

Standard Operating Procedures for the safe handling of Controlled Drugs (CDs) by Healthcare Professionals employed by the community providers or GP Surgeries in NHS England, South (South West)

Version 7

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(Unless significant changes to regulations require review sooner)

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Version	Date	Comments	Author/Reviewer
1	February 2008	First version	<p>These SOPs were designed and written by: Peter Kirmond (Practice Pharmacist, Bristol PCT) with guidance from Jonathan Campbell (Head of Medicines Management, Bristol PCT) and Tiffany Barrett (Locality Pharmaceutical Advisor (W+NW), Bristol PCT).</p> <p>Acknowledgements to Swindon PCT and Halton and St. Helens PCT for use of their Controlled Drug SOPs to form a basis for this document.</p>
2	April 2011	Revision of first version and addition of summary of controlled drug legislation, non medical prescribing information, travel information, cd self assessment and declaration	Lisa Jones (Locality Pharmaceutical Advisor) and Sue Mulvenna (Head of Medicines Management and Controlled Drugs Accountable Officer)
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6	April 2015	R/V and amendment Re changes to zopiclone, tramadol etc.	Lisa Rees (Medicines Management Pharmacist)
7	September 2015	Amended to cover South West and general update (links etc.)	Samantha Hazell (Senior Project Officer)

1. Introduction

The Shipman Inquiry's Fourth Report highlighted a number of serious shortcomings in the existing governance arrangements for the safe management of controlled drugs (CDs), and made a number of recommendations to improve their management. The Government responded to this report and introduced a number of new governance arrangements in the Health Act 2006 with the Controlled Drugs (Supervision of Management and Use) Regulations 2006 which came into effect on the 1st January 2007 in England.

As a consequence of the passing of the Health and Social Care Act 2012, these Regulations have been revised to reflect the new architecture for the NHS in England from April 2013. The Controlled Drugs (Supervision of Management and Use) Regulations 2013 ("the 2013 Regulations") came into force in England and Scotland on 1 April 2013. Further amendments to the legislation have also been brought in since this date.

The aims of these legal changes are to encourage good practice in the management of CDs and to help to detect unusual or poor clinical practice systems, criminal activity or risk to patients and public. The NHS England Area Team now has a responsibility to assure the quality of CD management, with external inspection where appropriate as an additional safeguard. There are also new arrangements for collaboration and information sharing between NHS and partner organisations. Compliance with appropriate legislation relating to the prescribing, supply, documentation, safe custody and administration of CDs is one of the core standards of the Healthcare Commission's Standards for Better Health.

2. Scope

This guidance addresses the safe handling of Controlled Drugs (CDs) by health care professionals in the community including; ordering, storage, prescribing, documentation, transport, administration and disposal of unused medicines.

Clear processes of appropriate documentation and information sharing regarding incidents related to Controlled Drugs will be embedded in all CD protocols.

The controlled drugs regulations highlight that approved Standard Operating Procedures for the handling of controlled drugs should be in place and that a robust system and audit trail should be in place for all stages in the handling of Controlled Drugs in primary care. It is the aim of this document to provide GP surgeries with the processes to enable them to achieve this.

Every effort has been made to ensure that the information provided in this document is accurate and up-to-date. However, the legal and regulatory framework governing CDs is continuing to change significantly and readers should always check that they are referring to the most up-to-date version of this guide, as well as cross-checking with other recognised sources of information e.g.

- A Guide to Good Practice in the Management of Controlled Drugs in Primary Care (England). Third Edition. National Prescribing Centre. December 2009
http://www.npc.nhs.uk/controlled_drugs/resources/controlled_drugs_third_edition.pdf

The policy applies to all staff directly employed by NHS England, South (South West) CCGs, including prescribers, GP practices working within the Bristol, North Somerset, South Gloucestershire, Somerset, Devon, Cornwall and Isle of Scilly boundaries or those subject to its policies and procedures under the terms of service level agreements as part of their statutory obligations.

It should be read in conjunction with other related local NHS England and CCG policies.

3. Principles & Purpose

- CDs will be managed and used safely and effectively
- Patients should have timely access to the CDs prescribed for them
- The opportunities for CDs to be abused or diverted should be limited
- Good practice will be shared and poor performance picked up quickly

4. Definitions

A Controlled Drug (CD) is a drug identified by the Misuse of Drugs Act 1971 and related Regulations as having potential for diversion and misuse. The Regulations divide the CDs into five Schedules with differing levels of control, depending on therapeutic benefit balanced against harm when misused. There is a summary of the current legislation relating to CDs in Appendix A.

Controlled Drug Accountable Officer (CDAO) – Each NHS Trust, NHS England local office, Foundation Trust, hospice and independent hospital must appoint an Accountable Officer for controlled drugs. He or she is charged with prescribed responsibilities in relation to the safe, appropriate and effective management and use of controlled drugs. The definition of safe and effective management includes destruction and disposal. A list of Accountable Officers for controlled drugs is held by the Care Quality Commission and is accessible via their website at: <http://www.cqc.org.uk/content/controlled-drugs-accountable-officers>

NHS England, South (South West) Controlled Drugs Local Intelligence Networks – Group of CDAOs and relevant persons from health, social care and police organisations meeting to share information on local CD concerns as required in the Controlled Drugs (Supervision of Management and Use) Regulations 2013. All organisations involved work together to use the intelligence gathered to improve patient and public safety with regards to the safe and secure handling, management and use of controlled drugs.

Nurses – where the term ‘nurse’ is used, this is intended to mean a nurse registered with the Nursing and Midwifery Council and may include health visitors, district nurses and nurse practitioners.

5. Roles and responsibilities

5.1 NHS England roles and responsibilities:

The NHS England local offices are required to appoint a Controlled Drug Accountable Officer who is responsible for ensuring the safe and effective use and management of CDs within local organisations subject to their oversight and must have regard to best practice in relation to the management of CDs.

- Secure the safe management and use of CDs, in particular:
 - Establish and ensure appropriate arrangements to comply with Misuse of Drugs legislation;
 - Ensure adequate and up-to-date SOPs are in place in relation to the management and use of CDs;
- Ensure adequate destruction and disposal arrangements for CDs;

- Ensure monitoring and auditing of the management and use of CDs;
- Ensure relevant individuals receive appropriate training;
- Maintain a record of concerns regarding relevant individuals;
- Assess and investigate controlled drugs related concerns;
- To take appropriate action if there are well founded concerns;
- To establish arrangements for sharing information.

5.1.1 Local Controlled Drugs Intelligence Network

The Health Act 2006 places a legal duty on local agencies to share information and intelligence about the use of CDs in the health and social care sector. Local agencies required to share information include: healthcare organisations, the police, social service authorities and relevant inspectorates (e.g. CQC and the General Pharmaceutical Council). Information will be shared through a Local Intelligence Network.

NHS England CDAOs are the assigned lead CDAOs for establishing LINs in England for a particular area. It is for NHS England to determine how many LINs there are to be in England and the number of lead CDAOs required to cover them. However, NHS England must ensure that the whole of England is covered by these arrangements. Membership of LINs is also determined by the NHS England. The network will enable agencies that have cause for concern about the activities of any health care professional(s) to share them as soon as possible with other local agencies who may be affected or who may have complimentary information.

5.2 GP Surgery role and responsibilities:

Introduction:

It is the responsibility of GP surgeries to ensure that they have processes in place which enable them to comply with current regulations and good practice guidance regarding all aspects of Controlled Drug management. This document is an aid to that end. Practices may, however, adapt this document to suit their own circumstances always provided this follows current regulations and good practice.

Role and responsibilities of the Health Care Professional:

Each GP practice should have a designated senior health professional (usually the senior GP partner or prescribing lead) who has overall responsibility for controlled drugs in the GP practice.

This includes:

- Ensuring prescribing, storage and record keeping of CDs complies with current regulations and good practice;
- Where appropriate and where current regulations and good practice allow, authorising other members of staff to conduct certain processes regarding CDs at the practice;
- If any CPD requirements relating to controlled drugs are highlighted these are addressed immediately.
- Having up to date SOPs in place for all processes involving CDs at the practice;
- Investigating discrepancies involving CDs when they occur;
- Reporting unresolved discrepancies or other concerns regarding CDs to the NHS England Accountable Officer for controlled drugs;
- Registered practitioners are expected to be familiar with, and follow at all times, their own professional code of practice in relation to medicines. These include:
 - Medical: GMC guidance on good medical practice
 - Nursing: NMC guidelines for the administration of medicines

- Pharmacist: GPhC Code of Ethics
- All practitioners are accountable for their actions and omissions. In all actions involving CDs they must exercise their professional judgement and apply their knowledge and skill in a given situation.

6. Equalities Impact Assessment

This guidance is intended to protect all NHS staff, patients and the wider public from any harm associated with the use or misuse of CDs, and to enable prompt access to prescribed CDs, especially out of hours.

7. The safe handling of Controlled Drugs (CDs) by Healthcare Professionals in the community

- All healthcare providers will have and comply with an approved SOP
- SOPs to be agreed by the relevant CD accountable officer
- Each GP practice or pharmacy will have clear written SOPs in place that are known, understood and followed by practitioners and their staff
- Every NHS England local office/CCG will have SOPs for handling CDs for all of its directly managed staff.

7.1 Storage of Controlled Drugs

- CD's requiring safe custody should be stored under lock and key in a safe/cabinet. This safe/cabinet will conform to the requirements of the Misuse of Drugs (Safe Custody) Regulations 1973.
- The locked safe/cabinet should preferably be as follows:-
 - made of steel, with suitable hinges;
 - fixed to a wall or the floor with rag bolts (these bolts should not be accessible from outside the cabinet).
- Ideally the safe/cabinet should be within a cupboard or some other position to avoid easy detection by intruders.
- If a safe is used to store CDs, then there should be a separate receptacle within the safe that keeps the CDs apart from other items, e.g. money, valuables, etc. Nothing should be displayed outside to indicate that CDs are kept within the container.
- The room containing the safe/cabinet should be lockable and tidy around the safe/cabinet area to avoid drugs being misplaced.
- The walls of the room should be constructed to a suitable thickness using suitable materials.
- The room should not normally be accessible to patients or other members of staff who are not permitted to have access to CD's. However, if others do have to enter the area where CDs are stored, it is good practice that they should be continuously supervised until such time as they leave the area.
- Stock should be kept to a minimum and nothing should be displayed outside to indicate that controlled drugs are kept within that receptacle.
- Other drugs that are liable to misuse can be locked in the cabinet if this is deemed appropriate by the relevant health care professional.

7.2 Access to Controlled Drugs Cabinet Keys

- The named person responsible for the storage of CD's within the service should take overall responsibility for the keys / codes to the controlled drug cabinet/safe. A written procedure to ensure that the keys to the CD cabinet/safe are secure at all times should be put in place.

- The keys should always be kept separate from the cabinet/safe and should never be accessible to unauthorised persons.
- The use of several sets of keys for the CD cabinet/safe should be avoided. However, if there is more than one set available strict controls on who is in possession of these keys should be implemented by the Service/Practice Manager.
- The number of sets of keys to the cabinet/safe, and who holds them, or who has access codes for digital key pads, must be known at all times by the Service/Practice Manager.
- Access to key cupboards should be restricted and removal of keys for CD cabinet/safe should be logged, so that it is known at all times who is in possession of the keys.
- An emergency spare set of keys to the CD cabinet/safe should be available. These should not be stored with the normal set of keys. Access to these should also be restricted and removal from the area should also be logged.

7.3 Access to Controlled Drugs Cabinet

- Only persons who are authorised to handle CDs will be allowed access to the CD cabinet/safe. The designated senior health professional remains ultimately accountable for the management of CDs.
- Access to the cabinet must always be witnessed by a second authorised person.
- A controlled drug register will be kept by the service maintained according to Misuse of Drug Regulations and good practice requirements.
- The CD register should be stored safely outside the CD cabinet/safe, in an appropriate location near the CD cabinet/safe; care should be taken to choose a location that does not advertise the location of the CD's.

7.4 The CD Register

- The register must:
 - Be bound (not loose-leaved) or a computerised system which is in accordance with best practice guidance;
 - Contain class sections for each individual drug;
 - Have the name of the drug specified at the top of each page;
 - Have the entries in chronological order and made on the day of the transaction or the next day;
 - Have the entries made in ink or otherwise so as to be indelible or in a computerised form in which every such entry is attributable and capable of being audited;
 - Not have cancellations, obliterations or alterations; corrections must be made by a signed and dated entry in the margin or at the bottom of the page;
 - Be kept at the premises to which it relates and be available for inspection at any time;
 - A separate register must be kept for each set of premises (for example, not just the main surgery);
 - A separate register must be kept for each place CDs are stored (for example, the main surgery CD cupboard and a GP's bag for home visits MUST have separate registers);
 - Pages must be sequentially numbered;
 - Be kept for a minimum of two years after the date of the last entry, once completed;
 - Not be used for any other purpose.
- Good practice suggest that the register should:
 - Specimen signatures and initials are to be included at the front or rear of each register in use, detailing the full name and professional registration number of each person who makes an entry in that register;

- Be uniquely numbered on the front cover;
- Kept for a minimum of 10 years.
- A running balance of stock will be kept in accordance with the SOP for Running Balance Stock Check.
- Any discrepancies found in the running balance will be brought to the attention of named person responsible for CD's, who will investigate the discrepancy further, and in accordance with the SOP for Discrepancy Resolution.
- There are commercially available CD registers which fulfil all the above requirements.

7.4.1 Register entries for controlled drugs

The example below shows how entries might be made in the personal register of Dr Julia Roberts, a partner at Dr Pitt & partners, ABC, Medical Centre. It includes the good practice points as recommended. This register covers the CDs held at ABC Medical Centre. The practice purchases CDs, which are then supplied, to each GP for his or her bag.

Receipt of controlled drugs						
Drug: <i>Diamorphine 5 mg for injection</i>						
Date	NAME	ADDRESS	Amount	Form in which obtained	Notes	
	Of person or firm from whom obtained		obtained			<i>Balance</i>
1/12/00	-----	-----	-----	<i>Balance brought forward</i>	0 ✓JR	
1/12/00	B Pitt	ABC Medical Centre	25mg	5 x 5 mg amps BN: 18245 Exp: April 02 Julia Roberts	5 ✓JR	
Here, Dr Roberts has signed the entry and has entered and checked a running balance. Dr Pitt is the practice clinical governance lead and acts as the "supplier" of CDs as he has taken responsibility for CDs in the practice (as described in section 5)						
Supply of controlled drugs						
Drug: <i>Diamorphine 5mg for injection</i>						
Date	NAME	ADDRESS	Authority to supply	Amount	Form in which supplied	Notes
	Of person or firm supplied			supplied		<i>Balance</i>
1/12/00	-----	-----	-----	-----	<i>Balance brought forward</i>	0 ✓JR
1/12/00	-----	Received from Dr B Pitt, ABC MC	-----	5 x 5 mg	5 x 5 amps for injection	5 ✓JR
4/1/01	[Jane Gay]*	42 West Wallaby Street	Admin by GP Julia Roberts	1 x 5 mg	Injection BN:18245 Exp: Apr 02	4 ✓JR
*Error - should be Jane Gray 4/1/01 JR						

In the above example the doctor has signed the register when she administered the drug. She realised she has entered the patient's name incorrectly, but has bracketed the error and made a correction in a footnote which she has dated and initialled.

7.5 Computerised controlled drug registers

The definition of a CD register in the 2001 Regulations was amended in November 2005 to allow (not require) the register to be held on a computerised system which complies with specified best practice guidance. The Regulations require that entries in computerised registers must be attributable and capable of being audited.

7.6. Controlled Drugs and Electronic Prescribing

From 1st July 2015, electronic prescribing of schedule 2 and 3 CDs will be permitted where the electronic prescribing system is used, once the systems meet national specifications.

8. Security of prescription pads

It is the responsibility of each prescriber to ensure the security of prescription pads at all times. In the event of loss or theft of a prescription pad (NHS or private CD prescription pad), the prescriber or staff member should notify the NHS England CDAO. The individual's line manager should be alerted and police should be contacted as required. An incident form should be completed and returned according to the incident management policy.

- CD Accountable Officer for NHS England can be contacted on Tel: 0113 825 3568 Email: England.southwestcontrolleddrugs@nhs.net

9. NHS England monitoring of the use of CDs

The use of CDs will be monitored through routine processes such as prescribing data analysis, audit and clinical governance, as an integral part of normal clinical governance arrangements.

9.1 Routine Monitoring

Controlled drug prescribing will be monitored by the controlled drugs Accountable Officer on a quarterly basis through prescription data contained on ePACT.net. This may be supported by the help of the CCG Medicines Management team. This monitoring includes a review of high volumes of individual controlled drugs and monitoring prescriptions for quantities of medicines which may be for greater than 30 days supply of that controlled drug. Where high or excessive quantities are identified, the prescribing support pharmacist for the relevant practice will be asked to investigate this further and provide feedback to the CDAO. Where no explanation can be found or the explanation is unsatisfactory, the CDAO will contact the prescriber to investigate further.

Routine monitoring of private controlled drugs prescribing will also be undertaken on a quarterly basis.

9.2 CD Declaration Statement and Self-Assessment

All Health Care Providers (HCPs) must complete a self assessment form and complete a declaration every two years on their CD use, as requested by NHS England. Information from the declaration and self-assessment, routine monitoring and other sources will be reviewed to decide whether any further action is necessary, in the form of additional monitoring or inspection. The review will assess clinical standards in the prescribing, supply, administration, storage, record keeping and disposal of CDs and assure that the HCP is complying with the Misuse of Drugs Act and associated regulations, medicines legislation and any relevant guidance and professional codes of practice. The declaration will be available from the CDAO and their project team.

The CDAO is responsible for arranging periodic inspection of premises used in connection with CDs where premises are not subject to inspection by other governance bodies. CDAO has power of entry and inspection to enter premises to inspect stocks and records of CDs.

Standard Operating Procedures:

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Controlled Drug Standard Operating Procedure (SOP):

PROCUREMENT: PROCESS

This is the procedure to follow when ordering Controlled Drugs

If the surgery does not currently hold ANY stocks of Controlled Drugs, please contact the CD Accountable Officer for details of how to proceed

Stock levels should be kept to the minimum necessary to meet clinical needs. Levels of stock to be held should be reviewed at least annually.

All supplies of CDs for Surgery stocks must come from authorised suppliers e.g. a pharmacy with the appropriate licences to supply

PATIENT'S OWN CDs MUST NOT BE USED TO REPLENISH SURGERY STOCKS UNDER ANY CIRCUMSTANCES

ORDERING

Prepare written requisition on standard CD Requisition Form (FP10CDF)*; Ensure ALL relevant sections of parts are completed; A (by supplier), B (by customer), C (by customer) & D (by customer).

In an emergency a practitioner may obtain a CD WITHOUT a prescription form PROVIDED they undertake to supply one within 24 hours.

Send the requisition to the supplier (pharmacy with appropriate licence's);
Retain a photocopy of the requisition (both sides)
See - PROCUREMENT: RECORD KEEPING SOP

If a 'messenger' is used to collect the CD they must carry a note from the recipient (signed & dated) authorising them to collect the CD and carry formal ID

RECEIPT

Two people authorised by the designated senior health professional (e.g. senior partner) should check the order's contents: Check product identity, quantity, expiry date & condition: Everything OK? Is what is being received exactly what was ordered on the requisition?

YES

NO

Accept delivery and sign the delivery note

Decline delivery and do not sign the delivery note

GO TO PROCUREMENT: RECORD KEEPING SOP

Report incident to designated senior health

* Note: FP10CDF are controlled stationary
Standardised requisition forms for schedule 1,2,3 will become mandatory on 30th November 2015

PROCUREMENT: RECORD KEEPING

This is the procedure to follow to record Controlled Drugs received for surgery stocks

The Controlled Drug Register MUST comply with current regulations and should follow good practice (see introduction).

Any responsible person authorised by the designated senior health professional may make the entry

Enter CDs received into the register as soon as possible after receipt
(Legally: on the day of receipt or the next day; Good practice: immediately upon receipt)

ENTRIES MUST BE LEGIBLE & PERMANENT AND MUST NOT BE ALTERED, CANCELLED OR OBLITERATED

To make corrections (surround mistakes with brackets)* and add a *footnote at the bottom of the page stating what the entry should say - initial and date the footnote

ON THE APPROPRIATE PAGE FOR THE DRUG RECEIVED RECORD:

- Date received;
- Name & Address or person/firm received from;
- Delivery note reference (if applicable);
- Name of the drug, its form, strength and quantity

Place stock in CD cabinet

The copy of the requisition and delivery note should be retained with the Controlled Drug register (e.g. in an envelope fixed to the inside back cover of the register) for a minimum of 2 years

GO TO RUNNING BALANCE CHECK SOP

Controlled Drug Standard Operating Procedure (SOP):

TRANSFERRING STOCK CDs TO A DOCTOR'S BAG: PROCESS & RECORD KEEPING

This is the procedure to follow to when transferring Surgery Stock Controlled Drugs to a Doctor's Bag

A 'doctor's bag' is a locked bag, box or case for home visits, etc. which should be kept locked at all times, except when in immediate use.

The person in lawful possession of this bag, or an individual authorised by them, must always retain the keys. (A digital combination lock on a case is often the most practical and convenient solution and avoids problems with keys).

Such a bag is regarded, once locked, as a suitable receptacle for storing CDs, but a locked car is not. Bags containing CDs should not be left in a vehicle overnight, or in a vehicle left unattended for long periods of time.

Many doctors only use the CD stock carried in their bag on rare occasions. The stock levels held in this bag should be kept to a minimum and informed by previous requirements. Normally, only one strength of each CD should be kept in a doctor's bag to avoid errors. Oral preparations of CDs would not routinely be considered essential items to be carried in such a bag.

When a 'doctor's bag' containing CDs is in the practice, it should be stored in a safe place away from patient areas in a locked room.

The doctor, or a delegated member of staff, should undertake a monthly stock check of CDs held within each bag for home visits (see **SOP for Running Balance of Stock Check**).

Each doctor is responsible for the receipt and supply of CDs from their own bag. Restocking of a bag from practice stock should be witnessed by another member of the practice staff, as should the appropriate entries into the practice's CD register.

A separate CD register should be kept for the CD stock held within a doctor's bag. This should fulfil the same requirements as the practice's main CD register (see **Introduction**). A separate register is needed for each doctor's bag containing CDs.

When stock is transferred from the main surgery stock to a 'doctor's bag' an entry must be made in the bag's register on the appropriate page for the drug **received**: ●Date received; ●Name of the drug, its form, strength and quantity; ●Running balance of stock updated

A similar record must be made in the main register on the appropriate page for the drug **supplied**: ●Date supplied; ●Name of the drug, its form, strength and quantity; ●Running balance of stock updated

For administering CDs from a Doctor's bag see **SOPs for Administering CDs**

For disposal of CDs in a Doctor's bag that are out of date or no longer required see **SOP for Disposal of Surgery Stock CDs**

Controlled Drug Standard Operating Procedure (SOP):

ADMINISTERING CDs: PROCESS

This is the procedure to follow when administering Controlled Drugs to a patient from surgery stocks

Safety: If there is any doubt about any aspect of administering a CD to a patient, advice MUST be sought before proceeding.

Administration of CDs will follow the appropriate procedures and record keeping laid down in professional and national guidance.

A valid prescription or Patient Specific Direction (PSD) should be in place that authorises the administration of the medicine to the patient. Any relevant Pathways / SOPs / Guidelines should be available for reference during the consultation.

All reasonable endeavours will be made to gain the patient's consent before administration is undertaken

The health professional administering the CD should be familiar with the therapeutic characteristics of the opioid to be administered as well as understand the prescription and should have knowledge of the common indications, side effects, dosages and compatibilities of the CDs prescribed. They should be able to justify any actions taken and be accountable for those actions.

A check will be made that:

- **THE CORRECT CONTROLLED DRUG** (the name, form & strength of the drug is the same as that on the prescription/PSD) **IS TO BE GIVEN TO**
- **THE CORRECT PATIENT** (patient's name corresponds to the name on the drug's label and the prescription/PSD) **AND THAT**
- **IT IS SUITABLE FOR USE** (correctly labelled, in date, in good condition) and **SAFE** to administer (appropriate dose and route for the patient)

IF, AND ONLY IF, ALL OF THE ABOVE HAS BEEN SATISFIED, THE CONTROLLED DRUG MAY BE ADMINISTERED

GO TO ADMINISTERING CDS – RECORD KEEPING SOP

On occasion, clinicians may be required to administer a controlled drug so that there is some drug left (e.g. a part ampoule). Under these circumstances, the remaining quantity of CD should be destroyed in line with the SOP for the Destruction of PATIENT'S OWN CDs (**NOT** surgery stock) since at the point of administration the CD becomes the patient's property.

Administration Errors

- Immediate help / treatment must be given to the patient dependent on the seriousness of the error and advice sought on how to proceed. The GP must be notified and a Clinical Incident Form completed.
- Any adverse incident or near miss must be recorded in accordance with the practice or NHS England Clinical Incident Policy.

Controlled Drug Standard Operating Procedure (SOP):

**ADMINISTERING CDs FROM STOCK:
RECORD KEEPING IN THE CD REGISTER**

This is the procedure to follow when recording **stock** Controlled Drugs in the CD register that have been administered to patients

N.B. This procedure does NOT apply to controlled drugs that have been supplied via an FP10

The Controlled Drug Register MUST comply with current regulations and should follow good practice (see introduction).

Stock CDs administered to patients should be entered into the register as soon as possible after they have been administered (Legally: on the day they are administered or the next day; Good practice: immediately after being given)

The entry should be made by the person administering the CD

**ENTRIES MUST BE LEGIBLE & PERMANENT AND
MUST NOT BE ALTERED, CANCELLED OR OBLITERATED**

To make corrections (surround mistakes with brackets)* and add a *footnote at the bottom of the page stating what the entry should say - initial and date the footnote

Record:

- Date administered;
- Name of the patient;
- Name and professional registration number of the prescriber;
- The name, strength, dose and quantity of the drug administered along with its batch number and expiry date;
- It is good practice to record the method of administration in the patient's notes
- Name and professional registration number of the professional administering the CD;
- Name of the person witnessing the administration of the CD (if applicable).

GO TO RUNNING BALANCE CHECK SOP

Any Healthcare Professional involved in administering a Controlled Drug should follow their profession's guidance on record keeping

Controlled Drug Standard Operating Procedure (SOP):

PATIENT'S OWN CDs ACCEPTED FOR DISPOSAL: PROCESS & RECORD KEEPING

ONLY IN EXCEPTIONAL CIRCUMSTANCES SHOULD THE SURGERY ACCEPT PATIENT'S OWN CDS FOR DESTRUCTION.

PATIENTS OR CARERS SHOULD BE ADVISED TO RETURN THEM TO A COMMUNITY PHARMACY.

CDS THAT HAVE BEEN PRESCRIBED FOR A PATIENT AND ARE NO LONGER REQUIRED, ARE THE PATIENT'S PROPERTY (EVEN AFTER DEATH).

This is the procedure to follow when accepting patient's own Controlled Drugs for disposal.

If you are aware that you are accepting a patient's own controlled drugs for destruction an IMMEDIATE written record of what is being accepted into the surgery's keeping should be made. It doesn't matter what the written record is on but it should include:

- The name, strength and quantity of the drug;
- The name of the member of staff accepting the drug;
- The name of the patient whose drug it is;
- The name and address of the person bringing the drug to the surgery;
- If possible, a second member of staff should cross check what is being accepted.

This should be signed and dated by both members of staff and the person bringing the CDs.

Patient's CDs accepted for destruction must be stored in the CD cupboard, separated from the surgery's own stocks of CDs, clearly marked as 'patient's CDs for destruction'.

They must be entered in a separate section of the CD register specifically for the recording of unwanted patient's drugs for destruction and state:

- the patient's name and address (if known);
- the name, address and role of the person returning the CDs (if known);
- details of the drug, form and quantity returned;
- the date on which they were returned;
- the name of the person accepting them into the surgery's safe keeping;
- the name of the second person checking the returned CDs;
- the entry should be initialled by both members of staff

The CD Register (whether paper or computer based) MUST comply with current regulations.

ENTRIES MUST BE LEGIBLE & PERMANENT AND MUST NOT BE ALTERED, CANCELLED OR OBLITERATED

To make corrections (surround mistakes with brackets)* and add a *footnote at the bottom of the page stating what the entry should say - initial and date the footnote

Patient's own CDs accepted for destruction DO NOT form part of the surgery stock of CDs and are therefore NOT included in running balance checks. UNDER NO CIRCUMSTANCES SHALL PATIENT'S OWN CDs BE USED TO REPLENISH SURGERY STOCKS.

PATIENT'S CDs ACCEPTED BY THE SURGERY FOR DESTRUCTION SHOULD BE DESTROYED AS SOON AS POSSIBLE (PREFERABLY IMMEDIATELY) AFTER BEING RECEIVED- see SOP for the Destruction of Patient's Own CDs

Controlled Drug Standard Operating Procedure (SOP):

CDs no longer required following the death of a patient in the community

Prescribed drugs, including CDs, are the property of the patient and remain so even after death. However, it is illegal for a person to possess CDs that have not been prescribed for them. In the first instance the patient/patient's relatives should be advised that all CDs no longer required should be returned to a pharmacy for safe destruction.

It should not normally be the responsibility of community nurses/ visiting GP to become involved in the disposal of unwanted CDs. However, there may be occasions when it is appropriate for nursing or medical staff to facilitate the recovery/ disposal of controlled drugs to ensure this is undertaken in a safe and appropriate way.

If return of controlled drugs by relatives/next of kin is not practical or possible, then one potential course of action could be that the nurse or visiting GP takes the controlled drugs to a local community pharmacy. It would, however, be important to ensure that a member of the pharmacy team countersigns the patient nursing or medical record to ensure a clear audit trail.

DISPOSAL OF SURGERY STOCK CDs: PROCESS

This is the procedure to follow when you have STOCK CDs in need of destruction

HEALTHCARE PROFESSIONALS (and other staff) MAY NOT DESTROY SURGERY STOCK CONTROLLED DRUGS WITHOUT AN AUTHORISED WITNESS.

Stock CDs (those that have not been issued to a patient) awaiting disposal, can be either expired (out-of-date) or no longer required (in-date).

Stock CDs for disposal must be stored in the CD cupboard, kept segregated from CDs in use, be clearly marked for disposal **but remain part of the running stock balance until destroyed**

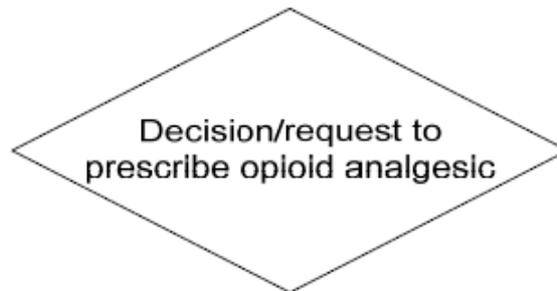
GP practices and other service providers within NHS England, South (South West) who have stock controlled drugs for destruction should contact NHS England who will arrange for an authorised person (authorised by the CD Accountable Officer) to visit to witness the destruction.

Email: england.southwestcontrolleddrugs@nhs.net

Tel: 0113 825 3568

PRESCRIBING OPIATES

Prescribing Opioids



Is prescriber familiar with therapeutic characteristics of opioid to be prescribed

No

Prescriber to familiarise themselves with therapeutic characteristics of opioid to be prescribed, or seek appropriate advice

Yes

Is patient already taking opioid?

Yes

Check previous dose and formulation

Prescribe appropriate dose

No

Prescribe starting dose

Ref: NPSA RRR005 <http://www.nrls.npsa.nhs.uk/resources/?entryid45=59888>

CD PRESCRIPTION WRITING: PROCESS

This is the procedure to follow when writing a prescription for Controlled Drugs

NHS Prescriptions for CDs must be on an FP10

Private prescriptions for CDs must be written on dedicated Private Prescription forms for Controlled Drugs (FP10PCD) and the clinician must contact the CDAO (via her team) to register a 6 digit private prescriber code from the PPA to enter on them

Prescriptions for CDs must be written so as to be indelible e.g. handwritten, typed or computer-generated. Electronic prescribing for schedule 2 & 3 CDs will be legally permitted from 1st July 2015, for systems meeting national specification.

N.B. If handwritten they must be written in the prescriber's own handwriting
(unless a handwriting exemption is held)

Prescriptions for S2&3 CDs must contain:

- the patient's full name, address, their age and date of birth and (where possible) their NHS number;
- the name, form and strength of the drug;
- the dose to be taken (N.B. 'As directed' etc. is NOT a dose);
- the total quantity of the preparation in both words and figures.

The name and address of the prescriber must be stated on the prescription, together with their registration number and profession

The prescriber's signature must always be present and in the prescriber's own handwriting.

The prescription must be dated.
(The date does not need to be handwritten)

The details of the CD prescribed must be recorded in the patient's medical records

By law prescriptions for CDs are only valid for 28 days from the date that the prescription is signed and dated by the prescriber

Good practice dictates that prescriptions for CDs should not normally provide the patient with more than 30 days supply

Prescription for CDs should not routinely be sent to the patients' pharmacy via the postal system, but should be collected from the surgery by a health care professional, a member of their staff, the patient or their representative. If, in exceptional circumstances, they need to be posted, an auditable means should be used (e.g. Special Delivery – where a signature is required on posting and delivery)

Controlled Drug Standard Operating Procedure (SOP):

TRANSPORTATION OF CDs: PROCESS

This is the procedure to follow when transporting Controlled Drugs

Prescription forms for Schedule 2 CDs should not routinely be sent to the patients' pharmacy via the postal system, but should be collected from the surgery by a health care professional, a member of their staff, the patient or their representative.

HEALTH CARE PROFESSIONALS INVOLVED IN THE DELIVERY OF PATIENT CARE SHOULD NOT ROUTINELY TRANSPORT A PATIENT'S OWN CDS TO AND FROM THAT PATIENT'S HOME.

However, health care professionals, plus formal carers and patients' representatives, are legally allowed to transport CDs to a patient, provided the CDs have been prescribed, by an appropriate prescriber, for that patient.

It is good practice to keep the CDs out of view during transit.

CDs should not generally be transported via mail, taxi services or equivalent. However, in exceptional circumstances, where urgent clinical need dictates, dispensed CDs can be sent to a patient, or stock CDs to premises, via such routes.

If such a route is used the transportation of the CDs must be auditable.

For example, if sent via taxi:

- The taxi driver must have written authorisation to carry the CD;
- A delivery note must be used that is signed by the healthcare professional, the taxi driver and the person receiving the CD;
- The completed delivery note must be returned to the surgery and retained.

If the postal service is used:

- An auditable means should be used (e.g. Special Delivery – where a signature is required on posting and delivery)

..

Controlled Drug Standard Operating Procedure (SOP):

Transportation of CDs

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.

Nurses, midwives, doctors, pharmacists, pharmacy staff and other health care professionals, plus formal carers' and patients' representatives, are legally allowed to transport CDs to a patient, provided the CDs have been prescribed, by an appropriate prescriber, for that patient. Any nominated individual is also allowed to return CDs from the patient to the pharmacy, or the practice, for destruction. The person authorised to possess may grant permission, and it should be in writing. It should be noted that community pharmacies and GP practices should not accept waste medicines, including CDs, from Care Homes with Nursing Care.

Health care professionals involved in the delivery of patient care should not routinely transport a patient's own CDs to and from that patient's home. Where this is essential, part of an organized service, or where pharmacies operate collection and delivery schemes to the housebound and other specific patients in need, it is good practice to keep the CDs out of view during transit.

CDs should not generally be transported via mail, taxi services or equivalent. However, in exceptional circumstances, where urgent clinical need dictates, dispensed CDs can be sent to a patient, or stock CDs to premises, via such routes. Where the mail route is used, the CD should always be sent as a special delivery item to ensure there are records of signatures and the pathway is auditable.

Prescription forms for Schedule 2 CDs should not routinely be sent to the patients' pharmacy via the postal system, but should be collected from the surgery by a health care professional, a member of their staff, the patient or their representative. However, prescriptions for the treatment of drug addiction are routinely sent to pharmacies as it is not always practicable for the pharmacist to collect prescriptions from practices, which may be some distance away, and it is not always desirable for the patient to be handed the prescription. Again it is good practice to have an auditable pathway.

If transport of CDs or CD prescriptions via mail, taxi services or equivalent has to be used a practice or pharmacy SOP should be developed which reflects a risk assessment.

Nurses may transport CDs, where patients or their carers / representatives are unable to collect them, provided the nurse is conveying the CD to a patient for whom the medicine has been prescribed, e.g. from a pharmacy to the patient's home. Nurse independent prescribers, or nurses acting under the direction of a nurse independent prescriber, can administer CDs that they are eligible to prescribe and that are being used for the purpose for which the CD may be prescribed.

Nurses should not routinely transport CDs. This should only be undertaken in circumstances where there is no other reasonable mechanism available. CDs should be kept out of sight during transportation.

Controlled Drug Standard Operating Procedure (SOP):

RUNNING BALANCE OF STOCK CHECK-PROCESS & RECORD KEEPING

This is the procedure to follow when checking stocks of Controlled Drugs

Running balances and expiry dates of ALL CD stocks (including any held in Doctor's bags) should be checked at least ONCE a MONTH. Where there is frequent changeover of responsibility for CDs (e.g. Out of Hours Services) the checks should be more frequent (e.g. weekly)

Whenever a CD is received, supplied or administered the running balance of the CD involved should be checked

The designated senior health professional is accountable for maintaining the running balance. However, they may delegate two other members of staff to conduct the checks.

The two delegated members of staff should:

Check the expiry date of all stock CDs – if any are out of date - see the SOP for the Disposal of Surgery Stock CDs.
Note that Out of Date Stock CDs awaiting destruction are STILL INCLUDED in the running balance.

Check actual stock against running balance in register:
do they agree?

YES

NO

Confirm balance by initialling and dating it in register by BOTH members of staff

Get a THIRD member of staff to check stock level and balance calculation

Error found and resolved?

No THIRD member of staff available

Confirm balance by initialling and dating it in register by ALL THREE members of staff

YES

NO

End of SOP

GO TO DISCREPANCY RESOLUTION SOP

Controlled Drug Standard Operating Procedure (SOP):

DISCREPANCY RESOLUTION – PROCESS & RECORD KEEPING

This is the procedure to follow if there is an unresolved discrepancy in the Running Balance of any Stock Controlled Drug

If, at the end of this SOP, the discrepancy is still not resolved or if the discrepancy is such that there is an immediate cause for concern, CONTACT THE CD ACCOUNTABLE OFFICER STRAIGHT AWAY.

The senior of the three members of staff who discovered the unresolved discrepancy MUST report it to the designated senior health professional in charge of Controlled Drugs at the practice as soon as possible after its discovery.

The senior health professional will record the discrepancy on a Clinical Incident Form. This should include:

- date and time discrepancy was discovered;
- drug, form and strength involved;
- the nature of discrepancy;
- the names of the 3 members of staff who discovered the discrepancy;

They MUST then personally investigate the discrepancy at the earliest opportunity by:

- examining current stock in CD cupboard;
- examining current and previous entries in CD register;
- checking the calculation of the running balance;
- any other relevant investigation.

Is the discrepancy resolved?

YES

NO

Make appropriate amendment in the Controlled Drug register – current balance confirmed as being correct dated and initialled by all members of staff concerned.

The Clinical Incident Form is to be completed within 24 hours of the discrepancy's discovery and the incident discussed at the practice's next Significant Event meeting.

End of SOP

All details of the discrepancy MUST be reported to the CD Accountable Officer within 24 hours of its discovery. An incident panel will be established to investigate it, when appropriate.

10. Other controlled drug related information

10.1 Patients travelling overseas and controlled drugs

From 1st January 2008 only those persons travelling for greater than 3 calendar months or carrying more than three months supply require a personal import or export licence. Licences are normally issued with an expiry date of one week after the expected return to the UK. A personal licence has no legal standing outside the UK and is intended to allow travellers to pass through UK customs unhindered. Some countries have their own importation regulations for CDs. It is recommended that travellers contact the country's Embassy to check these regulations. Personal licence application forms can be downloaded from:

<https://www.gov.uk/travelling-controlled-drugs>

It is recommended that patients should apply for a licence at least 10 working days before travel date to ensure sufficient time.

If a person is staying outside their resident country for a period exceeding 3 months, they are advised to register with a doctor in the country they are visiting for the purpose of receiving further prescriptions.

If you are travelling for less than three months and you are carrying less than three month supply, you will not need a personal import or export licence to enter or leave the United Kingdom. It is however advisable to obtain a letter from your prescribing doctor or drug worker, which should confirm your name, travel itinerary, names of prescribed controlled drugs, dosages and total amounts of each to be carried. If you are carrying prescribed medication which is not a controlled drug it is also advisable to obtain a letter.

In either case, the personal licence or doctor's letter should ordinarily be carried in your hand luggage along with the drugs. But as amounts will vary from person to person it is essential that this is always checked with the airline carrier and airport in advance of the travel date to ensure that carrying the entire amount of medication in your hand luggage is allowed as security arrangements may change at any time; for example restriction on volume of liquids.

Other countries may have their own import regulations for controlled drugs and prescription medicines. Therefore it is strongly advised that patients check this with the UK-based representatives of the country or countries that they are travelling to or through.

10.2 NHS repeat dispensing scheme

Repeat dispensing schemes are an essential service under the NHS contractual framework for community pharmacists. As part of this service the doctor issues a repeatable prescription, which gives details of how many instalments the prescription contains, and which the pharmacist dispenses at regular intervals following a patient review. Schedule 4 and 5 CDs may be ordered on prescriptions issued under the repeat dispensing scheme. For Schedule 4 CDs, the first prescription must be dispensed within 28 days from the appropriate date. Currently Schedule 2 and 3 CDs are not permitted on prescriptions issued under the repeat dispensing scheme.

10.3 Emergency and Out of Hours (OOH) supplies of CDs

Under no circumstances may an emergency supply of a Schedule 2 or 3 CD be made to a patient without a valid prescription, other than in the case of phenobarbitone for the treatment of epilepsy. An emergency supply of Schedule 4 or 5 CDs may be made as long as the other conditions for the supply of a POM to a patient in an emergency are satisfied, including the fact that the patient must request the emergency supply in person. However, the abuse potential of these drugs must be thought about when considering an emergency supply.

It is important to note that an emergency supply at the request of an EEA or Swiss doctor or EEA or Swiss dentist, or one of their patients, cannot lawfully be made for a schedule 1,2 or 3 Controlled Drug or for medicines that do not have a UK marketing authorisation.

Palliative care drugs needed urgently out of hours can be obtained from the OOH medical care providers. If the patient has a valid prescription, some pharmacies across the local area are participating in a Specialist Medicines Service where a range of medicines such as palliative care medicines and other urgently required medicines are kept in stock. The OOH providers and NHS England Team (pharmacy contracts) will have up to date details of the pharmacies participating in the service.

10.4 Non-medical prescribers

Nurse and pharmacist independent prescribers in Great Britain as of the 23rd April 2012 are now able to prescribe most controlled drugs, following amendments to the Misuse of Drugs regulations. The changes allow nurse and pharmacist independent prescribers to prescribe schedule 2, 3, 4 and 5 controlled drugs within their clinical competence. The changes mean that nurses are no longer restricted to prescribing only those controlled drugs that were listed in Part XV11B (ii) of the Drug Tariff.

Nurse and pharmacist independent prescribers, and supplementary prescribers when within the terms of a clinical management plan, are allowed to mix schedule 2 - 5 controlled drugs for administration to a patient and provide written directions for others to do so.

Nurse and pharmacist independent prescribers are allowed to possess, supply, offer to supply, administer and give directions to administer any controlled drug in schedules 2 - 5.

The amendments allow independent nurse and pharmacist prescribers to obtain controlled drugs by means of requisition. This must be on a standardised requisition form, FP10CDF, a legal requirement from November 2015.

The only restriction is that pharmacist and nurse independent prescribers **can not** prescribe cocaine, diamorphine or dipipanone – or any salts of these products or preparations containing these products – for the purpose of treating addiction, but they can be prescribed for the treatment of organic disease or injury.

Supplementary prescribers may prescribe any controlled drug as long as this is included in the patient's individual clinical management plan.

Nurse and Pharmacist independent prescribers should ensure that they only prescribe within their area of clinical competence and that they have up to date knowledge of the doses, side effects, interactions, cautions and contraindications of the controlled drug they intend to prescribe.

From 1st June 2015 physiotherapist independent prescribers and chiropodist/podiatrist independent prescribers will be able to prescribe a small amount of controlled drugs.

All prescribing by non-medical prescribers should conform to the principles included in this policy and the best practice recommendations of the Department of Health.

For further information see www.npc.nhs.uk/controlled_drugs

11. Contact Details

The CD Accountable Officer for NHS England, South (South West) is: Sue Mulvenna.

To report and incident, concern, error or discrepancy or arrange a controlled drug destruction contact Samantha Hazell, who will liaise with the CDAO:

Samantha Hazell, Project Officer

Telephone: 0113 825 3568

Email: England.southwestcontroledrugs@nhs.net

Controlled drugs destruction kits:	<ul style="list-style-type: none">• PHS Waste Management http://www.phs.co.uk/wastemanagement/healthcare-waste-services/pharmaceutical-waste-disposal Tel: 029 2080 9090• NPA Tel: 01727 858687 extension 4 (sales department) Note: GP Practice will have to pay non-members charge and make local arrangements for waste to be collected or can dispose of with practice pharmaceutical waste.
CD Practice Register or CD Bag register	<ul style="list-style-type: none">• Surelines http://www.surelines.com/cdregisters.html Tel: 01604 859000• Jordan Woodrow Stationers of Liverpool, Stationery House, Princes Street, Derby Road, Bootle, Liverpool L20 8QF Tel: 0151 9335000
Home Office regarding Overseas Travel Licences:	<p>https://www.gov.uk/travelling-controlled-drugs Email: DLCUCommsOfficer@homeoffice.gsi.gov.uk</p> <p>Tel: 020 7035 0467</p>

Further information about controlled drugs:

The Controlled Drugs (Supervision of Management and Use) Regulations 2013

<http://www.legislation.gov.uk/ukxi/2013/373/contents/made>

Safer management of controlled drugs: (1) guidance on strengthened governance arrangements (January 2007)

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_064460

A Guide to Good Practice in the Management of Controlled Drugs in Primary Care (England). Third Edition. National Prescribing Centre. December 2009

http://www.npc.nhs.uk/controlled_drugs/cdpublications.htm

Safer Management of Controlled Drugs: Requisitions for Schedule 1, 2 and 3 Controlled Drugs (NHSBSA)

http://www.nhsbsa.nhs.uk/PrescriptionServices/Documents/PrescriptionServices/Safer_Management_of_Controlled_Drugs_requisitions.doc

Safer management of controlled drugs: changes to requirements for requisitions for the supply of schedule 1, 2 and 3 controlled drugs. (Department of Health October 2007).
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079571

Safer Management of Controlled Drugs: Controlled Drug Prescribing (NHSBSA)
http://www.nhsbsa.nhs.uk/PrescriptionServices/Documents/PrescriptionServices/Safer_Management_of_Controlled_Drugs_prescribing.doc

Background for the Safer Management of Controlled Drug (NHSBSA)
http://www.nhsbsa.nhs.uk/PrescriptionServices/Documents/PrescriptionServices/Background_of_the_Safer_Management_of_Controlled_Drugs.doc

Sativex guidance sheet for Pharmacists, Royal Pharmaceutical Society
Visit <http://bit.ly/Z5qd1V>

The Misuse of Drugs (Amendment) (England, Wales and Scotland) Regulations 2011
<http://www.legislation.gov.uk/ukxi/2011/448/contents/made>

The Misuse of Drugs Regulations 2001
<http://www.legislation.gov.uk/ukxi/2001/3998/contents/made>

NPSA, Rapid Response Report: NPSA/2008/RR05, Reducing dosing errors with opioid medicines, July 2008
<http://www.nrls.npsa.nhs.uk/resources/?entryid45=59888>

Appendix A - Summary of Controlled Drugs Legislation

The Misuse of Drugs Act 1971

This Act identifies a range of drugs with the potential for diversion and misuse and divides them into three classes, A, B, and C. These classes have maximum penalties for the criminal offences of possession and supply, which reflect the relative harm to the individual and society. Many of these drugs have legitimate medical uses and so the Act has Regulations, which enable their legal use. The Regulations divide these Controlled Drugs (CDs) into 5 Schedules, which dictate the degree to which a CD's use is regulated, and the health care professionals who may legitimately possess and supply them.

The Schedule in which a CD is placed depends upon its therapeutic benefit balanced against its harm when misused. Schedule 1 CDs are subject to the highest level of control, and Schedule 5 CDs have a much lower level of control. (See next pages for examples)

The Regulations also establish controls around prescribing, administering, safe custody, dispensing, record keeping, and destruction or disposal. These regulations have since been supplemented by a series of amendments.

The Controlled Drugs (Supervision of Management & Use) Regulations 2013

These regulations came into force in England on 1 April 2013 and reflect the new architecture for the NHS in England from April 2013. The 2013 Regulations designate a number of health care providers that are required to appoint CDAOs and set out who may be appointed to the CDAO role, under what circumstances they should be removed from this role and the registration requirements for all CDAOs. They also continue to set out the core duties and functions of CDAOs.

Misuse of Drugs Regulations 2001

These regulations were created under the 1971 Act and refer to licensing of production, possession and supply of substances

Misuse of Drugs (Amendment) Regulations 2011

From 28th March 2011 the drugs Aminephine and Tapentadol have been classified as schedule 2 controlled drugs

Misuse of Drugs (Safe Custody) Regulations 1973

These specify that all Schedule 2 and some Schedule 3 CDs should be stored securely in a cabinet or a safe, locked with a key. It should be made of metal, with suitable hinges and fixed to a wall or the floor with rag bolts that are not accessible from outside the cabinet.

Misuse of Drugs (Supply to Addicts) Regulations 1997

These prohibit doctors from prescribing diamorphine, cocaine or dipipanone for the treatment of addiction or suspected addiction except under Home Office licence. A licence is not required to use these drugs for the treatment of organic disease or injury.

The Medicines Act 1968

This act sets out the requirements of a valid prescription. It also allows midwives to possess and administer diamorphine, morphine, pethidine or pentazocine. Some professional groups are permitted to supply or administer CDs in accordance with a Patient Group Direction.

Health Act 2006

All designated bodies such as healthcare organisations and independent hospitals are required to appoint a CD accountable officer. There is now a duty of collaboration to share intelligence on CD issues

Dangerous Drugs, England, Scotland: The Controlled Drugs (Supervision of Management and Use) Regulations 2006

These regulations describe the duties and responsibilities of CD Accountable Officers to improve the safe management and use of CDs. These requirements include ensuring the following take place:

- All organisations providing clinical services and relevant self care organisations that hold CDs are required to carry out a self assessment which will inform other monitoring and inspection activities. There will be a periodic declaration on whether the organisation keeps stocks of CDs. Those that do will need to complete the self assessment.
- All organisations holding stocks of CDs should have Standard Operating Procedures which have been agreed with the relevant CD accountable officer
- Prescribing of CDs will be monitored and analysed
- Systems will be in place to alert the Accountable Officer to any complaints or concerns involving the management and use of CDs
- Untoward incidents reported involving CDs to be monitored, analysed and acted on.

Amendments to the misuse of drugs regulations 2001

1st June

Changes to temazepan

Midwife supply orders

Changes to physiotherapist and chiropodist/podiatrist independent prescribers

1st July

EPS introduced

Appendix B - Controlled Drugs Schedules

The lists set out in this appendix are not comprehensive. For comprehensive lists please refer to the Misuse of Drugs Regulations 2001.

Schedule 1

This schedule contains the most strictly controlled CDs of all. They have no generally accepted therapeutic use and practitioners have no statutory right of access to them.

Cannabinol	Conc. of poppy straw	Coca leaf
Mescaline	Lysergide	Raw opium

Schedule 2

In practical terms this is the most important of the five schedules. These drugs cover pharmaceutical opioids and amphetamines in medical use.

Alfentanil	Dipipanone	Morphine	Dexamfetamine	Medicinal opium	Pholcodine
Diamorphine	Methadone	Secobarbital	Amphetamine	Oxycodone	Fentanyl
Pethidine	Cocaine	Methylphenidate	Hydromorphone	Dihydrocodeine	Amineptine
Tapentadol	Ketamine	Lisdexamphetamine			

(Nov 2015)

Schedule 3

This schedule includes most of the barbiturates and a small number of minor stimulant drugs which are not thought so likely to be misused as those drugs in Schedule 2, nor to be so harmful if they are misused.

Benzamphetamine	Meprobamate	Phenobarbital	Temazepam
Buprenorphine	Pentazocine	Flunitrazepam	Midazolam

Schedule 4

This Schedule is split into two parts, part 1 contains most of the benzodiazepines and part 2 contains most of the anabolic and androgenic steroids, together with the growth hormones.

Part I

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

Note Sativex (Cannabis extract) spray changed to a schedule 4 part 1 controlled drug from 10th April 2013 see <http://bit.ly/Z5qd1V>

Part II

Clostebol	Fluoxymesterone	Propetandrol	Ethyloestrenol	Nabilone
Stanozol	Drostanolone	Nandrolone	Quinbolone	

Schedule 5

This schedule contains preparations of certain CDs which are exempt from full control when present in medicinal products of low strength.

Co-codamol	Dihydrocodeine	Codeine phosphate tablets 15mg, 30mg
Co-dydramol	Co-proxamol	Oramorph oral solution 10mg/5ml