Controlled Drugs Policy

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1	December 2015	All	Complete review and rewrite of document taking into account updated legislation	
2	March 2017	13	Clarification on controlled drug cupboard keys	
3	June 2017	6	Reference to exemptions in specialist areas.	
4	March 2017	15	'two registered practitioners'	
5	June 2017	31	'and Chief Medical Officer'	
6	June 2017	37	Change of name and details of Accountable Officer	

Review Log

Include details of when the document was last reviewed:

Version Number	Review Date	Lead Name	Ratification Process	Notes
3	July 15 – Dec 15	Sarah Nolan	Medicines Committee/Policy Steering Group	Complete rewrite
4	March 17 – June 17	Raj Parekh	Medicines Committee/Policy Steering Group	As in amendments log above

Contents:

1 SUMMARY

1.1 The purpose of this policy is to promote the safe, secure and effective use of all controlled drugs (CDs), which are subject to special legislative controls because of the potential for them to be abused or diverted, causing possible harm.

1.2 This policy with its associated standard operating procedures, and in conjunction with the organisation's Medicines Policy, will ensure the safe handling of controlled drugs.

2 INTRODUCTION AND PURPOSE

2.1 The purpose of this policy is to promote the safe, secure and effective use of all controlled drugs (CDs), which are subject to special legislative controls because of the potential for them to be abused or diverted, causing possible harm. The arrangements to promote the safe, secure and effective use of CDs need to be implemented in a way that supports professionals and encourages good practice around the management and use of these important medicines when clinically required by patients.

2.2 The Government set up monitoring and inspection arrangements for CDs in the Health Act 2006. These work within and alongside other governance systems and should be seen as an integral part of the overall drive to improve quality in healthcare. The Controlled Drugs (Supervision of management and use) Regulations 2013 requires NHS Trusts to appoint an Accountable Officer (AO) responsible for the safe and effective use of CDs in their organisation. The 2013 Regulations also initiated standard operating procedures (SOPs) for the use and management of CDs. These are one of the practical measures that will help to ensure good practice throughout the health and social care system.

2.3 This policy must be read in conjunction with the organisation's Medicines Policy.

2.4 A glossary of terms used within this policy is included in Appendix 1.

2.5 Appendix 1 lists the contact details for key members of staff involved in the governance of CDs. The AO will be responsible for keeping this list up to date.

3 SCOPE AND DEFINITIONS

3.1 This policy, with associated procedures, applies to all staff working for or providing services within the organisation and who have responsibility for:

- The safe custody and accountability of CDs stored in their area of responsibility
- The ordering and receipt of CDs by Wards/Departments
- The prescribing of CDs
- The administration of CDs to patients
- The handling of patients' own medicines which are classified as CDs
- Record keeping in the CD Record Book
- The management and checking of CDs on Wards/Departments
- Disposal of unwanted CDs

3.2 Staff affected include, but is not exclusive to, doctors, dentists, nurses and midwives, pharmacists, healthcare professionals and associated practitioners.

3.3 At a local level, all healthcare and social care organisations are accountable for ensuring the safe management of CDs. Organisations directly providing clinical services are required to complete a self-assessment and declaration on whether they use CDs.

3.4 This policy also provides an overview of the law relating to CDs.

3.5 This Policy applies to all controlled drugs in Schedules 1, 2, 3 and 4 used within all services within the organisation. It will also apply to some Schedule 5 controlled drugs (e.g. Morphine Sulphate Oral Solution 10mg in 5ml) when used in some wards and services where additional controls are recommended by the Accountable Officer and Senior Nursing Management.

3.6 Controlled Drugs and drug dependence

The Misuse of Drugs Act, 1971 prohibits certain activities in relation to 'Controlled Drugs', in particular their manufacture, supply, and possession. The penalties applicable to offences involving the different drugs are graded broadly according to the harmfulness attributable to a drug when it is misused and for this purpose the drugs are defined in the following three classes:

- Class A includes: alfentanil, cocaine, diamorphine (heroin), dipipanone, lysergide (LSD), methadone, methylenedioxymethamfetamine (MDMA, 'ecstasy'), morphine, opium, pethidine, phencyclidine, remifentanil, and class B substances when prepared for injection

- Class B includes: oral amfetamines, barbiturates, cannabis, cannabis resin, codeine, ethylmorphine, glutethimide, ketamine, nabilone, pentazocine, phenmetrazine, and pholcodine

- Class C includes: certain drugs related to the amfetamines such as benzfetamine and chlorphentermine, buprenorphine, diethylpropion, mazindol, meprobamate, pemoline, pipradrol, most benzodiazepines, tramadol, zaleplon, zolpidem, zopiclone, androgenic and anabolic steroids, clenbuterol, chorionic gonadotrophin (HCG), non-human chorionic gonadotrophin, somatotropin, somatrem, and somatropin

  The Misuse of Drugs Regulations 2001 (and subsequent amendments) define the classes of person who are authorised to supply and possess controlled drugs while acting in their professional capacities and lay down the conditions under which these activities may be carried out. In the regulations drugs are divided into five schedules each specifying the requirements governing such activities as import, export, production, supply, possession, prescribing, and record keeping which apply to them.

- Schedule 1 includes drugs such as lysergide which are not used medicinally. Production, possession and supply are prohibited except in accordance with Home Office authority.

- Schedule 2 includes drugs such as diamorphine (heroin), morphine, nabilone, remifentanil, pethidine, secobarbital, glutethimide, the amfetamines, and cocaine and are subject to the full controlled drug requirements relating to prescriptions, safe custody, the need to keep registers, etc. (unless exempted in Schedule 5)

- Schedule 3 includes the barbiturates,buprenorphine, diethylpropion,, meprobamate, midazolam, pentazocine, phentermine, temazepam, and tramadol. They are subject to the special prescription requirements and to the safe custody requirements (except for any 5,5 disubstituted barbituric acid (e.g. phenobarbital), meprobamate, midazolam, pentazocine, phentermine, tramadol, or any stereoisomeric form or salts of the above).

- Schedule 4 includes in Part I benzodiazepines (except temazepam and midazolam, which are in Schedule 3), zaleplon, zolpidem, and zopiclone which are subject to minimal control. Part II includes androgenic and anabolic steroids, chorionic gonadotrophin (HCG), non-human chorionic gonadotrophin, somatotropin, somatrem, and somatropin. Controlled drug prescription requirements do not apply and Schedule 4 Controlled Drugs are not subject to safe custody requirements.

- Schedule 5 includes those preparations which, because of their strength, are exempt from virtually all Controlled Drug requirements other than retention of invoices for two years.

3.7 Further details of the levels of control of different CDs, and the practical arrangements in use on Solent NHS Trust wards, are given at Appendix 2 and 3.

3.8 Storage and security requirements may be increased locally at the discretion and direction of the Nursing Management in discussion with the Accountable Officer or their nominated deputy.

3.9 Any specialities unable to comply with this policy must seek exemption from the Accountable Officer. Any exemption from this policy must be supported by Standard Operating Procedure approved by the Accountable Officer, the Service Line Governance Group and the Medicines Management Committee.

DEFINITIONS

3.10 **Controlled Drugs** (CDs) – Preparations are indicated as Controlled Drugs in the BNF.

3.11 **Controlled Drugs Accountable officer**- The member of staff who is responsible for the management of Controlled Drugs within Solent NHS Trust

4 THE ACCOUNTABLE OFFICER (AO)

4.1 Each healthcare organization must appoint a fit, proper and suitably experienced person to be its Accountable Officer. This should be a senior executive officer of the organisation (i.e. an Executive Director or someone who reports directly to an Executive Director). The Accountable Officer does not, or does only exceptionally, prescribe, supply, administer or dispose of controlled drugs.

4.2 If staff have concerns about the practice of the Accountable Officer these should be raised with Solent NHS Trust's Chief Executive.

4.3 The Accountable Officer has overall responsibility to ensure that the Trust operates appropriate arrangements for the securing and safe management of CDs within the Trust, as described in this Policy and in standard operating procedures used across the trust.

4.4 The regulatory requirements for Accountable Officers are set out in full in the Controlled Drugs (Supervision and Management of Use) Regulations 2013; www.legislation.gov.uk.

4.5 The AO for Solent NHS Trust is the Chief Pharmacist.

5 LOCAL INTELLIGENCE NETWORK

5.1 The AO will be a member of the Local Intelligence Network (LIN) formed across NHS England Wessex area team (Hampshire and Isle of Wight).

5.2 The LIN will enable communication between organisations to take place on a regular basis and facilitate the agreement of protocols and the review of trends. In addition, the LIN will enable agencies that have cause for concern about the activities of any healthcare professional or organisation to share them. The LIN is managed by the Controlled Drugs Accountable Officer for NHS England (Wessex)

6 ORDERING STOCKS FOR INPATIENT UNITS OF SCHEDULE 2 CONTROLLED DRUGS, SCHEDULE 3 (SPECIALS) AND OTHER CONTROLLED DRUGS AS SPECIFIED BY THE ACCOUNTABLE OFFICER AND/OR CHIEF PHARMACIST

6.1 The Registered nurse in charge of a ward or department is responsible for the requisitioning of CDs for the use in that area. Even if the ward or department is managed by someone other than a nurse or midwife, under the present regulations the most senior nurse or midwife present is responsible for Controlled Drugs.

6.2 The registered nurse in charge can delegate the task of ordering to another registered nurse. However, legal responsibility remains with the registered nurse/midwife in charge.

6.3 Only registered nurses who have been authorised by the Clinical Ward Manager are permitted to order CDs. All orders must be countersigned. In exceptional circumstances a pharmacist may complete a CD requisition documenting the name of the nurse in charge who has delegated responsibility and countersigned. Where orders for controlled drugs are requisitioned from another trust, each order must be countersigned by a medical doctor or Dentist employed by or contracted by the organisation.

6.4 Signatures of each authorised practitioner able to countersign CD orders must be provided to the supplying pharmacy. The Clinical Ward Manager of each Ward/Department is responsible for keeping and updating this list every 3 months and ensuring that a copy is given to the Pharmacy Department. A copy of this list should be attached to the inside of the controlled drug cupboard. The Pharmacy Department will not supply CDs ordered by staff whose name and signature does not appear on the authorised list for that Ward/ Department. Approving medical doctors must sign and append their names and, where possible, their registration number when signing the order form (their names will not appear on the authorised signatory list).

6.5 CD stocks must be ordered using a controlled drug order book or controlled drug requisition book. Requisition books must be kept for 2 years after the date of the last entry.

6.6 Stock CDs may only be ordered from the designated pharmacies that provide drugs to the hospital. In general, this will be St Marys Pharmacy and Portsmouth Hospitals NHS Trust (PHT) at weekends and out of hours, for Solent East. University Hospitals Southampton Foundation NHS Trust supply CDs for Solent West. Dental supplies of Midazolam are also supplied by Winchester Hospital (HHFT) and Frimley Park Hospital (FPHFT).

Only one drug preparation may be ordered on each page of the order book.

Each order must clearly provide:

- The name of the ward or department
- The date the order was made
- The name of the drug
- The form of the drug
- The strength of the drug
- The total quantity to be provided (ideally a complete manufacturers original pack).
- The authorised registered practitioner's signature
- Countersignature
- Countersignature of a Medical Doctor or Dentist if ordering from a different trust to the supplying pharmacy.

6.7 The Medical Doctor or Dentist will sign the order as an independent verification that the CDs ordered are to be used within the requesting ward or department if the supplies are being requisitioned from another trust. The medical doctor or Dentist who countersigns the CD order

form is not responsible for the management and accountability for the CDs within the ward or department. This responsibility falls within the remit of the registered practitioner in charge**.** In addition to the usual controlled drug order book a requisition form must also be completed when ordering CDs from another trust. The form can be located at: http://www.nhsbsa.nhs.uk/PrescriptionServices/Documents/PrescriptionServices/6-1387-Form_FP10CDF_v5_final.pdf

6.8 Orders must be planned well in advance (before running out of stock) to provide time for obtaining a doctor's signature.

6.9 Wards should endeavour to obtain CDs within normal pharmacy working hours. A limited pharmacy service is available from Queen Alexandra Hospital on Saturdays from 9 am -12 pm for emergency supplies for Solent East. Outside these hours an on call pharmacist is available through Queen Alexandra Hospital Switchboard. There is no routine pharmacy service for controlled drug supply out of hours at Solent West sites. The UHS on call pharmacist should be contacted for advice on how to obtain CDs.

6.10 The order must be completed with carbon paper in place, to ensure a record is produced on the second copy. An original copy of the requisition must be sent to pharmacy before the order can be processed. Depending on the requirements of the supplying pharmacy, the complete order book may be sent to the pharmacy by the secure pharmacy box, or is delivered by hand or white top copy sent.

6.11 Liquid paper correction fluid (e.g.Tippex™) must never be used to change orders.

6.12 The pink carbon copy pages must never be torn out of the Ward CD Order Book.

6.13 A new Ward CD Order Book can be requested from Pharmacy Department when 5 blank pages or less remain in the current Ward CD Order Book.

6.14 The issuing Pharmacy Department maintains a written record of CD Order Books issued to each Ward/ Department. Duplicate books will not be provided

6.15 When the Ward Controlled Drugs Order Book is completed, the date of completion should be written on the front cover; it should be sealed and then stored securely at Ward/ Department level. It is a legal requirement that the Ward Controlled Drugs Order Book is kept for 2 years from the date of the last entry. It may then be destroyed as confidential waste.

6.16 Controlled Drugs will be supplied by the relevant Pharmacy following their own Trust's Standard Operating Procedure.

7 RECEIPT OF THE CONTROLLED DRUG ORDERS ON INPATIENT UNITS

7.1 Pharmacy sends the CD, with a delivery note and the Order Book, if sent, in a secure container to the ward / unit.

7.2 Transporting CDs will normally fall under the rules set by the supplying pharmacy and will follow their own Trusts SOP. Exceptions must be discussed and agreed with the Accountable Officer.

7.3 At each point where a CD moves from the authorised possession of one person to another during the supply journey, a signature must be obtained from the person receiving by the person transferring.

7.4 CDs must be conveyed in a secure, locked or sealed, container. The lock or seal of this container must be checked and verified by the person receiving the container at each point of transfer. Signatures will confirm that the container has been received intact, up to the final delivery to the authorised person on the ward.

7.5 CDs must be received and checked by two staff members, one of whom must be an authorised registered practitioner. The registered practitioner signs the delivery note or transport slip and faxes / sends it back to the supplying pharmacy.

7.6 Only an authorised registered practitioner may open the sealed container of CDs from the pharmacy. If sufficient staff are available, the practitioner receiving the CD should not be the same person who ordered the controlled drug.

7.7 The practitioner opening the sealed delivery container must confirm:

- The identity, form, strength, and quantity of the contents matches the order
- If there is a tamper-evident seal on the container, it must be checked carefully that it is intact, for each pack or bottle. If the seal is intact the total quantity as stated on the label can be assumed to be correct. This seal should remain intact until the contents are required for use. Some staff may choose to break the seal on a container in order to check the contents. If this is done the full contents and quantity must be checked against the order
- If there is no tamper-evident seal, or it is broken, the contents and quantity of the contents must be checked against the order
- The expiry date of the drug is appropriate

If the order is correct, the practitioner receiving the order must sign the pink copy of the order (in the book). If possible the pink copy should be signed in the presence of the messenger from the pharmacy or contracted courier, however, clinical pressures on wards may make this difficult to achieve, in which case CDs should be checked and signed as soon as practicably possible after delivery.

7.8 The person who has signed the pink carbon copy to receive the CDs is responsible and accountable for them until the CDs are signed into the Ward/ Department CD Record Book and securely locked away in the CD cupboard.

7.9 The CD stock items are then entered into the Ward/ Department CD Record Book. Entries should be countersigned. Where there is no second registered practitioner available, registered healthcare professionals (e.g. doctors, pharmacists) or HCSWs who have been assessed as competent, may witness and countersign the entry.

7.10 The CDs are then immediately placed inside the CD cupboard. Morphine and diamorphine ampoules of 30mg or more should be physically separated from lower strength ampoules within the CD cupboard. This can be done by keeping them (in their original packaging) on a separate shelf/compartment, or by placing them within a separate container.

7.11 Discharge prescriptions containing CDs are either issued directly to the patient or stored in the CD cupboard for subsequent issue to the patient. In either case, the transfer of the CDs to the patient or their representative is documented.

7.12 If there are any problems with the order or if the contents do not match the expected amount stated on the pack, the issuing pharmacy must be informed immediately. The Accountable Officer must also be informed at the first opportunity within normal working hours and an incident form completed.

8 RECORDING DETAILS OF CONTROLLED DRUG RECEIPTS IN CONTROLLED DRUG RECORD BOOK (CDRB)

8.1 The controlled drug record book (CDRB) must be a bound book, in which records are made of CDs received and administered in wards, theatres and departments. The law permits the use of approved electronic controlled drug registers but these are not yet in use within the organisation; this SOP will be reviewed prior to the introduction of electronic registers. The CDRB must not be stored in the CD cabinet but in a locked drawer, cupboard or treatment room.

8.2 The CDRB must have numbered pages.

8.3 Each formulation and strength of each drug must be recorded on a separate page within the CDRB.

8.4 Each entry must be on the appropriate page of the CDRB e.g. correct drug, form and strength.

8.5 Entries must be in ink or otherwise indelible form.

8.6 Entries must be in chronological order and made as soon as possible and in all cases within 24 hours.

8.7 Registers must be kept neat and orderly, so that entries can be quickly and accurately located.

8.8 Each entry must be made by the practitioner receiving the drug and witnessed by a second approved person. The second approved person can be a registered practitioner or authorised Health Care Support Worker (HCSW) working on the ward, a Pharmacist or Pharmacy Technician. Each entry line must state:

- Date the drug is received
- Name of pharmacy and address making the issue
- Amount received, it is good practice this is documented in words
- Signature of authorised registered nurse receiving the drug
- Signature of witness who must be an approved person
- Running balance, which will reflect the contents of the CD cupboard

8.9 Crossing out of an entry is not permitted. Errors must be contained in a bracket with an explanatory note in the margin. The correction must be signed and dated and witnessed by a second witness. To make absolutely clear a stock check should be carried out on the next line.

Liquid paper correction fluid (e.g.Tippex™) must NEVER be used

Pages or part-pages must NEVER be torn out of the CDRB.

8.10 Patients own drugs must also be entered into the CDRB on receipt on the ward. They must be entered in a different section of the CDRB to stock CDs or a separate CDRB maintained solely for patients own.

8.11 Each Ward/ Department CDs Record Book should have a dedicated index page.

Each preparation recorded in the Ward CDs Record Book should also be entered on the index page.

8.12 Page numbers for each preparation should be kept up to date on the index page. When starting a new Ward CDs Record Book it is useful to try and anticipate how many pages will be needed for each preparation by looking at the previous Ward CDs Record Book and leave more pages for high usage items. This will help to enable entries to be entered in sequential order rather than having to find blank pages later.

8.13 It is good practice to draw 15-20 vertical lines on the index page after the name of the drug, producing columns in which to record the corresponding page numbers, making the audit trail easier to follow.

8.14 A new page should be started only when the current page has no further room for new entries. Do not use the bottom line of the Ward CDs Record Book to record administration or stock checks. This line should be reserved for use to complete the audit trail for balance transfers from page to page and also when a new Ward CDs Record Book is started (See Appendix 4).

8.15 When a new page is started, cross-reference should be made on both the old and the new pages.

For example:

Bottom of completed page (p.14): "balance transferred to page 20"
Top of new page (p.20) "balance transferred from page 14"

8.16 When the balance for a preparation reads 'zero', this is not an indication to start a new page the next time the preparation is held on the ward

8.17 It may be useful to start a new page for new bottles (or a consignment) of oral liquid preparations such as morphine sulphate 10mg/5ml solution and buccal midazolam. This prevents small overage volumes accumulating which can cause measuring discrepancies. Refer to your Ward Pharmacist for advice if balances appear to require adjustment.

8.18 The index page should be updated to reflect the new page number.

8.19 A new CDRB should be started only when no further blank pages are left in the current Ward CDs Record Book.

8.20 The issuing Pharmacy Department maintains a written record of CDRB issued to each Ward/ Department. Duplicate books will not be provided.

8.21 All Controlled Drug balances should then be transferred from the old CDRB to the new one. This should be carried out by two Registered Nurses. In Wards/ Departments where there is no second Registered Nurse, another registered healthcare professional (e.g. pharmacist, doctor), or HCSW who has been assessed as competent, may check and countersign this process. The date of the last entry should be written on the front cover of the old CDRB, and the date of starting should be written on the front cover of the new one.

8.22 Appropriate cross-references should be made in both old and new CDRB Books for each balance transferred.

For example:

In Book 3 (just completed) "balance transferred to book 4, page 10"
In Book 4 (new book) "balance transferred from Book 3, page 54"

Any remaining blank space on pages in the old CDRB should be crossed through with a single diagonal line, therefore preventing any further entries.

Once decommissioned, the CDRB should be sealed and signed and dated. Old CDRBs must be locked in a secure place at ward/ department level. It is a legal requirement that CDRBs are kept for 2 years from the date of last entry and can then be destroyed as confidential waste.

9 KEY CONTROL FOR CONTROLLED DRUGS CUPBOARD

9.1 Keys must be kept by the authorised registered practitioner in charge of the ward / unit and only given to persons with delegated authority to enter the CD cupboard (authorised Nurse, Pharmacist or Pharmacy Technician, Controlled Drug Programme Manager). The controlled drug cupboard key must be kept on a separate key ring, but must also be held by the practitioner in charge. If both sets of keys are held by one practitioner it is acceptable to attach the CD key ring to the main bunch with a carabiner – it **must** be separated when handing to member of staff who either doesn't require the CD keys or who is unauthorised to hold the CD keys. After closing and locking the cupboard, the delegated person must return the keys to the practitioner in charge. The assigned key holder will challenge members of staff who request the keys to ensure that they have a legitimate and acceptable reason to access the CD cupboards and valid identification. Under no circumstances are student nurses permitted to be responsible for the any drug keys.

9.2 Duplicate keys must be securely kept by the registered practitioner in charge of the ward. Access to the duplicate keys is restricted to persons authorised by the registered practitioner in charge. The duplicate keys must be held in a sealed envelope, bearing two different signatures across the seal and held in a secure place.

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

9.3 Missing Keys

- If the CD keys cannot be found, after initial investigation, urgent efforts should be made to retrieve them (e.g. by contacting relevant staff who have gone off duty).
- If the keys are not located within 24 hours following investigation the Accountable Officer or their nominated deputy will be informed by the Modern Matron. Depending on the circumstances it may be appropriate to contact the police. This decision will be made by the Accountable Officer possibly in consultation with the Trust's Counter Fraud Advisor and/or Controlled Drug and Chemical Liaison Police Officer. If wrong doing is suspected the police must be involved.

If the original keys are lost, the Manager must arrange to have a new lock placed on the cupboard as soon as possible. The Accountable Officer must be informed at the earliest opportunity.

10 STORAGE OF SCHEDULE 2 AND SCHEDULE 3 CDS

10.1 CD storage rules within the NHS are not affected by the "ownership" of the CD. All CDs, whether stock or patient's own, must be stored correctly. CDs must be kept in a locked, secure medicines cupboard that is only used for CDs and is permanently fixed to a solid wall and/or floor.

10.2 CD cupboards should conform to the British Standard reference BS2881 or be otherwise approved by the AO. They must be fixed to the wall in a suitable locked treatment room.

10.3 Within Solent NHS Trust, storage regulations apply to all Schedule 2 medicines and the Schedule 3 drugs including those that legally do not require safe storage e.g. midazolam, tramadol. Whenever possible, CDs must be stored in the manufacturer's original container. If required, pharmacy may break down the stock container into smaller more manageable supplies. Anti-tamper seals on packs of CDs should be left intact until the pack is required for dispensing / administration. This will simplify routine balance checks.

10.4 The batch number and expiry date on the carton must reflect the contents accurately.

10.5 If low and high strength Morphine or Diamorphine injections are stocked, they must be stored in separate locations within the CD cupboard e.g. different shelf and outer packaging, to minimise the risk of selection error.

10.6 If ANY strength of Diamorphine or Morphine injection is kept, the ward must ensure at all times that they have a readily accessible stock of the opiate reversal agent, Naloxone. Naloxone can be administered IV or IM by a qualified practitioner or doctor who are competent in its use. A prescription is not required if administering Naloxone for the purpose of saving a life in an emergency.

10.7 The room housing the CD cupboard must be lockable and tidy, to avoid misplacing drugs. The room and the keys or combination code to it must not be accessible to patients.

10.8 The lead practitioner from each shift must take overall responsibility for the CD keys. Where keys are required by other practitioners during the shift, the identity of the key holder must be known at all times. Keys to CD cupboards and delivery containers must be kept on a separate key ring and held separately to all other keys. If both sets of keys are held by one practitioner it is acceptable to attach the CD key ring to the main bunch with a carabiner – it **must** be separated when handing to member of staff who either doesn't require the CD keys or who is unauthorised to hold the CD keys. On occasions where the lead practitioner from one shift cannot directly hand CD keys on to the next shift's lead practitioner, or is called away from their unit without being able to hand CD keys directly to another qualified practitioner acting as their deputy, it is permissible for CD keys to be locked in another cupboard/safe, providing that only qualified practitioners have access to that cupboard/safe and that systems are in place to ensure unauthorised persons cannot access the CD keys.

10.9 Other drugs that are liable to misuse may be stored in the CD cupboard with, but separate from, CDs, if deemed appropriate by the relevant health care professional.

10.10 A TTO (to take out prescription) supply of a CD should not be used in place of CD stock unless the patient has been assessed as fit for self-administration or in exceptional other urgent circumstances.

10.11 TTO CDs received from the issuing pharmacy for a patient must be stored in the CD cupboard and entered into a page designated for patients own CDs in the back of the CDRB or in a separate CDRB. They must be issued out to the patient from the register on day of discharge from the hospital. It is important to segregate these CDs from the stock CDs in the cupboard.

10.12 If the ward or department's CD Cupboard is found to be defective, this should be reported immediately to Kier and the Accountable Officer.

10.13 The security of CDs should be maintained at all times. Contact the ward pharmacist for advice during pharmacy working hours or the on-call pharmacist outside working hours. If it is

necessary to relocate CDs to alternative secure storage, this should only be done on the advice of a pharmacist.

10.14 On the arrival of Kier, they should be escorted to the CD cupboard by a Registered Practitioner. A registered practitioner should remain with the Kier Personnel whilst the CD cupboard is fixed.

10.15 Immediately after the CD cupboard is fixed a stock check of all CDs should be performed.

10.16 If a ward is to close or be re-designated on a permanent basis such that ward stocks of CDs are no longer required a pharmacist should remove stocks from the ward (see below) and return them to the pharmacy. If suitable for re-use the CDs should be "returned" on the pharmacy computer system and value credited to the ward and placed within pharmacy stock. If the drugs are unlikely to be used before their expiry date they should be written off as expired stock and not credited to the ward.

10.17 In the case of a temporary closure stocks need to be returned to pharmacy. For relocation of a ward the pharmacist and nurse in charge may elect to personally and physically remove the stock from one controlled drug cupboard, check the stock and move to the new CD cupboard. Alternatively, if there is likely to be a delay in the move or security is likely to be compromised by the presence of contractors or non-Solent personnel, stock should be removed from the ward CD cupboard and returned to the pharmacy for secure storage. These controlled drugs will be stored within the pharmacy CD cupboard separated from existing pharmacy stock. They may then be returned to the relocated ward when the move is complete and security is ensured.

11 STOCK CONTROL AND AUDIT TRAIL FOR CONTROLLED DRUGS

11.1 Monitoring and audit

11.1.1 An annual ward / unit audit of CD use, handling, record keeping and storage will be undertaken by pharmacy staff. Results will be fed back to service managers and the Accountable Officer. In addition a stock check of all CDs held by wards/ units will be checked every 6 months.

11.1.2 Ward managers / service leads will need to provide evidence that every member of staff involved in the administration of CDs has read and understood the SOPs. New starters will also need specific CD training. An example of a Ward / Unit Staff Confirmation Sheet for staff to sign to indicate that they have read the SOP is included at Appendix 9

11.1.3 SOPs and any Patient Group Directions (PGDs) relating to CDs will need a bi-annual review.

11.1.4 Compliance with Adverse Event and Serious Incident Requiring Investigation (SIRI) reporting policies will be monitored by the AO.

11.1.5 Routine monitoring of pharmacy data including:

a. Quantity of CDs prescribed – for apparent excessive amounts on an individual prescription.

b. Volume of CDs prescribed

c. Negative indicators for example:

- Adverse Event and Serious Untoward Event review or investigation (e.g. patient death, overdose involving CDs) which shows discrepancies between records.

- Patient or carer complaints involving the prescribing and use of CDs.

- Concerns expressed by colleagues.

- Concerns relayed from police or drugs misuse services about diverted medication.

11.2 **CD stock checks**

11.2.1 Each ward must check their CD supplies and records **at least** once weekly. Individual wards may increase this monitoring depending on local need. A record of the weekly CD check must be made in the CD register.

- Starting at the front of the CD Record Book work through the pages.

- Each item with a positive balance should be checked in turn, counting the quantity of that drug, strength and formulation in the CD cupboard. A record of the stock check must be made for each item.

- During the stock check, all pages of the CD Record Book must be checked to ensure there are no missing pages.

- With the exception of Schedule 2 CDs e.g. methadone and Oramorph 20mg/ml stock balances of liquid medicines should generally be checked by visual inspection but the balance must be confirmed correct at the completion of each bottle**.**

- It is not necessary to open packs with intact tamper evident seals, although the seals should be checked to ensure they are still intact.

11.2.2 The registered practitioner in charge of the ward/department is responsible for ensuring that regular CD stock checks are carried out by two registered practitioners on at least a weekly basis. Each drug checked must be documented in the CDRB showing date of check and signatures of registered practitioners checking the balances along with a witness, who must also be registered. It is recommended that drugs are checked “by the page”, rather than “by the drug”.

11.2.3 When the checks are made, the practitioner must ensure stocks are rotated in order to minimise the risk of waste due to expired stocks.

11.2.4 A pharmacist must check the CDRB every 6 months. The stock check must cover the following:

- A check that the quantity of each stock CD tallies with the balances recorded in the CDRB.

- A check of a sample of CD requisition copies to ensure that they have been entered correctly in the CDRB.

- A review of the security and quality of record keeping.

- A check for exceptional usage of CDs.
- A check of the physical security arrangements for the storage of CDs, CD stationery and the key-holding policy.
- Check that all stocks are in date.

Pharmacy stock check paperwork should be completed

11.2.5 The practitioner in charge of the ward/department must routinely check that excess or unnecessary stock is not being stored.

11.3 The practitioner in charge of the Unit is responsible for checking and updating (if required) the list of authorised signatories for CD requisitions.

11.4 Any discrepancies in CD balances must be reported to the person in charge of the ward or department without delay who will investigate thoroughly (see Appendix 6). If the investigation proves that an incident has occurred, the Matron and/or Service Manager and pharmacist must be informed and an appropriate incident form completed. The Accountable Officer must also be informed at the earliest opportunity (see contact details – Appendix 1).

11.5 The practitioner in charge of the Unit will inform the Accountable Officer or an authorised person (i.e. a person authorised by the AO to destroy controlled drugs) when stock CDs require destruction. The Accountable Officer is responsible for ensuring an authorised person witnesses the destruction of the stock CDs.

12 USE OF PATIENT'S OWN CONTROLLED DRUGS ON A WARD

12.1 Patients' own prescribed CDs brought into hospital may be considered for use if the patient has been assessed as competent to self-administer their own CD medicines, or administered by ward staff in exceptional other urgent circumstances to maintain patient care.

12.2 The following checks must be made before these drugs can be used:

- The drug has been prescribed to be used by that patient
- The identity and condition of the drug is suitable
- The expiry date is shown on the original container and has not been passed
- If the date does not appear, check label on the container to determine when the drug was dispensed. If the date of dispensing is greater than 3 months earlier, the drug must not be used.
- If there is any doubt about the suitability of the drug for use, it must not be used and a new supply obtained.

12.3 Patients' own CDs must not be entered into the ward stock. There may be a page in the back of the CDRB for Stock Drugs, or in a separate CDRB designated for patients' own CDs. A separate page must be used for each patient and for each CD belonging to that patient, following the same entry requirements as for stock CDs. Patients own controlled drugs should only be administered to the patient that they were issued to, according to the pharmacy label.

12.4 The entry and balance must be made by a registered practitioner and checked by a second approved person.

12.5 The patient's own controlled drug must be stored separately from stock CDs in the controlled drug cupboard and clearly labelled patient's own drug.

12.6 Each dose administered to patients must be recorded on the patient's page in the CDRB.

12.7 Patient's own CDs must be returned to the patient on the day of discharge, providing they are suitable for use and treatment with that drug/dose is to continue. An entry must be made in the CDRB indicating that the drugs have been returned to the patient. If unsuitable, they must be marked for destruction and be held in the CD cupboard. (See Section 13 TTOs).

12.8 Patients' own CDs must be transferred with the patient if s/he transfers to another ward. A record of this transfer must be entered into the relevant pages of the CDRB of each ward.

12.9 Patients' own CDs that are not to be used for administration to that patient should not routinely be stored on the ward and should be destroyed. If practicably possible consent for destruction should be gained from the patient.

12.10 Patient's own Drugs must never be used to treat another patient.

13 TO TAKE OUT (TTO) CDS

13.1 TTO CDs should be ordered in sufficient time to ensure that they are available on the ward for the planned time of discharge but not so early that they cause a problem for storage.

13.2 TTO CDs are prescribed and dispensed for a named patient.

13.3 TTO CDs must be protected according to their schedule and designation. If necessary, they must be locked in the CD cupboard, as Patient's Own CDs, until required for the discharge.

13.4 TTO CDs must be signed into and out of the Ward Record Book or other register, as patient's own. Where possible, the patient or their relative should sign the ward record book or on the TTO form for receipt of the drugs. For patients collected by ambulance transport crews, the transport booking reference must be recorded on the TTO prescription.

14 PRESCRIBING CONTROLLED DRUGS

Prescriptions for Controlled Drugs that are subject to prescription requirements [1] must be indelible[2] and must be signed by the prescriber, be dated and specify the prescribers address. The prescription must always state:

- The name and address of the patient
- In the case of the preparation, the form[3] and where appropriate the strength[4] of the preparation;
- For liquids, the total volume in millilitres (in both words and figures) of the preparation to be supplied; for dosage units, the number (in both words and figures) of dosage units to be supplied; in any other case, the total quantity (in both words and figures) of the Controlled Drug to be supplied;
- The dose[5]
- The words "for dental treatment only" if issued by a dentist

1. *All preparations in schedules 2 and 3*
2. *A machine-written prescription is acceptable. The prescriber's signature must be handwritten.*
3. *The dosage form (e.g. tablets) must be included on a Controlled Drugs prescription irrespective of whether it is implicit in the proprietary name (e.g. MST continus) or whether only one form is available.*
4. *When more than one strength of a preparation exists the strength required must be specified.*
5. *The instruction "One as directed" constitutes a dose but "as directed" does not.*

When opioid medicines are prescribed, in circumstances other than acute emergencies, the healthcare practitioner concerned, or their clinical supervisor, should:

- Confirm any recent opioid dose, formulation, frequency of administration and any other analgesic medicines prescribed for the patient. This may be done for example through discussion with the patient or their representative (although not in the case of treatment for addiction), the prescriber or through medication records.
- Ensure where a dose increase is intended, that the calculated dose is safe for the patient (e.g. for oral morphine or oxycodone in adult patients, not normally more than 50% higher than the previous dose).
- Ensure they are familiar with the following characteristics of that medicine and formulation: usual starting dose, frequency of administration, standard dosing increments, symptoms of overdose, common side effects.

14.1 **Corrections to Prescriptions**

14.1.1 A prescription may be dispensed if it has a minor technical error but where the prescriber's intention is clear.

14.1.2 All corrections must be signed and dated, such that it is clear who has made them.

14.1.3 Pharmacists may:

- Amend minor typographical errors or spelling mistakes;
- Add either the words or the figure for the total quantity of the preparation or the number of dosage units, but not both.

14.1.4 The pharmacist needs to have exercised due diligence, be satisfied that the prescription is genuine and that the supply is in accordance with the intention of the prescriber. The prescription should be marked to show that the amendments are attributable to the pharmacist (e.g. name, date, signature and GPhC registration number). Pharmacist cannot correct other amendments or omissions (e.g. missing date, incorrect dose, form or strength). The must be corrected by the original prescriber or, in an emergency, another prescriber authorised to prescribe Controlled Drugs. Amendments cannot be made by covering letter from the prescriber.

14.2 **Who can prescribe which CDs**

14.2.1 Before prescribing an opioid it is essential the prescriber is familiar with the therapeutic characteristic of the medicine. If in doubt seek advice.

14.2.2 Doctors with full registration may prescribe any CD in Schedules 2 to 5 for any medical condition. Doctors without full registration may prescribe CDs if the supervising practitioner takes full responsibility. It is best practice for the prescriber to write their GMC number on any Controlled Drug Prescription.

14.2.3 Nurse and pharmacist independent prescribers may prescribe any CD in Schedules 2 to 5 for any medical condition within their clinical competence.

14.2.4 Supplementary prescribers may write prescriptions for CDs, providing they are acting within a Clinical Management Plan, specific to that patient and agreed between the independent prescriber (doctor), the supplementary prescriber (registered nurse, pharmacist, registered midwife, chiropodist / podiatrist, physiotherapist, radiographer or optometrist) and the patient.

14.2.5 Schedule 2 and 3 CDs, except Midazolam, may not be supplied or administered under PGDs.

14.2.6 Doctors approved by the Department of Health are able to prescribe Diamorphine, Dipipanone and Cocaine to substance misusers for the treatment of addiction. All doctors may prescribe such drugs for patients, including substance misusers, for the relief of pain due to organic disease or injury without such approval.

14.2.7 Private prescribing of Schedule 2, 3 and 4 CDs may only be undertaken by practitioners who have registered with the PPSA for this purpose. The prescription is then to be written on a pink private prescription form.

14.3 **Period of validity**

14.3.1 Prescriptions for Schedule 2 to 4 CDs cannot be dispensed, or issued from a ward for a TTO, if more than 28 days have elapsed since the prescription was signed and dated by the prescriber or, if the prescription has a specified later start date, not more than 28 days after this date. Where a prescription specified that instalments are to be supplied at stated intervals, the first instalment will be supplied no later than 28 days after the appropriate date.

14.3.2 It is good practice for NHS and private prescriptions for Schedule 2 to 4 CDs to be limited to a total of 30 days supply. In exceptional circumstances where a prescriber believes a supply of more than 30 days is clinically indicated, and does not pose an unacceptable risk to patient safety, an extended amount may be prescribed. In such cases the reason for the extended supply must be recorded in the patient's notes and the prescriber must be able to justify their decision. Prescribers for Children's and Adolescent Mental Health Services, who are frequently treating ADHD long term, may write prescriptions for a total of 3 months at a time (see SOP for Prescribing and Handling CD Prescriptions within Children's' and Adolescent Mental Health Services).

14.4 Repeat prescriptions are not permitted for schedule 2 or 3 Controlled Drugs.

14.5 **Prescribing for self and family**

14.5.1 No prescriber can prescribe any CD for themselves or anyone with whom they have a close personal or emotional relationship.

14.6 **Prescribing for inpatients**

14.6.1 Prescriptions for CDs can only be written by registered prescribers. Authorised practitioners can only prescribe within the scope of their own professional practice and competence.

14.6.2 CDs must be prescribed on an authorised drug/prescription chart that provides space for doses administered to be documented and that provides space for patient name and allergy status (hypersensitivities) to be recorded.

14.6.3 The following details must be specified:

- Patient Name
- Allergy Status
- Drug name and form
- Route
- Dose
- Frequency (If prescribed "one when required" a minimum interval for administration must be specified)
- A finish date where appropriate
- Start date
- Where a drug is prescribed in two or more strengths, for administration at different times, the entries must be made adjacent to each other in the chart, in order to clarify the doses, strengths and times.
- It shall be indelible and signed by the person issuing it with their usual signature and dated by them
- It is good practice to ensure the patient's identity number is also included on the chart, e.g. NHS number.

14.7 **Prescribing for out-patients and patients on discharge.**

14.7.1 TTOs must be prescribed on a locally-approved form, an original copy of which can be kept by the pharmacy dispensing the drug. Out-patient prescriptions will be written on a locally approved out-patient prescription form or alternatively on an FP10.

14.7.2 A supply of discharge CDs on a TTO should not normally exceed 14 days, with a maximum of 28 days. For out-patients 30 days supply is the usual maximum.

14.7.3 The prescription must contain the following details, written so as to be indelible, i.e. written by hand, typed or computer generated:

- The patient's full name and address (a pre-printed hospital identity sticky label may be used provided the prescriber also signs over part of the label so as to make it tamper proof)
- The date of the prescription
- The name and form of drug

- The strength of the preparation
- The dose to be taken
- The total quantity of the preparation or number of doses to be supplied in both words and figures
- If possible, GMC Number or Prescriber Number
- It shall be indelible and signed by the person issuing it with their usual signature and dated by them
- If issued by a dentist, the word 'For Dental Treatment Only'.

14.8 **Prescribing in Instalments**

14.8.1 An instalment direction combines two pieces of information:
1. Amount of medicine per instalment
2. Interval between each time the medicine can be supplied.

14.8.2 The Home office has confirmed that an instalment prescription must have both a dose and an instalment amount specified separately on the prescription. The first instalment must be dispensed within 28 days of the appropriate date. The remainder of the instalments should be dispensed in accordance with the instructions (even if this runs beyond 28 days after the appropriate date).

14.8.3 If the only date on the prescription is the date of signing, the first dispensing needs to take place within 28 days of this date. If the prescriber indicates on the prescription a date before which the prescribed medicine should not be dispensed, this would be the appropriate date instead. The prescription must then be marked with the date of each supply.

14.8.4 The instalment direction is a legal requirement and needs to be complied with. However, because there are acknowledged practical difficulties with missed doses and dates when the pharmacy is closed (e.g. bank holidays), the Home Office has approved specific wording to be used that gives pharmacists a degree of flexibility when making a supply.

14.8.5 If daily doses are to be dispensed in separate containers the following wording should be on the prescription:
'Dispense daily doses in separate containers'.

14.8.6 The following wording allows a pharmacy to supply the balance of an instalment if the interval date is missed.:
'Consult the prescriber if 3 or more consecutive days of a prescription have been missed'

14.8.7 Approved wording for missed dose -supervised consumption:
'Supervise consumption on collection days. If an instalment's collection day has been missed, please still dispense the amount due for any remaining day(s) of that instalment.'

14.8.8 Approved wording for missed dose – unsupervised consumption:
'If an instalment's collection day has been missed, please still dispense the amount due for any remaining day(s) of that instalment.'

14.8.9 Approved wording for when the pharmacy is closed:
'Please dispense instalments due on pharmacy closed days on a prior suitable day'

15 ADMINISTRATION OF CONTROLLED DRUGS TO PATIENTS

15.1 CDs should not be administered as part of the routine drug administration round and in a timely manner to meet the prescriber's intentions and the patient's needs.

15.2 The administration of CD's must comply with the organisation's Medicines Policy.

15.3 Patient's own CDs may only be administered to the named patient appearing on the dispensed label.

15.4 Controlled drugs held as stock on the ward can only be administered to patients in the hospital / unit.

15.5 In the event that a patient requires a CD which is not held as stock on the ward but is held as stock on an adjacent ward (part of the same Trust), it is permissible for a practitioner from the holding ward to provide the required dose to a practitioner from the ward in need, in order that the practitioner from the ward in need may administer said dose to the patient. However, the CD must not be transferred from one CDRB to another; instead it must be signed out of the providing ward CDRB to the patient, by the providing practitioner with reference to the patient's drug chart, with a witnessing signature from the patient's ward. Similarly, the record of administration in the patient's records must be signed by both the providing and receiving practitioners. This procedure would only be appropriate in the most exceptional circumstances and the Accountable Officer must be informed that it has been used, at the earliest opportunity. CDs must not be administered to patients on an adjacent ward if that ward were managed by a different NHS Trust.

15.6 Controlled drugs can only be administered if correctly prescribed by an appropriately qualified practitioner authorised to prescribe by the organisation.

15.7 Verbal orders or remote prescriptions for the administration of CDs must not be accepted, but in exceptional circumstances, on inpatient wards, where a prescriber is unable to alter a prescription, a verbal order or remote prescription for a change in dose of a CD already prescribed may be accepted.

15.8 Only registered practitioners who are competent to administer CDs and have been approved by the practitioner in charge of the unit may administer CDs. Administration must be witnessed by a second person who has been trained appropriately and assessed as competent. However, the identification of the patient, the selection of the drug, dose and route, the completion of the prescription sheet and CDRB entry will be the responsibility of one practitioner throughout. It is not acceptable for two members of staff to select and prepare a dose of a Controlled Drug for administration by a third person

15.9 The person prescribing the CD should not also personally undertake all of the following tasks, unless exceptional circumstances exist; preparation, dispensing, transportation and administration. For safety reasons, it is good practice to ensure that another appropriate competent individual is involved, and can thus reflect on the process.

15.10 Those qualified to administer CDs act according to their own competence and must remain compliant with their own professional code of conduct.

15.11 If there is any doubt about a prescribed drug, the prescriber must be contacted before any drug is administered. This would apply to illegible instructions, doubt over appropriateness of the drug for the patient's condition or doubt over the legality of the prescription.

15.12 Where a calculation is required to obtain partial or complex doses, these must be checked by another practitioner, doctor or pharmacist. Again, talking through the calculation by telephone with another trained member of staff is better than nothing.

15.13 The following procedure must be followed when administering CDs:

- Read the prescription carefully
- Check the time of last administration
- Where the prescription is for a strong opioid, check the respiration rate of the patient. If this is less than 12 respirations per minute, the dose must not be administered and the doctor must be contacted, unless the patient is during final stages of palliative care where this step is not necessary.
- Select required drug from the CD cupboard
- Ensure drug is in date
- Check stock levels against the last entry in the CDRB
- Check appropriate dose against the prescription chart
- Ensure patient is not allergic to drug (see section on prescription chart)
- Prepare drug for administration
- Take the measured dose of the drug to the bedside with the prescription
- Confirm identity of the patient
- Administer the drug as prescribed
- Observe patient for any adverse side effects of the drug
- Make entry in the CDRB and sign the CDRB and prescription chart along with the time administered
- Entry in CDRB, drug chart and stock level to be checked and countersigned by witness
- Part vial administration must be recorded in full, for example 2.5mg given, 2.5mg wasted and destroyed as per destruction procedure below.

15.14 Cancellation, alteration or obliteration of entries is **not** permitted in the CDRB. If a mistake is made, it must be bracketed in such a way that the original entry is still clearly legible. The correction may be written on a line below the error, in the margin or at the bottom of the page. The corrected entry must be signed, dated and witnessed by a second approved person (see Appendix 7).

15.15 On reaching the end of a page in the CDRB, the balance must be carried forward to a new page and the new page number must be added to the bottom of the finished page and in the index in the front of the CDRB.

15.16 Completed CDRBs must be sealed and kept by the clinical area for at least 2 years from the date of last entry. Where space permits, this should be extended to a period of at least 7 years.

16 DISPOSAL OF STOCK CONTROLLED DRUGS

16.1 When a dose smaller than the total quantity in an ampoule or vial is drawn up into a syringe or when a dose is drawn up but not used, the surplus amount may be destroyed on the ward by the nurse, witnessed by an approved person. These small amounts must be rendered irretrievable by denaturing in a DIY doop kit available on the ward. This must be placed into a sharps waste bin designated for pharmaceutical waste.

16.2 The destruction of these small amounts must be documented in the CDRB. Both persons should sign the CDRB.

16.3 Larger amounts of waste / used CD, such as that from a syringe driver, must also be destroyed by denaturing and this must be suitably witnessed, as above. A denaturing kit must be used and the resulting resin must be placed into a waste medicines bin, sharps bin or yellow sack, for incineration.

16.4 Legislation does not state how empty methadone bottle should be disposed. However, the Department of Health has produced guidance about empty medicine containers. For liquid Controlled Drug containers, these should be first emptied as far as possible (within the dispensing process) and any excess liquid (e.g. patient returns) denatured. The container should then be placed into a pharmaceutical waste container for incineration.

16.5 Surplus stock of CDs must be notified to the supplying pharmacy. Those that can be used (i.e. unopened containers with a reasonable expiry date) will be collected from the ward by a pharmacist and returned to pharmacy stock. An entry must be made in the CDRB and signed and dated by the nurse in charge of the ward and the pharmacist.

16.6 Schedule 2 expired stock controlled drugs may only be destroyed in the presence of a person authorised by the Accountable Officer. The practitioner in charge of the ward should contact the Pharmacist allocated to the ward or the Accountable Officer when stock drugs need destruction. These must be destroyed as per the organisation's Standard Operating Procedure for the Destruction of Obsolete, Expired and Unwanted Controlled Drugs by an authorised witness.

16.7 CDs waiting to be destroyed must be kept in the ward controlled drug cupboard, clearly marked NOT FOR USE and separated from stock that is in use. They must not be deducted from the CDRB until they have been destroyed.

16.8 The authorised person will contact the ward staff to arrange a convenient time and date for the destruction to take place.

16.9 The method of destruction must follow current guidance given by the Royal Pharmaceutical Society of Great Britain and the SOP for the Destruction of Obsolete, Expired and Unwanted Controlled Drugs by an authorised witness.

16.10 The following details of destruction must be recorded on the appropriate pages of the relevant CDRB:

- Date of destruction
- Quantity being destroyed
- Name and signature of the authorised person who witnesses the destruction
- Name and signature of the pharmacist / practitioner destroying the drug

The authorised person will also complete a Destruction of Controlled Drugs Record and list the CDs destroyed on the record and return it to the AO.

17 DESTRUCTION OF PATIENTS' OWN CONTROLLED DRUGS

17.1 Patients' own CDs that are no longer required or that have reached their expiry date may be destroyed provided permission has been received from the patient or patients' relatives by an authorised witness only. In some cases (e.g. following the death of a patient) it will not be possible to seek permission from the patient or their relatives. In such cases practitioners should follow a pragmatic approach of destroying the controlled drug and informing the patient or their relatives if practicable to do so.

17.2 The practitioner in charge of the ward must store the drugs to be destroyed in the ward controlled drug cupboard clearly marked NOT FOR USE and separated from stock that is in use and arrange a date for destruction with the authorised pharmacist. These should not be deducted from the CDRB until they are destroyed.

17.3 Destruction must take place with sufficient frequency to ensure that excessive quantities are not stored in the cupboard.

17.4 At the time of destruction, the pharmacist / Clinical Manager / senior practitioner should make the drug unusable for use by placing it into a denaturing kit and following the instruction for use on the container. The destruction must be witnessed by an authorised person or a practitioner on the ward.

17.5 The used denaturing kit must be placed into a waste container reserved for pharmaceuticals and labelled according to the waste policy guidance.

17.6 A record of the destruction must be made in the CDRB used for patients' own drugs and must include the following:

- Date of destruction
- Name and signature of pharmacist / Clinical Manager / senior practitioner
- Name and signature of witness

The authorised person will also complete a Destruction of Controlled Drugs Record and list the CDs destroyed on the record and return it to the AO.

18 MANAGEMENT OF CONTROLLED DRUG ORDER BOOKS AND REGISTERS

18.1 All stationary related to the procurement and use of CDs must be stored in a secure place, with limited access by persons approved by the Clinical Manager or Practitioner in Charge of the ward or department.

18.2 Only one CD order book can be used at a time on the ward.

18.3 Only one CDRB for stock CDs is to be used at a time on the ward and if patients own drugs are recorded in a separate CDRB, only one book is to be used at a time.

18.4 When a new CDRB is started, the balance of CDs in stock must be written into the new book promptly and witnessed by designated ward staff approved by the Nurse in Charge.

18.5 Completed CD order books and CDRBs must be retained for at least two years (or 7 years, if space permits) after the date of the last entry.

18.6 Any loss or theft must be reported immediately to the relevant pharmacist and the Accountable Officer. Police should be informed if deemed appropriate by the Accountable Officer

19 CONTROLLED DRUGS IN THE COMMUNITY

19.1 Management of controlled drugs in patient's homes and in community settings must follow the same principles as described above for wards and departments, including where possible the requirements for signatures and audit trails.

19.2 Most patients in the community will have had CDs prescribed for them via an FP10 prescription. Whether supplied from a community pharmacy against an FP10 or from the local hospital pharmacy, CDs dispensed to a patient are the property of that patient. Prescriptions for CDs must meet the legal requirements as specified under section 14 – Prescribing Controlled Drugs. All patients must also have the CD medication details recorded on the medication sheet used within community nursing.

19.3 CDs dispensed for a patient are the property of that patient, and as such they retain the right to do what they chose with their CDs, within the bounds of legislation. However, on occasions community staff may observe CDs being stored or used in a way that constitutes a significant risk to children or vulnerable adults in the community setting. On such occasions community staff should advise parents and/or carers appropriately to remove the risk or reduce the risk to an acceptable level. If risk to children or vulnerable adults remains, this should be escalated to a senior manager in accordance with the Safeguarding Children and Young People Policy or the Safeguarding Vulnerable Adults Policy. In the interests of safety for children and vulnerable adults involved, removal of CDs and an alternative method of treatment may need to be considered.

19.4 Ordering of CDs will be via the patient's usual community pharmacy, or alternative community pharmacy if necessary to ensure sufficient supplies of CDs, with the patient or their representative collecting the medication. But in exceptional circumstances, practitioners, pharmacists, doctors, pharmacy staff and other health care professionals are legally allowed to transport CDs to a patient, provided the CDs have been legally prescribed for that patient. In addition, practitioners, doctors and other health care professionals are legally allowed to transport CDs for emergency use on patients. Any individual is allowed to return CDs from a patient to a pharmacy for destruction. However, healthcare professionals must not routinely transport a patient's own CDs to or from that patient's home. Whilst legal, this would not comply with best practice procedures.

19.5 All health care professionals in legal possession of a CD have a professional duty of care to take all reasonable steps to maintain safe custody of that CD at all times. All CDs must be kept out of view during transit.

19.6 Additional consideration must be given to personal safety when transporting / carrying CDs, particularly when this is a regular occurrence for a specific location or where a patient or family members will be aware of the delivery / return.

19.7 Where CDs are collected by staff or other agencies (e.g. taxis or drivers), the identity/bona fide of the collector must first be verified. A signature of receipt must be obtained for the sealed bag and the identity details of the package must be recorded. Standard forms of identification include personal recognition, NHS identity badge and driving licence. Other acceptable forms would include a passport but this would not normally be available.

19.8 **Collection of CDs**

19.8.1 Where a patient or patient's representative collects CD medication, the dispenser will request evidence of identification and may refuse to supply the drug if not satisfied with the identity of the person.

19.8.2 Where the person collecting CD medication is a healthcare professional, acting in a professional capacity, the dispenser must obtain that person's name and must request evidence of identity, unless familiar with the individual.

19.8.3 It is a legal requirement to record the following information for Schedule 2 CDs:

- Whether the person who collected the drug was the patient, the patient's representative or a health care professional acting on behalf of the patient.
- If the person who collected the drug was a health care professional acting on behalf of the patient, that person's name, address and registration number;
- If the person who collected the drug was the patient or their representative, whether evidence of identity was requested and what form of identity was provided.

19.9 Initial and subsequent supplies of each CD being administered by community nurses must be checked and recorded on the Medication Prescription, Controlled Drug Sheet. This must be done even if the drug(s) are not currently being required by the patient. Each dose administered must be recorded on the same sheet with a running balance of CD remaining in stock recorded. Regular (at least weekly) stock checks of CDs in use and those not being used must be carried out. There is no requirement to maintain CD records and stock balance checks for patients own controlled drugs for which community nurses have no responsibility for administering, e.g. oral medications.

19.10 All CD medication will be stored safely in the patient's home and remains their responsibility. Community staff will be expected to give storage advice, particularly if poor practice is noted. The Controlled Drug Sheet will provide a log of all CDs available in the patient's home, including a running balance of each controlled drug.

19.11 In order to administer a CD to a patient, the community practitioner must be in receipt of a written order from a Medical Practitioner, which must include:

- Name of drug
- Dosage and frequency of administration
- Method of administration

- Be in black ink or otherwise indelible
- Be signed by the prescriber with their usual signature and be dated
- Specify the patients name and if possible their NHS number
- Specify the form of the preparation, e.g. tablets, mixture
- Specify the strength of the preparation if more than one strength is available

19.12 In the community setting, a minimum of one Registered Practitioner will check and administer CDs. Extreme care must be taken where there are different medications and different strengths prescribed for the patient, as packaging can appear very similar. When administering CDs via a syringe driver, community staff must refer to the Syringe Driver Policy.

19.13 Where CDs are administered to a patient, any waste must be managed appropriately. Small amounts of residue from a single ampoule may be disposed of by denaturing. The used denaturing kit must be placed into a waste container reserved for pharmaceuticals and labelled according to the waste policy guidance.

19.14 Patients' own controlled drugs in the community which are no longer required should be returned to a community pharmacy by the family for disposal. In exceptional circumstances where this is not practical or reasonable, the drugs may be either returned to the community pharmacy by the medical or community practitioner once permission has been obtained (if appropriate), or destroyed in the patient's home. Where CDs are returned to the community pharmacy by staff, a note must be made in the patient's record, indicating the date the drug and the quantity returned and the Community Pharmacist asked to countersign the record. If the patient is willing / able to countersign the entry, that should be done as best practice. If the drug is destroyed in the patient's home, this must be done by two members of staff using a DOOP kit and the appropriate records of the date, drug and quantity destroyed made in the patient's notes.

19.15 A record of any CD discarded or returned to the community pharmacy must be made on the Controlled Drug Sheet.

19.16 Particular care must be taken when a third party collects a CD for a patient being treated for addiction – this should only be permitted in exceptional circumstances. A letter of authority is always required when a third party collects CDs on behalf of the patient and it must be retained in the pharmacy.

20 INCIDENTS INVOLVING CDS

20.1 If there is any risk of harm to an individual due to an incident involving medicines, priority must be given to the clinical care of that person(s).

20.2 Any incident or near miss in which medicines are involved must be reported in accordance with the incident reporting policy.

20.3 The incident must immediately be reported to the appropriate line manager, or person delegated to act on their behalf, who will arrange for the incident to be investigated. The incident must also be reported to the Accountable Officer.

20.4 Action to be taken if any discrepancies are discovered (see Appendix 6)

- A full, immediate search is to be conducted for “missing” drugs.
- Records are to be double-checked to ensure that the CD Register and Order Book are accurate and up-to-date.
- If the discrepancy cannot be resolved locally, it is to be reported to the Chief Pharmacist and Accountable Officer at the earliest opportunity, with details of whom and what are involved, and the time of discovery. A formal investigation will be instigated with reports to external agencies and authorities as appropriate.
- An on line incident form must be completed.

20.5 Accidental breakage of ampoules / bottles and other fragile containers has been known to occur from time to time. In this circumstance, the drug can be denatured and the used denaturing kit must be placed into a waste container reserved for pharmaceutical waste and labelled according to the waste policy guidance. The drug needs to be accounted for, so must be signed out of the CD Register by the two witnesses, stating the reason. In all cases of broken ampoules / bottles, the responsible person must be informed and an Adverse Event Report form must be completed and the AO informed.

20.6 If a CD medicine is found to be defective (packaging broken, contents appear cloudy or appear to be contaminated), the item(s) must not be used and must be returned to the pharmacy for assessment, with appropriate entries made in the CD Register.

20.7 Process for reconciliation when necessary.

- Once resolved, a note must be made in the CD Register to correct the discrepancy in the balance – the original entries must not be altered.
- A brief record of action(s) taken to resolve the discrepancy may also be recorded.

20.8 If routine monitoring reveals concerns or if alerted to specific concerns through other routes, the Accountable Officer will initiate a more detailed investigation, using local sources of advice and expertise as well as the wider network of AO colleagues.

21 ILLICIT CONTROLLED DRUGS

21.1 In the event of a patient entering the Trust in possession of an illicit substance or any substance thought to be of an illicit nature, Trust staff should follow the actions listed below. If unknown, the identity of the substance should not be assumed or guessed, but simply referred to as a ‘suspected illicit’ or ‘unidentified’ substance. If at any point a member of staff feels vulnerable or at risk following these actions, security must be called for assistance.

21.2 With the patients permission the illicit or suspected illicit substance should be removed from them. Illicit substances cannot be kept by patients on Trust premises. If patients refuse to give permission, it should be made clear to them that it is within their interests to hand over the substance as otherwise the police would become involved. If patients still refuse to give permission, then the police should be contacted via the duty manager.

21.3 It is reasonable to reassure patients that their names will not be given to the police providing that the amount of illicit substance is small and originally intended for personal use.

21.4 The illicit substance must be placed in an envelope by two staff, one of whom must be a registered practitioner, and sealed and both members of staff should sign across the seal. The

sealed envelope should then be placed in the CD Cupboard and an entry made by the two staff in the CDRB – either at the back or in the separate CDRB reserved for patients own drugs. For units that do not have a CD Cupboard or CDRB, the sealed envelope should be stored in a locked medicine cupboard of safe and a record made in the patient's notes. In some cases the nature of the substance will be known from pack labelling and the quantity may be apparent (e.g. so many tablets), in which case the details can be recorded accurately in the CDRB. However, more frequently the substance will be a miscellaneous powder or crushed leaf, in which case it should be recorded as an approximate amount (e.g. small amount or approx. so many grams) or suspected illicit substance.

21.5 Suspected illicit substances found within Trust premises or grounds should be collected by a member of staff and taken to the nearest in-patient area with a controlled drug cupboard or direct to Pharmacy if appropriate. The substance should be sealed in an envelope and recorded in the CDRB as in 21.4 above.

21.6 Illicit substances waiting to be destroyed must be kept in the ward controlled drug cupboard, clearly marked NOT FOR USE and separated from stock that is in use.

21.7 Contact the Pharmacy to arrange for destruction of the illicit substance (for contact details see Appendix 1). Illicit substances may only be destroyed in the presence of a person authorised by the Accountable Officer. The authorised person will contact the ward staff to arrange a convenient time and date for the destruction to take place.

21.8 The method of destruction must follow current guidance given by the Royal Pharmaceutical Society of Great Britain and the SOP for the Destruction of Obsolete, Expired and Unwanted Controlled Drugs by an authorised witness.

21.9 The following details of destruction must be recorded on the appropriate pages of the relevant CDRB:

- Date of destruction
- Quantity being destroyed
- Name and signature of the authorised person who witnesses the destruction
- Name and signature of the pharmacist / practitioner destroying the drug

The authorised person will also complete a Destruction of Controlled Drugs Record and list the illicit substance destroyed on the record and return it to the AO.

22 COLLECTION OF CDS BY PATIENTS FROM PHARMACY

Person collecting	Action	Notes
Patient Patient's representative	Pharmacist must request evidence of that person's identity, unless already known to the pharmacist	The decision whether to supply or not is at the discretion of the supplying pharmacist – based on their professional judgement
Healthcare professional acting in their professional capacity on behalf of the patient	Unless the patient already known to the pharmacist, obtain: 1. Name of the healthcare professional 2. Address of healthcare professional Also request evidence of identity	Where evidence of identity is not available, the pharmacist has discretion over whether to supply or not – based on their professional judgement

22.1 Where a patient or patient's representative collects CD medication, the dispenser will request evidence of identification and may refuse to supply the drug if not satisfied with the identity of the person.

22.2 Where the person collecting CD medication is a healthcare professional, acting in a professional capacity, the dispenser must obtain that person's name and home address and must request evidence of identity, unless familiar with the individual.

22.3 It is a requirement to record the following information in the CD register for Schedule 2 CDs supplied on prescription:

- Whether the person who collected was the patient, the patient's representative or a healthcare professional acting on behalf of the patient
- If the person who collected the drug was a healthcare professional acting on behalf of the patient, that person's name and address
- If the person who collected was the patient, or their representative, whether evidence of identity was requested and whether evidence of identity was provided by the person collecting the drug.
- Outpatients or their representatives will sign a receipt to record the number of doses (tablets, capsules, ampoules or volume of liquid) received.

22.4 The postal service will not be used for the delivery of CDs to patients' homes.

23 RAISING CONCERNS

23.1 Any person who has a concern either about a procedure or about an individual's conduct concerning CDs should contact the AO (see Appendix 1 for contact details).

23.2 Anyone who has a concern about the conduct of the AO should contact the Trust's Chief Executive and Chief Medical Officer.

23.3 The AO will keep records of any concerns raised and any requests for information from another responsible body, under regulation 11 (3) (6) (i) and (iii) CD (Supervision of Management and Use) Regulations 2013. A record will also be made of actions taken.

24 REPORTING

24.1 Within the organisation, the AO will oversee incidents and concerns involving CDs within the current policies for incident reporting and management of individual performance.

24.2 Staff must therefore report all incidents electronically via the Safeguard System as per the Trust's policy. The AO must be notified of all incidents involving CDs and will agree the level of investigation required with relevant senior staff.

24.3 The AO will report any concerns to the Medicines Management Group and hence Assurance Committee (by report) and directly to the Assurance Committee (Trust Board Committee annually so providing the assurance that the organisation and its services are compliant with current legislation and that any issues are being appropriately managed.

25 SELF-ASSESSMENT AND CD DECLARATIONS

25.1 All healthcare organisations providing clinical care are required to make a declaration, at least once every year, as to whether they keep stocks of CDs and whether there are any special circumstances that might explain unusual patterns of prescribing.

25.2 All those that hold stocks of CDs will be invited to complete a self-assessment of their management of CDs.

25.3 The AO is responsible for initiating and receiving the declaration and self-assessment to and from all services within the organisation. Where concerns are identified in the responses, further monitoring or inspection may be put in place.

26 ROUTINE MONITORING AND INSPECTION

26.1 The AO will arrange for CD stocks to be monitored every six months for all services holding CDs within the organisation.

26.2 The AO will make quarterly declarations on the management of CDs within the Trust to NHS England South

26.3 The AO will arrange periodic inspections of premises where CDs are used. In most situations, notice will be given of inspection. However, on occasions, an unannounced inspection may take place. These will be carried out by a member of the Solent NHS Trust Medicines Management Team

27 AUTHORISED PEOPLE

27.1 The AO will authorise specific individuals or groups of individuals from within the organisation to witness the destruction of CDs. These authorised persons must then work to the approved SOP for CD destruction.

27.2 An authorised person cannot witness the destruction of CDs that were supplied to them or by them.

27.3 In addition, all authorised people must be subject to a professional code of ethics and/or have been the subject of a DBS check.

27.4 The AO will maintain a list of all authorised persons for CD destruction.

28 CD STANDARD OPERATING PROCEDURES (SOPS)

28.1 CD SOPs are detailed documents describing the responsibilities and the procedures, including audit, necessary to safely and accountably manage CDs.

28.2 The Regulations require that:

- All health care providers will have and comply with approved SOPs.
- SOPs for organisations will be agreed by the relevant AO.
- The organisation must have SOPs for handling CDs for all of its directly managed services and staff.

28.3 The Regulations state that the SOPs must cover the following:

- Assigning responsibilities
- Ordering and receipt of CDs
- Who has access to CDs
- Where the CDs are stored
- Security in relation to storage and transportation of CDs
- Disposal and destruction of CDs
- Who is to be alerted if concerns or complications arise
- Record keeping, including CD registers and records of Schedule 2 drugs that have been returned by patients.

28.4. The St Mary's Community Campus Pharmacy Department will hold individual SOPs for its processes.

29 ROLES AND RESPONSIBILITIES

29.1 The Chief Executive has overall responsibility for the strategic and operational management of the organisation, including ensuring all policies are adhered to.

29.2 The Medical Director and Chief Nurse, on behalf of the Chief Executive, will ensure that clinicians and their practice comply with this policy.

29.3 The Trust's Assurance Committee (Board Committee) is responsible for ratifying this policy and ensuring it represents best practice and is based on current evidenced based information.

29.4 The AO is responsible for ensuring the safe and effective use and management of CDs within the organisation. In addition, the AO acts as the link with the Local Intelligence Network for CDs involving key local agencies.

29.5 All staff must be aware of their roles and responsibilities under the current legislation and adhere to the safe practices outlined in this policy and associated SOPs. Persons not complying with this policy will be subject to disciplinary procedures and may face legal action. Staff must also make themselves familiar with local procedures for their specific areas of work.

29.6 Ward/service managers are responsible for ensuring adequate dissemination and implementation of this policy and the associated procedures to enable adherence by staff.

29.7 All staff must comply with their responsibilities when undertaking their duties involving CDs. Incorrect storage or inadequate record keeping is illegal and may lead to disciplinary or legal action.

29.8 The pharmacy services to the Trust are currently provided by a combination of local acute hospitals and a Solent NHS trust managed pharmacy for Portsmouth and the surrounding areas. All pharmacy staff employed by those organisations, whose duties include CDs, must comply with the requirements of this policy as well as their own policies and to ensure that CDs are stored and distributed in accordance with the law and that proper records of transactions (including destruction) are kept.

Responsibility for CDs and for their records for inpatient wards / units lies with the health care professional in charge at each location.

29.9 The health care professional in charge of each location will authorise qualified practitioners for their location to order and handle controlled drugs. The list of authorised practitioners will be provided to the supplying pharmacy.

29.10 Ward/service managers are responsible for ensuring and incidents involving Controlled Drugs are reported to the Accountable Officer as soon as possible.

30 TRAINING

30.1 Solent NHS Trust recognises the importance of appropriate training for staff. For training requirements and refresher frequencies in relation to this policy subject matter, please refer to the Training Needs Analysis (TNA) on the intranet, referring to Medicines Management.

30.2 All Staff involved in any aspects of controlled drug use must have easy access to the SOPs relevant to their area of work and are required to sign a copy of these SOPs indicating they have read and understood the actions required of them.

30.3 Support and advice will be available from the Medicines Management Team where needed.

30.4 All staff handling CDs must be trained in the management of CDs and must be able to demonstrate competence in all their actions. At the basic level staff are required to be explicitly authorised by their line manager to carry out specific roles in medicines management and safety of patients is paramount. This must be reflected in the job description of the individual. All staff attending Clinical Update Training will receive regular training in the management of CDs.

31 SUCCESS CRITERIA AND AUDITING COMPLIANCE

31.1 Success of this policy will be monitored through adverse event reports and complaints related to the management and use of CDs within the organisation.

31.2 Compliance will be monitored through regular audit of the day-to-day management of CDs, including checks of orders and registers, storage arrangements, availability of appropriate SOPs and signature sheets. A suggested template for the signature sheet is included at Appendix 5. The Accountable Officer will ensure periodic assessment of compliance with this policy through this audit.

31.3 The effectiveness of this policy will be reviewed by the Medicines Committee and will be discussed prior to the stipulated review timeframe at the Medicines Committee meeting. Details of these discussions will be documented in the minutes.

31.4 When implemented this policy will result in increased awareness of the safe management of controlled drugs

31.5 All supervisory staff must be vigilant for signs that may indicate abuse or diversion of controlled drugs and take appropriate action or discuss with their manager. Additional advice can be sought from the Chief Pharmacist/Accountable Officer or Controlled Drugs Programme Manager in the first instance.

32 EQUALITY AND DIVERSITY

32.1 An Equality Impact Assessment has been completed for this policy and no significant equality and diversity issues were identified.

32.2 Under the Mental Capacity Act 2007, it has been recognised that this policy may require a decision to be made about a service user. Please refer to the organisation's Deprivation of Liberty and Mental Capacity Act Policy to assess for service user capacity and making decisions in the best interest of the service user.

32.3 This policy has been assessed and meets the requirements of the Mental Capacity Act 2007**.**

33 COMMUNICATION AND DISSEMINATION

33.1 This policy has been approved by the Trust's Assurance Committee.

33.2 This policy will be distributed to all service managers.

33.3 Ward/service managers are responsible for ensuring adequate dissemination and implementation of policies and the associated procedures to enable adherence by staff.

34 REFERENCES/ BIBLIOGRAPHY

- Security of Prescription Forms – DH Guidance
- NPC Guide: Implementation of Medicines Reconciliation
- Summary of Changes in Prescribing of CDs, Unlicensed Medicines and 'Off Label' Prescribing by Nurses and Pharmacists
- Technical Patient Safety Solution for Medicines Reconciliation on Admission of Adults to Hospital
- Guidance on the Destruction of CDs – New Role for AOs
- Law, Medicines and Changes to Prescribing for Practitioners: CD Update Nov 2007
- Safer Management of CDs: a guide to good practice in secondary care
- RPSGB – Guidance on CDs
- NTS Guidelines on the Clinical Management of Drug Misuse and Dependence in the UK
- Implementing Changes to the Record Keeping Requirement for CDs
- A Guide to Good Practice in the Management of CDs in Primary Care
- Statutory Instrument 2013/373: The CDs (Supervision of Management and Use) Regulations 2013,
- Safer Management of CDs: Private CD Prescriptions and Other Changes to the Prescribing and Dispensing of CDs
- Health Technical Memorandum 07-01: Safe Management of Healthcare Waste
- The Health Act 2006
- The Drugs Act 2005
- Statutory Instrument 2001/3998: The Misuse of Drugs Regulations 2001 (as amended)
- Statutory Instrument 1997/1830: The Prescription Only Medicines (Human Use) Order 1997 (as amended)

- Statutory Instrument 1997/1001: The Misuse of Drugs (Supply to Addicts) Regulations 1997 (as amended)
- Statutory Instrument 1973/798: The Misuse of Drugs (Safe Custody) Regulations 1973 (as amended)
- The Misuse of Drugs Act 1971 (as amended)
- NPC Handbook for Accountable Officers 2011
- BNF edition 70 September 2015 – March 2016 (Please refer to eBNF or current edition for updated guidance)
- Circular 027/2015: Approved mandatory requisition form and Home Office approved wording

35 LINKS WITH OTHER POLICIES AND PROCEDURES

- Medicines Policy
- Intravenous Drug Policy
- Adverse Event Reporting Policy
- Capability Policy
- Disciplinary Policy
- Investigation Policy
- Deprivation of Liberty Safeguards and Mental Capacity Act Policy
- Standard Operating Procedure for the use of Patient's Own Drugs
- Harmful Substances and Alcohol Use by service User's Policy.

Appendix 1 Key Staff – Contact Details

Title	Name	Daytime Contact	Out of Hours Contact
Chief Pharmacist	Raj Parekh	07584143756 Raj.parekh@solent.nhs.uk	Via Solent On Call Pharmacist via St James' Front Hall.
Controlled Drugs Programme Manager	Andy Palacio	07901110687 Andy.palacio@nhs.net Andy.palacio@solent.nhs.uk	
Authorised Persons for CD Destruction	Medicines Management Team at Western Community Hospital	02380 698503	
	Medicines Management Office, St James Hospital	02392 683305/683312	
Dispensary Manager, University Hospitals Southampton Foundation NHS Trust Pharmacy Service, Royal South Hants Hospital	Amanda Eldridge	02380 825551 amanda.eldridge@uhs.nhs.uk	

Appendix 2 Schedules 2, 3 and 4 CDs

NB. Whilst a CD may be listed here, it may not be formulary – the current district prescribing formulary should be consulted prior to prescription.

(This list is not comprehensive – the full list is contained in the Misuse of Drugs Regulations 2001 -as amended)

Drug	Strength/forms	Brand names® include but not exhaustive	Schedule/Notes
Alprazolam	All strengths and forms	Xanax	4 (Not prescribable under NHS)
Buprenorphine	tabs/patches	Butrans Temgesic Transtec Subutex Hapoctasin Suboxone	3 (Patches must be prescribed by brand to reduce confusion between differing dosages)
Cannabis sativa Extract	All strengths and forms	Sativex	4
Chordiazepoxide	All strengths and forms	Librium, Tropium	4
Clobazam	All strengths and forms	Frisium, Tapclob	4
Clonazepam	All strengths and forms	Rivotril	4
Cocaine	All forms and strengths		2
Codeine Phosphate	Injections only		2
Dexamfetamine	All strengths and forms	Dexedrine	2
Diamorphine	All strengths and forms		2
Diazepam	All strengths and forms	Rimapam, Tensium, Dialar, Diazemuls, Diazepam rectubes, Diazepam Desitin, Stesolid, Valclair	4
Dihydrocodeine	Injections only		2
Fentanyl	All strengths and forms	Actiq, Durogesic, Effentora, Recivit, Breakyl, Instanyl, PecFent, Matrifen	2
Flurazepam	All strengths and forms	Dalmane	4 (Not prescribable under NHS)

Drug	Strength/forms	Brand names® include but not exhaustive	Schedule/Notes
Hydromorphone	All strengths and forms	Palladone/SR	2
Lisdexamfetamine	All strengths and forms	Elvanse	2
Loprazolam	All strengths and forms		4
Lorazepam	All strengths and forms	Ativan	4
Lormetazepam	All strengths and forms		4
Meprobamate	All strengths and forms		3 (Not prescribable under NHS)
Methadone	All strengths and forms	Physeptone, Methadose, Synastone, Metharose	2
Methylphenidate	All strengths and forms	Ritalin, Concerta XL, Equasym XL, Medikinet	2
Midazolam	All strengths and forms	Buccolam, Hypnovel	3
Morphine	All forms BUT selected strengths only– Morphine sulphate solution/liquid/oral vials 30mg/5ml, 100mg/5ml	Oramorph unit dose vials 30mg Oramorph concentrated oral solution Oramorph unit dose vials 100mcg Sevredol Morcap SR Morphgesic SR MST Continus – tabs and susp MXL Zomorph Cyclimorph All strengths	2 Does not include the 10mg/5ml solution/liquid i.e. oramorph® 10mg/5ml
Nitrazepam	All strengths and forms	Mogadon, Remnos	4
Oxazepam	All strengths and forms		4
Oxycodone	All strengths and forms	Oxynorm, Oxycontin	2
Pethidine	All strengths and forms	Pamergan P100	2

Drug	Strength/forms	Brand names® include but not exhaustive	Schedule/Notes
Phenobarbital	All strengths and forms		3 (legally exempt from the safe storage requirements)
Somatropin	All forms and strengths	Genotropin, Humatrope, Norditropin, NutropinAq, Saizen, Zomacton, Omnitrope	4
Temazepam	All strengths and forms		3
Testosterone	All forms and strengths	Restandol, Striant SR, Nebido, Sustanon 250, , Virormone, Andropatch, Testim, Testogel, Tostran	4
Tramadol	All strengths and forms	Zydol, Mabron, Marol, Zeridame SR, Maxitram SR, Tramquel SR, Zamadol SR, Trandorec XL, Zamadol 24hr	3
Zalepon	All strengths and forms	Sonata	4
Zolpidem	All strengths and forms	Stilnoct	4
Zopiclone	All strengths and forms	Zimovane	4

Appendix 3

The legal and good practice requirements of commonly used controlled drugs
Solent NHS Trust Wards
Medicines Management Team November 2015

	Schedule 2	**Schedule 3**	**Schedule 4 part 1**	**Schedule 4 part 11**	**Schedule 5**
Designation	CD POM	CD No Reg POM	CD Benz POM	CD Anab POM	CD Inv P or POM
Examples	Morphine Diamorphine Fentanyl Methadone Methylphenidate Dexamphetamine Oxycodone Lisdexamphetamine	Temazepam Buprenorphine (Butrans, transtec, subutex,Temgesic, Hapoctasin,Suboxone) Midazolam Phenobarbital Tramadol	All other benzodiazepines Diazepam Lorazepam Ketamine Sativex Zopiclone Zaleplon Zolpidem	Somatropin Testosterone	Oramorph 10mg/5ml Co-codamol Co-dydramol
Prescription Requirement*	Yes	Yes	No	No	No
Prescription valid for	28 days	28 days	28 days	28 days	6 months
Requsition Necessary to order	Yes	Yes	No	No	No Except Oramorph***
Safe custody in CD cabinet	Yes	Yes	No Sativex must be kept in a lockable fridge**	No	No Except Oramorph***
CD Register entry	Yes	Yes	No	No	No Except Oramorph***
Good practice recommendations					

* - Prescription Requirements include the need for total quantity of supply to be included in words and figures

** Once opened, Sativex can be stored upright in a locked controlled drug cupboard at room temperature for 42 days.

*** Local practice to increase security

Appendix 4: Example Balance Transfer in Ward/Dept. CD Record Book

NAME, FORM OF PREPARATION AND STRENGTH *Morphine Sulphate modified release capsules 10mg (ZOMORPH)* **1**

AMOUNT(S) OBTAINED			AMOUNT(S) ADMINISTERED						
Amount	Date Received	Serial No. of Requisition	Date	Time	Patient's Name	Amount given	Given by (Signature)	Witnessed by (Signature)	STOCK BALANCE
			9/1/12	09:00	Balance transferred from book 1, pg 54		A. Nurse	A. Witness	100

Appendix 5 Staff Authorised to Sign Ward Controlled Drug Orders

Ward/Dept.		**Site:**	

This list is maintained by the nurse in charge of the above-named ward/dept. and should remain on the ward/dept. at all times. New staff authorised to order CDs should sign this list at the earliest opportunity and the names of former staff should be promptly deleted. Only Registered Nurses, Midwives or Operating Department Practitioners may sign CD orders. Following amendment of the list, a photocopy or faxed copy should be forwarded promptly to the pharmacy. CD requests signed by staff whose names do not appear on the pharmacy copy of this list **cannot** be fulfilled.

Date	Name (printed)	Usual Signature	Authorised by (Ward/Dept. Manager)

<u>Do not</u> send original copy to Pharmacy. Send fax (see below) or photocopy only.

SMCHC Fax: (023) 9268 0280

When this form has been superceded by a new signatory list, the original copy should be retained by the ward/dept. for TWO years and a copy retained by pharmacy for TWO years.

Appendix 6 - Procedure When a Discrepancy is discovered in the CD Register

MEMBER OF STAFF
Discovers balance discrepancy in CD Register

PRELIMINARY INVESTIGATION BY TRAINED MEMBER OF STAFF

- Inform person in charge of ward / department of the situation
- Perform initial review of the CD Register for cause of discrepancy
- Re-check daily count of CD cupboard stocks against register balances
- Check prescription record charts for omitted records of administration
- Question other members of staff that held CD keys during shift
- Take copies of all relevant documentation and store securely away from the Controlled Drug Cupboard.
- Initiate an Adverse Event Report form noting names of staff consulted and actions taken
- Bring incident to the attention of the clinical ward / department manager, Chief Pharmacist and Accountable Officer (normal hours)

Record-keeping error identified?

RECORD-KEEPING ERROR

- Do not cross out or attempt to alter any entry in the CD Register
- If an incorrect entry has been made, draw brackets around the mistake and write a concise explanation in the margin or at the foot of the page (e.g. "*entered in error*")
- Make a correct entry in an adjacent space or on the next line
- Complete the incident form stating resolution status
- Submit / Distribute Adverse Event Report form as instructed on form

TREAT INCIDENT AS 'MINOR' IF DISCREPANCY IS*:*

- *1 or 2 ampoules*
- *Small liquid measure difference excluding schedule 2 CDs(< 5% vol)*
- *Suspected record-keeping error*
- *Satisfactorily explained*

'MINOR' CD INCIDENT
ACTIONS BY PERSON IN CHARGE OF WARD/ DEPT:

- Establish cause
- Bring incident to the attention of the clinical site manager (if after hours)
- Discuss further course of action with clinical ward / department manager + Chief Pharmacist or clinical site manager (if after hours):
- Inform Accountable Officer (during normal hours)
- Complete the incident form with actions

TREAT INCIDENT AS 'MAJOR' IF DISCREPANCY IS*:*

- *More than 2 ampoules*
- *Large liquid measure difference or schedule 2 (> 5% vol)*
- *A trend of occurrences have been noted*
- *Remains unexplained or*
- *Is otherwise suspicious in any way*

'MAJOR' or 'SUSPICIOUS' CD INCIDENT
ACTIONS BY CLINICAL WARD/ DEPT MANAGER OR CLINICAL SITE MANAGER (IF AFTER HOURS)

- Undertake a more in-depth investigation
- Discuss next course of action with Accountable Officer
- Complete incident form with actions
- If graded red report *immediately* to risk dept
- Notify local counter fraud specialist
- Retain and secure any evidence / documentation
- Involve HR according to circumstances

ESCALATION
ACTIONS BY COUNTER FRAUD SPECIALIST AND ACCOUNTABLE OFFICER

- Ensure action has been taken to reduce further losses
- Discuss progressing investigation and possible sanctions with Accountable Officer
- Discuss involving the police
- Send briefing note to internal audit
- Statements taken and evidence reviewed
- Consult pharmacy for advice
- Consider for criminal court action
- Seek HR advice if to proceed as internal disciplinary
- Send updated reports to Director of Clinical Excellence and Delivery / Accountable Officer

Appendix 7: Example Correction of Error in Ward CD Record Book

NAME, FORM OF PREPARATION AND STRENGTH *Morphine Sulphate modified release capsules 10mg (ZOMORPH)* 1

AMOUNT(S) OBTAINED			AMOUNT(S) ADMINISTERED						
Amount	Date Received	Serial No. of Requisition	Date	Time	Patient's Name	Amount given	Given by (Signature)	Witnessed by (Signature)	STOCK BALANCE
30	9/1/12	2		09:00	Received from Pharmacy		A. Nurse	A. Witness	30
			10/1/12	08:00	JOHN SMITH		A. Nurse	A. Witness	*[30] 29

* Entered in error A. Nurse 10/1/12

Appendix 8– Equality Impact Assessment Form

Step 1 – Scoping, identify the policy's aims	Answer
1. What are the main aims and objectives of the policy?	This Policy sets out the standards for the safe secure and effective use of controlled drugs within the organisation.
2. Who will be affected by it?	All staff employed directly and indirectly by the organisation whose work involves them in any way with ordering, prescribing, dispensing, supplying, transporting, administering or disposing of controlled drugs.
3. What are the existing performance indicators / measures for this? What are the outcomes you want to achieve?	That all staff refer to the policy and follow all the principles it contains with regard to the use and handling of controlled drugs. Furthermore, that the policy is used as a framework for more detailed standard operating procedures that relate to controlled drugs.
4. What information do you already have on the equality impact of this policy?	None
5. Are there demographic changes or trends locally to be considered?	No
6. What other information do you need?	None

Step 2 – Assessing the impact, consider the data and research	Yes	No	Answer (Evidence)
1. Could the policy be used unlawfully against any group?		X	This policy is to ensure equality of access and the safety of controlled drugs across the organisation in a safe and effective manner. It applies equally to all groups.
2. Can any group benefit or be excluded?		X	This policy specifies the safe and effective use of controlled drugs equally to all groups, albeit that some requirements are specific to certain care settings, e.g. in community nursing.
3. Can any group be denied fair and equal access to treatment as a result of this policy?		X	This policy specifies the safe and effective use of controlled drugs equally to all groups, albeit that some requirements are specific to certain care settings, e.g. in community nursing.
4. Can this policy actively promote good relations with and between different groups?	X		All groups are treated equally within the policy and gives opportunity for shared training and learning.
5. Have you carried out any consultation internally / externally with relevant	X		Policy was originally formed by amalgamating policies of

individual groups?			Portsmouth and Southampton PCT's and circulated widely to service managers, Medicines Committee and Medicines Management Sub-Group members for comment.
6. Have you used a variety of different methods of consultation / involvement?		X	Not necessary
7. Mental Capacity Act implications?		X	Does not involve individual patients directly. Areas specific to Mental Capacity Act are dealt with according to best practice within the policy.
8. Will this policy require a decision to be made by or about a service user? (Refer to the Mental Capacity Act policy for further information)		X	Does not refer or relate to individual patients directly.

If there is no negative impact – end Impact Assessment here.

Appendix 9 – Ward/Unit Staff Confirmation Sheet

The Controlled Drug Policy must be read, agreed to and signed by each of the health professionals to whom it applies. One copy of the completed signature sheet should be forwarded to the AO. All professions must act within their appropriate Code of Professional Conduct.

I confirm that I have read and understood the content of the Controlled Drug Policy and that I have received the appropriate training in order to work within it effectively. I agree to work within its parameters*:*

Date	Name	Signature