Lincolnshire Community Health Services
NHS Trust

Management of Controlled Drugs (incorporating Policy and Organisational SOPs)

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Management of Controlled Drugs incorporating CD policy and organizational SOPs

Version Control Sheet

Version	Section/Para/ Appendix	Version/Description of Amendments	Date	Author/Amended by
1		Merged P_CIG14, G_CS58, G_CS57, G_CS58, G_CS27, C_CS61, G_CS62.	June 2016	Lorna Adlington
	Section One Section 6 Section 7	Updated audit tool. Updated disposal process Update relating to prescribing and transfer.	August 2016	Lorna Adlington
	Section 6 page 100 Section 7 page 110	Midazolam, diazepam and tramadol added to the daily checking schedule in unplanned care	September 2016	Lorna Adlington
	Page 23	Updated CDAO details	9th March 2017	Lorna Adlington
1.1	Policy page 20	New section – controlled drug discrepancies	26th June, 2017	Lorna Adlington
	Section 3	Minor amendments to SOP – section 2.5, 3.3, 3.4 and 3.7		
	Section 4	Minor amendments to SOP – section 2.5, 3.3, 3.4 and 3.7.		
	Section 5	Minor amendments to SOP – section 3.3		
	Section 6	SOP for management of controlled drugs in Louth Urgent Care – removed.		
	Section 7	Minor amendments to SOP – section 1,3,5,6 and 10.		
	Appendix One	Updated disposal guidance	August 2017	Karen Leggett
	Section 11	Details of interim CDAO	8th September 2017	Lorna Adlington

Management of Controlled Drugs

Document Statement

Background	The purpose of this document is to provide policy and operational guidance on all aspects of controlled drug management in Lincolnshire Community Health Services (LCHS).
Statement	This document incorporates all legislative changes published by the Department of Health up to the end of December 2015. It also recommends areas of good practice to strengthen the governance arrangements for controlled drugs.
Responsibilities	Implementation and compliance with the Policy and SOPs will be the responsibility of all staff.
Training	This reference document will be amended when further changes to legislation occur. All managers should ensure staff are working within the current legal and regulatory framework governing controlled drugs.
Dissemination	Lincolnshire Community Health Services Website: http://www.lincolnshirecommunityhealthservices.nhs.uk
Resource implication	All resources within this document have been developed in line with Department of Health guidelines to enable the appropriate management of controlled drugs within Lincolnshire Community Health Services. There are no additional resource implications.

Management of Controlled Drugs

Contents

SECTION 1

Policy for Prescribing, Supply, Storage and Disposal of Controlled Drugs within Lincolnshire Community Health Services NHS Trust

Policy for Prescribing, Supply, Storage and Disposal of Controlled Drugs within Lincolnshire Community Health Services NHS Trust

Contents

1. Background

1.1 This policy applies to all professionals and premises subject to inspection as part of the revised arrangements for the management and monitoring of Controlled Drugs (CDs). This includes all GP practices both dispensing and non-dispensing and all community health services handling CDs within Lincolnshire. Community pharmacies will be inspected to similar standards by the General Pharmaceutical Council Inspectorate. The current edition of this policy incorporates all of the updated Department of Health material published up to the end of December 2013. The June 2006 guidance from the Department of Health (DoH) clarified arrangements around private prescribing of CDs, validity of CD prescriptions and quantities of CDs to be prescribed. In addition, it was confirmed that pharmacists are now able to amend minor errors on prescriptions for Schedule 2 and Schedule 3 CDs. There have also been changes to record keeping requirements and the introduction of a requirement to ensure that the identity of persons collecting Schedule 2 CD prescriptions is confirmed if not already known. Subsequent material published by the DoH in October 2006 provided interim guidance on issues relating to destruction and disposal of CDs and final guidance on changes to record keeping requirements. Guidance on Standard Operating Procedures for Controlled Drugs was published in January 2007. New guidance has followed in December 2007 detailing changes to the requirements for requisitions and amended guidance on the destruction of CDs. Further changes to record keeping requirements were published in January 2008. Changes in November 2015 included making use of the standard requisition form mandatory and rescheduling Ketamine as a schedule 2 CD.

1.2 The **Misuse of Drugs Act 1971** controls 'dangerous or otherwise harmful drugs' which are designated as Controlled Drugs. The primary purpose of this legislation is to prevent the misuse of this group of drugs. It does this by imposing a total prohibition on the possession, supply, manufacture, import or export of Controlled Drugs except as allowed by regulations or by license from the Secretary of State. The medical use of Controlled Drugs is permitted through the **Misuse of Drugs Regulations 2001** and subsequent amendments. These Regulations classify CDs into five different schedules according to different levels of control with Schedule 1 being the most tightly controlled schedule and Schedule 5 the least tightly controlled. The five Schedules are summarised in tables at the end of this section.

1.3 Changes to the Misuse of Drugs Regulations 2001 have been made in the wake of the Shipman Reports. The requirement that Controlled Drug prescriptions should be written in the prescriber's own handwriting has been removed. Prescriptions will be valid as long as they are written indelibly and include all of the legally required elements. This means that CD prescriptions can now be type-written, hand written or computer printed; only the signature of the prescriber needs to be handwritten.

1.4 The definition of CD register has been amended to include a computerised system which is in accordance with best practice guidance endorsed by the Secretary of State under section 2 of the National Health Service Act 1977.

1.5 The Misuse of Drugs Regulations 2012 allow nurse and pharmacist independent prescribers to prescribe any schedule 2-5 controlled drug within their clinical competence but do not allow the prescribing of cocaine, diamorphine or dipipanone for the treatment of addiction.

1.6 The Controlled Drugs Regulations 2013 update and replace the 2006 Regulations to reflect the changes in the NHS in England from April 2013.

Summary Table

Schedules	Definition	Drugs included
Schedule 1 (CD Licence)	These drugs have virtually no therapeutic use. Production, possession and supply are only allowed for the purposes of research or other special purposes. A Home Office License is required.	Hallucinogenic drugs (e.g. LSD), ecstasy-type substances, cannabis etc.
Schedule 2 (CD POM)	These drugs are used medicinally, but prescribing, dispensing, administration and disposal are all tightly controlled. Enhanced prescription requirements are in place as are safe custody requirements (except secobarbital (quinalbarbitone)), record keeping requirements and tight controls on disposal. Prescriptions are valid for 28 days. Changes to legislation have removed the prescribers own handwriting requirement; prescriptions for Schedule 2 CDs can now be computer, type or hand written.	Cocaine, dexamfetamine, diamorphine, dipipanone, fentanyl, hydromorphone, ketamine, methadone, methylphenidate, morphine, nabilone, oxycodone, pethidine, secobarbital (quinalbarbitone), tapentadol etc.
Schedule 3 (CD No Register)	These drugs are used medicinally and are liable to abuse. Controls are less rigorous than with Schedule 2. Schedule 3 CDs are exempt from safe custody requirements (except flunitrazepam, temazepam, buprenorphine and diethylpropion) and special record keeping requirements. Prescriptions are valid for 28 days. Invoices should be kept for two years. Changes to legislation have removed the prescribers own handwriting requirement; prescriptions for Schedule 3 CDs can now be computer, type or hand written.	Barbiturates (e.g. amobarbital, butobarbital, phenobarbital), buprenorphine, diethylpropion, flunitrazepam, meprobamate, midazolam, pentazocine, phentermine, temazepam, tramadol etc
Schedule 4 Part I (CD Benzodiazepines)	This schedule has a lower level of control than those described above. Possession of a drug from this schedule is an offence without the authority of a prescription. Possession by practitioners or pharmacists acting in their professional capacity is authorised. There are no special prescription or handwriting requirements, nor is there a requirement for special record keeping. Prescriptions are valid for 28 days.	Benzodiazepines (except flunitrazepam midazolam and temazepam), zolpidem and ketamine (e.g. chlordiazepoxide, clonazepam, diazepam, loprazolam, lorazepam, lormetazepam, nitrazepam, oxazepam etc). *Sativex®
Schedule 4 Part II (CD Anabolic	There is no restriction on the possession of a drug from this Schedule when it is part of a medicinal product. There are no special	Anabolic and androgenic steroids and growth hormones e.g. testosterone, mesterolone,

Steroids)	prescription requirements, nor is there a requirement for special record keeping. Prescriptions are valid for 28 days.	nandrolone (Deca-Durabolin), chorionic gonadotrophin and somatropin.
Schedule 5 (CD Invoice: CD Inv P or CD Inv POM)	Schedule 5 contains preparations of certain CDs which are exempt from full control because they are present in these formulations in such low strength that their risk of misuse is reduced. There are no special prescription requirements, nor is there a requirement for special record keeping. Some Schedule 5 CDs (CD Inv P) are available for over the counter sale in registered pharmacies. Prescriptions are valid for six months. Invoices should be kept for two years.	Co-codamol, co-codaprin, codeine linctus BP, codeine phosphate tablets, co-dydramol, co-phenotrope, dihydrocodeine tablets, Gee's Linctus BPC, kaolin and morphine mixture, Oramorph® oral solution 10mg in 5ml.

*Sativex has been moved from Schedule 1 to Schedule 4 Part 1 in April 2013. Records should be kept for the receipt, supply and destruction of Sativex®, preferably in a CD register. These records should be kept for a minimum of two years. Sativex should be stored upright in a fridge with other prescription only medicines between 2-8 degrees. Once opened, it can be stored upright at room temperature for a maximum of 42 days.

2. Prescribing, Supply and Administration of Controlled Drugs

2.1 Medical Prescribers

2.1.1 Doctors, dentists and veterinary surgeons may prescribe all CDs in Schedules 2, 3, 4 and 5.

2.1.2 Doctors are only able to prescribe diamorphine, dipipanone and cocaine to substance abusers for addiction if they are approved by the Department of Health; they are covered by a general license issued by the Home Office. All doctors may prescribe these drugs for patients (including substance abusers) without a specific license if indicated for the relief of pain due to organic disease or injury.

2.1.3 Prescribers should not prescribe or administer CDs for themselves or for close family members except in an emergency. The General Medical Council advises that doctors should not prescribe a CD for themselves or someone close to them unless there is no other person with the legal right to prescribe available to assess the patient's clinical condition and to delay prescribing would put the patient's life or health at risk, or cause the patient unacceptable pain. The treatment should be immediately necessary either to save life or avoid significant deterioration in the patient's health or alleviate otherwise uncontrollable pain.

2.2 Non Medical Prescribers

2.2.1 Nurse and pharmacist independent prescribers may possess, prescribe, supply, administer, or direct another person to administer any schedule 2-5 controlled drug within their clinical competence. Nurse and pharmacist independent prescribers should ensure that they only prescribe within their clinical competence and that they have up to date knowledge of the doses, side effects, interactions, cautions, and contraindications of the CDs they intend to prescribe.

2.2.2 The changes in paragraph 2.2.1 do not apply to the prescribing of cocaine, diamorphine or dipipanone for the treatment of addiction. This is restricted to Home Office licensed doctors, see paragraph 2.1.2.

2.2.3 Supplementary nurse and pharmacist prescribers may prescribe and administer any CD (except diamorphine, dipipanone and cocaine for substance misuse) as long as it is within the clinical management plan (CMP) specific to that patient and agreed between the independent prescriber (doctor or dentist), the supplementary prescriber and the patient.

2.2.3.1 Chiropodists, podiatrists, physiotherapists, radiographers and optometrists who are supplementary prescribers are also able to prescribe CDs, in partnership with a doctor and according to the patient's CMP.

2.3 Midwives

2.3.1 Midwives, who are not trained as nurse independent prescribers, may possess, supply and administer any medicine from the Midwives Exemption List, provided it is in the course of their professional midwifery practice. This list includes the following CDs for parenteral administration: diamorphine, morphine and pethidine.

2.4 Paramedics

2.4.1 Registered Paramedics (acting in their capacity as such) may possess and supply diazepam and/or morphine sulphate injection (maximum 20mg) and/or oral morphine sulphate only for the purpose of administration for the immediate and necessary treatment of sick of injured persons.

2.5 Patient Group Directions

2.5.1 The following CDs may be supplied or administered under Patient Group Directions (PGDs):

- Nurses and pharmacists can supply or administer morphine or diamorphine under a PGD for the immediate and necessary treatment of a sick and injured person in any setting.
- Midazolam is the only Schedule 3 CD that can be included in a PGD.
- All drugs listed in Schedule 4 of the Regulations except anabolic steroids and injectable formulations for the purpose of treating a person who is addicted to a drug.
- All drugs listed in Schedule 5 of the Regulations.
- Ketamine (from 30th November 2015)

2.6 Requisitions for Controlled Drugs

2.6.1. Supplies of CDs as practice stock or stock for doctor's bags must not be acquired through the issue and collection of a named-patient prescription from a pharmacy/dispensary that is not destined for supply to that patient, even if the stock was used for that patient initially.

2.6.2 A standard requisition form, FP10 CDF for Schedule 2, and 3 CDs is available online http://www.nhsbsa.nhs.uk/PrescriptionServices/Documents/PrescriptionServices/6-1387-Form_FP10CDF_v5_final.pdf

All areas should use this form when requesting schedule 2 or 3 Controlled Drugs for their own stock from a pharmacy. This includes tramadol and midazolam. Any prescriber can sign this form. No supply will be made from any pharmacy if the request is not on this form. This requisition form is not required if the CDs are prescribed via FP10 or on site hospital pharmacy.

This requisition form allows for Schedule 2 and 3 Controlled drugs to be handwritten or computer generated.

2.6.3 The person ordering the CDs should issue a requisition that can be computer generated or handwritten and must contain the following information:

- signed by the recipient (must be handwritten)
- name, address and profession or occupation of the recipient
- purpose for which the drug is supplied and the total quantity to be supplied
- name, form and strength of the drug and the date on which it was ordered

2.6.4 The supplier of the CD must add their name and address indelibly onto the requisition at the time the supply is made e.g. using a stamp. The original requisitions for all Schedule 2, and 3 CDs must be submitted to the Prescription Pricing Division and copies kept by the supplier for at least 7 years.

2.6.5 The CD order book should be used and a copy of the CD order should be appended to the retained copy of the CD requisition form and the numbers must be cross referenced. The CD order book reference number should be annotated to the CD register upon receipt.

2.6.5 Pharmacists or doctors, who are purchasing Schedule 2 or 3 CDs from wholesalers for their dispensary, can order them electronically.

2.6.6 Doctors and other independent prescribers must always provide the wholesaler/supplier with a signed requisition on receipt of the CDs.

3. Schedule 2 Controlled Drugs (CD POM)

3.1 Storage: Legal Requirements

3.1.1 All healthcare professionals in legal possession of a CD have a professional duty of care to take all reasonable steps to maintain safe custody of that CD at all times.

3.1.2 Schedule 2 CDs are designated as subject to safe custody requirements under the Misuse of Drugs (Safe Custody) Regulations 1973. However, these Regulations only apply to the storage of CDs in retail pharmacies, private hospitals and care homes. In such premises, Schedule 2 and 3 CDs must be stored in an appropriate CD cabinet or approved safe. When purchasing a safe or cabinet, check that the product complies with the requirements stated in the Misuse of Drugs Regulations 1973. Alternatively, the police can provide an exemption certificate, which certifies that the safe or cabinet provides adequate security for holding CDs.

3.2 Storage: Good Practice

3.2.1 Many healthcare premises are not covered by the Misuse of Drugs (Safe Custody) Regulations 1973 (e.g. GP practices, out-of-hours services, hospitals, hospices etc.) Nonetheless, good practice recommendations should be followed.

3.2.2. All CDs must be stored in a locked secure container that is not portable. Ideally this should be an appropriate CD cabinet or approved safe.

3.2.3 The room containing the locked secure container should be lockable.

3.2.4 Access to the CD cabinet/safe should be restricted to authorised persons only.

3.2.5 When not in use, the keys to the CD cabinet or approved safe should be stored separately from the cabinet or safe (e.g. in a locked key cupboard).

3.2.6 The CD cabinet should be used solely for the storage of CDs. There should be no reason why an unauthorised person without legitimate business relating to the supply or stock control of the CD stock should need to access the cupboard. Cheque books, petty cash and other items requiring high security measures should be stored elsewhere. Where CDs are kept in the practice safe, the CDs should be kept in a separate locked receptacle within the safe.

3.2.7 It is recommended that all NHS premises where CDs are stored should be equipped with a lockable CD cabinet that is firmly fixed to the wall and complies with the safe custody requirements under the Misuse of Drugs (Safe Custody) Regulations 1973, or have arrangements in place where CD stocks are stored in the practice safe. A cupboard within a cupboard can provide a useful way to disguise the location of the cupboard from potential intruders. The cupboard should not be visible to members of the general public passing by outside windows.

3.2.8. All dispensed CDs should be stored in the CD cabinet or designated safe until they are collected.

3.2.9 It is best practice that patients own CDs are stored separately to stock items were possible.

3.2.10 Controlled drugs for all patients cared for within their own homes should be stored in a clear plastic container for security and monitoring.

3.3 Storage in a Doctor's Bag: Legal Requirements

3.3.1. Legally, a doctor's bag is regarded, once locked, as a suitable receptacle for the storage of CDs. A locked car is not regarded as a suitable receptacle.

3.4 Storage in a Doctor's Bag: Good Practice

3.4.1. A doctor's bag containing CDs should not be left in a vehicle overnight or in a vehicle left unattended for a long period of time.

3.4.2 The bag can be lockable either by key or by combination lock.

3.4.3 Stock levels of CDs stored in the doctor's bag should be kept to a minimum.

3.4.4 Oral preparations of CDs are not considered as essential components of a doctors' bag stock of CDs. Normally only one strength of each CD should be kept in the bag to minimise the risk of confusion, error or inappropriate administration.

3.4.5 In the practice, the doctor's bag should be stored in a safe place away from patient areas.

3.5 Prescription Requirements: Legal Requirements

3.5.1 The prescription must:

- be signed by the prescriber issuing it with his/her usual signature (this must be hand written).
- be dated (this does not have to be handwritten).
- be in ink or otherwise so as to be indelible.
- specify the address of the person issuing it.
- if issued by a dentist, have written on it the words 'for dental treatment only'.
- specify the full name, address and NHS number of the patient for whom the treatment is issued.
- specify the dose to be taken. This should be as specific as possible; the Home Office has stated that 'as directed' or 'when required' is insufficient, although 'one to be taken as directed/ when required' is acceptable.
- specify the form (e.g. tablets, capsules, oral solution) even where the form is implicit in the proprietary name (e.g. MST Continus) or where only one form is available.
- specify the strength of the preparation where appropriate (e.g. if the medicine is available in more than one strength).
- specify either the total quantity of the preparation (in both words and figures) or the number of dosage units (in words and figures) to be supplied.
- specify, in the case of a prescription for a total quantity intended to be dispensed in instalments, a direction specifying the amount of the instalments which may be dispensed and the intervals to be observed when dispensing.

NB The name of the medicine is also necessary to identify which medicine is being requested, however this is not a legal requirement. Additionally it is expected that the NHS number should also be added, however this is not yet a legal requirement.

In order for a Schedule 2 CD to be supplied the prescription must fulfil all of the legal requirements outlined above. In addition, the pharmacist/dispensing assistant must ensure that the address of the prescriber is within the United Kingdom and that they are familiar with the prescriber's signature or have no reason to suppose that it is not genuine.

3.5.2 Prescriptions will be valid as long as they are written indelibly and include all of the legally required elements. This means that CD prescriptions can be type-written, handwritten or computer printed. Only the signature of the prescriber now remains to be handwritten.

3.5.3 Prescribing a dose range for a CD in Palliative Care

3.5.3.1 If prescribing a dose range, ensure that the direction on the prescription and the Gold CD1 Form always reflects the dose instructions on the medicines box. For example, the prescription should be written – "Diamorphine 10mg ampoules: 10-20mg to be given as directed in association with a prescribed dose range written on the Gold Form (CD1)". The Gold CD1 form would also state the dose range as 10-20mg.

3.6. Prescription Requirements: Good Practice

3.6.1. Wherever possible the dosage and frequency of administration of the CD should be specified in full; this is particularly important when prescribing for syringe drivers, but is good practice with all CDs.

3.6.2 It is good practice (and will eventually become mandatory) for all prescriptions for Schedule 2 and 3 CDs, including private prescriptions, to include the patient's NHS number. This will enable the usage of CDs by individual patients to be audited.

3.7. CD Register (CDR): Legal Requirements

3.7.1. A register, compliant with the relevant regulations, must be kept to record all transactions involving Schedule 2 CDs.

3.8.4. The definition of a CDR in the 2001 Regulations has been amended to include a computerised system which complies with specified best practice guidance. If a CDR is held in computerised form, safeguards should be incorporated in the software to ensure that the author of each entry is identifiable, that entries cannot be altered at a later date and that a log of all data entered is kept and can be recalled for audit purposes.

3.8.5. Legally a CDR must:

- be bound if a hard copy is used (not loose leaved)
- contain individual sections for each class of drug
- use a separate page, within each section, for each strength and form of the drug
- have the name, strength and form of the drug specified at the top of each page
- have entries in chronological order and made on the day of the transaction or the next day
- have entries made in ink or otherwise indelible form, or be in a computerised form
- not have cancellations, obliterations or alterations; corrections must be made by a signed and dated entry in the margin or at the bottom of the page
- be kept at the premises to which it relates (or be accessible from those premises if computerised) and be available for inspection at any time. A separate register must be kept for each premises in which Schedule 2 CDs are stored (for example, not just in the main surgery)
- be kept for a minimum of seven years after the date of the last entry once completed
- contain records kept in their original form or copied and kept in an approved computerised form
- not be used for any other purpose

Entries made into the CDR in respect of drugs obtained and drugs supplied may be made on the same page or on separate pages in the register, as appropriate.

3.8.6. When a Schedule 2 CD is received into stock the following details must be recorded in the CDR:

- the date of receipt
- the name and address of the supplier (e.g. COOP, Witham St Hughes)
- the quantity received
- This should be recorded in both words and figures.
- The CD order number should be recorded in the CDR and the CD order book should be signed on receipt.

3.8.7. When a Schedule 2 CD is supplied to a patient (by prescription) or to a practitioner (by signed requisition or order) the following details must be recorded in the CDR:

- the date on which the supply was made

- the name and address of the patient or firm supplied
- particulars of the license or authority of the person who prescribed or ordered the CD. (NB record details of the signatory and not the named prescriber if they are not the same)
- quantity supplied
- person collecting the CD (patient/ patient's representative/ healthcare professional) and if it is a healthcare professional, their name and (work) address
- was proof of identity requested of patient/ patient's representative? (Yes/No)
- was proof of identity of person collecting provided? (Yes/No)
- in the case of a healthcare professional, proof of identity should be their professional registration number

These record keeping requirements are a minimum and do not prevent any person required to keep a register from including additional related information.

3.9. CD Register: Good Practice

3.9.1. All transactions relating to CDs should be checked by two members of staff and both individuals should initial the entry in the CDR.

3.9.2. It is recommended best practice that a running balance of current stock levels of all Schedule 2 CDs should be kept in the CDR. The running balance of drugs remaining should be calculated and recorded after each transaction and balances should be checked with the physical amount of stock at regular intervals. Registers with specific space for the recording of running balances are available. Expired controlled drugs must be kept in the running balance until destroyed by Pharmacist.

3.9.3 Wherever CDs are being stored, it is good practice for the accountable professional to carry out a daily stock check.

3.9.4 Regular stock checks should be carried out in line with any guidance from professional representative bodies and undertaken after a risk assessment has been carried out. Frequency of CD stock reconciliation will vary according to local circumstances, volume and frequency of CD dispensing but should be included in the Standard Operating Procedures. Regular stock checks will allow any errors or discrepancies to be more easily identified. If discrepancies arise, more frequent reconciliation should be undertaken until the problem is resolved.

3.9.5. The CDR may also be used to record the prescriber identification number (e.g. the six digit private prescriber code) and/or professional registration number of the prescriber (where known) and the name and professional registration number of the pharmacist or dispensing doctor.

3.9.6. Wherever a discrepancy is identified, a thorough investigation should be instigated as soon as possible and the outcome recorded. Any corrections to the CDR must be asterixed and a signed and dated entry annotated at the bottom of the relevant page. If the source of the discrepancy cannot be identified, the Controlled Drugs Accountable Officer (see point 9) should be notified, a formal internal investigation undertaken and an Incident Report Form will need to be completed; if the situation is not resolved satisfactorily the police will need to be informed. All of these steps need to be covered in the written Standard Operating Procedure for the handling of CDs in use in the workplace.

3.9.7. It is mandatory to keep registers, requisitions, orders and invoices for CD stock for seven years. In practice, it is advisable to keep invoices for much longer than this. Invoices should be stored for seven years to bring the system into line with value added tax (VAT) and tax storage requirements. Keeping records for this length of time will also help in the event of any subsequent police investigation as cases often come to court years after an event when paper records will ordinarily have been destroyed.

3.9.8 For CD stock held within any type of premises, the CDR should be stored safely, in a lockable cupboard, outside the cabinet or safe, near to but not easily visible. However it should be accessible to clinical staff.

3.10 Collection of CD Dispensed Medicine or CD Prescription Form by a Patient or Patient's Representative

3.10.1. Any patient, or person collecting medicines on their behalf, who is collecting CDs against a Schedule 2 or Schedule 3 CD prescription (whether NHS or private) should be asked to sign for them. The FP10 forms contain a box on the reverse where a signature for a Schedule 2 or 3 CD can be inscribed.

3.10.2. Where the patient, or person collecting medicines on their behalf, is collecting **Schedule 2 CDs**, it is a legal requirement to ask for evidence of identity if this person is not known to the pharmacist/dispensing assistant. If no evidence of identity is available, the pharmacist/dispensing assistant is able to use discretion to decide whether to supply the CD or not. The pharmacist also has the discretion to not ask for evidence of identity if he/she feels that to do so might compromise patient confidentiality. Requests for evidence of identity and whether identity is confirmed must be recorded in the CD register. Where concerns exist and the identity of the person collecting the CDs is unknown and cannot be confirmed, supply should be refused until adequate evidence of identity can be provided. Proof of identity is not a requirement for the collection of Schedule 3 CDs.

3.10.3 It is good practice to keep a record of the name, address and role/relationship of the person collecting **Schedule 2 CDs**, particularly those people not previously known to pharmacy/dispensary staff. This information can be recorded in the CDR or in a separate CD collection book. The time at which the dispensed CD prescription was collected can also be recorded.

3.10.4. It is a legal requirement for pharmacists/GP dispensary staff to ascertain whether the person collecting a Schedule 2 CD is the patient, the patient's representative or a healthcare professional acting in their capacity as such.

3.10.5. Where the person collecting the prescription is a healthcare professional acting in his/her professional capacity on behalf of the patient, the dispenser must obtain the person's name and address (may use professional or work address) and must request evidence of that person's identity in the form of their professional registration number (unless already known). A supply of the drug may be made even if the dispenser is not satisfied as to the identity of that person. This enables the dispenser to use discretion in situations where the withholding of a CD from a patient could prevent the patient from having access to medicines that are needed and have been prescribed for them.

3.10.6. It is good practice for surgeries to follow similarly stringent policies in their issue of Schedule 2 CD **prescription forms** to patients or persons collecting **prescription forms** on their behalf who have not been previously known to surgery staff. Again, staff should ascertain whether the person is the patient, the patient's representative or a health care professional acting in their capacity as such (where this is not already known). Where the individual is not already known to the surgery staff, proof of identity should be requested and confirmed and a record kept of the name, address and role/relationship of the person collecting the Schedule 2 CD prescription form.

3.10.7 The Home Office has advised that Schedule 2, 3, and 4 Part 1 CDs should not be held at or collected from a central collection point, e.g. a Post Office.

3.10.8 Schedule 2, 3 and 4 Part 1 CDs must always be collected from the service or delivered direct from there to the patient's home.

3.11 Validity of Prescription

3.11.1 The validity period for prescriptions for Schedule 2, 3 and 4 CDs is 28 days from the date on which the prescription was signed and dated. This should minimise the risk of individuals accessing supplies of CDs a significant time after the clinical need was originally identified.

3.11.2 Schedule 2 and 3 CDs can not be prescribed on repeat dispensing prescriptions. Repeat dispensing prescriptions for Schedule 4 CDs must be dispensed for the first time within 28 days of the appropriate date, after which the repeats are legally valid within the stated periods of validity of the repeatable prescription. Schedule 5 CDs must be dispensed for the first time within 6 months of the appropriate date, after which the repeats are legally valid within the stated periods of validity of the repeatable prescription.

3.11.3 Owing balances for Schedule 2, 3, or 4 CDs cannot be dispensed and supplied later than 28 days after the date on the prescription. Owing balances for Schedule 5 CDs cannot be dispensed and supplied later than 6 months after the date on the prescription.

3.12 Quantities to be Supplied: Good Practice

3.12.1 Prescribers (both NHS and private) are strongly advised to restrict prescribed quantities of Schedule 2, 3, and 4 CDs to a maximum of 30 days' supply. In exceptional circumstances, where the prescriber believes that a supply in excess of 30 days is indicated and will not pose an unacceptable risk to the patient, a justification of the decision should be recorded in the patient's notes. It is not illegal for a pharmacist to dispense a prescription for CDs for more than 30 days supply, but they must satisfy themselves as to the clinical appropriateness of the prescription before doing so.

3.13 Preservation of Records

3.13.1 Registers, requisitions and orders for CDs must be preserved for a seven years.

3.13.2 The 2001 Regulations have been amended to allow the information contained in these records to be preserved in the original paper form or in computerised form. Where records are preserved on computer, adequate safeguards should be in place to ensure that data cannot be altered at a later date, that all data can be recalled for audit purposes, that adequate backups are made and that systems are in place to minimise the risk of unauthorised access to the data.

4. Schedule 3 Controlled Drugs (CD No Register)

4.1 Storage

4.1.1 Schedule 3 CDs are subject to the same safe custody requirements as detailed in paragraphs 3.1 to 3.3. However, all drugs in the Schedule are exempted except temazepam, diethylpropion, buprenorphine and flunitrazepam. This means that all temazepam, diethylpropion, buprenorphine and flunitrazepam preparations must, by law, be stored in a locked receptacle, usually in an appropriate CD cabinet or approved safe, which can only be opened by the person in lawful possession of the CD or a person authorised by him/her.

4.1.2 Diamorphine 30mg, 100mg and 500mg, and morphine 60mg should be placed in opaque sealable polythene bags that state: Warning: contains high dose opioid.

4.2 Requisition and Prescription Requirements

4.2.1 All Schedule 3 CDs are subject to the same requisition requirements as designated for Schedule 2 CDs (see point 2.6). Schedule 3 CDs are subject to the same prescription requirements as designated for Schedule 2 CDs.

4.3 CD Register

4.3.1 There is no legal requirement to record transactions involving Schedule 3 CDs in a CD Register.

4.4 Validity of Prescriptions

4.4.1 The validity period for prescriptions for Schedule 2, 3 and 4 CDs is 28 days from the date on which the prescription was signed and dated. This minimises the risk of individuals accessing supplies of CDs a significant time after the clinical need was originally identified. Further detail is provided in point 3.11.

5. Disposal of Controlled Drugs

5.1 Background

5.1.1 It is crucial that CDs are disposed of efficiently, safely and with robust procedures in place to minimise environmental impact and risk to public safety. The safe disposal of all medicines is important, but is particularly acute with CDs as they are at risk of being diverted or misused if disposal is not managed efficiently and safely and is not properly witnessed and recorded.

5.1.2 The Home Office has advised that all Schedule 2, 3, and 4 Part 1 CDs must be destroyed / denatured before being placed into waste containers.

5.1.3 The Environment Agency as part of The Environmental Permitting (England and Wales) Regulations 2010 has exempted pharmacies and GP practices from needing a license to denature CDs prior to disposal. A T28 exemption needs to be registered with the Environment Agency, which can be done on their website (www.environment-agency.gov.uk).

5.2 Patient-Returned Controlled Drugs

5.2.1 'Patient-returned' CDs are those that have been prescribed and dispensed for named patients and then returned unused or part-used for disposal. All Schedule 2, 3 and 4 part 1 patient-returned CDs must be denatured before disposal. These CDs can be denatured by staff working within a dispensing practice or community pharmacy without the supervision of an external authorised witness. However, the destruction should be witnessed and recorded by an appropriate member of staff (e.g. Pharmacist).

5.2.2 All CD destruction should be undertaken using an appropriate CD destruction kit. Destruction kits are available through NHS Supply Chain. The Royal Pharmaceutical Society issues professional guidance to pharmacists on the safe destruction of CDs; local guidance based on this can be found in Appendix 1 of this policy document.

5.2.3 Under no circumstances should patient-returned CDs be re-entered into the CDR and taken back into stock for dispensing to another patient at a later time even during periods of shortage of supply or where a returned pack is unopened, in date and in good condition. Recycling of CDs in this way is potentially both fraudulent and illegal.

5.2.4 Requirements for safe custody of CDs apply equally to patient returned CDs. These must be kept in the CD cabinet, segregated from stock CDs and clearly marked as returns until they can be destroyed.

5.2.5 Within community hospitals, patient's own CDs which are no longer required will be destroyed by the Community Hospital Pharmacist.

5.3 'Expired Stock' Controlled Drugs

5.3.1 'Expired-stock' CDs can be defined as all Schedule 2, 3 and 4 part 1 CDs that have not been issued/dispensed to a patient. Schedule 2 CD stock can only be destroyed in the presence of a person authorised by the Controlled Drugs Accountable Officer to witness destruction.

5.3.2 Requests for stock CD destruction within community hospitals should be directed to the ward pharmacist during the weekly check. All requests for witnessed destruction from other LCHS services should be directed to the supplying pharmacy, Lorna Adlington lorna.adlington@lincs-chs.nhs.uk or Karen Leggett Karen.leggett@lincs-chs.nhs.uk

5.3.3 All services holding stock CDs should have complete records of 'expired-stock' Schedule 2 CDs destroyed. Records should clearly indicate which member of staff was involved in disposal of each CD. Details of the drug must be entered in the CDR including drug name, form, strength and quantity, as well as date of destruction, the words: 'Out of date stock destroyed' or similar, the signature of the authorised person who witnessed destruction and the person/professional destroying it (i.e. two signatures). It is good practice for the authorised witness to print their name and job title after their signature in the CDR.

5.3.4 'Expired-stock' CDs requiring safe custody must continue to be stored in the CD cabinet/safe segregated from other stock CDs, for example in an envelope, clearly marked and retained within the running total until they can be destroyed.

5.3.5 There is no legal requirement for CDs, other than those defined as Schedule 2, to be disposed of in the presence of an authorised witness.

5.3.6 An authorised person cannot witness destruction of CDs that have been supplied to or by them.

5.4 Destruction of 'Expired Stock' Controlled Drugs: Authorised Witnesses

5.4.1 An amendment to The Misuse of Drugs Regulations 2001 allows the Controlled Drugs Accountable Officer to authorise people to witness destruction of CDs. The Controlled Drugs Accountable Officer cannot act as a witness themselves as they should be independent of day-to-day management of CDs.

5.5 Destruction of Controlled Drugs in the community following a Patient's Death

5.5.1 On the death of a patient, all their medication technically forms part of their estate, and usually comes under the control of the patient's relatives. However, it is illegal to possess controlled drugs that have been prescribed for someone else. For this reason, and to minimise the risk that controlled drugs may be sold on to others, or accidentally ingested by children, it is recommended that controlled drugs are destroyed as soon as possible after a patient's death. There are three means of doing this:

- destruction in the patient's home by a healthcare professional
- transportation of the controlled drugs to a pharmacy or dispensing general practice by a healthcare professional
- transportation of controlled drugs to a pharmacy or a dispensing GP by a patient's relative

All three means are lawful. The preferred method is for community nursing staff (if they have been caring for the patient) is to destroy the controlled drugs in the patient's own home using a CD destruction kit, normally during the first visit to the patient's home following death. When this is not possible, the patient's family or carer should be asked to return the CDs to a community pharmacy or the dispensing general practice that supplied the drugs.

6. Controlled drug discrepancies

6.1 Stock balances within the Controlled Drug Register and the Patients own Controlled Drug Register must always correspond with the amounts of CDs in the cupboard. If they do not, the discrepancy must be investigated and resolved. A Datix should be completed.

6.2 It is the responsibility of the health care professional in charge to ensure that the procedure for dealing with discrepancies is followed.

6.3 In the first instance 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 controlled drug register.
- Items have not been accidentally put into the wrong place in the cupboard
- Arithmetic to ensure that balances have been calculated correctly
- Items have not been transferred into a new CD register if more than one register in use.

6.4 A physical visual check of the balance of the stock in the CD cupboard should be undertaken.

6.5 If the original error renders the running stock balance incorrect and in the opinion of the authorised signatory could lead to a subsequent error, the balance should be clarified:

- A physical check of the balance of stock in the CD cupboard should be undertaken.

- On the next available line on that page an entry should be made. This should include the following:
  - Date and time of entry
  - The text 'Balance clarification'
  - The correct stock balance
  - The signature and qualifications of the authorised signatory.
  - The signature of the authorised witness.

This does NOT permit correction of an incorrect stock balance except when the incorrect balance is due to an identified arithmetic error, an erroneous entry or balance rendered unclear by poor handwriting.

6.6 If the error or omission is traced, the pharmacist, clearly stating the reason for the entry can amend the register and annotate the corrected balance. The entry should be witnessed and both persons will sign the controlled drug register.

6.7 The original error should be asterisks and linked to the amended entry in the register to provide clear evidence of chronology and provide clarity.

6.8 If no errors or omissions are detected then the discrepancy should be reported to the Accountable Officer without delay and an incident form completed in line with the Trust incident reporting procedures. The register should be updated by the pharmacist to reflect the amended provisional running balance (this should be approved by the CDAO).

<u>Liquid Controlled Drug discrepancies.</u>

6.8 Discrepancies with liquid CDs can arise as a result of manufacturer's overage, the measurement process or spillage. Consequently an overage or underage of 5% (12.5mls in a 250ml bottle) will be considered reasonable providing this is clearly documented and all checks (section 6.3 above) have taken place.

6.9 Stock balance checks of liquid medicines should be by visual inspection. The balance should be confirmed as correct on completion of the bottle by the service pharmacist.

6.10 **Bungs and syringes (Medicina oral tip syringes) must be used for measuring liquid CDs.** Ward pharmacists will check the bungs during stock checks to ensure that there is no leakage and will replace as necessary. Bungs are to remain in the bottle and not be removed after each administration.

6.11 Each new bottle of a liquid controlled drug should be entered onto a new page within the CD register to reduce the opportunity for any discrepancy to be carried forward. New unused bottles should be stored in a zip lock bag until required to reduce the opportunity for multiple bottles to be open at once.

6.12 If the overage/underage is in excess of the 5%, further investigation should take place to determine the cause of the discrepancy and arrangements made for the service pharmacist to adjust the balance in the CD record book. This should be reported to the CDAO.

6.13 Should an overage be recorded the balance should be checked (see point 6.3 above) and confirmed by the ward pharmacist following a visual inspection and the overage destroyed by the pharmacist to remove the unaccounted for volume. The pharmacist should then annotate the corrected balance and the register signed by both pharmacist and witness.

7. Transportation of Controlled Drugs

7.1 Nurses, midwives, doctors, pharmacists, pharmacy staff and other professionals plus formal carers and patients' representatives are legally allowed to transport CDs to the patient, provided the CD has been prescribed by an appropriate prescriber for that patient.

7.2 Any nominated individual is allowed to return CDs from the patient to pharmacy / practice for destruction.

7.3 Health care professionals involved in the delivery of patient care should not routinely transport CDs to and from the patient's home. It is recognised that in some circumstances this will be the only practical solution to collection and delivery problems.

7.4 CDs should be kept out of view when in transit.

7.5 CDs should not generally be transported via mail, taxi services or equivalent. Where urgent clinical need dictates and there is no other option, dispensed CDs can be sent to a patient via such routes. If the mail route is unavoidable, special delivery should be used to ensure that the pathway is auditable. If mail or taxi delivery is considered necessary on a regular basis, a standard operating procedure should be developed to cover all aspects of the process including a risk assessment.

7.6 Prescriptions for Schedule 2 CDs should not routinely be sent to the pharmacy or patient via the postal system but should be collected from the surgery by the patient, their representative, a health care professional or a member of their staff. If posting is unavoidable, a standard operating procedure should be developed to cover all aspects of the process including a risk assessment.

7.7 The Home Office has advised that prescriptions for Schedule 2, 3, or 4 Part 1 CDs should not be delivered to a central collection point e.g. Post Office for onward collection by the patient or patient's representative.

8. Information for patients

8.1 **Document** and give information to the person taking the controlled drug or the carer administering it, including:

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

9. Standard Operating Procedures (SOPs)

9.1 Standard Operating Procedures are required in all premises where CDs are handled (e.g. general practice, community pharmacy, urgent care services, community hospitals, community nursing services).

9.2 The Controlled Drugs Regulations 2013 require commissioner and provider organisations to have in place up to date SOPs in relation to the management and use of CDs. There is no longer a minimum list of SOPs that every organisation has to have in place; instead, the development and dissemination of SOPs are left to local determination and the discretion of Controlled Drugs Accountable Officers. However, SOPs must cover the prescribing, supply and administration of CDs and the clinical monitoring of patients who have been prescribed CDs.

9.3 It is recommended that SOPs cover all areas of CD management relevant to the service provided, for example

(1) ordering and receipt of CDs;
(2) assigning responsibilities;

(3) where CDs are stored;
(4) who has access to CDs;
(5) record keeping;
(6) administration;
(7) incidents / concerns;
(8) transport of CDs;
(9) destruction of CDs and
(10) clinical monitoring.

SOPs must be specific for the premises to which they apply.

9.4 SOPs should cover all aspects of risk management and they should include audit trails for ordering, storing, prescribing, dispensing, recording, supplying, administering and destruction of CDs, appropriate to the setting and the team. SOPs should highlight the accountabilities and roles of all members of the relevant healthcare teams.

9.5 More details on SOPs are provided in the Department of Health Guidance on Standard Operating Procedures for Controlled Drugs and in the local Policy on the Development of SOPs.

9.6 All SOPs are attached within this document.

10. Summary Table

	Schedule 2	Schedule 3	Schedule 4, Part I	Schedule 4, Part II	Schedule 5
Designation	CD POM	CD No Reg POM	CD Benz POM	CD Anab POM	CD Inv P or CD Inv POM
Safe custody	Yes, except secobarbital (quinalbarbitone)	No, except temazepam, diethylpropion, buprenorphine and flunitrazepam	No	No	No
Prescription requirements	Yes	Yes, except temazepam	No	No	No
Requisitions necessary	Yes	Yes	No	No	No
Records to be kept in a CD register	Yes	No	No (NB records are required to be kept for Sativex preferably in a CDR)	No	No
Repeats allowed on prescription (applies to private prescriptions only)	No	No	Yes	Yes	Yes
Dispensing by instalments (NHS)	Yes	No, except buprenorphine but only on FP10 (MDA)	No, except diazepam but only on FP10(MDA)	No	No
Stock destruction to be witnessed	Yes	No	No	No	No
Invoices to be retained for 7 years	Yes	Yes	No	No	Yes
Address of prescriber must be in the UK	Yes	Yes	No	No	No
Validity of prescription	28 days	28 days	28 days	28 days	6 months (if POM)

11. Accountable Officer for Controlled Drugs

11.1 The Controlled Drugs Regulations 2013 have replaced the 2006 Regulations and designate those healthcare providers that are required to appoint a Controlled Drugs Accountable Officer (CDAO). The CDAO is required to oversee and monitor the prescribing, dispensing and destruction of controlled drugs, e.g. by healthcare professionals within their organisation or in those they contract from.

11.2 The core duties and functions of the CDAO include: ensuring compliance with the Misuse of Drugs legislation, establishing systems for recording and reporting concerns or untoward incidents about CD use and ensuring that a range of up to date SOPs are available and regularly reviewed to support these governance arrangements.

11.3 The CDAO is responsible for the regular review and analysis of ePACT (electronic Prescribing Analysis and Costs) data on the prescribing of controlled drugs and will investigate further if there are any unusual prescribing patterns.

11.4 Lead CDAOs for NHS England Area Teams are required to set up and run the Local Intelligence Network (LIN). The LIN should facilitate the co-operation of its members to identify and share information, incidents and concerns about the safe management and use of CDs and to agree actions to be taken in respect of these matters.

11.5 All incidents and concerns (including complaints) involving the safe use and management of CDs should be reported to your CDAO using the relevant form:

- The interim CDAO for Lincolnshire Community Health Services is Lisa Stalley Green. She can be contacted at Beech House, Witham Park, Waterside South, Lincoln LN5 7JH. Tel 01522 308687 or 07891 678263 or email lisa.green@lincs-chs.nhs.uk

12. Care Quality Commission (CQC)

12.1 All providers of NHS general practice and other health and social care providers, for example out of hours services, hospitals and care homes, must be registered with the CQC. The CQC is responsible for inspecting these services, including the management of controlled drugs. The CQC will check, as part of these inspections that providers continue to meet the essential standards of quality and safety. For more information, see the CQC website www.cqc.org.uk

13. Further Information

For advice and further information on all aspects of Controlled Drug prescribing and dispensing please contact your CDAO.

Appendix 1

Destruction of Controlled Drugs (based on Royal Pharmaceutical Society Guidance for Pharmacists on the safe destruction of Controlled Drugs)

Methods and procedures for destruction	
Tablets, capsules and other solid dose forms	Remove from blister packaging (ensure gloves are worn) or bottle and place in a CD denaturing kit. Best practice would be to grind (using grinder in the box) or crush tablets and capsules before adding to the CD denaturing kit. NB if grinding or crushing solid dosage forms, ensure any particles of CD dust released into the air are minimised. Wear a suitable face mask, gloves and ensure the area is well ventilated.
Liquids	Liquids can be poured straight into the CD denaturing kit. Large quantities of liquids may need to be added and adsorbed into an appropriate amount of cat litter and then disposed of via the usual waste disposal method for medicines. The empty bottle should be rinsed out and the liquid disposed of into a pharmaceutical waste bin. Labels and other identifiers from the container should be removed or obliterated. The clean, empty container should be disposed of in the recycling waste.
Suppositories	Suppositories can be dissolved in a small quantity of hot water. The resulting liquid should be poured into the CD denaturing kit or added to an appropriate amount of cat litter as for liquids above.
Fentanyl patches	Remove the backing and fold the patch over onto itself and place in the CD denaturing kit. Suitable gloves must be worn.
Fentanyl lozenges	Dissolve in a small quantity of warm water. The resulting liquid should be poured into the CD denaturing kit or added to an appropriate amount of cat litter as for liquids above.
Liquid ampoules	Liquid ampoules should be opened, the liquid placed in the CD denaturing kit and the ampoule itself placed into a sharps bin which is labelled “contains mixed pharmaceutical waste and sharps – for incineration”. Suitable gloves should be worn.
Powder ampoules	Powder ampoules should have water added to dissolve the powder; the resulting mixture should be poured into the CD denaturing kit. The ampoule should be placed into a sharps bin which is labelled “contains mixed pharmaceutical waste and sharps – for incineration”. Suitable gloves should be worn.
Multiple use vials	The contents should be removed from the vial (using a syringe and needle) and added to the CD denaturing kit. The vial should be placed into a sharps bin which is labelled “contains mixed pharmaceutical waste and sharps – for incineration”. Suitable gloves should be worn.
Aerosol formulations	Aerosols should be expelled into water (to prevent droplets of drug entering the air) and the resultant liquid poured into the CD denaturing kit.
Doses of CD injections or liquids that are prepared but not administered or only partly used (and less than 5ml) must be destroyed immediately by being emptied into the blue bins or sharps bin in the ward/dept. by a Registered Nurse and witnessed by a competent member of staff. There must be a gel sachet in the bottom of the bin. Any amount 5ml and over must be denatured in the provided denaturing kit. The CD register must detail the amount given to the patient and the amount destroyed.	

WARD/ SERVICE CONTROLLED DRUG MANAGEMENT AUDIT TOOL

Persons Present:----------

Service / Ward: ----------

Date of Audit:----------

Aim:	To ensure compliancy with regulation of controlled drugs
Requirements:	Self-audit to be completed monthly and returned to the Medicines Management Team

Item	Question	Result	Comments
1	There is a definitive list of staff who can gain access to the CD cupboard and a process of entry should they be unavailable (Unscheduled care).	**Compliant / Non-compliant**	
2	Key to Controlled Drug cupboard is held by the appointed Practitioner in Charge or a delegated Practitioner acting as deputy (Ward).	**Compliant / Non-compliant**	
3	There are current in-date, and suitable for use stock items. Satisfactory arrangement of stock within the cupboard including clear segregation of strengths, separation of expired stock and patients' own drugs.	**Compliant / Non-compliant**	
4	There is an up to date printed list of clinical staff, and their signatures, authorised to order Controlled Drugs and is available. **Note: This list requires updating at least annually and signed by Service Manager**	**Compliant / Non-compliant**	
5	The CD register is appropriate for the use of drugs within the service i.e. Ward register for Community Hospitals, Patients own register for Community Hospitals and Hospice and Issues register for Unscheduled care	**Compliant / Non-compliant**	
6	The Controlled Drug Order Book, CD requisition forms and CD Register are kept in a locked cupboard. These must be accessible at audit.	**Compliant / Non-compliant**	
7	There is an accurate index in use within the register. As each page is completed the page number should be transferred from the last page in use to the new one. The new page number should also be reflected in the index.	**Compliant / Non-compliant**	
8	A representative sample of requisitions coincides with the register on checking the last 3 orders (less if no orders)	**Compliant / Non-compliant**	
9	Entries in the CD register demonstrate details of receipt of drugs with two signatures. **Note: Entries are in chronological order; section for each drug type, pages should be clearly identified.**	**Compliant / Non-compliant**	
10	The CD requisition form, order book and CD register are cross referenced to ensure accuracy of order and receipt of drugs.	**Compliant / Non-compliant**	
11	Balance of all CD stock is accurate including drugs balances that are carried forward to the next page	**Compliant Non-compliant**	
12	Received CD quantities are recorded in words not figures. Name and address of	**Compliant /**	

	supplier should be included e.g. Received from COOP Pharmacy, Witham St Hughs.	**Non-compliant**	
13	CD stocks are reconciled against the Controlled Drug Register each time the drug is given. Note: an AP or HCSW can witness if a second practitioner is unavailable. (Two signatures on supply.)	**Compliant / Non-compliant**	
14	Controlled Drug (CD) Order and Record Books are retained for seven years from the date of the final entry.	**Compliant / Non-compliant**	
15	Any errors in the register are appropriately amended, signed, dated and witnessed (any error should be marked with an asterisk and recorded at the bottom of the page or margin and not crossed out for transparency).	**Compliant / Non-compliant**	
16	All copies of FP10CDF forms and requisition forms are to be kept somewhere accessible for audit purposes. Staff must be aware of where to locate these in case of a CD delivery.	**Compliant / Non-compliant**	
17	There is an awareness of the written policy for reporting and investigating discrepancies in CD stocks. Staff must be aware of where to locate their CD SOP and the Handling and storage of Controlled Drugs policy.	**Compliant / Non-compliant**	
18	Controlled Drug register has all sections appropriately completed including (where appropriate) full details of who the drug was issued to i.e. ECP or Marie Curie including professional base address and full patient details including NHS number must be annotated.	**Compliant / Non-compliant**	
19	Controlled Drugs are stored in the original container issued by pharmacy.	**Compliant/ Non-compliant**	
20	All CDs going out of the issue register to the community MUST be in a pre labelled box with name and date annotated. Boxes must be issued as originally dispensed. **Do not** split packs unless a GP/pharmacist has dispensed them	**Compliant / Non-compliant**	
21	Hospital: 3 hospital charts to be checked against administration recorded within the register Urgent Care: 3 FP10CD's to be checked against administration within the register	**Compliant / Non-compliant**	
22	There is evidence that the local procedure for the destruction of Controlled Drugs has been followed and that the CD register confirms destruction by the Pharmacist and witness.	**Compliant / Non-compliant**	

SECTION 2

Community Hospitals
Controlled Drug Management

Standard Operating Procedures for the Management of Controlled Drugs in Skegness Hospital John Coupland Hospital Johnson Hospital Butterfly Hospice

Contents

I. SOP statement

SOP statement

Standard Operating Procedure for the Management of Controlled Drugs stocks within Community Hospitals.

Background	To ensure a standardised approach to the management of all Controlled Drugs within Community Hospitals.
Statement	This document outlines the procedures which will be followed to maintain a stock of controlled drugs available for the purpose described. Adherence to these procedures will ensure that all aspects of medicines management are fulfilled adequately and that practice is lawful and compliant with the Misuse of Drugs Act 1971 and amendments, and the Safer use of Controlled Drugs regulations.
Responsibilities	It is the responsibility of the Accountable Officer for controlled drugs for LCHS together with the medicines management specialists to review and update this SOP to ensure that practice remains lawful and that it is updated when changes to regulations are made. It is the responsibility of all staff members to be familiar with this SOP and to act strictly in accordance with its requirements in every aspect. .
Trainers	There are no additional training requirements associated with the implementation of this SOP.
Dissemination	Website
Resource implication	There are no additional resource implications

SOP comes in to effect	June 2017
SOP review date	June 2019
Purpose of Procedure	To ensure the ordering, recording, administration, security and destruction of Controlled Drugs is performed to the appropriate standard within the Ward/service environment through controls assurance practice or equivalent standards.
Relevant staff	All clinical staff with a requirement to order, record, administer or store Controlled Drugs. This includes, but is not restricted to: • Medical Staff • Qualified nurses • Pharmacy staff All such staff should have documented competence to undertake these tasks
Related Documents	• Policy for Prescribing, Supply, Storage and Disposal of Controlled Drugs (2017) • Policy for the Safe and Secure Handling of Medicines (2016) • Non-Medical Prescribing Policy (Dec 2016)

All staff who will be working to this SOP should sign below to say they have read and understood the SOP and agree to act in accordance with its requirements.

Name	Job Title	Signature	Date

Reconciliation of Stock Balances.

- **Any stocks of controlled drugs held within a ward MUST be reconciled against the CD register with sufficient frequency to ensure that discrepancies can be identified in a timely way**
- **All stock balances will be checked daily to avoid any discrepancies.**
- **The registered nurse in charge is responsible for ensuring that the regular CD check is carried out by staff in the ward or department.**
- **Any stocks of controlled drugs held within a ward MUST also be independently verified and reconciled by a pharmacist every 3 to 6 months.**
- **Any discrepancy found between the stocks held and the balance in the CD register must be immediately investigated by the ward manager, team co-ordinator or delegated senior member of staff.**
- **Where incorrect drugs or amounts have been supplied, the responsible supplying pharmacist at the pharmacy concerned should be contacted.**
- **If the reason for the discrepancy cannot be identified and corrected (such as an arithmetic error) then the Trusts Accountable Officer for Controlled Drugs (CDAO) must be notified, an IR1 completed as per Trust policy and a formal internal investigation undertaken. If this does not resolve the situation satisfactorily, the police will need to be informed.**

Signing for balances of CD's at Handover.

- **The CD policy states stock balances are checked daily by two members of staff, one trained staff and the other individual must be a competent person.**
- **Both the trained nurse and competent person MUST sign the appropriate documentation stating that the stock is correct and corresponds with the Controlled Drug Register Book**
- **A stock review should be prompted and the reasons for keeping a CD examined by senior nursing staff. Any unused stock should be destroyed.**

- The nurse in charge of the ward remains responsible for ensuring that a delegated task is performed correctly by an authorised colleague.
- It is the ward manager's responsibility to ensure that the supplying pharmacy has a copy of all authorised signatures for the ward and that the list is accurate and up to date. Pharmacy retains the right to refuse to supply to an unauthorised signatory.

Ordering, Recording, Administration and Security of Controlled Drugs Standard Operating Procedure		
1. ORDERING CONTROLLED DRUGS AS A STOCK SUPPLY		
Task	Staff	Notes
1.1 Complete an order using the ward CD Order book and FP10 CDF	Authorised Signatory	• Ensure the carbon paper is correctly inserted before completing the order in the order book. • Ensure that the order in the CD order book specifies the following details of the required preparation: ▪ Name ▪ Form ▪ Strength ▪ Quantity • Complete the FP10 CDF. Ensure that part B and C are completed with the following information: ▪ Name ▪ Strength ▪ Form ▪ Quantity (in words and figures) ▪ Reason for supply • Quantities should be ordered in complete packs • Reference should be made to the sample FP10 CDF on the ward.
1.2 Sign and date the order	Authorised Signatory	• The registered healthcare professional must be identifiable to the supplying pharmacy via a system of signature verification • The FP10 CDF should be signed by a prescriber.
1.3 Send the completed FP10 CDF to the pharmacy. The order book should be retained on the ward.	Authorised Signatory	• DO NOT REMOVE TOP WHITE COPY FROM BOOK AT THE TIME OF ORDERING. • The FP10 CDF form should be photocopied and placed in the FP10 CDF folder. • The reference number from the order book should be written on the photocopy of the FP10 CDF and the number of the FP10 CDF should be recorded on the appropriate page (white top copy) of the order book for cross referencing.
1.4	Pharmacist	• Each ward area should have an agreed CD stock list with indicative quantities. • A stock balance check takes place every 3 months by the ward pharmacist.
Under no circumstances can a Controlled Drug listed in Schedule 2 or 3 be supplied against a fax. The appropriate FP10 CDF MUST be used and sent to pharmacy for supply. A fax of the order may be sent to enable medication to be prepared ready for arrival of the order. The order book should not be sent. If ordering injectable opiates such as morphine, diamorphine or oxycodone, the ward should have access to naloxone injection (400 micrograms in 1mL) to reverse respiratory depression should it occur. If naloxone is not available as ward stock then it should be ordered from pharmacy at the same time as the opiate.		

Ordering, Recording, Administration and Security of Controlled Drugs Standard Operating Procedure		
2. RECEIVING CONTROLLED DRUGS AS WARD STOCK		
Task	Staff	Notes
2.1 The pharmacy transport bag or box containing the CD should be handed to a qualified member of the ward staff.	Delivery staff • Transport driver • Hospital porter • Nominated member of ward staff • Pharmacy staff • Receiving staff • Authorised signatory	• The bag should be handed personally to the receiving staff member by the delivering staff member. • The bag should not be left unattended
2.2 The seal on the delivery bag should be checked for signs of tampering.	Authorised signatory	• Any discrepancy should be reported as soon as possible to the supplying Pharmacy and an incident reported via the Trust reporting system.
2.3 The secure bag/box should be opened and the contents checked against the order	Authorised signatory	• Any discrepancy should be reported as soon as possible to the supplying Pharmacy and an incident reported via the Trust reporting system.
2.4 Complete the receiving documentation	Authorised signatory	• The pink carbon copy of the ward CD order book should be signed on the last line to confirm receipt. • The white copy of the CD order book should be removed and attached to the FP10 CDF photocopy.
2.5 Record the receipt in the ward CD register	Authorised signatory	• An entry should be made on the existing page of the CD register to provide a running total. • The entry must show ▪ Date of receipt ▪ Where received from (specify which Pharmacy) ▪ The amount received in word form only e.g. seven ▪ CD order number ▪ Stock balance ▪ Signature of the authorised signatory ▪ Signature of witness When a new bottle of a Controlled Drug oral solution (for example Oxycodone) is received this should be recorded on a new page with a new balance rather than on an existing page and adding to the running balance. The new bottle should be segregated within a clear plastic bag

		until required to be opened to ensure that only one bottle is in use at a time.
2.6 Place CD in the CD cupboard	Authorised signatory	• Place the CD in the CD cupboard immediately. It must remain under constant visual supervision at all times.
2.7 Schedule 3 CDs		• All Schedule 3 CDs are exempt from CD register entries. • Schedule 3 CDs include Temazepam, Flunitrazepam, Midazolam, Buprenorphine, Diethylpropion, Pheobarbital, Amylobarbital, Tramadol and other Barbiturates except Secobarbital (this is a schedule 2 CD). • NOTE: some ward areas prefer to keep these schedule 3 CDs in their CD register. This practice should be discretionary, only after agreement between the ward manager and ward pharmacist. If schedule 3 CDs are detailed in the CD register there must be clear annotation of 2 signatures.
2.8 Schedule 3 CDs. Place the CD in the cupboard if applicable.	Authorised signatory	• All Schedule 3 CDs are exempt from safe custody **except temazepam, diethylpropion, buprenorphine and flunitrazepam.** If the CD is one of the 4 mentioned above place it in the CD cupboard immediately. No register entry is necessary. This can be done by one trained staff.

To correct an error in the register, reference must be made by placing an asterisk next to the error and writing a dated footnote on the page, with a signature. If the error makes the current running balance of the preparation unclear, then an entry should be made on the next available line on that page including the date of the clarification, the signature of the qualified nurse making the clarification, the signature of a witness, the correct stock balance and the text 'Balance clarification'. The original error must not be obliterated or altered but should remain clearly legible – do NOT use correction fluid. The ward pharmacist may make such clarifications.

Any discrepancy found between physical stocks held and the balance in the register must be immediately investigated. If the reason for the discrepancy cannot be identified and corrected (such as an arithmetic error) then the Accountable Officer for Controlled Drugs must be notified, who will then initiate appropriate action.

Ordering, Recording, Administration and Security of Controlled Drugs Standard Operating Procedure		
3. ADMINISTERING A CONTROLLED DRUG FROM WARD STOCK SUPPLY		
Task	Staff	Notes
3.1 Take e-prescription on the cart/laptop to CD cupboard and select the correct medication	Authorised nurse	The e-prescription chart will indicate when a CD is due to be administered, either as part of a regular regimen or on an 'as required/PRN' basis
3.2 If using injectable opiates, ensure Naloxone injection is available.	Authorised nurse	Naloxone is used to reverse the actions of opiates in cases of respiratory depression. It may be used intramuscularly, although intravenous injection is preferred if suitably qualified and experienced staff are available.
3.3 Collect or measure the correct dose	Authorised nurse	**Bungs and syringes (Medicina oral tip syringes) must be used for measuring liquid CDs.** Ward pharmacists will check the bungs during stock checks to ensure that there is no leakage and will replace as necessary. Bungs are to remain in the bottle and not be removed after each administration.
3.4 Check the dose	Authorised witness	• The dose collected or measured must be checked against the prescription chart. Any calculations performed must also be checked as per Trust Policy 'Prescribing, Supply, Storage and Disposal of Controlled Drugs (February 2017) • **This must be an independent second check and not a confirmation check Any mathematical calculations should be completed independently and both results should be compared and correlate to confirm the correct dose before administration to the patient.**
3.5 Complete the Ward CD register	Authorised nurse Authorised witness	• The record should be made on the existing page for that CD of the Ward CD register to ensure continuity of stock management. • The record should include ▪ Date of administration ▪ Name of the patient being administered to ▪ Signature of the administering nurse ▪ Amount administered ▪ Revised stock balance ▪ Signature of witness
3.6 Confirm the identity of the patient	Authorised nurse and witness	• Identity should be confirmed by visual identification and verbal questioning (such as requesting confirmation of full name and date

		of birth) • The patient's identity wrist band should be checked against the prescription chart. • If any doubt remains, the medicine should not be administered and advice should be sought.
3.7 Administer the CD	Authorised nurse and witness	Tell the person having the controlled drug the name and dose of the drug before it is administered, unless circumstances prevent this. • Record the administration on the e-prescribing chart within the electronic system. • Both the nurse and the witness should sign the CD register and confirm the new balance. • The Authorised witness must see the CD being administered.
3.8 Dispose of any unused CD	Authorised nurse and witness	• Any medicine not used, or only partly used must be destroyed in the presence of a witness and an entry made in the CD register, signed by both parties. (See section 6). • The method of destruction will depend on local policy, but must render the dose unavailable for any further use. • See page 26 for part used CDs
3.9 Management of expired stock	Authorised nurse and witness	• Identify any expired stock. • Separate the expired stock from the 'in date' stock but leave it as part of the current running total. • Contact the ward pharmacist to destroy.

Ordering, Recording, Administration and Security of Controlled Drugs Standard Operating Procedure		
4. USE OF A PATIENT'S OWN CONTROLLED DRUGS (PODS)		
Task	Staff	Notes
4.1 Assess the item for suitability for re-use	Authorised signatory	• Authorised staff may be a nurse, pharmacist or pharmacy technician with documented competence to assess PODs. • Assessment should comply with Trust Controlled drug policy • The patient MUST verbally agree to the use of any PODs that are brought into the ward, whether the PODs are accepted for use or destruction. This documentation must be kept in the patient's notes. (See Self Administration of Medication documentation)
4.2 Store and record CDs not suitable for use as PODs	Authorised signatory Authorised witness	• Medicines not to be used must still be stored securely in the ward CD cupboard and an entry made in the current ward POD CD register. • It is best practice that patients own CDs are stored separately to stock items where possible, • These medicines must be returned back to the patient's residence or sent for destruction at the earliest opportunity (See section 6).
4.3 Store and record CDs suitable for use as PODs	Authorised signatory Authorised witness	• The CD should each be entered onto a separate page of the ward POD CD Register, clearly identifying the patient to whom it belongs. The CD POD should be stored in the ward CD cupboard. • The entry will be made on a separate page specific to the individual and will include the following: ➢ Name, strength, form and quantity of each CD ➢ Date and time of receipt by the ward ➢ Name of the patient who the CD is intended for ➢ Signature of the person making the entry ➢ Signature of the witness to the entry. ➢ A corresponding entry must be made in the POD CD register when the CDs are removed from the ward when the patient is discharged, following the guidance in Section 4.5 and including the following details: ➢ Date and time of collection ➢ Name and signature of patient/representative.
4.4 Administration of CD PODs	Authorised signatory Authorised witness	• PODs must only be administered to the patient whose name is on the label. • Administration should comply with the guidance provided in section 3 of this document, including the requirement to have naloxone on hand before administering injectable opiates.

4.5 Returning CD PODs to patients	Authorised signatory Authorised witness	• When the patient is discharged they will either take any remaining CD (whether used as POD or not) with them OR it will be destroyed in accordance with the relevant procedures. In either case the CD will be signed out of the ward CD POD register confirming the quantity returned or destroyed by the Authorised signatory and the authorised witness. • Patient consent should be obtained prior to destruction. This should be documented in the SystmOne record.
4.6 Continuity of supply	Ward Manager	• Where a patient is receiving CD PODs there must be adequate mechanisms in place to ensure that a stock supply is obtained before POD supplies run out (see CD ordering pathway)
Any medicine brought into the ward by a patient and assessed for suitability for re-use (i.e. POD) remains their property. A record should be kept of any CD's handed over to staff for safe keeping in the patient's documentation.		

Ordering, Recording, Administration and Security of Controlled Drugs Standard Operating Procedure		
5. PRESCRIBING AND SUPPLYING OF CONTROLLED DRUGS FOR DISCHARGE.		
Task	Staff	Notes
5.1 Select the appropriate stationary	Prescriber	• The appropriate stationery will depend upon the nature of the prescription required. • For planned discharges stock should be ordered on an FP10 in advance.
5.2 Write the prescription	Prescriber	• The prescription must comply with legal and Trust requirements for the prescribing of CDs. This includes the following: ▪ The name and address of the patient. ▪ The drug name, form and strength of the preparation ▪ In the case where a specific brand is required due to particular drug release properties, the brand must be stated on the prescription. This may take the place of the drug name; e.g. MST Continus (a brand of sustained release morphine sulphate tablets), Durogesic DTrans (a brand of patches delivering transdermal fentanyl at a specific rate). ▪ The total required quantity of the preparation or number of dose units in words AND numbers, ▪ The dose to be taken and the frequency. ▪ The handwritten signature of the prescriber ▪ The date of the prescription. • Of Schedule 2 & 3 CDs only TEMAZEPAM (a Schedule 3 CD) is exempt from CD prescription requirements. • Prescribers are advised to limit quantities of CDs to a maximum of one month's supply, taking into account any additional arrangements with the supplying pharmacy. • CD prescriptions are valid for 28 days from the date of prescribing. Beyond this time they are invalid. • A pharmacist is NOT allowed to dispense a prescription for a CD that does not comply with all legal requirements and it is an offence to issue an incomplete prescription for a CD. However, there are certain situations where the pharmacist can amend a CD prescription to ensure that it does comply with legislation. • The 'Controlled Drugs and Drug Dependence' section of the current BNF provides advice on the prescribing and use of these medicines.

5.3 Send the prescription to pharmacy		• The CD will be dispensed by the pharmacy in accordance with the pharmacy's own standard operating procedures.
5.4 Collecting urgent prescriptions on FP10 forms	Hospital Porter Patient's carer Ward staff	• The person collecting the CD must provide identification.
5.5 Receiving non-urgent prescriptions onto the ward	Transport driver Hospital porter Authorised signatory Authorised witness	• The bag should be handed personally to the receiving staff member by the delivering staff member. (See Section 2). • The bag should not be left unattended • Any discrepancy should be reported as soon as possible to the supplying Pharmacy department and an incident reported via the Trust reporting system.
5.6 Record the CDs on the ward	Authorised signatory	• When CDs are delivered to the ward an entry must be made into the ward's POD CD register. The entry will be made on a separate page specific to the individual and will include the following: ▪ Name, strength, form and quantity of each CD ▪ Date and time of receipt by the ward ▪ Name of the patient who the CD is intended for ▪ Signature of the person making the entry ▪ Signature of the witness to the entry. • A corresponding entry must be made in the POD CD register when the CDs are removed from the ward when the patient is discharged, following the guidance in Section 4.5 and including the following details: ▪ Date and time of collection ▪ Name and signature of patient/representative.
Under no circumstances can a Controlled Drug listed in Schedule 2 or 3 be supplied against a fax, The appropriate prescription MUST be sent to the pharmacy for supply in accordance with the pharmacy's own standard operating procedure for the dispensing of CDs.		

Ordering, Recording, Administration and Security of Controlled Drugs Standard Operating Procedure		
6. DESTRUCTION OF PATIENTS' OWN CONTROLLED DRUGS (POD) ON SITE WHEN NO LONGER REQUIRED. **[NB expired Ward stock CDs should only be destroyed by an Authorised Person]**		
Task	Staff	Notes
6.1 If applicable and able, gain consent to destroy POD.	TWO Authorised Signatory	• Ensure that the CD is no longer required on the ward, (is out of date, if patient's own is either no longer prescribed for that patient or the patient has died). • If appropriate seek consent from the patient. This should be documented within the SystmOne record • The ward pharmacist should be involved in the process of destruction.
6.2 Select the correct CD from the ward cupboard	TWO Authorised Signatory	• Ensure that the correct CD is removed from the ward CD cupboard.
6.3 Use CD Destruction Kit for tablets, Trans dermal patches and suspensions	TWO Authorised Signatory	• Follow instructions of Destruction kit set out by the manufacture • All transdermal patches must be exposed and stuck together in half prior to adding to the Destruction kit • Once the destruction kit has been used it must be kept for 24 hours in the CD cupboard. The destruction kit should then be disposed of by the ward Pharmacist or Pharmacy technician following waste management policy.

Ordering, Recording, Administration and Security of Controlled Drugs Standard Operating Procedure		
7. CORRECTING ERRORS IN THE WARD CD REGISTER		
Task	Staff	Notes
7.1 Confirm an error has occurred	Authorised signatory	• Before recording an error, confirm an error has occurred • If necessary, refer to a colleague or contact the ward Pharmacist (within working hours).
7.2 Mark the error with an asterisk	Authorised signatory	• Place an asterisk next to the error. • The error should not be crossed out or otherwise amended or obliterated. • Highlight the error using brackets **( ).**
7.3 Enter a signed and dated footnote	Authorised signatory	• The signed and dated footnote should detail the nature of the error and the correct information.
7.4 Clarify the stock balance if necessary	Authorised signatory	• If the original error renders the running stock balance unclear and in the opinion of the authorised signatory could lead to a subsequent error, the balance should be clarified. • Check the physical balance of the stock in the CD cupboard • On the next available line on that page an entry should be made. This should include the following: ▪ Date and time of entry ▪ The text 'Balance clarification' ▪ The correct stock balance ▪ The signature and qualifications of the authorised signatory. ▪ The signature of the authorised witness. • This does NOT permit correction of an incorrect stock balance except when the incorrect balance is due to an identified arithmetic error, an erroneous entry or balance rendered unclear by poor handwriting. • If an incorrect stock balance is identified this must be reported in accordance with the relevant procedure to the ward manager. It should also be reported via the Trust's incident reporting system. • Any discrepancy found between the physical stocks held and the balance in the register must be immediately investigated. If the reason for the discrepancy cannot be identified and corrected (such as an arithmetic error) then the Accountable Officer for Controlled Drugs must be notified, who will then initiate appropriate action.

SECTION 3
Community Hospitals
Controlled Drug Management

Standard Operating Procedures for Ordering, Re-ordering, Administration and Security of Controlled Drugs
For
Louth Community Hospital

Contents

II. SOP statement

SOP statement

Standard Operating Procedure for the Management of Controlled Drugs stocks within Louth Community Hospital.

Background	To ensure a standardised approach to the management of all Controlled Drugs within Community Hospitals.
Statement	This document outlines the procedures which will be followed to maintain a stock of controlled drugs available for the purpose described. Adherence to these procedures will ensure that all aspects of medicines management are fulfilled adequately and that practice is lawful and compliant with the Misuse of Drugs Act 1971 and amendments, and the Safer use of Controlled Drugs regulations.
Responsibilities	It is the responsibility of the Accountable Officer for controlled drugs for LCHS together with the medicines management specialists to review and update this SOP to ensure that practice remains lawful and that it is updated when changes to regulations are made. It is the responsibility of all staff members to be familiar with this SOP and to act strictly in accordance with its requirements in every aspect.

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Trainers	No additional training requirements associated with implementation of this SOP.
Dissemination	Website
Resource implication	There are no additional resource implications

SOP comes in to effect	July 2017
SOP review date	July 2019
Purpose of Procedure	To ensure the ordering, recording, administration, security and destruction of Controlled Drugs is performed to the appropriate standard within the Ward/service environment through controls assurance practice or equivalent standards. To adhere to the Trusts' *Safe and Secure Handling of Medicines Policy (2016); Policy for Prescribing, Supply, Storage and Disposal of Controlled Drugs (2016) and ULHT (2014) Medicines Management policy: Section 6. Controlled Drugs.*
Relevant staff	All clinical staff with a requirement to order, record, administer or store Controlled Drugs. This includes, but is not restricted to: • Medical Staff • Qualified nurses • Pharmacy staff All such staff should have documented competence to undertake these tasks

All staff who will be working to this SOP should sign below to say they have read and understood the SOP and agree to act in accordance with its requirements.

Name	Job Title	Signature	Date

Reconciliation of Stock Balances.

- **Any stocks of controlled drugs held within a ward MUST be reconciled against the CD register with sufficient frequency to ensure that discrepancies can be identified in a timely way**
- **All stock balances will be checked daily to avoid any discrepancies.**
- **The registered nurse in charge is responsible for ensuring that the regular CD check is carried out by staff in the ward or department.**
- **Any stocks of controlled drugs held within a ward MUST also be independently verified and reconciled by a pharmacist every 3 months. This should be witnessed and countersigned by an authorised nurse on the ward.**
- **Any discrepancy found between the stocks held and the balance in the CD register must be immediately investigated by the ward manager, team co-ordinator or delegated senior member of staff.**
- **Where incorrect drugs or amounts have been supplied, the responsible supplying pharmacist at the pharmacy concerned should be contacted.**
- **If the reason for the discrepancy cannot be identified and corrected (such as an arithmetic error) then the Trusts Accountable Officer for Controlled Drugs (CDAO) (for contact details see Appendix 1) must be notified, an IR1 completed as per Trust policy and a formal internal investigation undertaken. If this does not resolve the situation satisfactorily, the police will need to be informed.**

Signing for balances of CD's at Handover.

- **The CD policy states checking stock balances are checked daily by two members of staff, one trained staff and the other individual must be a competent person. The process in Louth expects that stock balances are checked every 24 hours by 2 trained members of staff.**
- **Both trained nurses MUST sign the appropriate documentation, in line with ULHT policy stating that the stock is correct and corresponds with the Controlled Drug Register Book. Stock balances are recorded and signatures added for each product.**
- **A stock review should be prompted and the reasons for keeping a CD examined by senior nursing staff if stock is not being used with unused stock returned by correct procedure to the hospital pharmacy.**

Ordering, Recording, Administration and Security of Controlled Drugs Standard Operating Procedure		
1. ORDERING CONTROLLED DRUGS AS A STOCK SUPPLY		
Task	Staff	Notes
1.1 Complete an order using the ward CD Order book.	Authorised Signatory	• Ensure that the carbon paper is correctly inserted before completing the order in the order book. • Only order one preparation per page. • Ensure that the order in the CD order book specifies the following details of the required preparation: ▪ Name ▪ Form ▪ Strength ▪ Quantity • Quantities should be ordered in complete packs
1.2 Sign and date the order and print name.	Authorised Signatory	• The registered healthcare professional must be identifiable to the supplying pharmacy via a system of signature verification • The prescriber must countersign each page of the order book. • When completed and countersigned the order book should be sent to the hospital pharmacy.
1.3 Send the completed FP10 CDF to the pharmacy.	Authorised Signatory	• DO NOT REMOVE TOP WHITE COPY FROM BOOK AT THE TIME OF ORDERING. • More than one preparation can be requested at any one time, provided each is ordered on a separate page of the order book in accordance with point 1.1 and 1.2 above.
1.4 Stock levels	Pharmacists	• Each ward area should have an agreed CD stock list with indicative quantities. • A stock balance check takes place every 3 months by the ward pharmacist.
Under no circumstances can a Controlled Drug listed in Schedule 2 or 3 be supplied against a fax. The appropriate FP10 CDF MUST be used and sent to the pharmacy for supply. A copy of the medication chart can be sent to further clarify the order if necessary. A fax of the order may be sent to enable the medication to be prepared ready for the arrival of the order.		
If ordering injectable opiates such as morphine, diamorphine or oxycodone, the ward, unit or team should have ready access to naloxone injection (400 micrograms in 1mL) to reverse respiratory depression should it occur. If naloxone is not available as ward stock then it should be ordered from pharmacy at the same time as the opiate.		

Ordering, Recording, Administration and Security of Controlled Drugs Standard Operating Procedure		
2. RECEIVING CONTROLLED DRUGS AS WARD STOCK		
Task	Staff	Notes
2.1 The pharmacy transport bag or box containing the CD should be handed to a qualified member of the ward staff.	Delivery staff • Transport driver • Hospital porter • Nominated member of ward staff • Pharmacy staff • Receiving staff • Authorised signatory	• The bag should be handed personally to the receiving staff member by the delivering staff member. • The bag should not be left unattended
2.2 The seal on the delivery bag should be checked for signs of tampering and the seal number should correspond with the number recorded on the 'CD pink' copy.	Authorised signatory	• Any discrepancy should be reported as soon as possible to the supplying Pharmacy and an incident reported via the Trust reporting system.
2.3 The secure bag/box should be opened and the contents checked against the order	Authorised signatory	• Any discrepancy should be reported as soon as possible to the supplying Pharmacy and an incident reported via the Trust reporting system.
2.4 Complete the receiving documentation	Authorised signatory	• The pink carbon copy of the ward CD order book should be signed on the last line to confirm receipt.

2.5
Record the receipt in the ward CD register
	Authorised signatory	• Details of the CDs received should be annotated in the CD order book.
		• The entry must show
		  • Date of receipt
		  • Where received from
		  • Amount received recorded in word form e.g. (seven)
		  • CD order number
		  • Stock balance
		  • Signature of the authorised signatory
		  • Signature of witness
		
		When a new bottle of a Controlled Drug oral

		solution (for example Oxycodone) is received this should be recorded on a new page with a new balance rather than on an existing page and adding to the running balance. The new bottle should be segregated within a clear plastic bag until required to be opened to ensure that only one bottle is in use at a time.
2.6 Place the CD in the CD cupboard	Authorised signatory	• The CD should be placed in the CD cupboard immediately. It must remain under constant visual supervision at all times.
2.7 Schedule 3 CDs	Authorised signatory	• All Schedule 3 CDs are exempt from CD register entries. • Schedule 3 CDs include Temazepam, Flunitrazepam, Midazolam, Buprenorphine, Diethylpropion, Pheobarbital, Amylobarbital, Tramadol and other Barbiturates except Secobarbital (this is a schedule 2 CD). • NOTE: some ward areas prefer to keep these schedules 3 CDs in their CD register. This practice should be discretionary and only after agreement between the ward manager and the ward pharmacist. If schedule 3 CDs are detailed in the CD register there must be clear annotation of 2 signatures.
2.8 Schedule 3 CDs. Place the CD in the cupboard if applicable.	Authorised signatory	• All Schedule 3 CDs are exempt from safe custody except temazepam, diethylpropion, buprenorphine and flunitrazepam. If the CD is one of the 4 mentioned above place it in the CD cupboard immediately. No register entry is necessary. This can be done by one trained member of staff.
To correct an error in the register, reference must be made by placing an asterisk next to the error and writing a dated footnote on the page, with a signature. If the error makes the current running balance of the preparation unclear, then an entry should be made on the next available line on that page including the date of the clarification, the signature of the qualified nurse making the clarification, the signature of a witness, the correct stock balance and the text 'Balance clarification'. The original error must not be obliterated or altered but should remain clearly legible – do NOT use correction fluid. The ward pharmacist may make such clarifications.		

Ordering, Recording, Administration and Security of Controlled Drugs Standard Operating Procedure		
3. ADMINISTERING A CONTROLLED DRUG FROM WARD STOCK SUPPLY		
Task	Staff	Notes
3.1 Take the e-prescription on the cart/laptop to the CD cupboard and select the correct medication	Authorised nurse	• The e-prescription will indicate when a CD is due to be administered, either as part of a regular regimen or on an 'as required/PRN' basis
3.2 If using injectable opiates, ensure Naloxone injection is to hand.	Authorised nurse	Naloxone is used to reverse the actions of opiates in cases of respiratory depression. It may be used intramuscularly, although intravenous injection is preferred if suitably qualified and experienced staff are available.
3.3 Collect or measure the correct dose	Authorised nurse	**Bungs and syringes (Medicina oral tip syringes) must be used for measuring liquid CDs.** Ward pharmacists will check the bungs during stock checks to ensure that there is no leakage and will replace as necessary. Bungs are to remain in the bottle and not be removed after each administration.
3.4 Check the dose	Authorised witness	• The dose collected or measured must be checked against the prescription chart. • Any calculations performed must also be checked as per Trust Policy 'Prescribing, Supply, Storage and Disposal of Controlled Drugs (LCHS 2016)).' • This MUST be an independent second check and not a confirmation check. **This must be an independent second check and not a confirmation check Any mathematical calculations should be completed independently and both results should be compared and correlate to confirm the correct dose before administration to the patient.**

3.5 Complete the Ward CD register	Authorised nurse Authorised witness	• The record should be made on the page of the Ward CD register corresponding to the CD order number against which the supply was made. • The record should include ▪ Date of administration ▪ Name of the patient being administered to ▪ Signature of the administering nurse ▪ Amount administered ▪ Revised stock balance ▪ Signature of witness
3.6 Confirm the identity of the patient	Authorised nurse and witness	• Identity should be confirmed by visual identification and verbal questioning (such as requesting confirmation of full name and date of birth) • The patient's identity wrist band should be checked against the prescription chart. • If any doubt remains, the medicine should not be administered and advice should be sought.
3.7 Administer the CD	Authorised nurse and witness	• Tell the person having the controlled drug the name and dose before it is administered, unless circumstances prevent this. • Record the administration on the e-prescribing chart within the electronic system by signing in the appropriate column. • Both the nurse and the witness should sign the CD register and confirm the new balance. • The Authorised witness must see the CD being administered.
3.8 Dispose of any unused CD	Authorised nurse and witness	• Any medicine not used, or only partly used must be destroyed in the presence of a witness and an entry made in the CD register, signed by both parties. (See section 6). • The method of destruction will depend on local policy, but must render the dose unavailable for any further use. • See page 26 for part used CDs
3.9 Management of expired stock	Authorised nurse and witness	• Identify any expired stock. • Separate the expired stock from the 'in date' stock but leave it as part of the current running total. • Contact the ward pharmacist to remove.

Ordering, Recording, Administration and Security of Controlled Drugs Standard Operating Procedure		
4. USE OF A PATIENT'S OWN CONTROLLED DRUGS (PODS)		
Task	Staff	Notes
4.1 Assess the item for suitability for re-use	Authorised signatory	• Authorised staff may be a nurse, pharmacist or pharmacy technician with documented competence to assess PODs. • Assessment should comply with Trust Controlled Drugs Policy • The patient MUST verbally agree to use of any PODs that are brought to the ward, whether PODs are accepted for use or destruction. This documentation must be kept in patient's notes. (See Self Administration of Medication documentation)
4.2 Store and record CDs not suitable for use as PODs	Authorised signatory Authorised witness	• Medicines not to be used must be stored securely in the ward CD cupboard and an entry made in the current ward POD CD register. • It is best practice that patients own CDs are stored separately to stock items where possible. • These medicines must be returned back to the patient's residence or sent for destruction at the earliest opportunity (See section 6).
4.3 Store / record CDs suitable for use as PODs	Authorised signatory Authorised witness	• The CD should each be entered onto a separate page of the ward POD CD Register, clearly identifying the patient to whom it belongs. The CD POD should be stored in the ward CD cupboard.
4.4 Administration of CD PODs	Authorised signatory Authorised witness	• PODs must only be administered to the patient whose name is on the label. • Administration should comply with the guidance provided in section 3 of this document, including the requirement to have naloxone on hand before administering injectable opiates.
4.5 Returning CD PODs to patients	Authorised signatory Authorised witness	• When the patient is discharged they will either take any remaining CD (whether used as POD or not) with them OR it will be destroyed in accordance with the relevant procedures. In either case the CD will be signed out of the ward CD POD register confirming the quantity returned or destroyed by the Authorised signatory and the authorised witness. • The process to return patients own CDs to pharmacy is detailed in Section 6.3 below. • Patient consent should be obtained prior to destruction. This should be documented in the systemOne record.
4.6 Continuity of supply	Ward Manager	• Where a patient is receiving CD PODs there must be adequate mechanisms in place to ensure a stock supply is obtained before POD supplies run out.
Any medicine brought into the ward by a patient and assessed for suitability for re-use (i.e. POD) remains their property. A record should be kept of any CD's handed over to staff for safe keeping in the patient's documentation.		

Ordering, Recording, Administration and Security of Controlled Drugs Standard Operating Procedure		
5. RETURNING CONTROLLED DRUGS (STOCK) TO THE HOSPITAL PHARMACY WHEN NO LONGER REQUIRED.		
Task	Staff	Notes
5.1 Inform Pharmacy there is a CD on the ward which is no longer required and needs returning or there is expired stock which needs returning.	Authorised signatory	• Ensure that the CD is no longer required on the ward.
5.2 Select the correct CD from the ward cupboard	Pharmacist/ pharmacy technician/ Authorised witness/authorised signatory	• Ensure that the correct CD is removed from the ward CD cupboard.
5.3 Write CD out of Ward CD register	Authorised signatory /witness Pharmacist / pharmacy technician	• The entry should include the following: ▪ Date of return ▪ Where returned to ▪ Quantity being returned ▪ Amended stock balance ▪ Signature of the pharmacy staff ▪ Signature of the authorised witness.
5.4 Secure CD in a sealed container	Authorised signatory / pharmacy staff Authorised witness	• A pharmacy bag or box should be used
5.5 Complete the Pharmacy Returns book	Pharmacy staff/Authorised signatory Authorised witness	• The Pharmacy Returns book should be completed with the date, name of drug being returned, amount being returned. • The member of pharmacy staff and the authorised signatory should both sign the returns book. • Pharmacist/Pharmacy technician will retain the top copy and leave the Returns book on the ward. • Pharmacist/Pharmacy technician will then transport the CD in its secure bag/box back to Pharmacy for destruction.
Any discrepancy found between the physical stocks held and the balance in the register must be immediately investigated. If the reason for the discrepancy cannot be identified and corrected (such as an arithmetic error) then the Accountable Officer for Controlled Drugs must be notified, who will then initiate appropriate action.		

Ordering, Recording, Administration and Security of Controlled Drugs Standard Operating Procedure		
6. DESTRUCTION OF PATIENTS' OWN CONTROLLED DRUGS (POD) WHEN NO LONGER REQUIRED. **[NB expired Ward stock CDs should only be destroyed by an Authorised Person; usually the Hospital Pharmacist]**		
Task	Staff	Notes
6.1 If applicable and able, gain consent to destroy POD.	TWO Authorised Signatory	• Ensure that the CD is no longer required on the ward, (is out of date, if patient's own is either no longer prescribed for that patient or the patient has died). • All CDs (PODs and stock) are returned to the hospital pharmacy by the ward pharmacist. No destruction takes place in ward areas. This is best practice, ensures secure disposal and is consistent.
6.2 Select the correct CD from the ward cupboard	TWO Authorised Signatory	• Ensure that the correct CD is removed from the ward CD cupboard.
6.3 Write CD out of CD register	TWO Authorised Signatory	• The entry should include the following: ▪ Date of return ▪ Where returned to ▪ Quantity being returned ▪ Amended stock balance ▪ Signature of both Authorised Nurse and pharmacist returning the CDs to pharmacy. ▪ Amend to patients notes if applicable

Ordering, Recording, Administration and Security of Controlled Drugs Standard Operating Procedure		
7. PRESCRIBING AND SUPPLYING URGENT AND NON-URGENT CONTROLLED DRUGS FOR DISCHARGE		
Task	Staff	Notes
7.1 Select the appropriate stationary	Prescriber	• Planned discharges; use current discharge prescription ideally 24hrs prior to planned discharge • Urgent unplanned discharges, where hospital pharmacy is closed, use an FP10 form and obtain TTOs from a local pharmacy where this is acceptable
7.2 Write the prescription	Prescriber	• The prescription must comply with legal and Trust requirements for the prescribing of CDs. This includes the following: ▪ The name and address of the patient. ▪ The drug name, form and strength of the preparation ▪ In the case where a specific brand is required due to particular drug release properties, the brand must be stated on the prescription (Discuss with Pharmacist) ▪ The total required quantity of the preparation or number of dose units in words AND numbers, ▪ The dose to be taken and the frequency. ▪ The handwritten signature of the prescriber ▪ The date of the prescription. • Of Schedule 2 & 3 CDs only TEMAZEPAM (a Schedule 3 CD) is exempt from CD prescription • Prescribers are advised to limit quantities of CDs to a maximum of 2 weeks supply • CD prescriptions are valid for 28 days from the date of prescribing. Beyond this time they are invalid. • A pharmacist is NOT allowed to dispense a prescription for a CD that does not comply with all legal requirements and it is an offence to issue an incomplete prescription for a CD. • The 'Controlled Drugs and Drug Dependence' section of the current BNF provides advice on the prescribing and use of these medicines.
7.3 Send the prescription to pharmacy		• The CD will be dispensed by the pharmacy in accordance with the pharmacy's own standard operating procedures.

7.4 Collecting discharge prescriptions	RGN Patients carer or nominated representative	• Supply made in accordance with the supplying pharmacy SOP • The person collecting the CD must provide ID • The pharmacist is permitted to use their discretion as to whether to allow collection in the absence of such evidence of ID • Controlled drugs will be packaged in sealed wallets with a numbered security tag • On return to the ward, where patients are being discharged imminently, the medication may be handed to the patient with other discharge medication. The medication, including controlled drugs, must be checked with another appropriately trained nurse against the discharge prescription, and both nurses sign to indicate supply to the patient. If the discharge is to be delayed, the controlled drugs for discharge should be stored in a designated cupboard for patients own controlled drugs, and an entry made in the appropriate register. (See 7.6 below).
7.5 Receiving non-urgent prescriptions onto the ward	RGN or exceptionally pharmacy staff	• The bag should be handed personally to the receiving staff member by the delivering staff member. • The bag should not be left unattended • Any discrepancy should be reported as soon as possible to the supplying Pharmacy department and an incident reported via the Trust reporting system.
7.6 Record the CDs on the ward	Authorised signatory	• Where CDs for TTO are delivered to the ward, and the patient is not departing imminently, an entry must be made in the ward's POD CD register. The entry will be made on a separate page specific to the individual and will include the following: ▪ Name, strength, from and quantity of each CD ▪ Date and time of receipt by the ward ▪ Name of the patient who the CD is intended for ▪ Signature of the person making the entry ▪ Signature of the witness to the entry. • A corresponding entry must be made when the CDs are removed from the ward when the patient is discharged, following the guidance in Section 4.5 and including the following details: ▪ Date and time of collection ▪ Name and signature of patient/representative.

Ordering, Recording, Administration and Security of Controlled Drugs Standard Operating Procedure		
8. CORRECTING ERRORS IN THE WARD CD REGISTER		
Task	Staff	Notes
8.1 Confirm an error has occurred	Authorised signatory	• Before recording an error, ensure an error has occurred • If necessary, refer to a colleague or contact the hospital pharmacy (within working hours).
8.2 Mark the error with an asterisk	Authorised signatory	• An asterisk should be placed next to the error. • The error should not be crossed out or otherwise amended or obliterated. • Error should be highlighted using brackets **( ).**
8.3 Enter a signed and dated footnote	Authorised signatory	• A signed and dated footnote should detail the nature of the error and the correct information.
8.4 Clarify the stock balance if necessary	Authorised signatory	• If the original error renders the running stock balance for the CD unclear and in the opinion of the authorised signatory could lead to a subsequent error, the balance should be clarified. • Check the physical balance of the stock in the CD cupboard • On the next available line on that page an entry should be made. This should include the following: ▪ Date and time of entry ▪ The text 'Balance clarification' ▪ The correct stock balance ▪ The signature and qualifications of the authorised signatory. ▪ The signature of the authorised witness. • This does NOT permit the correction of an incorrect stock balance other than when the balance is incorrect due to an identified arithmetic error, an erroneous entry or a balance rendered unclear due to poor handwriting. • If an incorrect stock balance is identified this must be reported to the ward manager and hospital pharmacy. It should also be reported via the Trust's incident reporting system. • Any discrepancy found between the physical stocks held and the balance in the register must be immediately investigated. If the reason for the discrepancy cannot be identified and corrected (such as an arithmetic error) then the Accountable Officer for Controlled Drugs must be notified, who will then initiate appropriate action.

SECTION 4

Standard Operating Procedures for the Management of Controlled Drugs within the Theatre Department John Coupland Hospital

Lincolnshire Community Health Services
Contents

III. Policy statement

Policy statement

Standard Operating Procedure for the Management of Controlled Drugs within Theatres, John Coupland Hospital.

Background	To ensure a standardised approach to the management of all Controlled Drugs within the Theatre Department, John Coupland Hospital.
Statement	This document outlines the procedures which will be followed to maintain a stock of controlled drugs available for the purpose described. Adherence to these procedures will ensure that all aspects of medicines management are fulfilled adequately and that practice is lawful and compliant with the Misuse of Drugs Act 1971 and amendments, and the safer use of Controlled Drugs regulations.
Responsibilities	It is the responsibility of the Accountable Officer for controlled drugs for LCHS together with the medicines management specialists to review and update this SOP to ensure that practice remains lawful and that it is updated when changes to regulations are made. It is the responsibility of all staff members to be familiar with this SOP and to act strictly in accordance with its requirements in every aspect.

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Trainers	There are no additional training requirements associated with the implementation of this SOP.
Dissemination	Website
Resource implication	There are no additional resource implications

SOP comes in to effect	February 2017
SOP review date	February 2019
Purpose of Procedure	To ensure the ordering, recording, administration, security and destruction of Controlled Drugs is performed to the appropriate standard within the Ward/service environment through controls assurance practice or equivalent standards. To adhere to the '*Safe and Secure Handling of Medicines Policy' (2016)* and '*Policy for Prescribing, Supply, Storage and Disposal of Controlled Drugs' 1st Edition (2016).*
Relevant staff	All clinical staff with a requirement to order, record, administer or store Controlled Drugs. This includes, but is not restricted to: • Medical Staff • Qualified nurses • Pharmacy staff • Operating Department Practitioners. All such staff should have documented competence to undertake these tasks. Registered Operating Department Practitioners (ODP) work under the direct supervision of the Surgeon. The Surgeon directs administration and must be present when drugs are administered by these practitioners.
Related Documents	• Policy for Prescribing, Supply, Storage and Disposal of Controlled Drugs in Primary Care (2016) • Safe and Secure Handling of Medicines policy (2016) • Non-Medical Prescribing Policy (2015)

Author Signature: Date:	Name: Position:
Approval Signature: Date:	Name: Position: Service manager **Has responsibility for authorising the use of the SOP and ensuring it complies with any relevant legislation that may cover the procedures detailed within.**

All staff who will be working to this SOP should sign below to say they have read and understood the SOP and agree to act in accordance with its requirements.

Name	Job Title	Signature	Date

Reconciliation of Stock Balances.

- **Any stocks of controlled drugs held within the surgical day care department / theatres MUST be reconciled against the CD register with sufficient frequency to ensure that discrepancies can be identified in a timely way**
- **All stock balances will be checked daily when theatres are in use to avoid any discrepancies.**
- **The registered practitioner in charge is responsible for ensuring that the regular CD check is carried out by staff in the department.**
- **Any stocks of controlled drugs held within the department MUST also be independently verified and reconciled by a pharmacist every 3 to 6 months.**
- **Any discrepancy found between the stock held and the balance in the CD register must be immediately investigated by the department manager, team co-ordinator or delegated senior member of staff.**
- **Where incorrect drugs or amounts have been supplied, the responsible supplying pharmacist at the pharmacy concerned should be contacted.**
- **If the reason for the discrepancy cannot be identified and corrected (such as an arithmetic error) then the Trusts Accountable Officer for Controlled Drugs (CDAO) (for contact details see Appendix 1) must be notified, an IR1 completed as per Trust policy and a formal internal investigation undertaken. If this does not resolve the situation satisfactorily, the police will need to be informed.**

Signing for balances of Controlled Drugs.

- **The CD policy suggests checking stock balances are checked daily by two members of staff, one trained staff and the other individual must be a competent person. Within this department these daily checks will take place on the days that theatre is in use.**
- **Both the trained practitioner and competent person MUST sign the appropriate documentation stating that the stock is correct and corresponds with the Controlled Drug Register Book**
- **A stock review should be prompted and the reasons for keeping a CD examined by senior nursing staff. Any unused stock should be destroyed by department pharmacist and qualified member of staff.**

The practitioner in charge of the department remains responsible for ensuring that a delegated task is performed correctly by an authorised colleague.

It is the department manager's responsibility to ensure that the supplying pharmacy has a copy of all authorised signatures for the department and that the list is accurate and up to date. Pharmacy retains the right to refuse to supply to an unauthorised signatory.

Ordering, Recording, Administration and Security of Controlled Drugs Standard Operating Procedure		
1. ORDERING CONTROLLED DRUGS AS A STOCK SUPPLY		
Task	Staff	Notes
1.1 Complete an order using the CD Order book and FP10 CDF	Authorised Signatory	• Ensure the carbon paper is correctly inserted before completing the order in the order book. • Ensure the order in the CD order book specifies the following details of the required preparation: ▪ Name ▪ Form ▪ Strength ▪ Quantity • Complete the FP10 CDF. Ensure part B and C are completed with the following information: ▪ Name ▪ Strength ▪ Form ▪ Quantity (in words and figures) ▪ Reason for supply • Quantities should be ordered in complete packs • Reference should be made to the sample FP10 CDF within the department.
1.2 Sign and date the order	Authorised Signatory	• The registered healthcare professional must be identifiable to the supplying pharmacy via a system of signature verification. • The FP10 CDF should be signed by a prescriber.
1.3 Send the completed FP10 CDF to the pharmacy. The order book should be retained within the department.	Authorised Signatory	• DO NOT REMOVE TOP WHITE COPY FROM BOOK AT THE TIME OF ORDERING. • The FP10 CDF form should be photocopied and placed in the FP10 CDF folder. • The reference number from the order book should be written on the photocopy of the FP10 CDF for cross referencing. • Theatre staff will complete a delivery sheet and leave with the FP10CDF order form for the delivery driver to sign on collection. This should be kept by theatres
Under no circumstances can Controlled Drugs listed in Schedule 2 or 3 be supplied against a fax. The appropriate FP10 CDF MUST be used and sent to pharmacy for supply. A copy of the medication chart can be sent to further clarify the order if necessary. A fax of the order may be sent to enable medication to be prepared ready for arrival of the order. The order book should not be sent.		
If ordering injectable opiates, morphine, diamorphine or oxycodone, the Surgical Day Care department and theatres should have access to naloxone injection (400 micrograms in 1mL) to reverse respiratory depression should it occur. If naloxone is not available as stock then it should be ordered from pharmacy at the same time as the opiate.		

Ordering, Recording, Administration and Security of Controlled Drugs Standard Operating Procedure		
2. RECEIVING CONTROLLED DRUGS AS STOCK		
Task	Staff	Notes
2.1 The pharmacy transport bag or box containing the CD should be handed to a qualified member of the department staff.	Delivery staff • Transport driver • Hospital porter • Nominated member of department staff • Pharmacy staff • Receiving staff • Authorised signatory	• The bag should be handed personally to the receiving staff member by the delivering staff member. • The bag should not be left unattended
2.2 Check the seal on the delivery bag for signs of tampering.	Authorised signatory	• Any discrepancy should be reported as soon as possible to the supplying Pharmacy and an incident reported via the Trust reporting system.
2.3 The secure bag/box should be opened and contents checked against the order	Authorised signatory	• Any discrepancy should be reported as soon as possible to the supplying Pharmacy and an incident reported via the Trust reporting system.
2.4 Complete the receiving documentation	Authorised signatory	• The pink carbon copy of the CD order book should be signed to confirm receipt. • The white copy of the CD order book should be removed and attached to the FP10 CDF photocopy.

2.5
Record the receipt in the department CD register
	Authorised signatory	• An entry should be made on the existing page of the CD register to provide a running total.
		• The entry must show
		  • Date of receipt
		  • Where received from
		  • The amount received in word form only e.g. seven
		  • CD order number
		  • Stock balance
		  • Signature of the authorised signatory
		  • Signature of witness

2.6 Place the CD in the CD cupboard	Authorised signatory	• The CD should be placed in the CD cupboard immediately. It must remain under constant visual supervision at all times.
2.7 Schedule 3 CDs		• All Schedule 3 CDs are exempt from CD register entries. • Schedule 3 CDs include Temazepam, Flunitrazepam, Midazolam, Buprenorphine, Diethylpropion, Phenobarbital, Amylobarbital, Tramadol and other Barbiturates except Secobarbital (this is a schedule 2 CD).

2.8 Schedule 3 CDs. Place the CD in the cupboard if applicable.	Authorised signatory	• All Schedule 3 CDs are exempt from safe custody **except temazepam, diethylpropion, buprenorphine and flunitrazepam.** If the CD is one of the 4 mentioned above place it in the CD cupboard immediately. • No register entry is necessary. • This can be done by one trained staff.
To correct an error in the register, reference must be made by placing an asterisk next to the error and writing a dated footnote on the page, with a signature. If the error makes the current running balance of the preparation unclear, then an entry should be made on the next available line on that page including the date of the clarification, the signature of the qualified practitioner making the clarification, the signature of a witness, the correct stock balance and the text 'Balance clarification'. The original error must not be obliterated or altered but should remain clearly legible – do NOT use correction fluid. The department pharmacist may make such clarifications.		
Any discrepancy found between the physical stocks held and the balance in the register must be immediately investigated. If the reason for the discrepancy cannot be identified and corrected (such as an arithmetic error) then the Accountable Officer for Controlled Drugs must be notified, who will then initiate appropriate action.		

Ordering, Recording, Administration and Security of Controlled Drugs Standard Operating Procedure		
3. ADMINISTERING A CONTROLLED DRUG FROM STOCK SUPPLY		
Task	Staff	Notes
3.1 Take the treatment card to the CD cupboard and select the correct medication	Authorised practitioner	• The treatment chart will indicate when a CD is due to be administered, either as part of a regular regimen or on an 'as required/PRN' basis
3.2 If using injectable opiates, ensure Naloxone injection is to hand.	Authorised practitioner	Naloxone is used to reverse the actions of opiates in cases of respiratory depression. It may be used intramuscularly, although intravenous injection is preferred if suitably qualified and experienced staff are available.
3.3 Collect or measure the correct dose	Authorised practitioner	Bungs and syringes must be used for measuring all liquid CDs. **Bungs and syringes (Medicina oral tip syringes) must be used for measuring liquid CDs.** Ward pharmacists will check the bungs during stock checks to ensure that there is no leakage and will replace as necessary. Bungs are to remain in the bottle and not be removed after each administration.
3.4 Check the dose	Authorised witness	• The dose collected or measured must be checked against the prescription chart. This MUST be an independent second check and not a confirmation check. • Any pre-drawn up drugs MUST NOT be left unattended at any time. These drugs should remain with the surgeon and the patient for whom they are intended. Any unused CDs should be disposed of in the presence of a witness and an entry made in the CD register, signed by both parties. • Any calculations performed must also be checked as per Trust Policy 'Prescribing, Supply, Storage and Disposal of Controlled Drugs (2016)'
3.5 Complete the department CD register	Authorised practitioner Authorised witness	• The record should be made on the existing page for that CD of the departments CD register to ensure continuity of stock management. • The record should include ▪ Date of administration ▪ Name of the patient being administered to ▪ Signature of the administering practitioner ▪ Amount administered ▪ Revised stock balance ▪ Signature of witness

3.6 Confirm the identity of the patient	Authorised practitioner and witness	• Identity should be confirmed by visual identification and verbal questioning (such as requesting confirmation of full name and date of birth whilst the patient is conscious). • The patient's identity wrist band should be checked against the prescription chart. • Whilst the patient is undergoing surgery identification should have been confirmed prior to procedure and the patients identify wrist band should be checked at all times. • If any doubt remains, the medicine should not be administered and advice should be sought.
3.7 Administer the CD	Authorised practitioner and witness	• Record the administration on the treatment chart by signing in the appropriate column. Both the practitioner and the witness should sign. • The Authorised witness must see the CD being administered. • Additional doses of CDs required peri-operatively must be prescribed by the Surgeon prior to surgery. The registered practitioner will then be able to administer following instruction from the surgeon during the surgical procedure. • CDs should not be administered following a verbal order.
3.8 Dispose of any unused CD	Authorised practitioner and witness	• Any medicine not used, or only partly used must be destroyed in the presence of a witness and an entry made in the CD register, signed by both parties. (See section 4). • The method of destruction will depend on local policy, but must render the dose unavailable for any further use. • See page 26 for part used CDs
3.9 Management of expired stock	Authorised practitioner and witness	• Identify any expired stock. • Separate the expired stock from the 'in date' stock but leave it as part of the current running total. • Contact the department pharmacist to destroy the expired stock.

Ordering, Recording, Administration and Security of Controlled Drugs Standard Operating Procedure		
4. DESTRUCTION OF CONTROLLED DRUGS **[Note: expired department stock CDs should only be destroyed by an Authorised Person]**		
Task	Staff	Notes
4.1 Stock for destruction.	TWO Authorised Signatory	• Identify the stock for destruction – either expired stock or stock no longer required by the department. • For all department stock the ward pharmacist must be involved in the process of destruction.
4.2 Select the correct CD from the ward cupboard	TWO Authorised Signatory	• Ensure that the correct CD is removed from the ward CD cupboard.
4.3 Use CD Destruction Kit for tablets, Trans dermal patches, ampoules and suspensions	TWO Authorised Signatory	• Follow instructions of Destruction kit set out by the manufacture • All transdermal patches must be exposed and stuck together in half prior to adding to the Destruction kit • Once the destruction kit has been used it should then be disposed of by the department Pharmacist following local waste management policy.
4.4 Disposal of any unused CDs.	Authorised practitioner Authorised witness	• Any medicines not used, or only partly used, must be destroyed in the presence of a witness and an entry made in the CD register, signed by both individuals. • This includes all unused or partly used stock used peri-operatively.

Ordering, Recording, Administration and Security of Controlled Drugs Standard Operating Procedure		
5. CORRECTING ERRORS IN THE DEPARTMENT CD REGISTER		
Task	Staff	Notes
5.1 Confirm an error has occurred	Authorised signatory	• Before recording an error, ensure an error has occurred • If necessary, refer to a colleague or contact the hospital pharmacy (within working hours).
5.2 Mark the error with an asterisk	Authorised signatory	• Place an asterisk next to the error. • The error should not be crossed out or otherwise amended or obliterated. • Highlight the error using brackets **( ).**
5.3 Enter a signed and dated footnote	Authorised signatory	• The signed and dated footnote should detail the nature of the error and the correct information.
5.4 Clarify the stock balance if necessary	Authorised signatory	• If the original error renders the running stock balance for the CD unclear and in the opinion of the authorised signatory could lead to a subsequent error, the balance should be clarified. • Check the physical balance of the stock in the CD cupboard • On the next available line on that page an entry should be made. This should include the following: ▪ Date and time of entry ▪ The text 'Balance clarification' ▪ The correct stock balance ▪ The signature and qualifications of the authorised signatory. ▪ The signature of the authorised witness. • This does NOT permit the correction of an incorrect stock balance other than when the balance is incorrect due to an identified arithmetic error, an erroneous entry or a balance rendered unclear due to poor handwriting. • If an incorrect stock balance is identified this must be reported in accordance with the relevant procedure to the pharmacy and department manager. It should also be reported via the Trust's incident reporting system.

SECTION FIVE

Standard Operating Procedure for Management of Controlled Drugs within Community Nursing Services

Contents

i. Policy statement

SOP Statement

Background	This Standard Operating Procedure has been developed to promote the safe, secure and effective use of and destruction of all Controlled Drugs within Lincolnshire Community Health Services Community Nursing Teams
Statement	This SOP covers all aspects of the handling of Controlled Drugs within LCHS Community Nursing Services including ordering, receipt, transportation, safe storage, supply, administration, destruction and guidance for dealing with incidents involving controlled drugs.
Responsibilities	Compliance with the SOP will be the responsibility of Service Leads and all clinicians and practitioners who have signed up to work within its guidelines and processes.
Training	It is the responsibility of operational managers and service leads to ensure that appropriate mechanisms are in place to support the implementation of this SOP, including appropriate training and maintenance of the competencies outlined within the SOP.
Dissemination	Trust website, Email, Monthly Team Brief, Via Operational Managers and Service Leads
Resource implication	There are no additional resource implications
Consultation	Where possible all interested parties were involved and included in this process.

Section One

SOP comes into effect	February 2017
SOP review date	February 2019
Purpose	To promote the safe, secure, effective use and destruction of all controlled drugs (CDs) within Lincolnshire Community Health Services (LCHS) Community Nursing Services. It is a legal requirement that every Trust should have SOPs for handling CDs for all of its directly managed services and staff. These SOPs must be known, understood and followed by all practitioners and staff working within the Lincolnshire Community Health Services Integrated Community Teams.
Scope	This SOP covers all aspects of handling CDs within LCHS Community Nursing Services; ordering, receipt, transport, safe storage, supply, administration, destruction and guidance for dealing with an incident.

Lead Author Signature: Date:	Name:
Approval Signature: Date:	Name: Position: **Has responsibility for authorising the use of the SOP and ensuring it complies with any relevant legislation that may cover the procedures detailed within.**
SOP authorised for use by: -	
Signature: Date:	Name: Accountable Officer
Signature: Date:	Name: Clinical Governance Lead

All staff who will be involved in the handling of Controlled Drugs should sign the table below to say they have read and understood the SOP and agree to act in accordance with its requirements.

Name	Job title	signature	Date

1. Prescribing

Prescriptions for CDs may be computer generated or hand written.
The signature must be hand written by the prescriber and all amendments must be signed by the prescriber.
Verbal prescriptions are not permitted for CDs.
Prescriptions for schedule 2 and 3 CDs must fulfil all the legal requirements (see Controlled Drugs Policy 2016) to be valid.

When opioid medicines are prescribed or administered within the primary health care setting, the healthcare practitioner concerned should:

- Confirm any recent opioid dose, formulation, frequency of administration and any other analgesic medicines prescribed for the patient. This may be done for example through discussion with the patient or their representative or through patient held records.
- Ensure where a dose increase is intended, that the calculated dose is safe for the patient. Reference should be made to a current BNF, Palliative Care Formulary, Palliative Adult Network Guidelines (PAN guidelines) 2011 and / or other best practice guidance.
- Ensure they are familiar with the following characteristics of the specific medication and formulation: usual starting dose, frequency of administration, standard dosing increments, symptoms of overdose, common side effects.

Ensure that the written directions on the prescription and the Gold Form CD1 always reflect the instructions on the medicines box. For example the prescription should be written – *Diamorphine 10mg – 20mg ampoules: to be given as directed in association with a prescribed dose range written on the Gold Form (CD1). The Gold Form (CD1) would also state the dose range 10 – 20mg.*

1.1 Authority to prescribe

	• Doctors are able to prescribe all CDs in Schedules 2 – 5. NB doctors must hold a Home Office licence to prescribe diamorphine, cocaine and dipipanone to substance misusers for the treatment of addiction. • Nurse Independent Prescribers and Pharmacist Independent Prescribers are able to prescribe, administer and give directions for the administration of schedule 2, 3, 4 and 5 controlled drugs for any medical condition, except for diamorphine, cocaine and dipipanone for the treatment of addiction. • Nurse and Pharmacist Independent prescribers must only prescribe CDs within their sphere of clinical competence.

1.2 Prescription stationery

	• All individual prescribers are personally responsible for safe and secure storage of their prescription pads as per local Non-Medical Prescribing Policy (2015). • Under no circumstances should blank forms be pre-signed before use. • Only the correct FP10 forms should be used. • Prescription pads should be stored out of sight. • Prescription pads should never be left unattended in the car.

2. Collection of individual patient supplies of CDs.	
	• In exceptional circumstances community staff may be required to collect CDs on behalf of the patient. • This must only be undertaken as a direct journey from collection of the medicines to the patient home. • Positively confirm the patients' identity by checking NHS number, name, date of birth and address. • Confirm the CD issued by the pharmacy or dispensing practice is the medication that has been prescribed. Cross reference with the Gold CD1 form. • Anyone collecting Schedule 2 or Schedule 3 CDs will be asked to sign for them. You will be expected to sign in the appropriate box on the rear of the FP10 form. • When collecting CDs on behalf of a patient, staff will be expected to supply their name and work address to the dispenser and demonstrate evidence of identity in the form of their professional registration number.

3. Storage in the patients home	
	• This is the responsibility of the patient. • It is recognised good practice that Community Staff will advise patients on safe and secure storage within the home. • Best practice guidance should be followed. Keep out of sight and reach of children; store in a cool, dry cupboard within a clear plastic container with a secure fitting lid. • If medication is not in use, ensure a weekly stock check of all medication is recorded. Date and sign to show that this has been done. • When no longer required in the patient's home, collect the syringe driver box for return to the office. Check the contents of the box in the patient's home, ensuring that NO MEDICATION is left in the box and that all other equipment is present and correct. • Arrange for decontamination of the box following use.

4. Transportation	
Transportation of CDs	• The collection of CDs is the responsibility of the patient / family or carers. • Transportation of CDs by Community Staff should only be in exceptional circumstances where there is no other mechanism available, and not routine practice. • CDs should be kept out of view in a locked boot when in transit. This journey should be a direct journey to the patient's home.

	• All Community Nurses referred to in this SOP are legally allowed to transport CDs to the patient, provided the CD has been prescribed by an appropriate prescriber for that patient. • Community Staff must complete supplier's documentation to confirm receipt.

Section Three	
5.1 Authority to administer	
	• Nurse independent prescribers are able to administer or direct other staff to administer any CD they are legally allowed to prescribe. • It is best practice that the practitioner prescribing the CD should not personally be involved in transportation, preparation and administration (NPC 2007). • Practitioners will require a Gold CD1 form as authority to administer. These will be required on all occasions when CDs are administered by community staff.
PGDs	• At present there are no Patient Group Direction for the supply or administration of schedule 2 or 3 CDs in Lincolnshire Community Health Service.
Legal and clinical check	• CDs must only be administered in accordance with the written directions of the prescriber. • The written direction on the Gold CD1 form or prescription must always reflect the instructions on the medicines box. • It is best practice to ensure that wherever possible two competent members of staff are involved in the administration of all CDs. • Verbal prescriptions are not permitted for Controlled Drugs. • Check the patient identity against the Gold CD1 form.
5.2 Administration	
Administration	• Tell the person having the controlled drug the name and dose of the drug before it is administered, unless the circumstances prevent this.
Syringe drivers	• All practitioners who are required to set up and administer medicines via a syringe driver will need to attend local syringe driver training, as per the syringe driver policy. Mandatory two yearly face to face training and yearly review at appraisal reviews. • All practitioners will be expected to demonstrate their theoretical and practical competence by completing the LBR practice skills competencies for syringe drivers. • This competency should be reviewed on an annual basis at individual appraisal review. • The process for assembly and care of a syringe driver is outlined in the Lincolnshire

	Policy for the use of syringe drivers in Palliative Care (2016). • Best practice dictates that two competent members of staff are involved in the checking and setting up of the syringe driver. • At each daily visit to replenish a syringe driver the Community Nurse will check the drug stock balance.
IM / SC administration	• IM /SC CDs must only be administered in accordance with the written directions of the prescriber. • The Gold CD1 form must correspond to the dose annotated to the label on the medicine box. • Practitioners should ensure they are competent to undertake the role.
Transdermal patches	• Staff need to be aware of the safe process for application. Reference should be made to the individual product information leaflet. • Patches should be applied to dry, non irritated, non irradiated, non hairy skin on torso or upper arm. • Transdermal patches should be changed in accordance with the guidance of the individual product information leaflet.
Administration within a dose range	• Practitioners should follow the advice detailed in Appendix 1A. Further guidance can be found in the local Syringe Driver Policy. • Administration of a dose range should only be by practitioners who have demonstrated competency to undertake this role. • Practitioners should not be expected to administer against a dose range should they not feel competent to do so. • Prescription of a dose range should be dependent on the clinical assessment of the individual patient rather than expected routine practice. This can be at the discretion of the prescriber. • Titration 'up or down' within a dose range for a syringe driver should only be carried out in accordance with the guidance presented in Appendix 1A and the wider guidance presented in the syringe driver policy. • A dose should be reviewed at every condition change or every 24 hours as a minimum. • The dose administered should be clearly documented in the individual patient record. • The rationale for the dose change within the prescribed dose range should be clearly documented within the individual's patient record.
5.3 Patient Specific documentation	
	• The NHS number should be used on all documentation as the primary source of

	patient identification (NPSA 2009). • The following should be maintained and completed contemporaneously: 1. Gold CD2 drug stock form. 2. Gold CD3 record of administration 3. Gold CD1 patient record form.
Patient's notes	• A record of each administration should be made on the Gold CD1, CD2 and CD3 forms and SystmOne, including the NHS number, date, time, strength, presentation and form of the CD, dose administered and the names and job titles of the person administering and the witness. • A clear record should be made of any medicines refused by the patient or intentionally withheld. A clear rationale should be annotated to the patient's notes and the entry should be signed and dated. • Check the stock level and note the new balance on the Gold CD2 form.

Section Four

6. Disposal & recording arrangements for any unused portion	
Disposal of unused portions of CDs	• Small quantities of CDs (4ml and under) remaining in syringes or vials after administration of the required dose, should be rendered irretrievable by placing the syringe and vial in a yellow lidded sharps bin. • This action must be witnessed and recorded on the Gold CD2 form to account for the total content of the ampoule or vial.
Syringe drivers	• Any amount over 5ml in a syringe driver should be documented in the patient held record prior to disposal and the contents disposed of in a denaturing kit.
Transdermal patches	• After removal, the used patch should be folded in half, adhesive side inwards so that the adhesive is not exposed. • It is best practice to then place in a CD denaturing kit; however it is acceptable to place in a sharps bin. • Suitable gloves should be worn.
Unused patient stock	• Quantity and type of stock identified for return should be documented on Gold CD2 form. • If practicable ask patient or family / carers to return to the pharmacy / dispensing GP.
Process for CD destruction by practitioner.	• All CDs must be disposed of safely to minimise environmental impact and risk to public safety. • Prescribed drugs including CDs are the property of the patient and remain so even after death. However it is illegal to possess CDs that have not been prescribed for you. • Patients / patients relatives should be advised all CDs no longer required should be returned to a pharmacy or a GP practice (if dispensed from there) for safe destruction.

	• There may be occasions when it is appropriate for nursing staff to become involved in disposal of CDs.
Disposal / Removal of Obsolete Stock	• At prescription change or issue of new stock any stock labelled with the incorrect dose should be returned to the Community Pharmacy or the Dispensing GP for appropriate destruction. • Alternatively, if appropriate, this stock can be destroyed by the community nursing staff. • Any expired or unused stock should also be destroyed on site by community staff or returned to the community pharmacy or dispensing GP for appropriate destruction.

7. Methods and Procedures for destruction.

Following death, best practice suggests that the best method of destruction is for the health professional to advise that the CDs are returned to the Community Pharmacy or dispensing GP practice, from where they were issued, for destruction.
NOTE: Dispensing GP practices will only accept back the CDs that they themselves have prescribed. On rare occasions, it may be necessary for the health professional to destroy the CDs in the patient's home, if there are no other options available.

Following destruction the Gold Form Stock form CD2, must be amended to demonstrate the destruction of each Controlled Drug. This documentation should include: the drug name; form; strength; quantity and the date it was destroyed.

Destruction of controlled drugs must be witnessed by a second person. Both the person destroying the medication and witness should sign documentation. It is good practice to print name and job title. All labels should be obliterated.

7.1 Tablets, capsules and other solid dose forms	• Remove from blister packaging (ensure gloves are worn) or bottle and place in CD denaturing kit. • Best practice would be to crush tablets and capsules before adding to CD denaturing kit.
7.2 Liquids	• Small quantities of liquids can be poured straight into the CD denaturing kit. The empty bottle should be rinsed out. Labels and other identifiers from the container should be removed or obliterated. The clean, empty container should be disposed of in the recycling waste. • Any large quantities of liquids will need to be returned to the pharmacy or dispensing GP for destruction.
7.3 Suppositories	• Suppositories can be dissolved in a small quantity of hot water. • The resulting liquid should be poured into the CD denaturing kit.
7.4 Transdermal patches	• Remove the backing and fold the patch over onto itself. • Best practice is to place the destroyed patch in a CD denaturing kit. However it is acceptable to dispose of in a sharps bin. • Suitable gloves must be worn.
7.5 Lozenges	• Dissolve in a small quantity of warm water. • The resulting liquid should be poured into the

	CD denaturing kit.
7.6 Liquid ampoules	• Liquid ampoules should be opened, the liquid placed in the CD denaturing kit and the ampoule itself placed into a sharps bin which is labelled “contains mixed pharmaceutical waste and sharps – for incineration”. • Suitable gloves should be worn.
7.7 Powder ampoules	• Powder ampoules should have water added to dissolve the powder; the resulting mixture should be poured into the CD denaturing kit. • Place the ampoule into a sharps bin which is labelled “contains mixed pharmaceutical waste and sharps – for incineration”. • Suitable gloves should be worn.
7.8 Aerosol formulations	• Aerosols should be expelled into water (to prevent droplets of drug entering the air) and resultant liquid poured into CD denaturing kit. • Appropriate PPE should be worn – e.g. gloves and apron.

Section Five

8. Record Keeping	
Administration	• Practitioners will require a Gold CD1 form as authority to administer. • A record of each administration should be made on the Gold CD1, CD2 and CD3 forms and SystmOne, including NHS number, date, time, strength, presentation and CD form, dose administered and names and job titles of the person administering and the witness. • The stock level should be checked and the new balance recorded on the Gold CD2 form. • The NHS number should be used on all documentation as the primary source of patient identification (NPSA 2009). • The following should be maintained and completed contemporaneously: a. CD1 – Patient record form b. CD2 – Drug Stock form c. CD3 – Record of administration
Destruction	• Following destruction Gold Form Stock form, CD2, must be amended to demonstrate destruction of each Controlled Drug. This documentation should include: drug name; form; strength; quantity; date it was destroyed. • Destruction of controlled drugs must be witnessed by a second person. Both the person destroying the medication and the witness should sign the documentation. It is good practice to print name and job title.
Incident reporting	• Complete a Datix in line with Trust Incident Reporting Policy and Procedure (2016). • Annotate the patient records to reflect the discrepancy.

Section Six

9. Incidents	
9.1 Reporting	
Incorrect contents in a sealed carton	• The pack and contents should be kept as evidence to present to the supplier / manufacturer. • Practitioners should complete a Datix/IR1 as per Trust Incident Reporting Policy and Procedure (2016). • Practitioners should inform line manager. • Practitioners should return the pack to the originating dispensing GP or pharmacy for presentation to manufacturer.
Broken ampoules/bottles	• Accidental breakages can be safely disposed of in the presence of a witness • Amendment should be made to the gold drug stock balance form to account for the breakage and must be countersigned by the same witness as above.
Administration errors	• The error should be documented. • Inform the line manager / on call manager who will arrange for notification of the Accountable Officer • If foul play is suspected the manager will arrange for the Police to be notified. • Complete a Datix in line with the Trust Incident Reporting Policy and Procedure. • Annotate the patient records to reflect the discrepancy. • Inform the prescriber. • Inform the patient / carers.
Lost or stolen prescriptions or prescription Forms	• Reported to line managers immediately. • The prescriber must report this loss or theft immediately it has been confirmed to the Trust's Local Security Management Specialist, (Tel No: 01623 622515 or the main office number 01623 622515 ext 3792) • The incident should also be reported to the Practitioner Services Team (Tel No: 01522 515373) who will initiate the information cascade and inform the prescriber of any further action required. • The Practitioner Services Team will be responsible for notifying local Pharmacists and deciding upon action to minimize the abuse of prescriptions. This will include instructions to the prescriber to sign all scripts in a particular colour (usually Red) for a period of two months. • Complete a datix as soon as possible.

Defective medicines	• If a CD appears to be contaminated in any way it must not be used and should be returned to pharmacist or dispensing GP. • An entry must be made on the Gold CD2 form to demonstrate that the CD has been returned. This entry should be countersigned by a witness. • If an ampoule has been prepared for administration and then is unable to be used, for example the powder has not dissolved completely, the ampoule should be disposed of in front of a witness (this may be a patient) and a replacement used. • An entry must be completed on the Gold CD2 form to demonstrate the disposal. This entry should be countersigned by a witness. • Complete a Datix in accordance with Trust Incident Reporting Policy.
Action to be taken if discrepancies in drug stocks.	• The discrepancy should be confirmed. • Inform the line manager / on call manager who will arrange for notification of the Accountable Officer • If foul play is suspected the manager will arrange for the Police to be notified. • Complete a Datix in line with Trust Incident Reporting Policy. • Annotate patient records to reflect the discrepancy. • Inform the prescriber. • Inform the patient / carers.

Section 7

10. Audit	
10.1 Routine monitoring of CDs is required by all service providers within the Trust.	
10.2 The Head of Clinical Services has been identified as responsible for conducting annual audits of the processes covered by this SOP.	
10.3 Format	
Review of positive indicators	• For example - adherence to national and local guidelines, audit of CD use, handling and destruction, evidence of SOP review.
Review of negative indicators	• For example – Datix/IR1, incident and significant event reporting, complaints.
Benchmarking	• For example – training, monitoring of ePACT data, costs, quantities and choice of CDs, local audits.
10.4. Frequency Audit should be undertaken in line with the organisation rolling audit programme. Re-audits to be undertaken as necessary.	
10.5 Reporting route All audits should be reported to the Head of Clinical Services, Safeguarding and Patient Safety Committee and appropriate Clinical Governance Forums.	

APPENDIX 1A

Guidance for administration of syringe driver medication within prescribed dose range.

Prescribers may prescribe symptom management drugs within a specified dose range using the Gold CD1 form. This practice facilitates prompt and patient specific management of symptoms, giving autonomy to competent practitioners to effectively manage patients within their own homes.

Competency
Practitioners are deemed competent after:

- satisfactory completion of the Learning beyond Registration Practice Skills theoretical and practical workbook (countywide training for the use of CME McKinley T34 syringe driver for adults in palliative care.).
- Attendance of a mandatory 2 yearly face to face syringe driver update. (Policy and Protocol for the use of the CME McKinley T34 Syringe Driver for Adults in Palliative Care 2016)

Guidance
In order to underpin this practice the following guidance applies:

1. The registered nurse must consider the doses of breakthrough medication given within the previous 24 hours to achieve symptom management in addition to the syringe driver dose over the previous 24 hours.

2. As stated in the Gold CD1 form guidance, the total amount of the breakthrough doses received plus the syringe driver dose received indicates the next syringe driver dose required to achieve management of symptoms for the next 24 hours. This is guidance only and should be used to support clinical judgement.

3. If this total exceeds the current prescribed dose range of any of the drugs, the registered nurse must contact a prescriber for advice and review of the prescription.

4. If the registered nurse is concerned that symptoms are not being appropriately managed despite the additional doses of breakthrough medication then the decision may be taken to increase the syringe driver dose within the prescribed dose range. The practitioner must be confident that this action is within their level of competence or should take additional advice.

All related documentation must be completed including the Gold forms – CD1, CD2 and CD3.

CD1 Direction to administer treatment for symptom Management and Controlled Drugs

Section Page Number: ……

Patient's Name: …….. NHS No: ……..

DOB: ……. Drug Allergies: ……

TRANSDERMAL OPIOIDS

Date	Drug Name	Dose	Frequency	Signature in full Print name below

DRUGS TO BE GIVEN VIA A SYRINGE DRIVER

To be given subcutaneously over 24 hours (including pre-emptive)

Please see guidance on reverse of form for administration within a dose range

Date Prescribed	Date Commenced	Drug	Dose Range	Indications for Use	Signature in full Print name below

OTHER MEDICATION (including pre-emptive) and PRN

DATE	Indications for use	Drug	Dose Range	Route	Frequency	Signature in full Print name below
	Pain					
	Nausea/ Vomiting					
	Agitation					
	Respiratory secretions					
	Breathlessness					
	Other					

INITIATED BY:

GP

LCHS

ULHT

LPFT

ST. Barnabas Hospice

Community Prescriber to review within 72 hours.

NB: The pre-emptive prescriptions should be reviewed at least weekly and ensure PRN doses are adjusted as required by any change in syringe driver doses.
For clarity, all 'old' prescriptions should be scored through and dated with the date discontinued.

PRESCRIBING GUIDELINES

- The information within these guidelines is referenced to and should be used in conjunction with Palliative Care Formulary 4, Palliative Adult Network Guidelines 2011 and the current British National Formulary. Be aware of drug accumulation in **renal failure** and seek guidance to alternative medication.
- **Prescribing responsibility remains with the prescriber.**
- **Maximum doses may be extended** and some maximum doses only to be used **following discussion** with a Specialist Palliative Care Clinician.
- Please note that only Diamorphine, Oxycodone and Levomepromazine are licensed for subcutaneous use. It is accepted practice in palliative care to administer other appropriate drugs via the subcutaneous route.
- It is recommended that **no more than 3 drugs** are combined in one syringe. Drug compatibility information can be found in the PCF4 and on the following websites: **www.palliativedrugs.com** and **www.pallcare.info**

Guidance for administration within a prescribed dose range
Adjustments should be made in the context of your clinical assessment.

Add the previous 24 hours infusion dose (**A**) to the total breakthrough doses in the last 24 hours (**B**) to calculate the next 24 hour infusion dose (**C**) **A+B=C**

- **A** = Previous 24 hour infusion dose
- **B** = Total of all breakthrough doses in the last 24 hours =
- **C** = Next 24 hour infusion dose (if this exceeds the dose range prescribed, seek advice from an appropriate prescriber)

Drugs for subcutaneous use in syringe driver over 24 hours The following are suggested starting doses and usual maximum doses. The dose used should be adjusted according to individual patients, previous oral medication and symptoms.			Subcutaneous STAT doses of drugs Stat doses vary according to the dose of medication in the syringe driver and individual patient.
ANALGESIC **Diamorphine** Calculate previous 24 hours total oral morphine dose and divide by 3. If **opiate naïve** starting dose 5mg.			1/6th of syringe driver dose given over 24 hours. If opiate naïve: 2.5mg 2 – 4 hourly.
Morphine injection Calculate previous 24 hours total oral morphine dose and divide by 2.			1/6th of syringe driver dose given over 24 hours. 2 – 4 hourly.
Oxycodone 'Oxynorm Injection' Calculate total oral oxycodone dose in last 24 hours and divide by 2. **NB Not compatible with Cyclizine**			1/6th of syringe driver dose given over 24 hours. 2– 4 hourly.
	STARTING DOSE	**MAXIMUM DOSE IN 24 HOURS (Including PRN)**	
ANTI-EMETIC **Cyclizine** Needs to be well diluted to prevent crystallisation and/or skin irritation and should **never** be diluted in normal saline 0.9%.	100 – 150mg	150mg	50mg 8 hourly Choose Haloperidol or Levomepromazine for stat dose
Haloperidol	1.5mg	5mg	500 micrograms – 3 mg 8 hourly
Levomepromazine Also sedative at any dose	6.25mg – 25mg	50mg	6.25mg –12.5mg 4-6 hourly
Metoclopramide	30mg – 60mg	100mg	10mg – 30mg 8 hourly (Large volume more suited for I.M. route)
ANTI-SECRETORY **Hyoscine Butylbromide**	20mg – 60mg	120mg	10mg – 20mg 8 hourly
Glycopyrronium	600 micrograms	1.2mg	200 micrograms – 400 micrograms 6-8 hourly
ANTI-SPASMODIC **Hyoscine Butylbromide**	60mg	120mg	20mg 8 hourly
CONFUSION / RESTLESSNESS **Midazolam**	5mg – 30mg	60mg (**100mg***)	2.5mg –10mg 4 hourly
Levomepromazine (Dilution with water for injection is normal practice. However, if the site reacts, normal saline 0.9% is suggested.)	6.25mg – 75mg	150mg (**250mg***) ***Under specialist advice only**	6.25mg – 12.5mg 4-6 hourly

If symptoms do not respond please seek early advice; contact a Macmillan Nurse or St Barnabas Hospice on: 01522 511566

OR Thorpe Hall Hospice on: 01733 225900

SECTION SEVEN

Standard Operating Procedure for Management of Controlled drug stocks within Urgent Care Services

Standard Operating Procedure for Management of Controlled Drugs within Urgent Care Services

Contents

ii. SOP statement

Standard Operating Procedure for Management of Controlled Drugs within Urgent Care Services

	SOP Statement
Background	To promote the safe, secure and effective use of all controlled drugs (CDs) within Lincolnshire Community Health Services Urgent Care Centres. It is a legal requirement that every NHS organisation should have SOPs for handling CDs for all of its directly managed services and staff. These SOPs must be known, understood and followed by all practitioners and staff working within the Urgent Care Centres.
Statement	This SOP covers all aspects of the handling of CDs within the Urgent Care Centres: ordering, receipt, transport, safe storage, supply, administration, destruction and guidance for dealing with an incident.
Responsibilities	It is the responsibility of the Accountable Officer for controlled drugs for LCHS together with the pharmacist leads for all sites to review and update this SOP to ensure that practice remains lawful and that it is updated when changes to regulations are made. It is the responsibility of all staff members to be familiar with this SOP a to act strictly in accordance with its requirements in every aspect. It is the responsibility of all staff of other agencies: Marie Curie, MacMil District nurses, LADMS to be familiar with this SOP and to act strictly ir accordance with its requirements in every aspect.
Training	There are no additional training requirements associated with the implementation of this SOP.
Dissemination	Website.
Resource implication	This policy has been developed in line with the NHS Litigation Authority Guidelines.

Standard Operating Procedure for Management of Controlled Drugs within Urgent Care Services

SOP comes into effect	1st July 2017
SOP review date	30th June 2019
Purpose	To promote safe, secure and effective use of all controlled drugs (CDs) within Lincolnshire Community Health Services Urgent Care Centres. It is a legal requirement that every NHS organisation should have SOPs for handling CDs for all of its directly managed services and staff. These SOPs must be known, understood and followed by all practitioners and staff working within the Urgent Care Services.
Scope	This SOP covers all aspects of the handling of CDs within the Urgent Care Services: ordering, receipt, transport, safe storage, supply, administration, destruction and guidance for dealing with an incident.

Responsibilities Staff	All staff following the SOP are responsible for identifying any deficiencies in the SOP and notifying their line manager accordingly. All staff have a duty of care under the Health and Safety at Work Act 1974. Staff should be familiar with the organisation's Whistle- Blowing Policy and be able to share concerns without fear of recrimination. All staff have a responsibility to access, be familiar with and comply with all policies relating to this SOP. Staff must practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct if applicable. All staff are responsible for reporting near misses, adverse and serious untoward incidents as outlined in the Trust Incident Reporting Policy.
Responsibilities Manager	It is the overall responsibility of the Matron for Urgent Care Service to ensure this SOP is followed by staff and that staff are aware of their responsibilities / accountability regarding CDs. It is the responsibility of the manager to inform staff of the implementation of this SOP and ensure the necessary training has been undertaken to enable staff to carry out safely the procedures detailed in the SOP. It is the responsibility of the Accountable Officer for Controlled Drugs in Lincolnshire Community Health Services to ensure that the contents of this SOP conform to legal requirements currently in force.

All staff who will be working to this SOP should sign below to say they have read and understood the SOP and agree to act in accordance with its requirements.

Name	Job Title	Signature	Date

Standard Operating Procedure for Management of Controlled Drugs within Urgent Care Services

1. Procurement and ordering of controlled drugs

1.1 Controlled drugs for supply to patients in line with this SOP (hereafter named CDs) must be obtained from a registered pharmacy currently holding a contract to supply medication to the Urgent Care Centre (hereafter named UCC) and legally permitted to over-label. Currently, this is the Lincolnshire Cooperative pharmacy.

1.2 When a CD needs to be ordered, form FP10CDF requisition form must be completed. Requisition forms should be kept in a locked cupboard.

1.3 The FP10CDF requisition form must be completed by a prescriber and must detail the CD required, including the form, strength and quantity.

1.4 The prescriber must sign the form and include their name, qualifications and registration number. The Trusts Organisation Code (RY500) must be included.

1.5 It is the responsibility of individual Urgent Care Services to ensure that the Coop Pharmacy and Medicines Management hold an up to date list of authorised signatories for ordering CDs. This signatory list should also be kept for reference at each individual site for reference.

1.6 The completed FP10CDF requisition form should be faxed to the Cooperative pharmacy (Fax Number: 01522 869795). The original requisition form should be approved by the Clinical Team Lead, or designated other, and posted to the Coop Pharmacy to ensure arrival before the date of supply. (Orders may only be lawfully dispatched on receipt of the original document).

1.7 The CD order book number should be added to the requisition form to ensure that the order and requisition correspond.

1.8 File and keep copies of all requisition forms.

1.9 The CD order book should also be completed. A copy of the CD order should be appended to the retained copy of the CD requisition form and the numbers must be cross referenced.

1.10 Any orders not received should be followed up with Coop pharmacy. A note should be in the delivery to say item not delivered and this should be attached to requisition. Alternatively a note confirming verbal communication should be added to the order.

1.11 File and keep copies of all requisition forms for a period of seven years.

2. Delivery

2.1 Deliveries of the CDs are the responsibility of the supplier.

2.2 Delivery times to be arranged in between supplier and unscheduled care service management.

3. Receipt

3.1 Only practitioners whose names are listed as having authority to order and receive CDs are permitted to receive and sign for delivery of CDs. (This list is retained in the UCS and should be updated annually by the individual services. A copy must be sent to the Co-op pharmacy service).

3.2 Check delivered CDs against the order book and obtain signature of delivery driver. This should be cross referenced with attached requisition order.

3.3 Any tamper evident seals on the packs can be left intact as sealed containers can be assumed to contain the full amount stated on the pack.

3.4 Any discrepancies should be reported to the supplier immediately or by the next working day and to the Clinical Team lead for the site.

3.5 If the discrepancy cannot be resolved, or there is disagreement, an IR1 should be completed, and the Accountable Officer for CDs notified.

3.6 Complete any necessary paperwork if the CDs are to be returned to the supplier.

3.7 Receipt of all CDs must be signed for by the practitioner receiving the delivery in the CD order book. The member of staff who takes responsibility for the receipt of CDs also is responsible for entering those CDs in the register.

3.8 A second member of staff should countersign as a witness the entry for the receipt of the CD, checking that the name, strength and quantity of the preparation is correct and that the final balance is recorded in the register is also correct.

3.9 The CD order book reference number should be annotated to the CD register upon receipt.

3.10 The controlled drug received must also be recorded in the Controlled Drug register, detailing, on the relevant page for that product:

- Date of receipt
- Order book reference number
- Supplier name and address (see example below)
- Signature of members of staff receiving
- Signature of staff member witnessing receipt
- Quantity received (in words and numbers)
- The correct (and checked) balance

3.11 Note that there are no columns headed for supplier name and address, and receiving member of staff. These details may just be written on the same line as the date:

Date of transaction	**Drugs into stock (amount received in words)**	**CD order book No**	**x x**	**x x**	**x x**	**x x**	**x x**	**x x**	**x x**	**x x**	**x x**	**Signature**	**Signature**	**Balance In stock**
25.12.2012	20 (TWENTY)	040	Received from COOP Pharmacy, Witham St Hughs / Burton Road etc											25(assuming 5 already in stock)

3.12 Where there is a discrepancy in the delivery, or where the incorrect product is supplied / received, the product and accompanying delivery note should be placed in the CD cupboard with an explanatory note. No entry should be made in the CD registers, and the site lead pharmacist contacted at the earliest opportunity. Arrangements will be made with the supplier to collect the incorrect supply.

3.13 Entries made into the CDR in respect of drugs obtained and drugs supplied should be made on the same page so as to maintain a running stock balance. For liquid CDs, i.e. Oxycodone liquid, a new page should be commenced for each new bottle.

3.14 CDs must be unpacked, added into the CD register and stored in the CD cupboard immediately.

3.15 Delivery notes and invoices for CDs should be retained for 7 years.

4. Storage

4.1 CDs should be placed in a locked CD cupboard specifically for the purpose of CDs for issue to patients on prescription in line with this SOP.

4.2 The keys should be held in accordance with the Trust's Safe and Secure Handling of Medicines policy.

5. Prescribing and Home Visits

5.1 Where a prescriber, in the urgent care centre is satisfied that a patient in the community is urgently in need of a CD and there is no reasonable alternative source for this medication, s/he may write on the appropriate FP10 prescription for the CD which may be dispensed in the UCC for supply to the patient during a home visit. Within community pharmacy opening hours the FP10 should be dispensed by a community pharmacy.

5.2 Prescriptions must be for a minimum of one original pack of medication. (I.e. for diamorphine, this will be 5 ampoules of 10mg or 30mg); or multiples of original packs.

5.3 Prescriptions must conform to the requirements for CD (schedule 2) prescribing, and include:

- The name and address of the patient
- The name of the drug prescribed, form and strength
- The dose ((note 'as directed' is not permitted, although a fixed dose followed by as directed is permitted e.g. inject s/c as directed is not permitted, inject 2.5mg s/c as directed is permitted).
- If prescribing a dose range, ensure that the direction on the prescription and the Gold CD1 Form always reflect the instructions on the medicines box. For example, the prescription should be written – *Diamorphine 10- 20mg: to be given as directed in association with a prescribed dose range written on the Gold Form (CD1).* The Gold CD1 form would also state the dose range as 10 – 20mg.
- The total quantity of dose units (i.e ampoules) in words and figures.
- The date
- The signature of the prescriber
- NHS number

5.4 Any blank space below the prescription should be ruled through.

5.5 Requests for supply to external services, i.e. Maria Curie, should be directed through the on-call coop pharmacy service and not supplied from an Urgent Care Centre. Reference should be made to the SOP for supply of controlled drugs out of hours.

6 Issue

6.1 The prescription should be passed to a practitioner authorised to issue CDs.

6.2 The particulars of the prescription should be checked to ensure they conform to the requirements for CD prescriptions detailed above under 'Prescribing.'

6.3 The practitioner must ensure that a complete pack has been prescribed. There is no facility to split packs.

6.4 When the practitioner is satisfied that the prescription is complete, the CD Issues register should be completed.

6.5 The following should be recorded:

Date of transaction	Patient details		Name of person collecting / delivering or administering (include Organisation and or address)	ID requested and type presented	Prescribers name	Signature	Signature	Amount supplied	Balance
	Name & NHS No.	Address							
(1)	(4)	(5)	(6/7)	(8)	(10/11)	(12)	(13)		

25.12.2012	Patient And No.	Patient address	Rx's name	Yes/No Driving License	Practitioner issuing	Signature	Signature	FIVE	FIVE

NB Columns 2-3 do not need completing
6.6 CDs are provided by the supplier with partially completed labels. These should be completed according to the prescription by the practitioner.

6.7 The prescription should be annotated with the quantity supplied and the signature/initials of the practitioner.

6.8 The prescription and the CD should then be passed to the doctor or prescribing practitioner who will check the item dispensed is correct with the requirements of the prescription, and that the label has been completed satisfactorily.

6.9 The doctor or prescribing practitioner should initial/sign the prescription as an indication that the dispensing has been checked.

7. Administration of a CD from Stock
7.1 CDs should only be administered in accordance with the written directions of the prescriber.

7.2 Prescription should be passed to practitioner for administration

7.3 If using injectable opiates, ensure naloxone injection is available.

7.4 Collect or measure the correct dose – bungs and syringes must be used for measuring liquid CDs

7.5 The dose to be administered must be checked against the prescription. This must be an independent second check and not a confirmation check.

7.6 Tell the person having the controlled drug the name and dose of the drug before it is administered, unless the circumstances prevent this.

7.7 Complete the CD register. The record should include:
- Date of administration
- Name of patient being administered to.
- Signature of administering nurse
- Amount administered
- Revised stock balance
- Signature of witness providing a second independent check.

7.8 Confirm the identity of the patient

7.9 The authorised witness must see the CD being administered

7.10 Record administration within the CD register

7.11 Dispose of any unused CDs – any medicines not used or only partly used, must be destroyed in the presence of a witness and an entry made in the CD register signed by both parties.

8. Transport
8.1 Where medication is to be taken by a healthcare professional to a patient's home, the identity of the HCP should be confirmed and recorded in the CD Issues register.

8.2 In columns 5 – 8 the HCP name and their work base address should be written. Their ID should be requested and should be seen by the issuing nurse before the CD is handed to them.

8.3 A Bearer's Note (see Appendix 1) should also be provided and signed by the prescriber,

giving the HCP authority to possess the CD to transport it to the patient. Blank Bearer's Notes are kept in the CD cupboard. It should detail the name of the HCP authorised to transport the CD, the name and signature of the doctor, the date and the destination of the CD.

NOTE: the prescriber and bearer's names should be the same as recorded in the CD Issues register.

8.4 All CDs dispensed from an UCC and then transported by someone other than the patient or their representative require a bearer's note.

8.5 The CD should be kept out of sight during transport. The transport bag should be returned to the UCS after delivery of the CD.

9. Reconciliation, record keeping and stock control

9.1 Every movement of CD stock into, within and from UCS's should be recorded and the name(s) of personnel associated with each step identified. This will provide an audit trail for any future investigation.

9.2 It is the responsibility of UCS staff to ensure that the range and quantity of CD stock maintained is adequate and appropriate for requirements.

9.3 Stock balances of CDs should be checked each day and the date, time, stock balance and the initials of two practitioners should be recorded for each CD kept. In exceptional circumstances a HCSW can be the authorised second signatory. Midazolam, diazepam, codeine and tramadol should be included within these daily stock counts.

9.4 Effective stock control and stock rotation should be practiced to minimise either stock out or date expiry.

9.5 Where stock does reach its expiry, the site lead pharmacist should be contacted and the stock will be destroyed in line with Trust policy.

10. Security of medication and documentation

10.1 Controlled Drugs must be stored in a locked approved medicine cupboard.

10.2 Forms FP10CDF and blank Bearer's Notes must be kept in the controlled drugs cupboard.

10.3 Controlled Drug registers: Receipts and Issues must be kept in a locked drawer or cupboard and be available for audit purposes.

10.4 Completed and filled FP10 prescriptions for CDs supplied must be retained in the CD cupboard for checking prior to being sent to the NHSBSA. Where CDs are administered within the urgent care setting, a copy of the treatment card should be retained for checking.

10.5 To access the CD cabinet when there is a GP and Nurse/ECP on duty, both the professionals will be present for administration or supply to another service. The CD register will be completed by the GP/NP/ECP and countersigned.

- When there is only one registered professional on duty a HCSW will access the coded key safe with the GP/NP/ECP and hand the key to them.
- The Key will then be passed to the GP/NP/ECP to open the CD cabinet; the CD's required will be removed and prepared for administration or supply. The CD register will be annotated by the GP/NP/ECP and countersigned by the HCSW.
- The HCSW will sign to indicate they are aware of the key safe code. If the HCSW is not on duty for any reason the code for the key safe will be held by the practitioners at the Urgent Care Centre.

11. Regular Checks / Audit

11.1 CD register checks. A daily check should be undertaken to confirm the running balance entries for all CDs. This should be recorded in the blue daily checks book.

11.2 This check should be carried out by a clinician and one other member of staff.

11.3 Each member of staff should add their initials, date and time to confirm each running balance total on the relevant page.

11.4 Any discrepancies should be dealt with immediately in accordance with CD policy.

11.5 Compliance with CD policy and procedures incorporated in the Safe and Secure Handling of Medicines Policy will be audited every 3 months.

SECTION EIGHT

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SECTION NINE
GLOSSARY

Authorised nurse	A registered healthcare professional permitted by Trust policy and with documented competence to administer medication to a patient in accordance with the directions of a prescriber or PGD.
Authorised signatory	A registered healthcare professional (eg nurse, Medical doctor or pharmacist) permitted by Trust policy and with documented competence to perform a particular task relating to the ordering, recording, administration or supply of Controlled Drugs. In most cases this will be a registered nurse, but some tasks may be carried out by other professionals as appropriate.
Authorised witness	A member of healthcare staff permitted to witness the correct performance of a task relating to the ordering, recording, administration or supply of Controlled Drugs. An authorised witness must be familiar with the task that they are witnessing.
BNF	The British National Formulary
Controlled Drug (CD)	A preparation subject to prescription requirements under the Misuse of Drugs regulations 1985. They are divided into three classes (A-C) under the Misuse of Drugs Act 1971 and into five schedules, each specifying the requirements governing such activities as import, export, production, supply, possession, prescribing, storage and record keeping that applies to them. For further guidance see the 'Controlled Drugs and Drug Dependence' section of the current BNF. Schedule 1, CD License is not specifically included. These require a license from the Home Office to allow their use and are not in general medicinal use. They include illicit substances.
CD Order book	A book containing pre-printed and numbered pages, each suitable for the request to supply a single Controlled Drug preparation and the production of a carbon-copy of the request. The carbon-copied pages remain bound within the book.
CD Ward Register	A bound book with numbered pages suitable for the recording of all Controlled Drug transactions on a ward. In most cases, wards will need two such registers, one for stocks of CDs ordered in the CD order book and one for Patient's Own Drug (POD) CDs. These are referred to as: • Ward Stock CD Register • Ward POD CD Register
Documented Competence	This may take the form of a Trust-level programme of training and assessment, or may be considered to be satisfied by the terms of an individual's professional registration at the Trust's discretion.
FP10	A NHS prescription form used by General Practitioners and community non medical prescribers, that can be dispensed at a registered community pharmacy or dispensing GP practice.
FP10 CDF	A dedicated controlled drug requisition form for schedule 2 and 3 CDs

FP10 (HP)	A type of FP10 that is used by Hospital Prescribers and may be dispensed at a registered community pharmacy or a hospital pharmacy.
GPhC	General Pharmaceutical Council
POD	Patient's Own Drugs. This describes medicines which are the property of an individual, whether prescribed for, or purchased by them.
Pharmacist	A pharmacist registered with the GPhC
Pharmacy Technician	A qualified pharmacy technician registered with the GPhC.
Prescriber	A registered healthcare professional with the legal right to prescribe medication and authorised to do so by Trust policy.
CDAO	Accountable Officer for Controlled Drugs
RPSGB	The Royal Pharmaceutical Society of Great Britain, the body that represents and oversees the registration of pharmacists and pharmacy technician within a written ethical framework.
S.O.P	Standard Operating Procedure. A detailed list of activities describing how a particular task should be performed.
Ward	Although the term 'ward' is used, these S.O.P refer to all departments within Community Hospitals where Controlled Drugs are ordered, administered or stored.

Appendix One: Bearer's Note for Controlled Drugs

Lincolnshire Community Health Services NHS
NHS Trust

Bearer's Note for Controlled Drugs

……in their capacity of ……

is authorised to carry the enclosed controlled drug from

Urgent Care Centre, ……, to

……

on ……/……/20….

Prescriber: ……..

Signature: ……

Appendix Two

NHSLA Monitoring Template

Minimum requirement to be monitored	Process for monitoring e.g. audit	Responsible individuals/ group/ committee	Frequency of monitoring/audit	Responsible individuals/ group/ committee (multidisciplinary) for review of results	Responsible individuals/ group/ committee for development of action plan	Responsible individuals/ group/ committee for monitoring of action plan
Controlled Drugs audit	**Quarterly audit**	**Service Leads and Matrons** **Medicines Management Officer** **CD Accountable Officer**	**Quarterly and unannounced**	**Service Leads, Matrons and Quality and Risk Committee** **CD Accountable Officer** **Medicines Management Officer**	**CD Accountable Officer** **Medicines Management Officer**	**Safeguarding and Patient Safety Committee** **Lincolnshire Intelligence Network (NHS England)**

Appendix Three

Equality Analysis

Name of Policy/Procedure/Function*	
Management of Controlled Drugs	
Equality Analysis Carried out by:	Lorna Adlington
Date:	February 2017
Equality & Human rights Lead:	Rachel Higgins
Director\General Manager:	Susan Ombler

A.	Briefly give an outline of the key objectives of the policy; what it's intended outcome is and who the intended beneficiaries are expected to be	The policy applies to all professionals and premises subject to inspection as part of the revised arrangements for the management and monitoring of Controlled Drugs (CDs).		
B.	Does the policy have an impact on patients, carers or staff, or the wider community that we have links with? **Please give details**	This policy applies to all healthcare staff, including bank and agency involved in the administration of Controlled Drugs • Medical and Nursing staff • Emergency Care Practitioners • Pharmacy associated staff • Allied Health Care Professionals		
C.	Is there is any evidence that the policy\service relates to an area with known inequalities? **Please give details**	No.		
D.	Will/Does the implementation of the policy\service result in different impacts for protected characteristics?			
		Yes	No	
	Disability		X	
	Sexual Orientation		X	
	Sex		X	
	Gender Reassignment		X	
	Race		X	
	Marriage/Civil Partnership		X	
	Maternity/Pregnancy		X	
	Age		X	
	Religion or Belief		X	
	Carers		X	
	If you have answered 'Yes' to any of the questions then you are required to carry out a full Equality Analysis which should be approved by the Equality and Human Rights Lead – please go to section 2			
The above named policy has been considered and does not require a full equality analysis				
Equality Analysis Carried out by:		Lorna Adlington		
Date:		February 2017		