Livewell Southwest

Controlled Drugs Policy and Standard Operating Procedures (SOP's) for Wards and Departments

Version No.2.1
Review: May 2019

Notice to staff using a paper copy of this guidance

The policies and procedures page of LSW Intranet holds the most recent and procedural version of this guidance. Staff must ensure they are using the most recent guidance.

Author: **Chief Pharmacist and Controlled Drugs Accountable Officer**

Asset Number: **756**

Reader Information

Title	Controlled Drugs Policy and Standard Operating Procedures (SOP's) for Wards and Departments. V.2.1
Asset number	756
Rights of Access	Public
Type of Paper	Policy and Procedure
Category	Corporate
Document Purpose and Description	Section A is the CD Policy explaining the over-arching management of Controlled Drugs within LSW. This includes legislation, monitoring, duties / responsibilities, implementation, training and related policies. There follows section B with eight SOPs describing the procedures which must be followed by all staff handling CDs on wards and departments of LSW.
Author	Chief Pharmacist and Controlled Drugs Accountable Officer
Ratification Date and Group	Medicines Governance Group May 2016
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Disposal Date	The PRG will retain an e-signed copy for the archive in accordance with the Retention and Disposal Schedule. All copies must be destroyed when replaced by a new version or withdrawn from circulation.
Job Title	Chief Pharmacist and Accountable Officer for Controlled Drugs
Target Audience	All Pharmacy Staff and Authorised witnesses All ward staff involved in the handling of CDs on wards or departments of LSW.
Circulation List	Electronic: Livewell Southwest (LSW) intranet and website (if

	applicable) Written: Upon request to the PRG Secretary on ☎ 01752 435104. Please contact the author if you require this document in an alternative format.
Consultation Process	1. Each SOP and the policy as a whole have been considered in detail by the MGG
Equality Impact Assessment	Yes – no issues identified, form enclosed.
References/Source	1. LSW Safe and Secure Handling of Medicines Policy v. 6.3 2. The Misuse of Drugs Regulations 2001: http://www.legislation.gov.uk/uksi/2001/3998/contents/made 3. National Patient Safety Agency (NPSA) Safer Practice Notice no. 12 (May 2006) "Ensuring safer practice with high dose ampoules of diamorphine and morphine" 4. Department of Health / Royal Pharmaceutical Society of Great Britain: Safer Management of Controlled Drugs: A Guide to good practice in secondary care (England), May 2007 5. Department of Health: Guidance on Standard Operating Procedures for Controlled Drugs, Gateway ref:7585, Jan 2007 6. Royal Pharmaceutical of Great Britain: Medicines, Ethics and Practice, the professional guide for pharmacists; edition 39 July 2015 7. Department of Health: Controlled Drugs (Supervision of management and use) Regulations 2013 8. NICE: NG46: "Controlled drugs: safe use and Management" April 2016 **9.** Additional Guidance issued by the Home Office on the use of the mandatory requisition form for Schedule 2 and 3 controlled drugs 20160121
Supersedes	Controlled Drug SOPs for wards and departments v. 1.1

Document	
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Document Review History

Version No.	Type of Change	Date	Originator of Change	Description of Change
0.1	New Document	April 2009	S Cooke	
0.2	Consultation	April – May 2009	S Cooke	CD Management Group
0.3	Consultation	May 2009	S Cooke	Provider Governance Committee and wide consultation
1.	Minor amendments	June 09	S Cooke	Final amendments following Policy Ratification Group meeting.
1.1	Major review	July 2013	Author	Re-format to PCH standard Update in line with new DH guidance 2013 Update in line with NHS reorganization 2013 and appointment of CDAO for LSW
2.0	Ratified MGG 06/05/16	April 2016	S. Cooke	Section 1 converted to a policy, final amendments and incorporation of NICE NG46 and High Dose Opiates Policy. Review of Naloxone protocol.
2.1	Minor amendments	Sep 2016	S Cooke	Addition of competency assessment for HCAs plus other minor changes

Abbreviations

ADIOS	**Abusable Drugs Investigational Software**
BNF	**British National Formulary**
CD	**Controlled Drug**
CDAO	**Controlled Drug Accountable Officer**
CDLIN	**Controlled Drug Local Intelligence Network**
CDRB	**Controlled Record Book**
DH	**Department of Health**
DHP	**Derriford Hospital Pharmacy**
MGG	**Medicines Governance Group**
NHSE	**National Health Service England**
POM	**Prescription Only Medicine**
SOP	**Standard Operating Procedure**
SQP	**Safety, Quality and Performance Committee**
SWDF	**South and West Devon Formulary and Referral**
TTA	**To Take Away (prescription)**

Section A: Controlled Drugs Policy.

1. Introduction

1.1 This policy and procedures apply to drugs listed in schedules 2 and 3, 4 (part 1) and 5 of the Misuse of Drugs Act 1971 (Controlled Drugs). These drugs are marked with the symbol **CD, and the appropriate schedule** in the BNF. Stock supplies of CDs in schedules 2 and 3 will be labelled "Store in a Controlled Drug Cupboard" by Derriford Hospital Pharmacy (DHP). A current list of the drugs contained in Schedules 2, 3, 4 and 5 is provided in appendix A

1.2 The procedure for dealing with illegal substances brought onto LSW premises by patients or visitors is covered in section 25 of Safe and Secure Handling of Medicines Policy.

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

1.4 Following a risk assessment it was decided that all schedule 3 stock CDs will be treated in the same way as schedule 2, that is they will require:

- Storage in the CD cabinet (apart from midazolam when required in an emergency)
- Ordering on a CD requisition
- Receipts, supplies and destruction to be recorded in the CDRB
- Denaturing when no longer required, in the presence of an authorised witness
- Full prescription requirements for TTAs

1.5 This policy and procedures now incorporates the requirements of the "High Dose Opiates Policy".

This policy promotes safe practice with these medicines. It is not intended to prevent appropriate clinical use in patients who need them. The policy arose from the NPSA alert[3] Major risks identified were:

- Dosing errors can arise because the packaging of different strengths of diamorphine and morphine ampoules is the same; the outer carton and ampoule labelling are poorly differentiated;

and 5mg, 10mg, 15mg, 20mg and 30mg products have similar appearances.

- Higher strength ampoules of diamorphine and morphine (30mg, for example) stored alongside lower strength products (10mg, for example) in clinical areas, partly due to lack of space within the controlled cabinet to segregate them.
- Insufficient therapeutic training and understanding on the part of the healthcare staff of the risks and precautions when prescribing, dispensing and administering higher doses of diamorphine and morphine injections.

2. Legislation

2.1 The primary legislation concerning CDs is 'The Misuse of Drugs Act 1971' with more detail provided by 'The Misuse of Drugs Regulations 2001' referred to as the '2001 regulations'. The Government introduced monitoring and inspection arrangements for CDs in the Health Act 2006. The regulations that relate to wards and departments are detailed in the document "Safer Management of CDs: a guide to good practice in secondary care (England)" [DH Jan 2007] referred to as 'the 2006 guide' The '2013 regulations' relate to the 'Supervision and management arrangements' for organisations to appoint a Controlled Drug Accountable Officer (CDAO) and the duties required of this role.

2.2 These CD SOPs incorporate the requirements of the above national documents with adaptations base on local circumstances and accepted practice with the Plymouth Health Community. Reference has also been made to the recently published NICE appraisal: NG46: https://www.nice.org.uk/guidance/ng46

2.3 The convention adopted in this section of the policy is consistent with the '2006 guide' document: the term **"must"** relates to statements governed by legal requirements; whereas **"should"** relates to best practice guidance, some agreed nationally and others agreed locally. However, LSW employees working to these procedures are expected to comply with all statements whether legally binding or not. Any employee who thinks they cannot comply with a specific aspect should bring the matter to the attention of their manager.

2.4 In line with regulation 8 of the 2013 regulations, the Controlled Drugs Accountable Officer (CDAO) for LSW is ultimately responsible for all aspects of the safe and effective use of CDs within LSW. Any staff concerns about individuals or processes in the handling of CDs should be reported to the CDAO, who is responsible for reporting and investigating concerns:

The Controlled Drugs Accountable Officer (LSW)
Pharmacy Office, Local Care Centre, Mount Gould Hospital,
Plymouth PL4 7PY.
Tel: (01752) 434723 (internal 34723)
Bleep: 85244; Fax: 01752 272437 (int. 2437)
Email: steve.cooke1@nhs.net

3. Monitoring

3.1 The CDAO has developed, disseminated and will monitor compliance with these procedures. The measures below allow the CDAO for LSW to give an on-going assurance to the LSW Board and the NHSE CDAO that all statutory and best practice issues relating to CDs are being complied with.

3.2 Incident reports involving all medicines are automatically forwarded to the Pharmacy generic email address which is monitored daily Mon – Fri. Any incidents involving CDs are sent to the CDAO by the pharmacist doing the daily monitoring.

3.3 The CDAO will assess all CD incidents and immediately investigate any that require a prompt response. All CD incidents will be saved in the file used to inform the quarterly occurrence report

3.4 The CDAO for LSW provides a quarterly occurrence report on CDs to the CDAO for the NHS England Sub-Regional Team and attends the Local Intelligence Network for Controlled Drugs (CDLIN) meetings (3 per year). Learning and information from the CDLINs is shared with LSW staff on a need to know basis by the CDAO

3.5 The CDAO ensures a 3 monthly audit of all inpatient units is performed by pharmacy technicians and that any deficiencies are immediately reported back and appropriate actions taken.

3.6 Monthly monitoring of supply data via the ADIOS software provided by Derriford Pharmacy is used to identify any sudden or insidious changes in usage patterns, which are then investigated via ward pharmacists or ward managers as appropriate.

3.7 EPACT data for CD prescribing via FP10s is monitored for trends and appropriateness quarterly by the CDAO.

3.8 The CDAO has access to the SW internal audit team if a more detailed or extensive audit of CDs is deemed appropriate.

4. Duties and Responsibilities

4.1 The **Chief Executive** is ultimately responsible for the content of all policies, implementation and review.

4.2 Responsibilities of **Director(s)**

- Directors are responsible for identifying if this policy is relevant in their area and its subsequent implementation.

4.3 Responsibility of **line managers**

- Embed this policy within the practice of relevant staff
- Keep a signature list of staff who have read this policy, declaring that they are familiar with its contents and will work within its boundaries
- Include this policy in induction of new **staff**
- Follow-up prescribing / medication errors / incidents
- Make staff aware of prescribing / medication errors / incidents

4.4 Responsibility of all **staff**

- Follow the content of this policy and associated SOPs
- Act within their confidence and competence
- Inform the prescriber, nurse in charge or manager of any circumstances in which safe practice may be compromised
- Report medication / prescribing incidents / errors in a timely way, ideally within 48 hours

4.5 **Over-arching responsibilities** for each SOP are:

- The CDAO is responsible for ensuring that there are adequate and up to date SOPs in place in relation to the management and use of CDs within the organisation.
- The CDAO is responsible for the writing, consultation, monitoring, review and dissemination of the SOPs to all wards and departments that stock Controlled Drugs.
- The Medicines Governance Group (reporting to the Safety, Quality and Performance Committee) is responsible for the ratification of the SOPs for use within the organisation.
- National Medicines Safety Alerts and Guidance are incorporated into the CD SOPs within the required timeframe.

4.6 **Individual responsibilities** are defined on the first page of each SOP.

5. Dissemination and Implementation

5.1 Each section comprises a Standard Operating Procedure (SOP), which are unambiguous documents describing the responsibilities of staff, the processes to be followed and the monitoring that must occur to manage the use of CDs safely and accountably within LSW.

5.2 Each SOP is a standalone document with a date, review date and criteria for review. However they are closely linked together and should be referred to as a whole document available on LSW IntraNET but should also be printed and kept in a wallet with the Controlled Drugs record book (CDRB), for ease of reference.

5.3 For the purposes of record keeping in the CDRB for receipt and administration, a counter signatory may be a Registered Nurse, Authorised Pharmacy Staff or Doctor. However, in units where only one Registered Nurse is on duty at any one time and where a pharmacist or doctor is not available, Assistant Practitioners or Healthcare Assistants may be trained to be a counter signatory They must have read and understood the CD SOPs and passed the competency assessment (appendix D) and signed the signature sheet before being authorised by the Nurse in Charge. **The term "authorised witness" for destruction of CDs has a different connotation; only persons approved by the CDAO may perform this role.**

6. Workforce Planning and Training

6.1 All staff members who are involved in the prescribing, supplying, administering or disposing of Controlled Drugs need to be familiar with the SOPs. The SOPs should also be used as a training tool for new and existing staff. The Nurse in Charge will ensure each staff member involved in the handling of CDs has completed the signature sheet at the end of these SOPs. Bank and Agency staff will complete a signature sheet at induction

6.2 Training on the safe use of CDs including high dose opioids will be included in the following programmes:

- Registered Nurse Medicines Management update training
- Junior doctor induction and training

As these programmes are already provided by the organisation, the workforce planning issues are around pharmacist availability which will be addressed by the CDAO.

7. Related Policies

7.1 These procedures apply in all wards and departments of LSW where Controlled Drugs are, or might be kept for administration to inpatients. For advice on the safe handling of Controlled Drugs in the community see Safe and Secure handling of Medicines Policy v 6.1 appendix S. Alternative procedures have been agreed with the Dental Access Centre (see Safe & Secure Policy appendix M).

7.2 This document now incorporates the requirements of the **High Dose Opiates Policy** which was produced in response to the NPSA Safer Practice Notice 12 (May 2006)[2]:
This policy promotes safe practice with high doses of Morphine and Diamorphine (30mg or greater).

The guidance covers the following key areas:

- Risk assessment and procedures for safely prescribing, labelling, supplying, storing, preparing and administering diamorphine and morphine injections.
- Therapeutic guidance on the appropriate clinical use of high strength diamorphine and morphine.
- Recommendations for the training of staff who may be required to give high dose injectable diamorphine and / or morphine.
- Requirements for audit to ensure the guidance is achieving its objectives.
- A Protocol for the emergency use of naloxone by registered nurses, which is required to be stocked in all clinical areas where opioids are stocked or administered.

It is not intended to prevent appropriate clinical use in patients who need them.

The major risks are:

- Dosing errors can arise because the packaging of different strengths of diamorphine and morphine ampoules is the same; the outer carton and ampoule labelling are poorly differentiated; and 5mg, 10mg, 15mg, 20mg and 30mg products have similar appearances.

- Higher strength ampoules of diamorphine and morphine (30mg, for example) stored alongside lower strength products (10mg, for example) in clinical areas, partly due to lack of space within the controlled cabinet to segregate them.
- Insufficient therapeutic training and understanding on the part of the healthcare staff of the risks and precautions when prescribing, dispensing and administering higher doses of diamorphine and morphine injections.

The High Dose Opiates policy included requirements for prescribing, ordering, pharmacy supply, ward storage, administration and patient monitoring. These requirements have been added to the applicable SOPs in this document.

Patient monitoring

Following the administration of opioids, respiratory depression may develop, characterised by a reduction in the respiratory rate to below 10 breaths / minute and/or the onset of drowsiness or confusion, probably with pupil constriction.

Members of staff are reminded that respiratory depression may occur in any patient who is opiate-naïve and the elderly are at particular risk.

In an emergency situation the CPR team must be notified immediately. Whilst waiting for the team to arrive it is permissible for an appropriately trained senior registered nurse to administer 100 - 200 micrograms Naloxone (IV / SC / IM) without a formal medical prescription, as defined in appendix C – "Naloxone Hydrochloride – Protocol for Administration in Opioid Induced Respiratory Depression". An accurate record must be maintained on the prescription chart.

7.3 Other LSW policies that mention Controlled Drugs include:

- Medicines Policy (formerly Safe and Secure Handling of Medicines)
- Medicines Management Policy
- Non-medical Prescribing Policy
- Self-Administration Policy

Whilst every effort has been made to ensure these policies are consistent with each other, in case of any ambiguity the SOPs for Controlled Drugs should be taken as definitive. Any such ambiguities noticed should be brought to the attention of the author.

Controlled Drug SOP no. 1:

Prescribing of Controlled Drugs (CDs)

Applies to: All prescribers working on wards and departments of LSW

Approved by: Medicines Governance Group

Date approved: May 2016

Date for review: Three years or sooner if any of the following apply:

- Following a serious untoward incident, if learning points identify the need for a change to the SOP
- Following a significant change in legislation or best practice guidance

Purpose

To ensure all prescribers are aware of the agreed LSW procedures for prescribing CDs for inpatients, at discharge and to outpatients and of their individual responsibilities and accountability for this process

Scope

This SOP provides advice and guidance to prescribers on the correct procedures for prescribing all Schedule 2 or 3 CDs for inpatients, at discharge and to outpatients, including cautions about the prescribing of high dose opioids.

Relates to

Guidance and other CD SOPs in this document; section 6 (Prescribing) of Safe & Secure Handling of Medicines Policy current version

Responsibilities

The prescribing of CDs on a ward or department is solely the responsibility of the prescriber (for definition see: Safe & Secure Handling of Medicines Policy v 6.0 section 4.1.4 – 4.1.6). Prescribers are also responsible for the security of any FP10 (NC) prescription pads issued to them.

Non-medical Prescribers (NMPs)

The Misuse of Drugs (amendment no.2) 2012 allows Nurse and Pharmacist Independent Prescribers to prescribe any CD in schedules

2 to 5 apart from those listed in part 6B of the regulations (Cocaine, Diamorphine or Dipipanone). As with all prescribing NMPs should only do so where it is appropriate to do so and within their professional competence (see NMP policy)

Remote Orders

Controlled Drugs are not to be prescribed by remote order, apart from adjustment of dose within a previously prescribed dose range.

Making and recording prescribing decisions

When making decisions about prescribing controlled drugs take into account:

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

When prescribing controlled drugs:

- document clearly the indication and regimen for the controlled drug in the person's care record and include the indication on the drug chart.
- check the person's current clinical needs and, if appropriate, adjust the dose until a good balance is achieved between benefits and harms
- discuss with the person the arrangements for reviewing and monitoring treatment
- be prepared to discuss the prescribing decision with other health professionals if further information is requested about the prescription.

When prescribing 'when required' controlled drugs:

- document clear instructions for when and how to take or use the drug in the person's care record. Include the indication on the drug chart.
- include dosage instructions on the prescription (with the maximum daily amount or frequency of doses) so that this can be included on the label when dispensed
- ask about and take into account any existing supplies the person has of 'when required' controlled drugs.

When prescribing, reviewing or changing controlled drug prescriptions, prescribers should follow local (where available) or national guidelines and take into account the:

- appropriate route
- dose (including when dose conversions or dose equivalence is needed)
- formulation (including changes to formulations).

If guidance on prescribing is not followed, document the reasons why in the person's care record.

Use the opioid dose conversion guide (see link below) when prescribing, reviewing or changing opioid prescriptions to ensure that the total opioid load is considered:

http://southwest.devonformularyguidance.nhs.uk/documents/Formulary-documents/Pallative-Care/Guide_to_equivalent_doses_for_opioid_drugs_Dec-2014.pdf

Prescribing for Inpatients:

CDs should be prescribed on the standard inpatient medicines chart as described in: Medicines Policy current version. section 6
When prescribing controlled drugs for inpatients that are to be administered by different routes, prescribe each as a separate item and clearly state when each should be used to avoid administration errors.

High Dose Opioids

The prescribing of high dose (30mg or greater) injectable diamorphine / morphine can only be undertaken by consultants, speciality doctors or GPs (in GP led community hospitals).

All prescriptions must be written on approved prescription forms and include the following information:

- Patient name and NHS number
- Drug name (in CAPITALS): use generic name
- Total dose to be administered
- Volume to be administered
- Route of administration
- Rate of administration
- Be signed with a start date and a finish date as appropriate
- Frequency (PRN doses must give clear instructions of the indication for use, the maximum single dose, minimum interval and maximum total quantity to be administered in 24 hours)
- PRN maximum daily doses should be inclusive of any doses on the regular chart

The lowest clinically appropriate dose must be prescribed.

a) Patient monitoring

Following the administration of opioids, respiratory depression may develop, characterised by a reduction in the respiratory rate to below 10 breaths / minute and/or the onset of drowsiness or confusion, probably with pupil constriction.

Members of staff are reminded that respiratory depression may occur in any patient who is opiate-naïve and the elderly are at particular risk.

In an emergency situation the CPR team must be notified immediately. Whilst waiting for the team to arrive it is permissible for an appropriately trained senior registered nurse to administer 100 - 200 micrograms Naloxone (IV / SC / IM) without a formal medical prescription, as defined in appendix C – "Naloxone Hydrochloride – Protocol for Administration in Opioid Induced Respiratory Depression". An accurate record must be maintained on the prescription chart.

Specialist advice can be obtained from the palliative care team (01752 482384) and / or the pain clinic (01752 762525).

Prescribing for discharge patients:

Prescriptions must be written on the locally approved TTA form, for dispensing to a named patient by Derriford Hospital Pharmacy (DHP). These prescriptions must conform to all requirements of the Misuse of Drugs Regulations for CDs (see below)

Prescription requirements for TTAs and outpatients:

The approved TTA form or FP10 (NC) prescription **must be written so as to be indelible**, i.e. written by hand with indelible pen, typed or computer generated. It must contain the following details:

- The patient's full name, address and patient's age (if under 16 years)
- The patient's NHS number (good practice, not a legal requirement)
- The name and form of the drug, even if only one form exists
- The strength of the preparation where appropriate
- The dose to be taken (in the case of as directed or as required prescriptions, this should be stated as a number of dose units e.g. 'one as directed', not 'as directed')
- The total quantity of the preparation, or the number of dose units, to be supplied **in both words and figures**
- Doses that require the use of two or more strengths of a preparation must have each written out in full e.g. Zomorph MR capsules 40mg twice daily for one week should state:
  Zomorph MR capsules 30mg, take one capsule every 12 hours, supply 14 (fourteen) capsules
  Zomorph MR capsules 10mg, take one capsule every 12 hours, supply 14 (fourteen) capsules

The date **in addition** the prescription must be signed by the prescriber with

his/her usual signature, in his/her own handwriting. This is the only part of the prescription that **must** be handwritten

Providing information and advice to people taking or carers administering CDs

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.

Inform people who are starting controlled drugs that they or their representative may need to show identification when they collect the controlled drugs.

When prescribing controlled drugs for use in the community, advise people how to safely dispose of

- unwanted controlled drugs at a community pharmacy
- used controlled drugs.

Pre-printed sticky addressograph labels:

These should not be used for CD prescriptions because they are not properly tamper-evident. If one has already been applied to the prescription, the prescriber should sign it to indicate that the prescription is for that patient.

Validity:

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

Maximum length of supply:

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

Security and dispensing of TTAs:

Prescription pads must be kept in a locked receptacle when not in use. Original TTA prescriptions for CDs should be sent to DHP securely in the Pharmacy Box or a Pharmacy wallet sealed with a tamper evident seal, allowing a minimum of 24 hours (preferably 48 hours) for it to be dispensed. If the prescription is needed urgently it should be faxed in advance to 53425 then the original sent (as above) in a taxi to DHP.

Prescribing of Injectable Schedule 2 CDs for Substance Misuse Patients

This can only be done by prescribers with a Home Office licence to prescribe to substance misuse clients. These patients should always be referred to the Clinical Lead in Substance Misuse.

Controlled Drug SOP no. 2:

Ordering of Stock Controlled Drugs (CDs)

Applies to: All registered nurses working on wards and departments of LSW, also named prescribers and pharmacists (for the countersigning of orders)

Approved by: Medicines Governance Group

Date approved: May 2016

Date for review: Three years or sooner if any of the following apply:

- Following a serious untoward incident, if learning points identify the need for a change to the SOP
- Following a significant change in legislation or best practice guidance

Purpose

To ensure all staff are aware of the agreed procedure for ordering CDs for inpatients and of their individual responsibilities and accountability for this process

Scope

This SOP must be followed when seeking to obtain any Schedule 2 or 3 CDs for use on the ward or department

Relates to

Guidance and other SOPs in section 8 of Safe & Secure Handling of Medicines Policy current version

Responsibilities

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

Using requisition forms to obtain stock controlled drugs

- When obtaining stocks of controlled drugs in Schedule 2 and 3 from an organisation's contracted external pharmacy, a requisition signed by a doctor or dentist employed or engaged in the organisation must be provided, in line with Regulation 14 of the 2001 regulations.
- **Additional Guidance issued by the Home Office on the use of the mandatory requisition form for Schedule 2 and 3 controlled drugs has confirmed that when an organisation such as LSW obtains CDs from a different legal entity (PHNT):**
  the person in charge or acting person in charge of a hospital can issue a 'bulk' or 'global' requisition based on previous year's orders to a separate legal entity which supplies its wards. Hospital wards can then draw on this 'bulk' requisition throughout the year using the duplicate order forms as happens presently.
- The CDAO for LSW has agreed with the CDAO for PHNT that a yearly requisition for the whole of the organisation will suffice, signed by the Medical Director and / or the Chief Executive.

CD Stock

The ward stock list of CDs should be agreed between the Nurse in Charge and the Authorised Pharmacy Staff, and reviewed at least once a year as part of the Ward CD Checking Procedure (CD SOP no. 8). It should be the minimum possible to meet reasonable foreseeable demands. A list of the agreed CDs and quantities should be kept at the front of the CDRB.

Ordering of injectable morphine / diamorphine

- Ampoules of 5mg and 10mg of morphine or diamorphine may be kept as routine ward stock. These should be ordered in the routine "CD order book" which should be sent to pharmacy. A supply will be sent to the ward at the earliest opportunity, in line with the standard trust policy.
- Low dose ampoules must be used for all bolus dose administration and for patients newly commenced on diamorphine infusions and those requiring less than 30mg in 24 hours.
- **Higher dose ampoules of either drug must not be routinely stored in clinical areas.** Should a specific clinical need arise these can be obtained from pharmacy on a named patient basis – e.g. for the management of a registered diamorphine addict or a palliative care patient requiring 30mg or more diamorphine or morphine in 24 hours.
- When there is a clinical need for higher dose ampoules **a photocopy of the prescription chart (that has been screened by a pharmacist) must be sent to pharmacy together with the CD order book**.

- High strength ampoules will only be supplied by Pharmacy when there is a specific clinical need. A photocopy of the prescription chart will be required together with the CD order book.
- Only whole boxes of ampoules will be issued.
- A fluorescent sticker highlighting the high opioid content will be attached to every box.
- A record of all wards storing a high dose preparation will be maintained within pharmacy. The continuing need for these should be assessed on a weekly basis. High strength ampoules no longer required must be removed and returned to pharmacy via the pharmacy technician as per SOP no. 6.

Temporary CD Stock

If a CD that is not in common use has been prescribed for a patient, the ward or department may keep this as temporary stock and must inform the Authorised Pharmacy Staff. Once the patient no longer requires this medicine Pharmacy Services, LSW must be informed so that the applicable return and destruction procedure is followed (see CD SOP no. 6).

Authenticity

All persons ordering CDs must have previously provided a specimen signature to DHP (and copied to the CDAO, LSW) as proof of authenticity (Derriford Pharmacy form CD06 v.2 see appendix 1 at the end of this SOP). These persons will then become “authorised signatories”, a list of which will be maintained by the ward / department and any changes notified to Pharmacy Services and Derriford Pharmacy immediately. The current list should be kept securely in the CD cupboard, not in the CD order book.

The CDAO, LSW will keep up to date lists of authorised signatories.

The Nurse in Charge of the ward / department will be asked periodically (at least once per year) to verify that the list of authorised signatories held by Pharmacy is current and correct. Any changes must be notified immediately to the CDAO, LSW and DHP Pharmacy.

Orders

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

- Name and address of Hospital
- Ward or Department
- Drug name, form, strength, ampoule size (if applicable and more

than one size available)
- Total quantity
- Signature and printed name of Registered Nurse
- Counter signature of a Pharmacist or Doctor (see below)

The book containing the order must be sent to DHP securely in the Pharmacy Box or a Pharmacy wallet sealed with a tamper evident seal. Only one CD order book per ward or department should normally be in use.

Security

- The CD Order Book must be kept locked in the CD Cupboard at all times when not in use
- Loss or theft should be reported immediately to the CDAO, LSW

Counter-signature

All orders for CDs **must** be counter-signed by either:
- A Pharmacist employed by LSW (but not the CDAO), or
- A Registered Medical Practitioner (or Dentist where applicable) employed by LSW

These persons must have previously provided a specimen signature to DHP and the CDAO, LSW for proof of authenticity (as above). They are signing as an independent verification that there is a clinical need for the CDs to be used on the ward or department. They are not responsible for the management and accountability of the CDs.

Our policy is that only consultants, speciality doctors, or registrars / other grades with at least a one year contract can be authorised signatories for the purpose of counter signing CD orders. Short term registrars, senior house officers and house officers are not eligible to be included.

In the exceptional case of emergency orders placed out of normal working hours, if no pharmacist or doctor is available to counter sign the order, the order will be supplied without the counter signature. In this case the CD order book will be returned to the ward with the white copy of the order. The order must then be counter signed by a pharmacist or doctor and the white copy returned to DHP within 24 hours (or the next working day at weekends or during bank holidays). Such orders should be for the minimum pack size available to cover the emergency requirement only.

Emergency Supplies:

If a CD is required in an emergency and there is no stock on the ward / department, the following steps should be taken:

- If the patient has been admitted when DHP is closed and with their own CDs, these may be administered for a short period of time with the agreement of the Doctor responsible for the patient (see CD SOP no. 7). If this is not the case:
- Check if any neighbouring LSW wards on the same site have any stock that can be spared. **Note: no transfers between different organisations (e.g. PHNT and LSW) are allowed**.
- If so an appropriate quantity of the required CD (sufficient to treat the patient until DHP re-opens) may be transferred by following the procedure below:
- The Nurse in Charge or Designated Nurse should take the patient's medicine chart and the ward CD Register to the nearest LSW ward holding a stock of the CD
- The Nurse in Charge or Designated Nurse from each ward should check the CD against the medicine chart, and an entry should be made in the CDRB of both wards to reflect the transfer (in the supply section for the supplying ward and in the receipt section for the receiving ward). Both entries should be signed by both Nurses.
- The Nurse in Charge or Designated Nurse of the borrowing ward should return promptly to secure the CDs borrowed in the CD cupboard and administer the medicine as per the prescription (see CD SOP no. 5)
- If no stock is available on neighbouring wards, URGENTLY REQUIRED CDs may be obtained by faxing the order to DHP. When the Pharmacy is closed, the on-call Pharmacist must first be contacted. The order must be confirmed by sending a hard copy of the order in the CD Order Book to Pharmacy within 24 hours or the next working day at weekends or bank holidays.
- Verbal or telephoned orders for CDs are not permissible.

Transit and receipt: See CD SOP no.3

Appendix 1: **CD06 v.2** PLYMOUTH HOSPITALS NHS TRUST

PHARMACY CONTROLLED DRUGS

AUTHENTICATION FORM FOR THE ORDERING OF CONTROLLED DRUGS BY AGENCIES OTHER THAN PHNT

Due to the legal requirements for the supply of controlled drugs (CDs), ALL personnel involved in the requisitioning of CDs must have the prior approval of Derriford Pharmacy by supply of a sample signature using the form below. Whilst nurses may initiate a requisition for a CD order and are responsible for the safe keeping and management of CDs, a supply can only be made when the order is countersigned by an authorised doctor, dentist or pharmacist.

To be completed by parties wishing to be supplied by Derriford Pharmacy

Name (block capitals).....

Profession.....Registration no.....

Employing Organisation.....

Ward(s) or Department(s) where responsible for CDs.....

Contact details: Tel no.....Fax no.....

Email.....I certify that I am registered with the appropriate body and competent in the ordering process for controlled drugs. There is a clinical need as part of my daily duties to order or counter sign controlled drug orders for the above ward(s) or department(s). I understand that I must inform Derriford Pharmacy immediately should this no longer be the case.

Signature.....**Date.**.....

Please note that orders will not be processed without a completed and in date Authentication Form.

It is the responsibility of the authorising signatory to ensure that all personnel ordering CDs are registered with the appropriate body and have a need to order or countersign orders for CDs as part of their daily duties.**All forms must be authorised and witnessed by: Pharmacist or Unit Manager**

Name (Block letters)	Profession	Registration No.	Signature	Date

Controlled Drug SOP no. 3:

Receipt and Storage of Stock Controlled Drugs (CDs)

Applies to: All wards and departments of LSW

Approved by: Medicines Governance Group

Date approved: May 2016

Date for review: Three years or sooner if any of the following apply:

- Following a serious untoward incident, if learning points identify the need for a change to the SOP
- Following a significant change in legislation or best practice guidance

Purpose

To ensure all staff are aware of the agreed procedure for receipt and storage of CDs for inpatients and of their individual responsibilities and accountability for this process

Scope

This SOP must be followed when receiving and storing any Schedule 2 or 3 CDs for use on the ward or department

Relates to

Guidance and other CD SOPs in this document; sections 8 & 9 of Medicines Policy current version

Responsibilities

The receipt and storage of Stock CDs on a ward or department is the responsibility of the Nurse in Charge (see SOP no.2)

Receipt

When CDs are delivered to a ward or department they should be identified as such by the person making the delivery and a signature for receipt obtained from a Registered Nurse. As a matter of good practice this Nurse should not be the same as the Nurse who ordered the CDs. On no account should they be left unattended.

Immediately after delivery the Nurse in Charge or Designated Nurse,

must take the following steps in the presence of a counter signatory (see Policy section 5.3):

- Check the drug name, preparation and quantity against the order and sign and date the 'receipt' portion of the order book.
- Any tamper-evident seals on packs of medication should be left intact when they are received as this will speed up routine checks. A seal should only be broken when the pack is required for administration.
- In the case of any discrepancies, inform Derriford Pharmacy immediately and complete an incident form. Then proceed as below.
- Lock the CDs in the ward CD cupboard.
- Enter the received stock into the Controlled Drug Record Book (CDRB), update the running balance and check that the balance tallies with the quantity that is physically present (see CD SOP no. 4).

Storage

- Ward CD cupboards should conform to British Standard reference BS2881 and BS3621. They must be bolted at 4 points to a structural wall or floor in a locked clinic room. As wards are continuously manned the security risk is deemed to be low (level 1).
- The storage environment should be suitable for the products stored: sufficient space for ease of selection and a maximum temperature of 25C. CDs requiring refrigeration must be stored in a locked refrigerator and the key held and possession restricted as with the CD cupboard key.
- Cupboards must be kept locked when not in use
- The lock must not be common to any other lock in the Hospital
- Access to the CD cupboard must only be available to persons who can lawfully be in possession of CDs i.e. the Nurse in Charge (or Designated Nurse) or another Registered Nurse. Authorised Pharmacy Staff are permitted access for the purposes of stock balance checks or return of CDs for destruction only (see SOP nos. 6 and 8).
- The cupboard should be dedicated to the storage of CDs. This may include midazolam or other schedule 3 CDs for which safe custody is not a legal requirement. Midazolam should be stored in a CD cupboard unless to do so would prevent its timely use in an emergency.
- Low dose and high dose (30mg or greater) morphine / diamorphine injections must always be segregated with the CD cupboard.
- Patients' own or discharge CDs may be kept in the CD cupboard prior to discharge or destruction (see CD SOP no.7). These medicines should be segregated from ward stock. No other

medicines or other items may be stored in a CD cupboard.
- CDs must always be locked away when not in use.
- Unwanted or expired CDs must be segregated from ward stock until collected or destroyed.

Key Holding

- The Nurse in Charge is responsible for the CD keys
- The CD key must be kept separate from the other medicine cabinet keys
- Key-holding may be delegated to a Designated Nurse or another Registered Nurse, but the legal responsibility rests with the Nurse in Charge. The key holder should be readily identifiable at all times.
- The CD key should be returned to the Nurse in Charge immediately after use by another authorised member of staff
- On occasions, for the purpose of stock balance checks or return of CDs for destruction, the CD keys may be handed to an Authorised Pharmacy Staff, who must return them immediately after use.

Missing CD Keys

- If the CD keys cannot be found then urgent efforts should be made to retrieve the keys as speedily as possible by contacting nursing staff who have just gone off duty, or others who may have been given access to the keys e.g. Authorised Pharmacy Staff.
- The senior Nurse or Matron for the directorate on duty should be informed as soon as possible.
- The spare CD key kept in the reception area should be signed out for temporary use by the senior Nurse or Matron for the directorate on duty.
- If a spare CD key is not available and CDs are required for patients then arrangements should be made with an adjacent ward where possible (see CD SOP no.2 – emergency supplies)
- The LSW CDAO (or deputy) should be informed as soon as practicable, who will consult with other senior staff as appropriate. Depending on the circumstances, the police may be contacted by the CDAO, out of hours Director on call or other senior staff member.

Temporary closure or transfer of wards

- The applicable Locality Manager is responsible for the overall management of the project when a ward is closed or transferred.
- The Nurse in charge of each ward affected is responsible for the security of their CD stock and the keeping of the required records.

- In the case of temporary closure of a ward, all stocks of CDs should be transferred to a neighbouring ward. The stock should be written out of the CDRB of the closing ward by the Nurse in Charge and an Authorised Pharmacy Staff. The stock should then be written into the neighbouring ward CDRB by the same Authorised Pharmacy staff and the Nurse in Charge of the receiving ward. All stock balances must be reconciled at the end of this process.
- If a ward transfers to a new location, the removal of CD stock from the old location to the new should be witnessed by the Nurse in Charge and an Authorised Pharmacy Staff, both of whom should also reconcile all stock balances at the end of this process.

Controlled Drug SOP no. 4

Record Keeping for Stock Controlled Drugs (CDs)

Applies to: All wards and departments of LSW

Approved by: Medicines Governance Group

Date approved: May 2016

Date for review: Three years or sooner if any of the following apply:

- Following a serious untoward incident, if learning points identify the need for a change to the SOP
- Following a significant change in legislation or best practice guidance

Purpose

To ensure all staff are aware of the agreed procedure for record keeping of CDs for inpatients and of their individual responsibilities and accountability for this process

Scope

This SOP must be followed when receiving, storing, administering or arranging for destruction any Schedule 2 or 3 CDs for use on the ward or department, including patient's own CDs. Regular balance checks must also be recorded.

Relates to

Guidance and other SOPs in section 8, 9, 10 & 13 of Medicines Policy current version

Responsibilities

The record keeping requirements for CDs on a ward or department is the responsibility of the Nurse in Charge (see SOP no.2 for delegated authority)

CD Record Books (CDRB) – General Points

Each ward or department that hold stocks of CDs should keep a record of CDs received, administered and removed for destruction in a CDRB.

The Nurse in Charge is responsible for keeping the CDRB up to date and in good order.

- The CDRB should be bound (not loose-leaf) with sequentially numbered pages. Separate pages should be kept **for each stock drug and strength,** so that a running balance may be kept easily, and an index of all preparations in stock should be kept at the front of the book. The book should be marked prominently on the front as for Stock CDs only.
- Entries should be made in chronological order, in ink or otherwise indelible, on the day the transaction took place.
- All entries should be made and signed by a Registered Nurse, and witnessed and signed by a second Registered Nurse. If a second nurse is not available then a counter signatory (see 5.4) may sign as a witness.
- On reaching the end of a page of the CDRB, the balance should be transferred to another page. The new page number should be added to the bottom of the finished page and the index updated. The transfer should be witnessed as above.
- **No entry in a CDRB may be cancelled, obliterated or altered.** If a mistake is made it should be bracketed in such a way that the original entry is clearly legible. An asterisk should be placed against the bracketed entry and a marginal or footnote made, which should be signed and dated and also witnessed (signed and dated) by another Registered Nurse.
- Only one stock CDRB should be in use at a time. When a new CDRB is started the balance of CDs in stock should be written into the new book promptly by a Registered Nurse. The transfer should be witnessed by a Registered Nurse or Authorised Pharmacy Staff.
- The CDRB should be kept securely in either the CD cabinet or in a locked cupboard or drawer. Loss or theft should be reported immediately to the LSW CDAO

Patient's Own CDs

- If patient's own CDs are **held on the ward / unit a separate CDRB should be obtained for these only. It should be marked prominently on the front as for Patient's Own CDs**

Records of Receipts

It is a legal requirement that a record is kept of all Schedule 2 CDs that are received, administered or destroyed. Within LSW this

requirement is also extended to Schedule 3 CDs such as Buprenorphine, Temazepam, Tramadol and Midazolam, as a matter of good practice. For CDs received, the following details should be recorded in the CDRB:

- At the top of each page: Name of drug, form of preparation and strength
- For each receipt
  - Amount received – record in words and figures e.g. ten (10)
  - Date of receipt
  - Serial number of the requisition
  - Name / signature of Nurse making the entry and of the witness
  - Balance in stock

Records of Administration

- For each CD administered to inpatients the following details should be recorded:
  - Date and time when dose administered
  - Name of patient and NHS number
  - Amount given in words and figures
  - Name / signature of authorised nurse who administered the dose
  - Name / signature of witness
  - Balance in stock

- If part of a ampoule / vial is administered to the patient a record should be made of the amount administered and the amount wasted e.g. if the patient is prescribed 2.5mg diamorphine and only a 5mg ampoule is available, the record should show “2.5mg given and 2.5mg wasted”. Such an entry should be witnessed as above.

Records of Disposal

- Individual doses of CDs which have been prepared but not administered should be destroyed a Registered Nurse, stating the reason for destruction in the left hand margin of the CDRB with the entry witnessed by a second Registered Nurse (see CD SOP no.6 for method of disposal).
- CDs that are time expired, no longer required or otherwise unfit for use must be either returned to Pharmacy by an Authorised Staff or denatured on site by Pharmacy and an Authorised Witness (see CD SOP no.6). An entry should be made in the CDRB by the Authorised Staff and witnessed by a Registered Nurse to state:
  - Date

- Amount of drug being returned or denatured
- The statement “Denatured for destruction”
- Names and signatures of the Authorised Pharmacy Staff , Registered Nurse and Authorised Witness (where applicable)
- Balance remaining

Stock Balance Checks

- A balance check must be performed after every receipt, administration or disposal of a CD. The Check must be performed by a Registered Nurse and counter signed by another Registered Nurse (or other counter signatory authorised by the Nurse in Charge – see policy section 5.3) and recorded in the CDRB as above.
- In addition a balance check must be performed every 24 hours for all CDs kept in stock. The balance should be recorded on the “CD daily stock reconciliation check” form, a copy of which is provided at the end of this SOP.
- Where possible the staff undertaking this check should be rotated periodically.
- There should be a separate form for all CD preparations kept in stock.
- To ensure all balances are checked, each drug entered in the CDRB should be checked against the contents of the cupboard, then making sure there is no stock for which an entry in the CDRB has not been made.
- It is not necessary to open original packs with intact tamper-evident seals for stock checking purposes. Opened packs should never be re-sealed for the purpose of avoiding having to count the stock subsequently.
- Stock balances of liquid medicines should be checked daily by visual inspection, but weekly accurate volume checks are required using calibrated measuring cylinders (which must be fully drained back into the bottle after use).
- To aid subsequent visual checks a piece of tape may be placed on the outside of the bottle with the top of the tape level with the meniscus of the liquid. The measured volume should then be recorded on the tape, dated and initialled. A new piece of tape must be applied if a dose is administered.
- The total balance must be confirmed by measurement to be correct on completion of a bottle.
- The date, time, the signature of a Registered Nurse and another Registered Nurse (or other staff authorised by the Nurse in Charge) to witness and the balance physically in stock should all be recorded on the form.
- CD daily balance check forms should be kept securely in a dedicated file and kept in chronological order, so that at audit it can

be shown that the requirements for stock balance checks have been met.

Dealing with Discrepancies

- If at first sight the balance check appears to indicate a discrepancy, the following should be carefully checked:
  - All requisitions received (by reference to the order book) have been entered into the correct page of the register
  - All CDs administered (by reference to the drug chart(s) of patients known to be receiving CDs) have been entered into the CDRB on the correct page
  - Items have not been accidentally put into the wrong place in the cupboard
  - The item has not been received as a different brand or in new packaging resulting in it not being recognised
  - Re-check arithmetic to ensure balances have been calculated correctly
  - Stock receipts or administrations from stock have not been entered on patients' own drugs pages (or vice-versa)
- If the error or omission is traced the Nurse in charge should make an entry in the CDRB clearly stating the reason for the error and the corrected balance. This entry should be witnessed by a second Registered Nurse, Authorised Pharmacy staff or doctor.
- Any discrepancy not explained by the above must be reported immediately to the LSW CDAO and the line manager of the Nurse in Charge and a LSW Incident Form completed.
- Such incidents will be reported by the LSW CDAO to the Devon CDLIN Accountable Officer routinely in the Quarterly Occurrence Report. If there is any suspicion of misuse or diversion, the Accountable Officer must be informed immediately, along with the Risk Manager and Head of Governance who will instigate an immediate investigation.

Archiving of Controlled Drug Records

- All, CD order books, CD returns books and CD daily balance check forms must be kept for **a minimum of two years** from the date of the last entry. Books not in use may be kept in a locked cupboard or drawer rather than the CD cupboard.
- If records of destruction (including patient's own) are included in the CDRB then the retention period required is **seven years**. If there have been no records of destruction in the CDRB it only needs to be retained for two years.

Controlled Drug Daily Stock Reconciliation Check

Ward / Unit_____ **Site** _____

Drug Name_____

Dose Form and Strength_____

Date	Time	1st witness: Signature	2nd witness Signature	Quantity in Stock

Controlled Drug SOP no. 5

Administration of Controlled Drugs (CDs)

Applies to: All wards and departments of LSW

Approved by: Medicines Governance Group

Date approved: 6th May 2016

Date for review: Three years or sooner if any of the following apply:

- Following a serious untoward incident, if learning points identify the need for a change to the SOP
- Following a significant change in legislation or best practice guidance

Purpose

To ensure all staff are aware of the agreed procedure for the administration of CDs for inpatients and of their individual responsibilities and accountability for this process

Scope

This SOP must be followed when administering any Schedule 2 or 3 CDs to an inpatient on the ward or department.

Relates to

Guidance on medicines administration in section 10 of Safe & Secure Handling of Medicines Policy v 6.2

Responsibilities

The ultimate responsibility for administration resides with the nurse or doctor administering the drug to the patient.

Standards and safety checks for administering controlled drugs

Follow the relevant standards set by the professional regulator when administering controlled drugs, and when necessary check with the prescriber about any safety concerns such as:

- whether the prescribed dose is safe for the person

- whether other formulations have already been prescribed for the person
- whether the formulation is appropriate
- that any past doses prescribed have been taken.

Providing information and advice to people having controlled drugs administered

- Tell the person having the controlled drug the name and dose of the drug before it is administered, unless the circumstances prevent this.
- Provide advice on how different formulations of controlled drugs are administered, and check that the person understands the advice. Ensure that appropriate equipment is available for the correct dose to be administered.

Procedure for Administration of CDs

- CDs may only be administered to inpatients from stock, apart from in an emergency when a patient's own supply may be used prior to a stock supply being obtained (see below).
- CDs must be administered by the Nurse in Charge or a designated Nurse and must be checked by another Registered Nurse or counter signatory (see Policy section 5.4)
- **Both these persons must remain present throughout the entire procedure** of checking, preparation and administration of the CD.
- **If in any doubt staff administering CDs should ask for advice from other healthcare professionals as appropriate**
- Administration of CDs is as for any other medicine (see section 10. of Safe and Secure, appropriate section is indicated against each bullet point) apart from the additional actions listed below.
- Both persons must:
    - Check the prescription is legible and valid (see Safe & Secure section 10.3)
    - Select the correct Controlled Drug (in accordance with Safe & Secure section 10.5)
    - Low dose ampoules of diamorphine/ morphine must be used for all bolus dose administration and for patients newly commenced on infusions and those requiring less than 30mg in 24 hours.

    - Check the stock balance of the CD against the balance remaining in the CDRB (see CD SOP no. 4)
    - Complete the entry in the CDRB (see CD SOP no.4)
    - Prepare the medicine for administration and lock the remaining CD away in the CD cupboard.
    - Take the medicine and the prescription chart to the patient and confirm the identity of the patient. If the patient is not

wearing an identiband be especially careful and ask them to confirm their date of birth if unsure.
- The Nurse administering the CD should initial the patient's prescription chart at the time of administration.
- Both people must ensure the remaining details are recorded in the CDRB i.e. the time of administration and the full signature of the Nurse administering the CD and the witness.
- If for any reason the CD is not administered a record of the reason for non-administration must be made in the left hand margin of the CDRB (see CD SOP no.4). A reason code should be entered on the prescription chart and the details recorded in the patient's notes.

Administration of Patient's Own Drugs (PODs) and TTA supplies

- If a patient is admitted when the Pharmacy is closed and is prescribed a Controlled Drug not stocked by the ward and not available from another ward on the same site, the patients' own supply may be used.
- The patient's own supply should only be used temporarily until such time as a stock supply can be obtained, unless the patient is self-administering (see below).
- The normal procedure for checking PODs (see Medicines Management Policy & Procedures) should be followed to ensure they are fit for purpose.
- Additionally, the patient's doctor should be informed and must agree to the use of the CD POD.
- The patient's own CD should be recorded on a new page of the patients' own CDRB, and all doses administered should be recorded on that page. The patient's own CD should be stored in the CD cupboard, but segregated from stock CDs.
- The same procedure as above can be used to administer CDs supplied as a TTA if no stock supply is available.
- The procedure for dealing with other aspects of patient's own and discharge Controlled Drugs is dealt with in CD SOP no.7

Self-Administration by Patients

- Patients who are assessed as competent to self-administer their medication will need to have any prescribed controlled drugs administered by nurses in the usual way, but should be encouraged to request these drugs as part of the self-administration process.

Controlled Drug SOP no. 6

Removal of Controlled Drugs (CDs) for Destruction

Applies to: All wards and departments of LSW

Approved by: Medicines Governance Group

Date approved: May 2016

Date for review: Three years or sooner if any of the following apply:

- Following a serious untoward incident, if learning points identify the need for a change to the SOP
- Following a significant change in legislation or best practice guidance

Purpose

To ensure all staff are aware of the agreed procedure for the destruction of CDs from wards or departments and of their individual responsibilities and accountability for this process

Scope

This SOP must be followed when collecting for destruction or denaturing any **Schedule 2, 3 or 4 (part 1) CDs** (see definition in CD Policy Introduction) from stock or patients' own supplies on the ward or department.

Relates to

- Other CD SOPs in this series.
- Medicines Policy:
  - Section 25 (Policy and Procedure for Dealing with Suspected Illegal Drugs or Substances brought onto LSW premises by a Patient or Visitor)
  - Section 15: Policy for the disposal and re-use of pharmaceuticals

Abbreviations and definitions

CD	Controlled Drug
CDAO	Controlled Drug Accountable Officer
CDRB	Controlled Drug Record Book
Denaturing	The process of rendering controlled drugs irretrievable prior to disposal
Denaturing kit	Plastic jar of varying sizes containing a soluble sachet of a gelling agent which dissolves in contact with water. The gelling agent then solidifies the contents
RPS	Royal Pharmaceutical Society

Responsibilities

- The **Accountable Officer for Controlled Drugs (CDAO)** is responsible for (in relation to CD destruction):
  - Writing and reviewing this SOP in line with the latest legal and best practice guidance
  - Ensuring the approved SOP is read, understood and followed by all relevant members of LSW staff
  - Authorisation of pharmacy staff to collect and denature CDs
  - Approval of authorised witnesses for the denaturing of CDs
  - Producing a timetable of denaturing sessions for the pharmacy staff and approved witnesses as agreed with both parties
  - Overseeing the smooth operation of the denaturing sessions
  - Application to the Environment Agency for a T28 exemption certificate for each site of LSW that may stock CDs. Ensuring the T28 is current and renewed as required by the Environment Agency.
  - Investigation of any incidents relating to destruction of CDs
  - Audit of the process of collection / denaturing and destruction to monitor compliance.

  - The **Nurse in Charge** of each ward or unit is responsible for ensuring that the agreed procedures are followed by all staff involved in the handling of CDs on the ward / department. The

Nurse in charge is also responsible for witnessing the removal of CDs for destruction by Pharmacy Staff (MGH and Glenbourne sites); or for witnessing the denaturing of CDs by Pharmacy staff in the presence an authorised witness (other sites)

- **Registered Nurses** are responsible for destroying part doses or non- administered individual doses on the ward as described below. Registered Nurses are also responsible for informing Authorised Pharmacy Staff (Pharmacy Services, Mount Gould Hospital, not Derriford Hospital) of any time-expired or no longer required CDs in their CD cabinets.

- **Authorised Pharmacy Staff** are responsible for:

- Timely removal of CDs for destruction from wards on the Mount Gould site witnessed by the nurse in charge of the ward
- MGH wards: Transportation of such stock to MGH Dispensary and completion of the appropriate records.
- Glenbourne wards: Transportation of such stock to Glenbourne Dispensary and completion of appropriate records
- Denaturing of CDs in the presence of an authorised witness at the dispensary, MGH or at the dispensary, Glenbourne.
- Denaturing of CDs in the presence of an authorised witness and the nurse in charge at other registered sites of LSW

- **Disposal of small quantities of CDs**

- The law allows small amounts of CDs to be destroyed on wards[2]. This includes the surplus when the dose administered is less than the smallest ampoule or vial available; or when an individual dose is prepared but not administered:
- All doses disposed of must be documented in the Controlled Drug Record Book (CDRB) as detailed in CD SOP no.4.
- None of the controlled drugs in schedules 2, 3 or 4 are on the hazardous medicines list and may therefore be placed into yellow lidded bins as detailed below.
- Small amounts for disposal should be destroyed by emptying into a yellow lidded sharps bin. The emptied ampoule or vial, together with the syringe and needle used to give the dose, should also be placed into the sharps bin.
- When a bin containing such waste is sent for destruction it should be labelled “contains mixed pharmaceutical waste and sharps – for incineration”

6.10.2 Larger quantities, for example stock and patients’ own CDs that are time-expired or surplus to requirements; discontinued infusions or patient controlled analgesia syringes containing CDs must be destroyed following the procedure below

6.10.3 No expired / unwanted drugs (including CDs) may be taken or sent back to Derriford Pharmacy – please follow the procedures below depending on your location.

6.11 Return of CDs to Pharmacy for destruction – Mount Gould and Glenbourne sites only

6.11.1 The Environment Agency requires a separate T28 exemption certificate (to exempt LSW from requiring a permit) for each site where CDs are destroyed. Thus all wards on the MGH site are covered by the same T28 and this allows us to transport unwanted CDs back to the dispensary in the Local Care Centre. Similarly for Glenbourne both wards' unwanted CDs will be returned to the Glenbourne Dispensary.

6.11.2 All other sites require their own T28 and CDs must be destroyed at that site only – they cannot be transported back to Pharmacy (see section 6.12)

6.11.3 Authorised Pharmacy Staff (Pharmacy Services, Mount Gould Hospital, #34726 or Glenbourne #39006) should be informed if any CDs held are excess to requirements or time-expired.

6.11.4 Authorised Pharmacy Staff will visit the ward to collect the CDs at the earliest opportunity and certainly within one week.

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

6.11.6 The Authorised Pharmacy Staff will record CDs returned to Pharmacy in a returns advice note with duplicate pages so that both the pharmacy and the ward have a record of the transaction. The following details should be recorded on the returns advice note and in the appropriate page of the CDRB when CDs are returned to Pharmacy:

- Date
- Name, form, strength and quantity of drug being returned
- Reason for return ("Returned to pharmacy for destruction")
- Name and signature of the Nurse in Charge (or deputy) and of the Authorised Pharmacy Staff
- The top (white) page in the duplicate book will be removed and kept in the back of the ward CDRB as a cross reference.
- The book and CDs will be taken back immediately to the dispensary by the Authorised Pharmacy Staff. The CDs will be entered into the Pharmacy CDRB by the Authorised Pharmacy Staff and witnessed by a second Authorised Pharmacy Staff. At this point the stock balance for each preparation returned must be checked. The CDs will be stored in the CD cupboard in the

dispensary until the next scheduled denaturing session.

6.11.7 The procedure for Patient's own CDs is essentially the same as for stock CDs with the proviso's listed below. Patient's own CDs that are not to be used for self-administration should not routinely be stored on the ward (see CD SOP no.7). Please note:

- Patients' own drugs are the property of the patient, so consent must be obtained before they are removed for destruction.
- A "Consent for Destruction" form (Appendix 1) should be completed and signed by the patient. It should be countersigned by a Registered Nurse, Authorised Pharmacy Staff or Doctor. If the patient is unable to sign, a relative should be asked to do so, on their behalf. If there is no relative the form can be signed by another healthcare professional.
- Patient's own CDs for deceased patients can be removed from the ward for destruction without the consent of the patient's estate (or relatives) i.e. signed by the Authorised Pharmacy Staff and the Nurse in charge (or deputy).

6.12 Denaturing of CDs at the dispensary (Mount Gould Hospital or Glenbourne)

6.12.1 A timetable of denaturing sessions will be produced by the CDAO up to one year in advance and distributed to pharmacy staff and authorised witnesses. Prior to the next scheduled MGH or Glenbourne denaturing session the Authorised Pharmacy Staff will make contact with the scheduled authorised witness to arrange the time of the session.

6.12.2 The Authorised Pharmacy Staff will check the range and quantity of CDs to be denatured to advise on the duration of the session and to ensure the appropriate size(s) of denaturing kits (see below) are available.

6.12.3 At the start of the session a bench in the dispensary will be cleared of all other drugs and clutter and the CDs for destruction removed from the CD cupboard to the bench.

6.12.4 Taking each container of CDs in turn the appropriate page in the CDRB will be located. The quantity of the CD will be counted by both the Authorised Pharmacy Staff and the authorised witness and reconciled with the quantity in the CDRB. The stock balance will be adjusted and checked by both parties before signing the CDRB.

6.12.5 The CDs will be removed from all outer packaging which will be recycled as per Policy for the Handling of Pharmaceutical Waste (section 15 Safe & Secure Handling of Medicines Policy)The RPS

guidance on denaturing CDs will be followed before placing the CDs in the denaturing kit.

6.12.6 A “denaturing toolkit” will be kept in the CD cupboard at MGH and Glenbourne dispensaries to consist of the following:

- Dispensing triangle for counting tablets and capsules
- Pestle and mortar for crushing tablets
- 500ml and 100ml graduated measures for measuring liquids
- Surgical gloves and face masks
- Range of denaturing containers 250ml – 2 litres.
- RPS guidance on denaturing controlled drugs
- This procedure, sample signatures of authorised pharmacy staff and authorised witnesses.

6.12.7 Gloves should be worn when denaturing CDs to prevent skin contact. When crushing tablets it is recommended that a small amount of water is used to reduce dust production. Nevertheless it is also recommended that a face mask is worn to reduce particulate inhalation.

6.12.8 . Remove or obliterate labels and other identifiers from the container. Bottles should be rinsed and the liquid added to the denaturing kit.

6.12.9 An entry will be made in the CDRB on the page for each specific drug and strength in turn to include date, time, quantity of drug, the words “denatured for destruction”, signature of authorised pharmacy staff and authorised witness and new stock balance (which should be zero).

6.12.10 CD denaturing kits are available in a range of sizes – select the size appropriate for the quantity of drugs being denatured (for ordering codes see appendix 1). The kits consist of a rigid container with a water soluble sachet of a gelling agent. The CDs are added to the kit (with the gel sachet in situ) up to a maximum of half full. Solid doses, liquids and patches may be mixed together in a single kit. The kit should then be filled to the line near the top with cold water, the lid replaced and the container shaken vigorously. Within a few seconds to a minute the gel sachet will dissolve and the whole of the contents will progressively become solid. It is important that shaking continues until a solid state is reached as this is necessary for the contents to be irretrievable.

6.12.11 The filled kit should then be placed in a yellow lidded sharps bin which will then be collected for removal by the porters prior to be taken by the appointed carrier to the incinerator at Derriford.

6.13 Denaturing of CDs at Peripheral LSW sites

6.13.1 At all LSW sites other than MGH or Glenbourne a different procedure for destruction of CDs is required as detailed below. This procedure applies to:

- Lee Mill Hospital
- Syrena House
- Plym Bridge House
- Dental Access Centre
- South Hams Hospital
- Tavistock Hospital

6.13.2 Pharmacy Services, Mount Gould Hospital, #34726 should be informed if any CDs held are excess to requirements or time-expired. These requests will be recorded in a log book. The ward will be informed of the proposed date of the next peripheral denaturing session (scheduled every two months)

6.13.3 Prior to the next scheduled “Peripheral Sites” denaturing session the Authorised Pharmacy Staff will make contact with each of the above units to check if any CDs requiring destruction are held, recording any additional requests in the log book. Based on the records in the log book a route for the visits can then be planned. The Authorised Pharmacy staff will contact the scheduled authorised witness to arrange the time and starting point of the session.

6.13.4 The authorised pharmacy staff and authorised witness will meet as arranged, assemble the CD denaturing toolkit and visit each peripheral unit requiring CD destruction in turn, making contact with the unit manager or nurse in charge.

6.13.5 Denaturing of CDs will then proceed as in section 6.12.4 – 6.12.9 above, the only difference is that three signatures will be required on each page of the CDRB where destruction takes place:

- Nurse in charge (or appointed deputy)
- Authorised pharmacy staff
- Authorised witness

6.13.6 The denaturing kit must be placed in a sharps bin in the unit where denaturing has taken place. Part used kits must not be transported between units.

6.13.7 When the session is completed the denaturing tool kit must be returned to the dispensary from which obtained. The authorised pharmacy staff must ensure any items used or broken are replaced.

Appendix 1

Oracle Order Codes for Denaturing Kits

250ml	DOSCDDK250
1000ml	SOCDDK1
2000ml	SOCDDK2L

Controlled Drug SOP no. 7

Patients' own and discharge Controlled Drugs (CDs)

Applies to: All wards and departments of LSW

Approved by: Medicines Governance Group

Date approved: 6th May 2016

Date for review: Three years or sooner if any of the following apply:

- Following a serious untoward incident, if learning points identify the need for a change to the SOP
- Following a significant change in legislation or best practice guidance

Purpose

To ensure all staff are aware of the agreed procedure for the handling of patients' own and discharge supplies of CDs and of their individual responsibilities and accountability for this process

Scope

This SOP must be followed when handling patients' own and discharge supplies of any Schedule 2 or 3 CDs on the ward or department.

Relates to

Guidance and other SOPs in section 12 of Medicines Policy

Responsibilities

The **Nurse in Charge or Designated Nurse** is responsible for the safe custody of patient's own and discharge CDs on their ward or department. They are also responsible for ensuring the maintenance of the audit trail for CDs when patients are discharged.

Authorised Pharmacy Staff are responsible for removing patient's own CDs for destruction, when requested to do so by the Nurse in Charge (MGH and Glenbourne only).

Authorised Pharmacy Staff, Registered Nurses and Doctors are responsible for confirming the suitability of patient's own CDs for administration on the ward and for issue as a TTA.

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

- Patient's own CDs may be used on the ward in either of the following situations (see SOP no. 5):

- Temporary use whilst a stock supply of the CD is being obtained
- For patients self-administering their own medication

- If patient's CDs are not required for either of these purposes then one of the following procedures should be followed and all actions recorded:
  - If the patient or the patient's agent agrees, the CDs may be removed from the ward for destruction by the Authorised Pharmacy Staff (see CD SOP no. 6).
  - If the patient wishes, the CDs may be returned home via an identified adult to whom responsibility for security is given. An entry in the back of the CDRB should be made, the details of which should match those required for the collection of a CD TTA by a patient representative (see below).
  - In Mental Health & Learning Disabilities, where the patient may not have the capacity to make a decision, the CDs may be held on the ward until discharge.
  - If the CDs are not safe and / or appropriate for use, then the patient and / or patient's agent should be advised and they should be encouraged to allow the destruction of the CDs.
- Patient's own CDs must never be used to treat other patients.

Record Keeping, Administration and Destruction of Patient's Own CDs

For more detail of these aspects, please refer to CD SOP nos. 4, 5 and 6 respectively

Procedure for TTA Controlled Drugs

- The TTA should be completed by the Doctor a minimum of 24 hours (preferably 48 hours) prior to the discharge of the patient. Prescriptions must comply with all legal requirements (see CD SOP no. 1)
- The **original** copy of the prescription must be sent to the Pharmacy to be dispensed (faxes or photocopies are not acceptable)

- **Receipt of TTA drugs:**
  - On receipt a Registered Nurse and a counter signatory (see 5.4) should check the TTA supply:
  - Ensure that the drug, preparation, strength, directions and quantity exactly match the prescription. Any discrepancy should be reported to an Authorised Pharmacy Staff and / or Derriford Pharmacy, and an incident form completed.
  - Enter full details of the TTA CD prescription in the patients' own CDRB to include:
    - Date
    - Patient's name and NHS number
    - Drug name, preparation and strength
    - Amount received
    - Signature of both Nurses
  - Re-seal the bag containing the TTA CD and place in the CD cupboard, clearly segregated from the stock in the cupboard.

Providing information and advice to people receiving controlled drugs

- When supplying more than one formulation (for example immediate-release and sustained-release formulations) of a controlled drug, discuss the differences between the formulations with the person, and their family members or carers if appropriate, and check that they understand what the different formulations

are for and when to take them.

- When supplying controlled drugs, advise people how to safely dispose of: unwanted controlled drugs at a community pharmacy used controlled drugs.

Provide advice and information to people who are prescribed controlled drugs about how to store controlled drugs safely. Discuss storage options taking into account:

- the person's preference for a lockable or non-lockable storage box
- whether the controlled drugs will be accessible to people who should and should not have access to them
- whether the storage method could increase the risk of controlled drug-related incidents, including patient safety incidents.

- **When the patient is ready for discharge:**
    - A Registered Nurse and counter signatory (see 5.4) should check the CDs out of the cupboard, confirming again that they conform to the prescription.
    - An entry should be made at the back of the CDRB to confirm:
        - Date of discharge
        - Drug name, preparation, strength and quantity
        - Signature of both Nurses
        - Whether the CDs are given to the patient, a representative or a health care professional acting on behalf of the patient.
        - If given to a representative, evidence of identity should be recorded, or a reason why evidence was either not requested or provided.
        - If given to a health care professional, that person's name, position and employing organisation.
        - The signature of the person receiving the CD.

- **Patients discharged to Care Homes or CDs needing to be delivered after discharge**
    - If the patient going to a Care Home is considered able to sign for their own medication then the procedure above should apply, with no additional paperwork.
    - If the patient is not able to sign a representative e.g. ambulance driver should be asked to sign for them
    - If CDs need to be delivered to a patient's home or a care home after discharge then the ward should book transport of these with City Sprint Tel: 01752 333550. City Sprint provides an electronic audit trail which can be downloaded and printed or saved in SystmOne. The printed receipt should be kept at the back of the CDRB.

Appendix 1

Controlled Drug Delivery Form

Date	Patient		Drug			Delivered By		Received (signature)
	Name	NHS no.	Drug name	Strength	Quantity	Print name	Signature	

Controlled Drug SOP no. 8

Pharmacy checking and audit of Controlled Drugs (CDs)

Applies to: All wards and departments of LSW

Approved by: Medicines Governance Group
Date approved: 6th May 2016

Date for review: Three years or sooner if any of the following apply:

- Following a serious untoward incident, if learning points identify the need for a change to the SOP
- Following a significant change in legislation or best practice guidance

Purpose

To ensure all staff are aware of the agreed procedure for the handling of patients' own and discharge supplies of CDs and of their individual responsibilities and accountability for this process

Scope

This SOP must be followed when handling of patients' own and discharge supplies of any Schedule 2 or 3 CDs for use on the ward or department.

Relates to

Guidance and other SOPs in section 12 of Safe & Secure Handling of Medicines Policy

Responsibilities

The Nurse in Charge is required to co-operate with the Authorised Pharmacy Staff when performing their quarterly check; and to co-operate with the inspection team when the ward is subject to a monitoring inspection.

The Authorised Pharmacy Staff is responsible for performing a regular quarterly check of CDs and CD procedures on their allocated wards or departments.

The CDAO is responsible for ensuring the above checks and any actions identified are completed.

The CDAO is also responsible for monitoring the usage of CDs in schedule 2-5 in all wards and departments of LSW by use of the ADIOS software on a bimonthly basis.

The CDAO is required to monitor and investigate all incidents relating to CDs. A summary of concerns on an "occurrence report" is required to be sent to the NHSE S(SW) CDAO once per quarter.

Pharmacy Quarterly CD checking procedure

A CD check must be undertaken routinely every three months for all wards and departments that stock CDs by a pharmacist or medicines management technician (Authorised Pharmacy Staff).

- The following checks must be made for each drug preparation and the corresponding register entry:
  - A separate page of the register must be used for recording the details of each drug preparation stocked. The pages must be clearly headed to avoid possible confusion, e.g. headings such as 'Epidurals' or 'morphine 10mg' is not adequate. Pages must not be removed from the register.
  - The actual stock balance must agree with the register balance.
  - The actual stock held must be in date and in good condition.
  - Stock which is out-of-date, rarely used or is judged to be present in excessive amounts must be returned to pharmacy (with the agreement of the Nurse in Charge) for destruction. Items no longer required should be returned to the Pharmacy in accordance with CD SOP no.6
  - Register entries must be neat and legible and must be complete i.e. each entry must be made by one nurse and witnessed by a counter signatory (see Policy section 5.4). There must not be any crossings out or use of correcting fluid. In the event of an incorrect entry it is appropriate for the nursing staff to mark the entry as being 'made in error'.
  - Patients' own medication including TTAs should be recorded in full in the Patient's Own CD register (see CD SOP no. 7). Patients' own medication should not be administered on the ward except in an emergency, or for self-administration. The entries and balances should be checked. In Mental Health and Learning Disabilities it may be necessary to retain the CDs on the ward until discharge.

  - Patient's own CDs not required for the above purposes should be removed as soon as possible (see CD SOP no. 7)

  - When satisfied, the Authorised Pharmacy Staff must endorse and sign each register entry 'Balance checked and correct' (or balance checked and correct, excess stock/out of date stock returned to Pharmacy etc.) and have this entry witnessed by a Designated Nurse.

- Wards/departments should routinely check stock balances for all CDs once every 24 hours (or at shift change) using the form provided (see CD SOP no. 4). Records of these checks should be inspected every three months by the Authorised Pharmacy Staff at the same time as the stock check. Records must show each preparation stocked has been checked and the quantity verified.

- Using the ward's CD order book select the orders for 2 whole weeks from the previous three months for the ward concerned. Use these orders to perform an 'audit trail', checking the orders against the records in the ward register.

- Any discrepancies or omissions must be brought to the attention of the Nurse in Charge and the Pharmacy Services Manager and must be investigated promptly.
  - A follow-up visit must be arranged to check that discrepancies which could not be resolved on the initial visit have been remedied.
  - Incident forms must be completed by the nursing staff, depending on the circumstances of an unresolved discrepancy.

- Check that the ward has a stock of Naloxone injection.
- At each visit the Authorised Pharmacy Staff must complete a CD Ward Check Report Form and this must be filed in the appropriate folder kept in the Pharmacy Services office Local Care Centre for reference.

All policies are required to be electronically signed by the Lead Director. Proof of the electronic signature is stored in the policies database.

The Lead Director approves this document and any attached appendices. For operational policies this will be the Locality Manager.

The Executive signature is subject to the understanding that the policy owner has followed the organisation process for policy Ratification.

Signed: **Adam Morris**

Position: **Medical Director**

Date: **23/09/16**

Appendix A

Controlled Drug List (2016-17)

There follows a list of the most commonly encountered controlled drugs in practice (from schedules 2, 3, 4 (1) and 5 of the regulations). This list includes the CDs in the current BNF but is not exhaustive or definitive, and some of the products listed are non-formulary (marked *), so are not recommended for prescribing locally. For each schedule a brief description of the legal requirements is included – see current BNF for further details (p. 7-10 in BNF no.70). All controlled drugs in schedules 1-5 are marked CD schedule _ as appropriate in the current BNF. Prescriptions issued to patients for drugs from **schedules 2, 3, 4** are **only valid for 28 days** from the date of prescribing and there is a strong recommendation from the Department of Health that prescriptions should be for a maximum of 30 days (longer supplies must be justified in the clinical notes). **Note: the requirements for validity and length of supply do not apply to in-patient prescriptions, where stock supplies are generally used.**

CDs in schedules 2, 3 and 4 (part 1) for destruction must be witnessed by an authorised witness (see SOP no. 6)

Schedule 2 - full prescription requirements, requisitions, safe custody, record in CDRB, 28 day validity, denaturing prior to destruction

Alfentanil	Ketamine	Pethidine*
Cocaine	Lisdexamphetamine	Papaveretum*
Dexamphetamine	Methadone	Quinalbarbitone*
Diamorphine	Methylphenidate	Sodium Oxybate*
Dipipanone*	Morphine *(apart from 10mg/5ml oral solution)*	Tapentadol
Fentanyl	Nabilone	
Hydromorphone*	Oxycodone	

Schedule 3 - prescription requirements, safe custody (legal or LSW requirement), requisitions, 28 day validity, record in CDRB (LSW (not legal) requirement), denaturing prior to destruction

Amylobarbitone*	Midazolam	Phentermine*
Buprenorphine	Pentazocine*	Temazepam
Meprobamate	Phenobarbitone	Tramadol

Schedule 4 Part I – POM, 28 day validity, denaturing prior to destruction

Alprazolam*	Flurazepam*	Oxazepam*
Chlordiazepoxide	Loprazolam*	Zaleplon*
Clobazam	Lorazepam	Zolpidem
Clonazepam	Lormetazepam*	Zopiclone
Diazepam	Nitrazepam*	

Schedule 5 –POM only, but all are potentially drugs of abuse or diversion.

Codeine Phosphate	Co-codamol	Pholcodine
Dihydrocodeine Tartrate	Co-dydramol	
Diphenoxylate	Morphine sulphate *(oral solution 10mg / 5ml)*	

Appendix B

Nurse in Charge Record of Staff Trained and Authorised to Handle Controlled Drugs.

Ward / Department…… **Nurse in Charge……..**

I have read and understood the CD SOPS 1 to 8 inclusive and agree to comply with the LSW Policy and Procedures for CDs.

Staff Name & Professional Designation	Date of CD training or reading of CD SOPs	Signature of Practitioner	Authorising Manager	Date

Appendix C

Naloxone Hydrochloride: Protocol for Administration in Opioid Induced Respiratory Depression

Particulars of staff authorised to use this protocol	
Appropriately trained senior registered nurses (ward sisters or bleep holders)	
Qualification or competencies	Local training by the resuscitation officer is available for staff that may need to administer naloxone in an emergency. Managers in conjunction with the medical team will decide who needs to be trained in the administration of naloxone.
Continuing education and training	ILS and ALERT Training, to be updated annually and to include proficiency in basic life support.
Clinical Details	
Clinical condition / indication	Naloxone is indicated for the treatment of respiratory depression induced by opioids such as codeine, morphine, diamorphine and methadone. It is also indicated in cases of suspected acute opioid over dosage. Following the administration of opioids, respiratory depression may develop, characterised by a reduction in the respiratory rate to below 10 breaths / minute and/or the onset of drowsiness or confusion, probably with pupil constriction. For the use of naloxone in suspected overdose by substance misuse patients please refer to the naloxone PGD (for inpatients of Mental Health units and at the Minor Injury Units)
Patient criteria for inclusion	Adult patients with suspected or actual opioid overdose as indicated by the clinical criteria above.

Patient criteria for exclusion	Patients with known hypersensitivity to naloxone
Cautions / need for further advice	• Naloxone must be given with great caution to patients who have received longer-term opioid/opiate treatment for pain control or who are physically dependent on opioids/opiates. Use of naloxone in patients where it is not indicated, or in larger than recommended doses, can cause a rapid reversal of the physiological effects for pain control, leading to intense pain and distress, and an increase in sympathetic nervous stimulation and cytokine release precipitating an acute withdrawal syndrome. Hypertension, cardiac arrhythmias, pulmonary oedema and cardiac arrest may result from inappropriate doses of naloxone being used for these types of patients. Actual or suspected pregnancy as naloxone could precipitate withdrawal symptoms which could adversely affect the foetus. However, it should be realised that failure to administer naloxone in an emergency could result in both the death of the mother and the foetus. • Refer to the current edition of British National Formulary (BNF) for the latest information on cautions or contraindications.
Action to be taken if patient is excluded.	**Seek urgent medical attention** and record all decisions and actions in patient's notes.
Description of treatment	
Name, strength and formulation of medicine	Naloxone hydrochloride injection 400 micrograms/ml (1ml amp).
Legal status of medicine	POM
Dose to be given	100 - 200 micrograms (1.5 to 3 micrograms / kg) initially then 100 micrograms every two minutes as necessary for an adequate response

Method / route of administration	Ensure optimal oxygen administration. Give naloxone by intravenous injection If the intravenous route cannot be used naloxone may be administered by intramuscular (IM) or subcutaneous (SC) routes – onset of action will be slower by these routes.
Frequency of administration	Repeat administration of 100 micrograms at 2 minute intervals until reversal of respiratory depression is achieved (defined as respiratory rate of 10 or more, but see number of doses below).
Number of doses to be given / duration of treatment	**A total of three doses may be given by staff following this protocol, by which time the emergency team should have arrived.** **If the respiration rate is still depressed, medical advice and support should be urgently obtained.**
Advice to be given to the patient/carer	Reassure the patient and explain the course of action taken.
Identification & management of adverse reactions	Abrupt reversal of narcotic depression may result in nausea, vomiting, sweating, tachycardia, tremor, hyperventilation and increased blood pressure Hypotension, hypertension, ventricular tachycardia and fibrillation, hyperventilation and pulmonary oedema have been associated with the use of naloxone post-operatively. Seizures have occurred on rare occasions after administration of naloxone but a causal relationship to the drug has not been established. Significant reversal of analgesia may result from larger than necessary dosages following the use of opiates in surgery.

Arrangements for referral for medical advice (if appropriate)	If the patient does not respond after three doses have been given the diagnosis of opioid toxicity should be questioned and alternative drugs or disease processes considered. Additional doses may be necessary at one to two hour intervals depending on the response of the patient and the duration of action of the opioid administered.
Special considerations/ additional information (if appropriate)	Continue to monitor patient's respiratory rate until length of action of the offending opioid is determined. Contact on-call pharmacist or the National Poisons Information Service 0870 600 6266 (24hour services) to ascertain half-life of the opioid. Patients who have responded to naloxone should be carefully monitored, since the duration of action of some opioids may exceed that of naloxone.
Records	
Documentation to be completed	Note and record the response to treatment with naloxone (including any adverse reaction) in the patient's notes. Contact the duty doctor and record an accurate account of what happened including doses given etc.
Arrangements for audit	In all cases where the use of this protocol has been necessary there will be a review of the case by the multi-disciplinary team and a medication incident will be completed. Concordance with the Controlled Drugs Policy and Naloxone Protocol will be monitored by review of medication incident data.

Appendix D

Competency Assessment for HCAs / APs to be Counter Signatories for Controlled Drugs

Healthcare Support worker Competence; acting as second checker for the administration of Controlled medication in the absence of a second registered nurse or doctor. (adapted from Skills for HealthCHS2 and PHARM28)

This standard describes the knowledge and understanding required to demonstrate competence in undertaking the second accuracy and quality check for receipt, administration and balance checks of Controlled drugs, where a Registered Nurse (or Doctor) has carried out the first check.

You will always work with a Registered Nurse within this context, whose role is to lead the process. You will always work within your own role and area of responsibility.

Universal Infection Prevention and Control procedures must be adhered to at all times.

Users of this standard will need to ensure that practice reflects up to date information and policies.

Knowledge and understanding

You will need to know and understand;

1	The limits of your own role and when to refer to an appropriate person
2	Standard Operating Procedure relating to the safe and secure handling of Controlled drugs
3	Knowledge of the requirements for recording schedule 2 and 3 controlled drugs
4	Understanding the rules for completion of the Controlled Drug Record Book (CDRB)
5	Current legal, professional and organisational requirements that govern the checking of a prescription
6	How to identify near misses and dispensing errors
7	Causes and consequences of near misses and dispensing errors
8	Clinical Governance, error reporting and recording
9	The importance of performing a second check separately to the first.
10	The actions you should take if you disagree with the first checker
11	The importance of communication and different ways to communicate
12	The importance of identifying the person for whom the medication is prescribed
13	How to check common proprietary and generic names against the BNF
14	The importance of keeping accurate up-to date records
15	The importance of immediately reporting any issues to the relevant member of staff

Performance criteria

You must be able to do the following

O	**Awareness through observation**
A	**Performing with assistance**
S	**Performing under supervision**
C	**Competence, performing independently**

	Action	O	A	S	C
1	Ensure that you work in accordance with current Standard Operating Procedures at all times				
2	Refer any queries to an appropriate person and challenge any discrepancies/clarify any details				
3	Read the administration record, • check and confirm the medication required, • time, dose and route of administration, • that the medication has not already been given, • expiry date of medication, • stock level before dispensing against the Controlled drug record book, • and confirm the remaining stock level after administration				
4	Accompany the administrating nurse to the patient, check the identity of the patient, observe the patient taking the medication				
5	Countersign the Controlled drug record book once patient has taken the medication				
6	Countersign the Controlled Drug Record Book for receipts of Controlled Drugs				
7	Countersign the CD daily stock reconciliation form for all CDs held in stock				

Statement of competency
Admission / Initial Assessment

I certify that I am aware of my professional responsibility for continuing professional development and that I am accountable for my actions. With this in mind I make the following statement:
I am competent to undertake an initial assessment without further training.

Print Name: ……Designation:…….

Signature of practitioner: Date: ……..

Print Name: ……Designation:…….

Assessors signature: Date:……..