designated Nurse". However, the Nurse in Charge retains accountability for ensuring the agreed procedures are followed.

9.1.2 All persons ordering CDs or counter signing requisitions must have previously provided a specimen signature to the Pharmacy as proof of authenticity. These persons will then become "authorised signatories", a list of which will be maintained by pharmacy and any changes notified to Pharmacy immediately.

For wards that use Cedar, the ward sister will authorise their nurses by emailing support@meht.nhs.uk with a completed clinical systems training and access request form once training has been received from the ward pharmacist or technician. Cedar access will then be arranged through IT and a login will be supplied.

9.1.3 For wards not using Cedar, the Nurse/Midwife/ODP in Charge of the ward / department will be asked at the time of the 3 monthly stock check to verify that the list of authorised signatories held by Pharmacy is current and correct.

9.1.4 Stock CDs are ordered using the CD Ward Order Book for wards that are not using the electronic ordering system called CEDAR. Wards that are using the CEDAR system should only order stock CDs using the CEDAR system.

9.1.5 Weekends/Bank Holidays - only urgent orders will be supplied. Controlled Drugs should only be ordered if it is absolutely necessary. Orders must be marked as urgent if required at the weekend or bank holidays otherwise they will not be supplied.

9.1.6 Temporary staff are not permitted to order CDs.

9.2 Ordering CDs using the Ward CD Order Book

9.2.1 Pharmacy holds the CD order books. The book number, date, ward and member of staff issuing the new book must be logged in the CD requisition record book in pharmacy.

9.2.2 The order for CDs should be written in indelible ink in the Ward CD Order Book by an authorised signatory. Each order should be written on a separate page. Orders must contain the following details:

- Name of Hospital;
- Ward or Department;
- Drug name, form, strength, ampoule size (if more than one size available);
- Total quantity;
- Signature and printed name of Registered Nurse/Midwife/ODP or authorised pharmacy staff;
- Temporary staff are not permitted to order CDs.

9.2.3 CDs should only be issued if the requesting member of staff has a signature example in pharmacy. This should be checked by the dispenser in pharmacy. If the signature is not on the list, the ward should be contacted for the member of staff to sign the list or another member of staff who has provided a signature can order the CD.

9.2.4 The book containing the order must be sent to Pharmacy by 1pm on Monday to Friday to ensure that the CDs can be delivered with the porters CDs run at 2pm. Orders received after 1pm will need to be collected in person by a registered nurse from pharmacy. CDs will never be sent via the chute system.

9.2.5 Only one CD order book per ward or department should be in use at any one time.

9.3 **Ordering CDs using the CEDAR system**

9.3.1 The order for CDs should be entered onto the CEDAR system by a registered nurse using their personal login credentials. Temporary nurses cannot order CDs.

9.3.2 Ordering stock CDs via CEDAR:

1. Log on to CEDAR using your windows password.
2. Select the ‘ORDER’ tab.
3. Select your ward location.
4. Select the controlled drug to be ordered.
5. Select the quantity you want to order (this is in whole boxes).
6. Click on the ‘ADD TO ORDER’ button.
7. If more drugs are needed repeat from step 4.
8. When order is complete select the ‘place order’ button.

9.3.3 Orders should be submitted by 1pm on Monday to Friday to ensure that the order can be delivered with the porters CDs run at 2pm. Orders received after 1pm if required the same day will need to be marked as urgent and will need to be collected in person by a registered Trust nurse from pharmacy.

9.3.4 Weekends/Bank Holidays - only urgent orders will be supplied. Controlled Drugs should only be ordered if it is absolutely necessary. Orders must be marked as urgent if required at the weekend or on bank holidays otherwise they will not be supplied.

9.4 Ordering of Stock Controlled Drugs for offsite wards and departments

9.4.1 The order for CDs should be written in indelible ink in the Ward CD Order Book by an authorised signatory. Each order should be written on a separate page. Orders must contain the following details:

- Name of Hospital;
- Ward or Department;
- Drug name, form, strength, ampoule size (if more than one size available);
- Total quantity;
- Signature and printed name of Registered Nurse/Midwife/ODP or authorised pharmacy staff;
- Agency staff are not permitted to order CDs.

9.4.2 A Home Office form must also be completed for non MEHT wards. CD Order books and this form should be sent in a locked black box with the hospital transport.

9.4.3 The original CD Order book is always required before the CD can be sent to the ward.

9.5 Receipt of Stock Controlled Drugs

9.5.1 When CDs are delivered to a ward or department they should be identified as such by the person making the delivery. Stock orders placed on CEDAR before 1pm will be delivered in a locked trolley via a porter who will sign a porter's book. On receipt, the nurse/ midwife/ODP who accepts delivery of stock CDs must also sign the porter's book. At weekends or after hours, nurses will be asked to collect urgent stock CD's from the in-patient pharmacy and will sign the porter's book. If the order is placed using a CD order book the nurse collecting will sign the collection part of the CD order form.

9.5.2 As a matter of good practice this Nurse/Midwife/ODP should not be the same as the Nurse/Midwife/ODP who ordered the CDs.

9.5.3 On no account should CDs be left unattended.

9.5.4 Immediately after delivery the Nurse/Midwife/ODP in Charge or Designated Nurse/Midwife/ODP, witnessed by an authorised witness, must take the following steps:

9.5.5 For wards ordering CDs using the Ward CD Order Book:

- Check the drug name, preparation and quantity against the order and sign and date the 'receipt' portion of the order book.

9.5.6 For Wards ordering CDs using the CEDAR system;

- Check the drug name, preparation and quantity against the order. Each order will have an order number generated which will be printed on a label that is with the drugs;
- Log on to CEDAR using your windows password;
- Select the ' RECEIVE' tab;

- Fill in the order number from the label on the item, in the field supplied and click 'search';
- Your order will be displayed, check it against the item received;
- Click the 'RECEIVE' button;
- Your order is received, log out of CEDAR;
- Enter the stock CDs into your ward CD register and check the balance. The balance check must be performed by a Registered Nurse. Midwife or ODP who initially received the CD and witnessed by another Registered Nurse/midwife/ ODP, a non UK nurse awaiting PIN, a pharmacist, pharmacy technician doctor, dentist or other witness authorised by the Nurse/Midwife in Charge or Senior ODP, and recorded in the CDRB.

9.5.7 For wards using the CEDAR system or the Ward CD Order Book system, continue with the following steps:

- Lock the CDs in the ward CD cupboard;
- Any tamper-evident seals on packs should be left intact when they are received as this will speed up routine checks. A seal should only be broken when the pack is required to be administered;
- Enter the received stock into the Controlled Drug Record Book (CDRB), update the running balance and check that the balance tallies with the quantity that is physically present which should be countersigned. The balance check must be performed by a Registered Nurse. Midwife or ODP who initially received the CD and witnessed by another Registered Nurse/midwife, ODP , a non UK nurse awaiting PIN, a pharmacist, pharmacy technician doctor, dentist or other witness authorised by the Nurse/Midwife in Charge or Senior ODP.

9.5.8 In the case of any discrepancies, follow the procedures outlined in section 20.

9.5.9 When opening a tamper-evident seal on a pack, if the quantity inside the box is not correct, inform Pharmacy immediately and complete a DATIX form.

9.6 Out of hours supplies

9.6.1 If a CD is required out of hours and there is no stock on the ward / department, the following steps should be taken:

9.6.2 If the patient has been admitted when the Pharmacy is closed and with their own CDs, these may be administered for a short period until pharmacy is next open and ordered and supplied. Before administration the nurses/midwives must check that the medicine is fit for purpose, is in date and is identifiable as the medication that is stated on the packaging. If in any doubt, do not administer and contact on-call pharmacist for further advice.

9.6.3 If this is not the case, neighbouring wards should be checked to see if they have any stock that can be spared. If so an appropriate quantity of the required CD (sufficient to treat the patient until the Pharmacy re-opens) may be transferred by following the procedure below:

- The Nurse/Midwife in Charge or Designated Nurse/Midwife should take the patient's medicine chart and the ward CD Register to the nearest ward holding a stock of the CD.

- The Nurse/midwife in Charge or Designated Nurse/midwife from each ward should check the CD against the medicine chart, and an entry should be made in the CD Registers of both wards to reflect the transfer. Both entries should be signed by both Nurses/midwives.
- The Nurse/midwife in Charge or Designated Nurse/midwife of the borrowing ward should return promptly to secure the CDs borrowed in the CD cupboard and administer the medicine as per the prescription.

9.6.4 If no stock is available on neighbouring wards when the Pharmacy is closed, the on-call Pharmacist should be contacted via the site co-ordinator.

9.6.5 Verbal or telephoned orders for CDs are not permissible.

10. Discharge Controlled Drugs

10.1 Ordering Discharge Controlled Drugs for onsite wards (TTAs)

10.1.1 The TTA letter should be completed by the Doctor prior to the discharge of the patient. Prescriptions must comply with all legal requirements as per 11.3.

10.1.2 The **original signed** copy of the prescription and the current drug chart(s) must be sent to the Pharmacy to be dispensed (faxes or photocopies are not acceptable).

10.1.3 The “ordered by” section of the CD order book will be filled in by authorised pharmacy staff in indelible ink, with a separate page used for each CD required and the name of the patient and “TTA” written on each request. Another member of authorised pharmacy staff will sign “supplied by” section when the CD is dispensed.

10.1.4 Orders must contain the following details:

- Name of Hospital;
- Ward or Department;
- Drug name, form, strength, ampoule size (if more than one size available);
- Total quantity;
- Name of the patient, hospital number/NHS number and the words “TTA”;
- Signature and printed name of the authorised pharmacy staff;
- Agency staff are not permitted to order CDs.

10.2 Ordering Discharge Controlled Drugs for offsite wards (TTAs)

10.2.1 The TTA letter should be completed by the Doctor prior to the discharge of the patient. Prescriptions must comply with all legal requirements as per 11.3.

10.2.2 The prescription and current drug chart(s) must be faxed to the Pharmacy to be dispensed along with a copy of requisitions from the CD order book.

10.2.3 The order for CDs should be written in indelible ink in the Ward CD Order Book by an authorised signatory. Each CD required should be written on a separate page. Orders must contain the following details:

- Name of Hospital;
- Ward or Department;
- Drug name, form, strength, ampoule size (if more than one size available);
- Total quantity;
- Name of the patient, hospital/NHS number and the words “TTA”;
- Signature and printed name of the doctor prescribing the CD.

10.2.4 The original prescription and CD order book should be sent to pharmacy on the next available transport.

10.2.5 The medication will be sent on the next available transport as soon as possible after the original prescription and CD order book have been received in pharmacy.

10.3 **Receipt of Discharge Controlled Drugs**

10.3.1 Only registered Trust nurses/midwives may collect a CD TTA from pharmacy.

10.3.2 On collection from pharmacy, the registered nurse/midwife must show their Trust ID to the member of the pharmacy team handing out the medication. The registered nurse/midwife must then ensure that the drug, preparation, strength, and quantity exactly match the prescription and the entry in the CD order book. The nurse/midwife must then sign the ‘’received’’ line in the CD order book. In the case of any discrepancies, follow the procedures outlined in section 20.

10.3.3 On receipt of TTAs containing a CD onto the ward, the CD should be checked against the discharge prescription.

10.3.4 The CD must be entered into the Patients Own Drugs (PODs) CDRB. All TTA CDs must be recorded, even if the patient is to be discharged straight away.

10.3.5 After receiving the CDs on the ward, the following details of the TTA CD prescription must be recorded in the PODs CDRB:

- Date;
- Patient’s name and NHS number;
- Drug name, preparation and strength;
- Amount received;
- Signature of both Nurses/midwives;
- Re-seal the bag containing the TTA CD and place in the CD cupboard, clearly segregated from the stock in the cupboard.

10.3.4 For Farleigh Hospice CD TTA’s the original signed copy must be received before the TTA can be released. The CD’s must be sent back to Farleigh in a locked black box with a pharmacy transport sheet. The transport sheet must be signed by Trust transport staff or Farleigh Hospice staff who are accepting the delivery. The ID of Farleigh Hospice staff must be checked prior to handing over.

10.4 **When the patient is ready for discharge:**

10.4.1 A Registered Nurse/midwife and an authorised witness should check the CDs out of the cupboard, confirming that they conform to the prescription.

10.4.2 If an entry has been made in the PODs CDRB upon receipt of the TTA then an entry should be made at the back of the CDRB upon discharge to confirm:

- Date of discharge;
- Drug name, preparation, strength and quantity;
- Signature of both Nurses/midwives;
- Whether the CDs are given to the patient, a representative or a health care professional acting on behalf of the patient;
- If given to a representative, evidence of identity should be recorded, or a reason why evidence was either not requested or provided;
- If given to a health care professional, that person's name, position and employing organisation;
- The signature of the person receiving the CD.

11. Prescribing of Controlled Drugs

11.1 **Prescribing Responsibility**

11.1.1 Responsibility for prescribing rests with Registered Medical Practitioners and Non Medical prescribers. It is essential that prescribers are aware of the legal requirements when writing prescriptions for controlled drugs. Prescribing advice within the online version of the BNF should also be followed.
Issuing an incomplete prescription for a controlled drug is an offence, and it is illegal for a pharmacist to make a supply from an inaccurately written or incomplete script. Prescriptions for controlled drugs must be signed and dated by the prescriber in ink.

11.1.2 When making decisions about prescribing controlled drugs all prescribers must take into account:

- the benefits of controlled drug treatment
- the risks of prescribing, including dependency, overdose and diversion
- all prescribed and non-prescribed medicines the person is taking (particularly any centrally acting agents) and whether the person may be opioid naive
- Evidence-based sources, such as NICE and the British National Formulary (BNF), for prescribing decisions when possible.

11.1.3 Prescribers must ensure they consult standard reference text information relating to doses and formulations;

- British National Formulary (Individual product monographs and 'Prescribing in palliative care' section)
- British National Formulary for Children
- Palliative Care Formulary or www.palliativedrugs.com.
- Local policies and guidance on Intranet
- Summary of Product Characteristics (SPC) of individual products

Up-to-date information and guidance on nurse and pharmacist independent prescribing is available on the Department of Health website at www.dh.gov.uk/health/2012/04/prescribing-change

11.1.4 Provisionally registered medical staff i.e. House Officers/FY1 may only prescribe for in-patients, including their discharge but not for out-patients.

11.1.5 Pharmacist independent prescribers are able to prescribe any controlled drug listed in schedules 2-5 for any medical condition within their competence, except diamorphine, cocaine and dipipanone for the treatment of addiction (pharmacist independent prescribers are able to prescribe other controlled drugs for the treatment of addiction). Pharmacist independent prescribers are able to requisition controlled drugs and are authorised to supply or administer the drugs they are able to prescribe. The existing authorities for pharmacists to possess supply and offer to supply schedule 2-5 controlled drugs remain. Persons acting in accordance with the directions of a pharmacist independent prescriber are authorised to administer any schedule 2-5 drugs that the pharmacist can prescribe.

11.1.6 Nurse independent prescribers can prescribe any controlled drug listed in schedules 2-5 for any medical condition within their competence, except diamorphine, cocaine and dipipanone for the treatment of addiction (nurse independent prescribers are able to prescribe other controlled drugs for the treatment of addiction). Nurse independent prescribers are able to requisition controlled drugs and are authorised to possess, supply, offer to supply and administer the drugs they are able to prescribe. Persons acting in accordance with the directions of a nurse independent prescriber are authorised to administer any schedule 2-5 drugs that the nurse can prescribe.

11.1.7 Up-to-date information and guidance on nurse and pharmacist independent prescribing is available on the Department of Health website at www.dh.gov.uk/health/2012/04/prescribing-change

11.1.8 It is the responsibility for every clinician to keep up to date with any changes to the CD regulations.

11.2 **Prescribing of Controlled Drugs for Inpatients**

11.2.1 The prescribing of CDs on a ward or department is solely the responsibility of the prescriber.

11.2.2 Nurse Independent Prescribers are legally allowed to prescribe any CD listed in Schedule 2-5 for any medical condition within their competence, except diamorphine, cocaine and dipipanone for the treatment of addiction. Please refer to the non-medical prescribing policy for further guidance

11.2.3 CDs should be prescribed on the standard inpatient medicines chart. There are not additional recording requirements.

11.2.4 When prescribing there should be a check of the person's current clinical needs and, if appropriate, adjustment of dosing until a good balance is achieved between benefits and harms

11.2.5 Prescribers are expected to discuss with the patient the arrangements for reviewing and monitoring treatment and be prepared to discuss the prescribing decision with other health professionals if further information is requested about the prescription.

11.3 Prescribing Controlled Drugs for Discharge Prescriptions

11.3.1 A discharge letter must be written on Lorenzo or a discharge prescription which contains the controlled drug that is required for discharge. It must contain the following details:

- The date;
- The name and form of the drug, even if only one form exists (Please ensure the preparation selected is one the Trust stocks);
- The strength of the preparation where appropriate;
- The dose to be taken (in the case of as directed or as required prescriptions, this should be stated as a number of dose units e.g. 'one as directed', not 'as directed');
- The number of dose units, to be supplied in both words and figures
- Doses that require the use of two or more strengths of a preparation must have each written out in full.
  e.g. Patient requires Zomorph capsules 40mg twice daily for one week should state:
  Zomorph MR capsules 30mg, take one capsule every 12 hours, supply 14 (fourteen) capsules ;
  Zomorph MR capsules 10mg, take one capsule every 12 hours, supply 14 (fourteen) capsules.

11.3.2 The TTA letter must be printed and signed by the prescriber with his/her usual signature, in his/her own handwriting in indelible ink. This is the only part of the prescription that must be handwritten. It is good practise to write the bleep number of the prescriber so that any problems can be quickly dealt with. If written on Lorenzo, and clinically validated by a pharmacist on the ward, the drug chart does not need to be sent to pharmacy with the TTA for dispensing.

11.3.3 **Validity**

All prescriptions for CDs are valid for 28 days from the date of the prescription. After this time they cannot be dispensed so would have to be re-written.

11.3.4 **Maximum length of supply**

Usually 14 days will be dispensed. Up to a maximum of 30 days (28 days on a TTA) supply should be prescribed as a matter of good practice. If the prescriber believes there is a genuine need for a longer supply that would not pose an unacceptable threat to patient safety, this can be given provided the reason is recorded in the patient's notes.

11.4 **Prescribing for Outpatients**

11.4.1 Provisionally registered medical staff i.e. FY1 doctors may only prescribe for in-patients, including their discharge but not for out-patients.

11.4.2 Prescribers should ensure that they comply with the legal requirements for controlled drugs prescribing as mentioned in 11.3.

11.4.3 Usually 14 days' worth of supply should be prescribed. Up to a maximum of 28 days' supply should be prescribed as a matter of good practice.

11.4.4 The bleep number/contact number of the prescriber should be written on the prescription.

11.5 **Conversion of Opioids**

11.5.1 Prescribers must ensure where a change in formulation, route or medicine is required, references are consulted for dose conversion to aid calculation of a safe dose.

11.6 **Documentation of Controlled Drug Prescribing**

11.6.1 The prescribing plan should be documented in the patient record and any communications to the patient or GP (i.e. TTA, outpatient prescription, clinic letter etc.). Information must be given to the person taking the controlled drug or the carer administering it. This includes:

- How long the person is expected to use the drug;
- How long it will take to work;
- What it has been prescribed for;
- How to use controlled drugs when sustained-release and immediate-release formulations are prescribed together;
- How it may affect the person's ability to drive (see the advice from the Department of Transport on drug driving and medicine: advice for healthcare professionals);
- That it is to be used only by the person it is prescribed for.

11.7 Intravenous Opiate Therapy

11.7.1 Intravenous opiate therapy requires careful prescribing and administration with on-going monitoring. Opiates for administration by the intravenous route must not be prescribed in clinical areas where there is not the appropriate monitoring available. Generally this is most inpatient wards, except where there is higher level of care beds with appropriately competent and trained staff.

11.8 Pharmacist Amendments to Prescriptions

11.8.1 The only errors that pharmacists can amend are:

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

11.8.2 A pharmacist may make certain amendments to Schedule 2 and 3 CD prescriptions provided that:

- Having exercised all due diligence, the pharmacist is satisfied on reasonable grounds that the prescription is genuine;
- Having exercised all due diligence, the pharmacist is satisfied on reasonable grounds that they are supplying the CD in accordance with the intention of the prescriber.

11.8.3 The pharmacist amends the prescriptions in ink or otherwise indelibly (i.e. electronically) to correct the minor typographical errors or spelling mistakes or so that the prescription complies with the Misuse of Drugs Act 1971, CDs prescription requirements. The pharmacist marks the prescription so that the amendment they have made is attributable to them (amended electronically or for paper prescriptions, sign name and date amendment).

12. Collection of Controlled Drugs for Outpatient Prescriptions

12.1 For patients or their representatives collecting any schedule 2 or 3 CDs, pharmacy staff should seek suitable identification details (see list below) and record in the CD register, the name of the person collecting and form of ID provided. If proof of identity is not asked for (at pharmacist's discretion) or not seen, this must be recorded in the CD register. Pharmacy staff should also ask the person collecting to sign in the box on the reverse of the prescription.

12.2 Pharmacists must ascertain the role of anyone collecting a Schedule 2 CD supplied against a prescription, be it:

- the patient themselves OR
- patient's representative OR
- a healthcare professional acting within their professional capacity on behalf of the patient.

12.3 In order not to deny patients' access to the drugs that they require, it will not be a criminal offence to supply a Schedule 2 CD without proof of identity, even when the pharmacist does not know that person.

12.4 Types of ID acceptable from patients or their representatives. The following may be considered suitable:

- Professional registration number for a healthcare professional;
- Driving licence (including photo card section);
- Any official photo ID;
- Passport;
- Cheque guarantee, debit or credit card;
- Birth/Marriage certificate;
- Utility bills (two different ones but NOT mobile phone statement);
- Pension or benefit book;
- Council tax payment book;
- Recent bank or building society statement (within last 6 months);
- Bank or building society book;
- Store charge card (not a loyalty card);
- Council rent book;
- National savings book.

13. Storage of Controlled Drugs

13.1 Ward CD cupboards should conform to British Standard reference BS2881. This cupboard must be constructed of metal and securely attached to a wall or floor.

13.2 Cupboards must be kept locked when not in use.

13.3 The lock must not be common to any other lock in the Hospital.

13.4 Access to the CD cupboard must only be available to persons who can lawfully be in possession of CDs i.e. the Nurse/Midwife/ODP in Charge (or Designated Nurse/Midwife/ODP) or another Registered Nurse/midwife/ODP. Authorised Pharmacy Staff are permitted access for the purposes of stock balance checks or return of CDs for destruction.

13.5 The cupboard should be dedicated to the storage of CDs. This may include schedule 3 CDs for which safe custody is not a legal requirement but a requirement of the Trust. No other items must be stored in the controlled drugs cupboard.

13.6 Patients' own or discharge CDs may be kept in the CD cupboard prior to discharge or destruction. These medicines should be segregated from ward stock. No other medicines may be stored in a CD cupboard.

13.7 CDs must always be locked away when not in use.

14. Controlled Drug Cupboard Key Holding

14.1 The Nurse in Charge, Midwife or Senior ODP if appropriate, is responsible for the CD keys. The person in charge is responsible for controlling access to the CD keys and access to CD cupboard on that ward or department for that shift.

14.2 The CD key must be kept separate from the other medicine cabinet keys and held in person and not in a drawer. At the shift changeover, the nurse in charge, midwife or Senior ODP must hand the keys to the Nurse in Charge, midwife or Senior ODP of the next shift, who then assumes responsibility for the custody of CD's on the ward.

14.3 Key-holding may be delegated to a Designated Nurse/midwife/ODP or another Registered Nurse/midwife/ODP who should be a permanent member of staff wherever possible but the legal responsibility rests with the Nurse/midwife/ODP in Charge. The key holder should be readily identifiable at all times.

14.4 The CD key should be returned to the Nurse in Charge, midwife, Senior ODP immediately after use by another authorised member of staff. The assigned key holder will challenge members of staff who request the keys to ensure that they have a legitimate and acceptable reason to access the CD cupboards and valid identification. Under no circumstances are student nurses permitted to be responsible for any drug keys.

14.5 On occasions, for the purpose of stock balance checks or return of CDs for destruction, the CD keys may be handed to an Authorised member of Pharmacy Staff, who must return them immediately after use.

14.6 The keys for the CD cupboards should not be kept with any keys that may be accessed by staff who are not authorised to hold CD keys.

14.7 Security requirements may be increased at the discretion of the Nursing Management after agreement with the Accountable Officer.

14.8 If a ward or department closes overnight it is the responsibility of the nurse in charge to ensure drug keys are stored securely, preferably in a manned clinical area or arrangements made with switchboard for secure storage with an authorised signatory list.

15. Security- Missing CD Keys

15.1 If the CD keys cannot be found then urgent efforts should be made to retrieve keys as speedily as possible by contacting nursing/midwifery, theatre staff who have just gone off duty, or others who may have been given access to the keys e.g. Authorised Pharmacy Staff. The senior Nurse/Midwife/ODP or director of nursing on duty should be informed as soon as possible.

15.2 If CDs are required for patients then arrangements should be made with an adjacent ward where possible.

15.3 The pharmacy technician/pharmacist should be informed as soon as practical, who will consult with other senior staff and / or the Accountable Officer as appropriate.

Depending on the circumstances, the police may be contacted by the Accountable Officer, out of hours Director on call or other senior staff member.

15.4 If the keys are not located within 24 hours the Accountable Officer will be informed by the relevant staff mentioned above. Depending on the circumstances it may be appropriate to contact the police; this decision will be made by the Accountable Officer. If wrong doing is suspected the police should be involved.

15.5 Any occasion where the Police are notified of missing CD Keys, a datix form should be completed and the AO must notify the LSMS.

15.6 Security requirements may be increased at the discretion of the Nursing Management after agreement with the Accountable Officer and LSMS.

16. Record keeping for Controlled Drugs

16.1 Each ward or department that hold stocks of CDs should keep a record of CDs received, administered and removed for destruction in a 'stock' Controlled Drugs Record Book (CDRB). The Nurse in Charge, midwife or Senior ODP is responsible for keeping the CDRB up to date and in good order.

16.2 The CDRB should be bound (not loose-leaf) with sequentially numbered pages. Separate pages should be kept **for each drug and strength,** so that a running balance may be kept easily, and an index of all preparations in stock should be kept at the front of the book. Where similar products exist it is important to distinguish between them e.g. modified release and plain formulations, the brand name should be included in brackets.

16.3 Entries should be made in chronological order, in ink or otherwise indelible.

16.4 All entries should be made and signed by a Registered Nurse/midwife/ODP, and witnessed and signed by a second Registered Nurse/midwife/ODP. If a second nurse/midwife/ODP is not available then another authorised witness may sign as a witness e.g. doctor or pharmacist.

16.5 On reaching the end of a page of the CDRB, the balance should be transferred to another page. The new page number should be added to the bottom of the finished page and the index updated. The transfer should be witnessed as above.

16.6 **No entry in a CDRB may be cancelled, obliterated or altered.** If a mistake is made it should be bracketed in such a way that the original entry is clearly legible. An asterisk should be placed against the bracketed entry and a marginal or footnote made, which should be signed and dated and also witnessed (signed and dated) by another Registered Nurse/midwife/ODP. Pages or part-pages must **never** be torn out of the Ward CD Record Book.

16.7 Ideally only one stock CDRB and one PODs CDRB should be in use at any one time. Although it is acknowledged that areas of high usage of CDs may have more than one stock CDRB in use at any one time. When a new CDRB is started the balance of CDs in stock should be written into the new book promptly by a Registered Nurse/Midwife/ODP. The transfer should be witnessed by a Registered

Nurse/Midwife/ODP or Authorised Pharmacy Staff.

16.8 The CDRB should be kept securely in either the CD cabinet or in a locked room. Loss or theft should be reported immediately to the NPT/pharmacist, who will inform the Accountable Officer if necessary.

17. Records of Administration

17.1 For CD administered to inpatients the following details should be recorded in the CDRB (with the exception of pregabalin and gabapentin that do not need to be recorded in the CD register):

- Date and time when dose administered. Ditto marks or arrows to indicate the same day or time is NOT acceptable;
- Full name of patient e.g. first name and surname;
- Quantity administered;
- Signature of authorised nurse/Midwife/ODP/Clinician who administered the dose
- Signature of witness (registered nurse/midwife/ODP/Doctor/Pharmacist /Pharmacy technician/Non UK registered nurse awaiting PIN,);
- Balance in stock;
  If part of an ampoule / vial is administered to the patient a record should be made of the amount administered and the amount wasted e.g. if the patient is prescribed 2.5mg diamorphine and only a 5mg ampoule is available, the record should show “5mg Supplied (S), 2.5mg Administered (A) and 2.5mg Destroyed (D)”. Such an entry should be witnessed as above.

18. Records of Disposal

(in conjunction with Section 27.1)

18.1 Individual doses of CDs which have been prepared but not administered should be destroyed by a Registered Nurse/midwife/ODP and placed in a yellow lidded sharps bin, stating the reason for destruction in the CDRB with the entry witnessed by a second Registered Nurse/midwife/ODP.

18.2 CDs that are time expired, no longer required or otherwise unfit for use must be returned to Pharmacy. The ward should contact the ward pharmacist/NPT, to arrange for collection of the controlled drugs and if required subsequent destruction will be completed within pharmacy. An entry should be made in the CDRB by the Pharmacy technician /pharmacist and witnessed by a Registered Nurse/midwife/ODP to state:

- Date;
- Name, form and quantity of drug being returned;
- Reason for return if required;
- Names and signatures of the Authorised Pharmacy Staff and Registered Nurse/Midwife/ODP;
- Balance remaining.

18.3 Used PCA or epidural bags must NOT be discarded in ward drains. The ward must

use an approved **Controlled Drug Disposal kit.**

18.4 **Controlled Drug Disposal Kits** must be kept securely in the ward/department clean utility room or drug storage room to ensure that patients do not have access to them.

18.5 Any surplus opioid remaining after an infusion (e.g. PCA or epidural), containing a controlled drug, that has been discontinued should be measured (information taken from infusion pump) and disposed of by adding directly to an approved **Controlled Drug Disposal Kit.** This can then be returned to pharmacy for disposal with the pharmaceutical waste or disposed of as clinical waste on the ward. This disposal must be recorded in the CDRB as detailed in point 18.5.

18.6 A separate entry should be made in the ward Controlled Drug Record book under the heading e.g. “Morphine Sulphate 100mg/100ml as PCA bags waste”. The entry shall record:

- Date and time of disposal;
- Patients name;
- The volume remaining in the bag which is waste;
- The signature of the nurse/midwife/ODP disposing of the solution;
- The signature of the nurse/midwife/ODP witnessing the disposal.

The balance on this page in the Controlled Drug Record book should always be zero.

18.7 Any surplus volume remaining in a syringe driver containing controlled drugs if less than 10mls can be disposed of in a yellow lidded sharps bin. If the volume is more than 10mls this should be disposed of by adding directly to an approved **Controlled Drug Disposal Kit**. This can then be returned to pharmacy for disposal with the pharmaceutical waste. This disposal must be recorded in the CDRB as detailed in point 18.7.

18.8 A separate entry should be made in the ward Controlled Drug Record book under the heading e.g. “Syringe driver waste”. The entry shall record:

- Date and time of disposal;
- Patients name;
- The volume remaining in the syringe which is waste and has been disposed of;
- How it has been disposed;
- The signature of the nurse/midwife/ODP disposing of the solution;
- The signature of the nurse/midwife/ODP witnessing the disposal.

The balance on this page in the Controlled Drug Record book should always be zero.

18.9 The pages for the waste of PCA’s, epidurals and syringe drivers should be at the back of the CDRB.

19. Stock Balance Checks

19.1 A stock balance check must be performed after every receipt of stock or TTA CDs on the ward/department (only on the CDs that have been received). The Check must be performed by a Registered Nurse. Midwife or ODP and witnessed by another Registered Nurse/midwife, ODP, a non UK nurse awaiting PIN, a pharmacist, pharmacy technician doctor, dentist or other witness authorised by the Nurse/Midwife in Charge or Senior ODP, and recorded in the CDRB.(see also section 9.5.6/9.5.7) The check must be performed by a substantive MEHT member of staff. Temporary staff can only act as the witness.

19.2 A stock balance check must be performed after each administration or disposal of a CD (only on the CD's that are being administered or disposed of) to ensure that it matches the quantity physically present. The Check must be performed by a Registered Nurse. Midwife or ODP and witnessed by another Registered Nurse/midwife, ODP, a non UK nurse awaiting PIN, a pharmacist, pharmacy technician doctor, dentist or other witness authorised by the Nurse/Midwife in Charge or Senior ODP, and recorded in the CDRB. See section 24.3 for exceptions to this check being witnessed.

19.3 In addition a complete stock balance check must be performed **twice daily at the commencement of the shift.** These checks may be performed with staff from separate shifts i.e. night shift to early shift. The balance should be recorded in the section at the back of the CD register for stock checks.

19.4 In Theatres, a stock balance check must be carried out before and after each planned/emergency operating session. Additional stock balance checks must also be completed if there is a change in staff in the theatre i.e. day staff handing over to night staff, this check must be completed before the staff member goes off shift.

19.5 For wards and departments not open every day e.g. those open Monday to Friday checks must be completed at the start of the week, once every 24 hours when open and at the end of the week when closing.

19.6 The balance Checks, referred to in point 19.2 (must be performed by a Registered Nurse. Midwife or ODP and witnessed by another Registered Nurse/midwife/ODP, , a non –UK nurse awaiting their PIN a pharmacist, pharmacy technician doctor, dentist or other witness authorised by the Nurse/Midwife in Charge or Senior ODP and recorded in the section for stock checks at the back of the CDRB.
The check must be performed by a substantive MEHT member of staff. Temporary staff can only act as the witness.

19.7 Where possible the staff undertaking this check should be rotated periodically.

19.8 To ensure all balances are checked, each drug entered in the CDRB should be checked against the contents of the cupboard, making sure there is no stock for which an entry in the CDRB has not been made.

19.9 It is not necessary to open original packs with intact tamper-evident seals for stock checking purposes. Opened packs should never be re-sealed for the purpose of

avoiding having to count the stock subsequently.

19.10 Stock balances of liquid medicines should generally be checked by visual inspection, but periodic volume checks may be helpful. The balance must be confirmed to be correct on completion of a bottle.

19.11 The date, time, the signature/initials of a Registered Nurse/midwife or ODP and another Registered Nurse/Midwife/ODP (or other staff authorised by the Nurse in Charge as per 19.3) to witness and the balance physically in stock should all be recorded at the back of the CRDB.

20. Dealing with Discrepancies

20.1 If at first sight the balance check appears to indicate a discrepancy, the following should be carefully checked:

- All requisitions received have been entered into the correct page of the register;
- All CDs administered have been entered into the CDRB on the correct page;
- Items have not been accidentally put into the wrong place in the cupboard;
- The item has not been received as a different brand or in new packaging resulting in it not being recognised;
- Arithmetic checked to ensure balances have been calculated correctly.

20.2 If the error or omission is traced the Nurse in charge, midwife or senior ODP should make an entry in the CDRB clearly stating the reason for the error and the corrected balance. This entry should be witnessed by a second Registered Nurse/Midwife/ODP, Authorised Pharmacy staff or doctor.

20.3 Any discrepancy not explained by the above must be reported immediately to the NPT/pharmacist, ward manager and Accountable Officer and an “Investigation and escalation of CDs following loss/theft” form completed (appendix 5).

20.4 Such incidents will be reported by the Accountable Officer routinely in the Quarterly Occurrence Report.

20.5 Any suspicion of misuse or diversion, will be immediately investigated by the Accountable Officer ,the LSMS and other appropriate parties including senior nursing or medical staff.

21. Archiving of Controlled Drug Records

21.1 All CDRBs, CD order books, CD returns books and CD daily balance check forms must be kept for **a minimum of two years** from the date of the last entry and then destroyed as confidential waste.

21.2 Ward CDRB and CD order books must be kept securely on the ward in a locked cupboard or secure room.

21.3 Loss or theft of any controlled order or record books, which may be used to order CDs, should be reported to the Accountable Officer or their nominated deputy. In

addition, any suspected misuse of CD order or record books (e.g. unauthorised amendments or ripped pages) should be reported immediately to the Accountable Officer or their nominated deputy.

22. Security of the CD Book at off site MEHT units

(This section applies to off site MEHT units only. On site, wards now use the electronic CEDAR ordering system)

22.1 The CD Order Book must be kept locked in the CD Cupboard at all times when not in use.

22.2 Loss or theft should be reported immediately to the ward pharmacist, who will investigate and if necessary will inform the Accountable Officer.

22.3 If the book is not located within 24 hours the Accountable Officer will be informed by the investigating pharmacist. Depending on the circumstances it may be appropriate to contact the police; this decision will be made by the Accountable Officer. If wrong doing is suspected the police should be involved.

22.4 A stop will be put on this Order Book to prevent any unauthorised ordering and interim arrangements will be agreed with the AO.

22.5 Stocks of CD order and record books held in pharmacy departments will be kept in a secure area that is locked when pharmacy staff are not present.

22.6 CD order and record books will only be supplied by the pharmacy.

22.7 Any unused order or record books returned to the pharmacy will be recorded as a returned, with details as in the supply record above.

22.8 Completed Ward CD Ordering and Record books should be dated with the last entry, sealed with tape and retained by the ward for two years from the last entry then destroyed as confidential waste.

22.9 If the ward or department closes the Ward CD Ordering and Record books should be archived along with other controlled stationery until the due destruction date.

22.10 Any occasion where the Police are notified of missing CD Book, a DATIX form should be completed and the AO must notify the LSMS.

22.11 Security requirements may be increased at the discretion of the Nursing Management after agreement with the Accountable Officer and LSMS

23. Temporary Closure or Transfer of Wards

23.1 In the case of temporary closure of a ward, all stocks of CDs should be returned to pharmacy. The stock should be written out of the CDRB of the closing ward by the Nurse in Charge and an Authorised Pharmacy Staff. The stock should then be returned to pharmacy. The CD keys must be returned to pharmacy for safe storage.

23.2 If a ward transfers to a new location, the removal of CD stock from the old location to the new should be witnessed by the Nurse in Charge and an Authorised Pharmacy Staff, both of whom should also reconcile all stock balances at the end of this process.

23.3 The Head of Department should be informed of all temporary or permanent closures. During out of hours, the on call pharmacist should be notified.

24. Administration of Controlled Drugs

24.1 CDs may only be administered to inpatients from stock, apart from in an emergency when a patient's own supply may be used prior to a stock supply being obtained, see section 25.

The only exception where patient's own drugs can be administered routinely is the following:

- Gabapentin (all forms);
- Pregabalin (all forms).

24.2 CDs must be administered by the Nurse in Charge/Midwife/ODP or a designated Nurse/midwife or clinician and must be checked by another Registered Nurse/midwife/ODP or authorised witness (non UK registered nurse awaiting PIN, Doctor, Dentist, Pharmacist, Pharmacy technician).
(Refer also to section 24.3)
Note student nurses/midwives must not administer CDs.

There are exceptions to the need for a second checker (witness) where a single registered nurse/midwife can administer the following controlled drugs:

- Gabapentin (all forms);
- Pregabalin (all forms).

24.3 **Both these persons must remain present throughout the entire procedure** of checking, preparation and administration of the CD and destruction of any surplus dose not required. It is not acceptable for two members of staff to select and prepare a dose of a CD for administration by a third person and this should be followed where possible.
The following are the exceptions to this:

- **General ITU, Burns ITU** where 2 registered nurses can sign the CD out of the cupboard and enter the details in the CDRB for supply including the stock balance. One of these 2 registered nurses must then take the CD and the CDRB to the registered nurse/clinician administering the drug. The person administering the CD will sign as the responsible person in the administered section and the nurse taking it to the patient will sign the witness box in the administered section. This process will ensure that there is at least one nurse who follows the CD through from supply to administration This exception does not apply to Burn's HDU patients where the 2 same nurses can be present throughout the entire procedure.
- **Theatres –** if the CD is administered by a doctor then a witness administration signature is not required due to the doctor being an autonomous practitioner. The doctor will sign as the responsible person for the administration. The

clinician will also sign the supplied witness box but the ODP will be the practitioner taking responsibility for the stock balance check being correct at this stage and for handing the CD to the doctor. The ODP will sign as the responsible person for supply.

- **Labour ward (epidurals only) –** if the CD is administered by a doctor then a witness signature for administration is not required due to the doctor being an autonomous practitioner. The epidural will be signed out of the CD cupboard by 2 registered midwives who will enter and sign the details in the CDRB for supply including the stock check. The epidural will then be handed to the doctor administering the epidural who will sign as the responsible person for the administration. There will be no witness signature for the administration.

24.4 When administering CDs the following additional actions must be taken in addition to those for any other medicines by both staff members involved (see also section 24.3 for exceptions to having both staff members involved):

- Check the prescription is legible and valid;
- Select the correct drug;
- Check the stock balance of the CD against the balance remaining in the CDRB;
- Fully complete the entry in the CDRB.

24.5 Prepare the medicine for administration and lock the remaining CDs away in the CD cupboard.

24.6 Take the medicine and the prescription chart to the patient and confirm the identity of the patient. If the patient is not wearing an identity band be especially careful and ask them to confirm their date of birth.

24.7 The Nurse/midwife/ODP administering the CD should initial the patient's prescription chart at the time of administration.

24.8 Both people must ensure the remaining details are recorded in the CDRB i.e. the time of administration and the full signature of the Nurse/Midwife/ODP administering the CD and the witness.

24.9 If for any reason the CD is not administered a record of the reason for non-administration must be made in the left hand margin of the CDRB. A reason code should be entered on the prescription chart and the details recorded in the patient's notes.

24.10 In the case of the administration of morphine or Pethidine in the community by Community Midwives, the requirement for an authorised witness for the administration of CDs is not required. The patient should act as the witness and sign the administration record and CSDB accordingly.

25. Use of a Patient's Own Controlled Drugs on a Ward

25.1 All patient own CDs must be locked in a CD cupboard and should be recorded in the patient's own (PODs) CDRB. The record must state:

- The date of the record;
- Patient's full name;
- Hospital number;
- Drug name, form, strength and quantity.

The record must be signed by a registered nurse/midwife and an authorised witness.
(Refer to section 19.3)

25.2 There should only be one entry per page of the CDRB.

25.3 Patient's own CDs may be used on the ward in either of the following situations:

- Temporary use whilst a stock supply of the CD is being obtained;
- For patients self-administering their own medication (see point 25.6).

25.2 If patient's CDs are not required for either of these purposes then one of the following procedures should be followed and all actions recorded:

25.3 If the patient or the patient's agent agrees, if no longer needed due to prescription changes, the CDs may be removed from the ward for destruction by the Authorised Pharmacy Staff. If the patient wishes, the CDs may be returned home via an identified adult to whom responsibility for security is given. An entry in the PODs CDRB should be made, the details of which should match those required for the collection of a CD TTA by a patient representative.

25.4 In mental health and learning disabilities, where the patient may not have the capacity to make a decision, the CDs may be held on the ward until discharge. If the CDs are not safe and / or appropriate for use, then the patient and /or patient's agent should be advised and they should be encouraged to allow the destruction of the CDs.

25.5 Patient's own CDs must never be used to treat other patients.

25.6 Self administration of CDs should be allowed only in exceptional circumstances because of the security and reconciliation issues concerning CDs. Where this is allowed it should be agreed with the Accountable Officer or their nominated deputy, the consultant in charge of the patient and the lead nurse for the area concerned.

25.7 Patient's own supplies of CDs should be checked by a member of pharmacy staff before use.

25.8 When patients who self-administer CDs require further supplies, these should be dispensed as discharge medication (TTAs), hence a discharge prescription is required.

25.9 Supplies of CDs for self administration should be entered in the Ward CD Patients Own (PODs) Record Book to ensure that there is an auditable record of their arrival on the ward.

25.10 CDs for patients who are to self-administer their medicines should be stored in the ward CDs cupboard and supplied to the patient, one dose at a time and signed for by the nurse/midwife supplying the dose and the patient self-administering it. In the case of morphine sulphate oral solution 10mg/5ml (Oramorph), which is a schedule 5 CD this may be stored in the patients POD locker.

26. Pharmacy checking and audit of Controlled Drugs

26.1 A ward CD check should be carried out every three months by two people at least one of whom should be a pharmacist or designated pharmacy technician. The other should be a pharmacy technician or designated pharmacy assistant whose role is to undertake the physical count. Alternatively, the second person could be a nurse/midwife/ODP employed in the clinical area.

26.2 Procedures are detailed in the Pharmacy SOP: Procedure for Clinical Area Controlled Drugs Checks which all pharmacy staff should refer to before performing a check.

26.2 The check is to ensure that:

- All controlled drugs are within expiry date;
- Controlled drugs in the clinical area correspond with the current drug register;
- All register entries are consecutive and unaltered;
- Register entries do not demonstrate an unusual pattern of use;
- There is no inappropriate stock;
- Trust policy is being followed.

27. Destruction of Controlled Drugs

27.1 **Disposal of small quantities of CDs**

27.2 In the interests of safety and containment of environmental pollution, only small amounts CDs for example 10mls or less should be destroyed on wards (see also section 27.3). This includes the surplus when the dose administered is less than the smallest ampoule or vial available; or when an individual dose is prepared but not administered.

27.3 Small amounts for disposal (for example 10mls or less) should be rendered irretrievable by emptying into a sharps bin. The emptied ampoule or vial, together with the syringe and needle used to give the dose, should also be placed into the sharps bin.

27.4 Any surplus opioid remaining after an infusion e.g. PCA, epidural, syringe driver), containing a controlled drug, that has been discontinued should be measured (information taken from infusion pump) and disposed of by adding directly to an approved **Controlled Drug Disposal Kit.** This can then be disposed as clinical

waste or can be then returned to pharmacy for disposal with the pharmaceutical waste.
(Refer also to section 18.4-18.8)

27.5 **Controlled Drug Disposal Kits** must be kept securely in the ward/department clean utility room or drug storage room to ensure that patients do not have access to them.

27.6 All doses disposed of must be fully documented in the Controlled Drug Record Book.

27.7 All other CDs requiring destruction, such as expired stock must be notified to Pharmacy asking for destruction to take place there.

28. Return of Stock CDs to Pharmacy for destruction

28.1 Under no circumstances should any CDs be returned to Pharmacy by ward staff.

28.2 Authorised Pharmacy Staff should be informed if any CDs held are excess to requirements or time-expired.

28.3 Authorised Pharmacy Staff will return the CDs to Pharmacy for destruction at the earliest opportunity.

28.4 Authorised Pharmacy Staff may also discover time-expired or excess CDs during their quarterly visit and with the agreement of the Nurse in Charge will return these to Pharmacy for destruction.

28.5 The ward or department will keep a record of stock CDs returned to Pharmacy in the CDRB by endorsing the CDRB accordingly.

28.6 Pharmacy staff should enter the drugs into the controlled drugs register for Destruction. The drugs must be stored in the appropriate place in the controlled drugs cupboard in pharmacy.

28.7 On a weekly basis, authorised pharmacy staff will liaise with the nurse in charge and remove any unwanted stock CDs from the wards and departments as requested.

29. Removal of Patient's Own CDs for Destruction

29.1 If a patient is suspected of being in possession of a **schedule 1 CD** it should be immediately removed where possible and stored in the ward CD cupboard .The item should be logged into the patient's own section of the CDRB annotated as for example: "unknown white powder" or "unknown resinous substance" unless absolutely certain the recording nurse should not make assumptions as to the nature of the product. The ward pharmacist, CDAO or the on-call pharmacist must be informed as soon as possible they will then arrange for the item to be collected and stored securely within pharmacy, the agent must not be left in the ward CD cupboard for longer than necessary. The CD Accountable Office and LSMS (Local Security Management Specialist) should be consulted as soon as it is suspected

that a patient is in possession of a schedule 1 CD, the AO and LSMS will then notify the police and the item will be held securely in pharmacy until the police can collect it for destruction or obtain as evidence in an ongoing case. Where appropriate the police may arrange for witnessed destruction within pharmacy.
(Refer to Policy 13024 The Management of Illicit or Unknown Substances belonging to Patients)

29.2 Patient's own CDs that are not to be used for self administration should not routinely be stored on the ward.

29.2 Patient's own drugs are the property of the patient, so consent must be obtained before they are removed for destruction.

29.3 Patient's own CDs for deceased patients can be destroyed without the consent of the patient's estate (or relatives) i.e. signed by the Authorised Pharmacy Staff and a Registered Nurse or Doctor.

29.4 The ward or department will keep a record of CDs returned to Pharmacy in the PODs CDRB by endorsing the CDRB accordingly.

29.5 Pharmacy staff should enter the drugs into the controlled drugs register for Destruction. Patients own drugs and ward stock drugs are treated separately.

29.6 On a weekly basis, authorised pharmacy staff will liaise with the nurse in charge and remove any unwanted POD CDs from the wards and departments as requested.

30. Disposal of Controlled Drugs in Pharmacy

30.1 POD CDs can be destroyed by a pharmacist and a pharmacy technician/ assistant technical officer. Stock CDs in schedule 2, 3 must be destroyed by LSMS and a pharmacist or pharmacy technician.

30.1 Schedule 2, 3 and 4 Part 1 Controlled Drugs must be denatured before being placed into waste containers.

30.2 Schedule 4 Part 2 Controlled Drugs do not need to be denatured before being placed into waste containers.

30.3 Schedule 5 Controlled Drugs do not need to be denatured before being placed into waste containers. There is no requirement for the destruction of Schedule 5 Controlled Drugs to be witnessed by an Authorised person.
(Refer to section 33)

30.4 When disposing of controlled drugs in the pharmacy an apron and gloves must be worn. For drugs that need to be denatured, the following processed should be used:

- tablets must be crushed and mixed with the CD destruction granules;
- liquids must be mixed in with the CD destruction granules as much as possible;
- sachets must be emptied and mixed in with the CD destruction granules;
- patches must be cut in half and disposed of in the CD destruction granules;
- capsules must be emptied and mixed in with the CD destruction granules;

- lozenges must be crushed and mixed with the CD destruction granules;
- ampoules must be emptied and mixed in with the CD destruction granules;
- suppositories must be mixed in with the CD destruction granules;
- PCA's and epidurals emptied and mixed in with the CD destruction granules.

30.5 Two members of pharmacy staff, one of which may be an Assistant Technical Office or a qualified technician and the other must be pharmacist, must work together to destroy any unwanted controlled drugs.

31. Implementation and Communication

31.1 A hard copy of the policy must be present in all clinical areas and this will be audited by pharmacy. The policy will be on the intranet and MEHT website.

31.2 The policy will be communicated to nurses at Sisters/Charge Nurse meetings and to doctors through pharmacy teaching sessions.

31.3 Ward based pharmacists and pharmacy technicians will communicate this policy to medical and nursing staff on the wards and ensure that the policy is followed.

32. Audit and Monitoring

32.1 Pharmacy will audit the use of controlled drugs in all areas where controlled drugs are used or kept by way of a three monthly check and audit process as outlined in section 26. The aim of this three monthly audit is to ensure that this policy is being followed in the clinical area.

32.2 The data from this audit will be used by the Chief Pharmacist to present at the regular Ward Sisters/Charge Nurse meetings and any concerns about the management of controlled drugs in clinical areas will be addressed then.

32.3 The Patient Safety Group will receive a 3 monthly report from the Accountable Officer (Controlled Drugs) on all matters of medicines management including CDs and the appropriate risk control measures to eliminate or reduce and identified risks.

32.4 All incidents are reported to the CD Local Intelligence Network (LIN) as necessary and also reviewed by the Medicines Optimisation and Safety Group (MO&MSG). The MO&MSG submit an annual report to the PSQ.

33. Responsibilities

33.1 The specific responsibilities are as follows:
Chief Executive:
Overall responsibility for Controlled drug management delegated to the Head of Pharmacy and Accountable Officer.

Accountable Officer (AO)

33.2.1 A senior officer of the Trust will be appointed to serve in this capacity, this officer may hold another senior position within the Trust such as Chief Nurse or Head of Pharmacy, however this person should not be routinely involved in the prescribing supply or administration of CDs but should be familiar with CDs their actions and uses and should as part of their role report directly to an Executive Director.

33.2.2 The Accountable Officer (AO) has organisational responsibility for controlled drugs as designated in the 2006 Controlled Drugs (Supervision of Management and Use) Regulations. The details of the Trust AO will be notified to the CQC in accordance with current requirements.

33.2.3 The AO will report and share information between organisations, regulators and agencies through the PCT led controlled drug local intelligence network (CD LIN) The AO Works with the LSMS for investigations as required by the statutory instrument 2006 No 3148 of CD (supervision of management and use) regulations 2006.

33.2.4 If Trust staff have concerns about the practice of the Accountable Officer they should initially raise these concerns either with the Trust Medical Director or the Chief Executive who will investigate further.

33.3 **Head of Pharmacy**
Responsible for all aspects of medicines management within the Trust including the development of SOPs pertaining to CDs, the procurement, storage and monitoring of CD use and destruction of unwanted CDs. Works with the AO and the LSMS to assist in any investigation as required.

33.3 **Local Security Management Specialist (LSMS):**
Works with the AO for investigations as required by the statutory instrument 2006 No 3148 of CD (supervision of management and use) regulations 2006.

33.4 **Pharmacists**
Responsible for the safe management of CDs on their wards, including a 3 monthly CD check and audit. Work with the ward manager and authorised ward staff to resolve any CD issues.

33.5 **Authorised pharmacy staff**:
Technicians who can undertake CD checks and can liaise with ward staff to resolve CD issues under the supervision of a pharmacist.

33.6 **The Authorised person**
Any officer of the healthcare organisation, who, is directly accountable to an executive officer of the organisation to witness the destruction of CDs .However these individuals must be independent of the routine supply and administration of CDs")That person must also be approved by the Controlled Drugs Accountable Officer.

33.7 **Chief Nursing Officer:**
Liaises with AO and LSMS as necessary to resolve CD issues within the Trust.

33.8 **Lead Nurse/ Ward Sister/registered nurse in charge**:
Responsible for the safe and appropriate management of CD on their ward. Ensure that ward staff know and comply with Trust policy. Can delegate control of

access i.e. key-holding to the CD cabinet to another registered nurse however, legal responsibility remains with them.

33.9 **Registered nurse**:
Can take responsibility for tasks relating to CDs. Must be aware and comply with the policy.

Appendix 1

Mid Essex Hospital Services NHS
NHS Trust

Appendix 2: Procedure for release of CDs for patients undergoing interhospital transfer patients with anaesthetic support

The designated doctor/anaesthetist will sign the CDs out of the ED CD register for transportation with the accompanying nurse/ODP who is going on the transfer as witness.

Any CDs administered through the journey will be administered by the doctor and witnessed by the other professional.

On return from transfer the designated doctor/anaesthetist and ODP are responsible for completing the register to log how much was used, destroyed and returned.

Appendix 3: Transfer of PCA's and epidurals from theatres to ICU, GHDU, Heybridge or Rayne wards

When a patient is transferred from theatres to ICU, GHDU, Heybridge or Rayne ward on a PCA or epidural the following procedure must be followed:

If PCA/epidural is required by ICU, GHDU, Heybridge or Rayne ward this needs to be prescribed onto a drug chart for the patient.

A registered nurse from ICU, GHDU, Heybridge or Rayne ward needs to take the chart to theatre recovery, where this nurse along with a registered nurse in Recovery will sign out the PCA/epidural of theatre recovery CD book as a **stock** transfer to ICU, MHDU, Heybridge or Rayne ward.
Patient details should be included for audit purposes but do not sign out to the patient.

The registered nurse from ICU, GHDU, Heybridge or Rayne ward is then the responsible person to ensure safe transfer of the epidural/PCA back to ICU, MHDU, Heybridge or Rayne ward.

The same registered nurse from ICU, GHDU, Heybridge or Rayne ward and another registered nurse on ICU, GHDU, Heybridge or Rayne ward will sign the PCA/epidural into **ward stock.**

These nurses will then sign the PCA/epidural out to the patient (therefore there will be two entries -one receiving the stock from theatre recovery and the next to sign it out to the patient - this need to be done so we can have an audit trail of the PCA/epidural bags)

Appendix 4: High Strength Opioid injections

High strength opioids include:

Ampoules of diamorphine 30mg or greater,

Ampoules of morphine injections of 30mg/mL or greater*,

Ampoules of alfentanil injections of 5mg/mL or greater

Ampoules of oxycodone injections 50mg/mL

*Morphine 1mg/mL (50ml syringe and 100ml bag) do not have to be ordered using this policy, as they do not fall within the definition of high strength morphine.

High strength ampoules can be held as stock GICU, GHDU, Burns ITU

The person placing the order must ensure that naloxone injection is available on the ward/department. If no naloxone is available, an order must be placed at the same time as the order for the high strength injection, using the usual order process.

High strength opioid injections must be returned to pharmacy from wards that are not authorised to keep these as stock medicines when no longer required.

When the patient for whom the high strength opioid injection was ordered no longer requires the medication, the ward pharmacist/technician must be notified at the first opportunity within normal pharmacy working hours to arrange return to pharmacy.

The ward pharmacist or near patient technician should remove the medication from the controlled drug cupboard on their next visit to the ward and return it to the pharmacy department in accordance with the Controlled Drug Policy.

Out of hours, wards/departments, not listed above, requiring high strength opioid injection urgently may transfer an appropriate quantity from the designated ward in the hospital following the Controlled Drug Policy until such time as they receive an order from the pharmacy department. Ampoules must only be transported in the original container.

Appendix 5

Mid Essex Hospitals NHS trust – Broomfield Hospital
Safer Management of Controlled Drugs
Investigation & Escalation of Controlled Drugs following Loss/Theft

To be completed within 24 hours of suspected controlled drug loss or theft
(Complete form electronically and email immediately to Sarah.ferguson@meht.nhs.net and Alison.felton@meht.nhs.uk

Enter 'CD Escalation - Ward name' as the title of the email)

Key Details (all boxes MUST be completed)		
Ward/Dept (inc Theatre no.):		
Drug name:	Drug formulation:	Drug Strength:
Quantity missing (as number of dose units):		
Date loss identified: (DD/MM/YYYY)	Time loss identified(using 24-hour clock):	
Who performed CD check where discrepancy identified:		
When was discrepancy identified: Stock Check ☐ or when administering a dose ☐		
Date/time when stock check last recorded as correct		
Who performed the stock check when was recorded as correct: and		
Brief description of reported loss/theft		

Investigation: to be completed by Senior Nurse/Midwife/ODP	
Select box in margin when done and complete all sections	
☐	**Check running totals of affected drug to ensure addition/subtraction undertaken correctly**

	State page numbers and any issues identified:

	Recount stocks & check total recorded in register
☐	State page number, total in stock, total in register for ALL relevant stock held (inc other packs of same drug etc.

	Check areas in close proximity for loose tablet/s etc, State outcome:	
☐	a) Cupboards:	Click here and select from List
	b) Floor:	Click here and select from List
	c) Workbench:	Click here and select from List
	d) Bins below cupboards:	Click here and select from List
	Further details, if required:	

	Check all drug charts theatre list records and prescriptions for records of administration against CD register since stock level last correct.					
	State exact checks made:					
☐	a) Patient Initials	b) Unit No	c) Dose prescribed	d) Number of doses given?	e) Recorded in register?	f) What was found
					Click here and Select	Click here and Select
					Click here and Select	Click here and Select
					Click here and Select	Click here and Select
					Click here and Select	Click here and Select
					Click here and Select	Click here and Select
	Further details, if required:					

	Provide details of which staff involved. Attach rota of staff by email to this report, persons who hold CD keys (Names and Designation of all staff present at time):
☐	

	Request statements and provide documented written evidence		
	Persons involved	**Has a written statement been received**	**Has the report been attached to this document**
☐	a) Person who last made entry in register	YES ☐ NO ☐ N/A ☐	YES ☐ NO ☐ N/A ☐
	b) ALL Nurse/s-in-charge of CD keys during time period	YES ☐ NO ☐ N/A ☐	YES ☐ NO ☐ N/A ☐

	identified above		
	c) Staff who last undertook shift change stock check	YES ☐ NO ☐ N/A ☐	YES ☐ NO ☐ N/A ☐
	d) Staff who identified discrepancy	YES ☐ NO ☐ N/A ☐	YES ☐ NO ☐ N/A ☐

☐	**Previous incident history:**
	Has a similar incident to this occurred in the past in this ward/dept? Click here and Select from list:
	State details of previous incident and what similarity is:

Summary of Key findings

Escalation and Recording	
Complete DATIX entry for incident, enter ID number (not F number) :	
Escalate to Senior Nurse/Matron (state name):	Date/Time:
Escalate to Pharmacist (state name):	Date/Time:

Nursing/Midwifery/ODP Investigation Completed by:

FULL Name	
Designation:	
Contact extention:	Email:
Date completed:	Time:

Now please email immediately to Sarah.Ferguson@meht.nhs.uk & Alison.felton@meht.nhs.uk

In email title write: '**CD Escalation and *Ward name'***

For Pharmacy use only:

Pharmacist-in-charge:

Before continuing – please allocate a reference number for this investigation and enter in the designated box on the top right of the 1st page of this document.
Summary of findings

Name:		
Date completed:	Time:	
Actions		
No further action required ☐		
EMR Required? YES ☐ NO ☐	Sent date/time:	Sent to (name):
Early Management Report (EMR)		
Outcome of report (embed report within this document)		
Does this need to be managed via the Disciplinary policy? YES ☐ NO ☐		
Performance Management Review(staff / dates issued etc.)		
Escalation to CDAO? YES ☐ NO ☐	**Date/Time of escalation:** N/A ☐	

Controlled Drug Accountable Officer (CDAO):	
Comments:	
Date completed:	Time:
Escalation to CDLIN? YES ☐ NO ☐	**Date:**

Investigation Closure		
Investigation closed by:	Date:	Time:

File electronically in the 'CD Escalation' folder in the pharmacy governance drive.
Create a folder titled with the reference number and date

Retain records for two years from investigation closure date.

Appendix 6: Preliminary Equality Analysis

This assessment relates to: 08083 Controlled Drug Policy

A change in a service to patients		A change to an existing policy	**X**	A change to the way staff work	
A new policy		Something else (please give details)			

Questions	Answers
1. What are you proposing to change?	Full Review
2. Why are you making this change? (What will the change achieve?)	3 year review
3. Who benefits from this change and how?	Patients and clinicians
4. **Is anyone likely to suffer any negative impact as a result of this change?** If **no**, please record reasons here and sign and date this assessment. If **yes**, please complete a full EIA.	No
5. a) Will you be undertaking any consultation as part of this change? **b) If so, with whom?**	Refer to pages 1 and 2

Preliminary analysis completed by:

Name	Alison Felton	**Job Title**	Head of Pharmacy	**Date**	June 2019