Safer Management of Controlled Drugs

A guide to good practice in secondary care (England)

October 2007

Royal Pharmaceutical Society of Great Britain

Safer Management of Controlled Drugs: a guide to good practice in secondary care (England)

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For Recipient's Use			

Contents

1 Executive Summary

The purpose of this guidance is to promote the safe and effective use of controlled drugs in healthcare organisations providing secondary care. The new strengthened governance arrangements for controlled drugs and legislative changes that flow from the Government response to the fourth report of the Shipman Inquiry impose significant new responsibilities on healthcare organisations. This guidance sets out how these changes apply to the use and management of controlled drugs in secondary care settings and will support healthcare professionals and organisations in implementing the new arrangements. It has been developed following widespread consultation with key stakeholders chaired by the Royal Pharmaceutical Society of Great Britain on behalf of the Department of Health.

The Government's response to the Shipman Inquiry's Fourth Report was set out in *Safer Management of Controlled Drugs.* The response accepted the need for strengthening the current systems for managing controlled drugs to minimise the risks to patient safety of the inappropriate use of controlled drugs. Controlled drugs are subject to special legislative controls because there is a potential for them to be abused or diverted, causing possible harm. However, as the Inquiry recognised, there have been major advances in the therapeutic use of controlled drugs in the last few years. Controlled drugs are now an essential part of modern clinical care. Strengthened controls must be implemented in a way that supports professionals and encourages good practice in the use of these important medicines when clinically required by patients.

Safer Management of Controlled Drugs set out a substantial programme of work to improve the management of controlled drugs. As a result a number of changes affecting the prescribing, record keeping and destruction of controlled drugs were introduced through amendments to the Misuse of Drugs Regulations (2001) (SI 2001 No. 3998) (MDR). The Health Act (2006) provided for Regulations to be laid relating to strengthened governance and monitoring arrangements for controlled drugs. The Health Act 2006 is primary legislation and applies to the whole of the UK. The Regulations developed under the Health Act may differ in each of the home countries. In England the Controlled Drugs (Supervision of Management and Use) Regulations 2006 **(**SI 2006 No. 3148) [*http://www.opsi.gov.uk/si/si2006/20063148.htm*] came into force in January 2007. The legislative changes, guidance from the Department of Health and new governance arrangements are described in detail in Chapter 2

This document is intended to provide guidance on good practice for the management of controlled drugs (CDs) in secondary care **in England**. It aims to set out robust systems for procuring, storing, supplying, transporting, prescribing, administering, recording, and disposing safely of CDs, whilst at the same time helping to ensure appropriate and convenient access for those patients that require them. It is not designed to provide advice on the clinical choice or use of CDs. However, individual professional organisations provide a range of advisory services to their members (see Appendix 4). Although this guidance is focussed on the safe use and management of controlled drugs in secondary care settings, patients and healthcare professionals will move and work across care sectors. The National Prescribing Centre has published a guide to good practice in the management of controlled drugs in primary care which is available on its website www.npc.co.uk

The statutory appointment of Accountable Officers (AOs) who will have responsibility for the safe use and management of CDs within their trusts provides an opportunity for organisations to review their processes and procedures to ensure that they are robust and fit for purpose. It is recognised that this will promote active discussion about local systems and processes, especially where custom and practice is out of step with Home Office Regulations. Organisations will need to review their systems, clarifying, for example, those issues which are a matter for individual clinical judgement and those which are not and discuss with their AOs in order to develop strong governance arrangements that fit with the current legal framework.

This guidance recognises developments that have taken place to modernise working practices in recent years: the changing roles of healthcare professionals, the need to ensure optimal use of skill mix and the key contribution of pharmacy technicians and other healthcare professionals, for example, Operating Department Practitioners, and seeks to clarify how these fit within the existing legal framework for controlled drugs. .

Controlled Drugs are those defined in the MDR, and within this document the emphasis is placed on those contained in Schedule 2, as these are subject to the highest levels of control. On occasions, health care organisations choose to manage non-CDs and CDs in other Schedules in the same way as Schedule 2 CDs to ensure a higher level of governance. This is a matter for local decision and does not form part of this guidance.

This guidance is intended to build on and augment the advice provided in *The Safe and secure handling of medicines: A team approach* (the Revised Duthie Report, March 2005). It is concerned specifically with CDs and readers are encouraged to refer to the Revised Duthie Report (March 2005) [http://www.rpsgb.org.uk/pdfs/safsechandmeds.pdf.] for guidance on more general aspects of medicines' management.

This guidance has been organised into chapters dealing with the legislative requirements, governance arrangements and guiding principles. Chapters that deal with the management of CDs in wards, operating theatres and pharmacies follow. A chapter on special situations has been included to accommodate a number of situations that do not obviously fit elsewhere. There is also a brief chapter on training. Separate sections have not been written for each hospital department, because the requirements for the safe management of CDs do not differ between medical and surgical wards or general wards and high-dependency wards. Although the guidance includes most of the commonly-encountered situations, inevitably, as practice continues to develop, users will on occasions find gaps or points which fit uneasily with their situation. In such cases we hope that the principles listed in Chapter 3 will provide a basis for policy formulation.

The style of the Revised Duthie Report (March 2005) has been adopted. The term "should" has been used for recommendations that relate to good practice and "must" for those governed by legal requirements. Recommendations have also been inserted that "may" be followed as matters of good practice, if they are relevant to local circumstances.

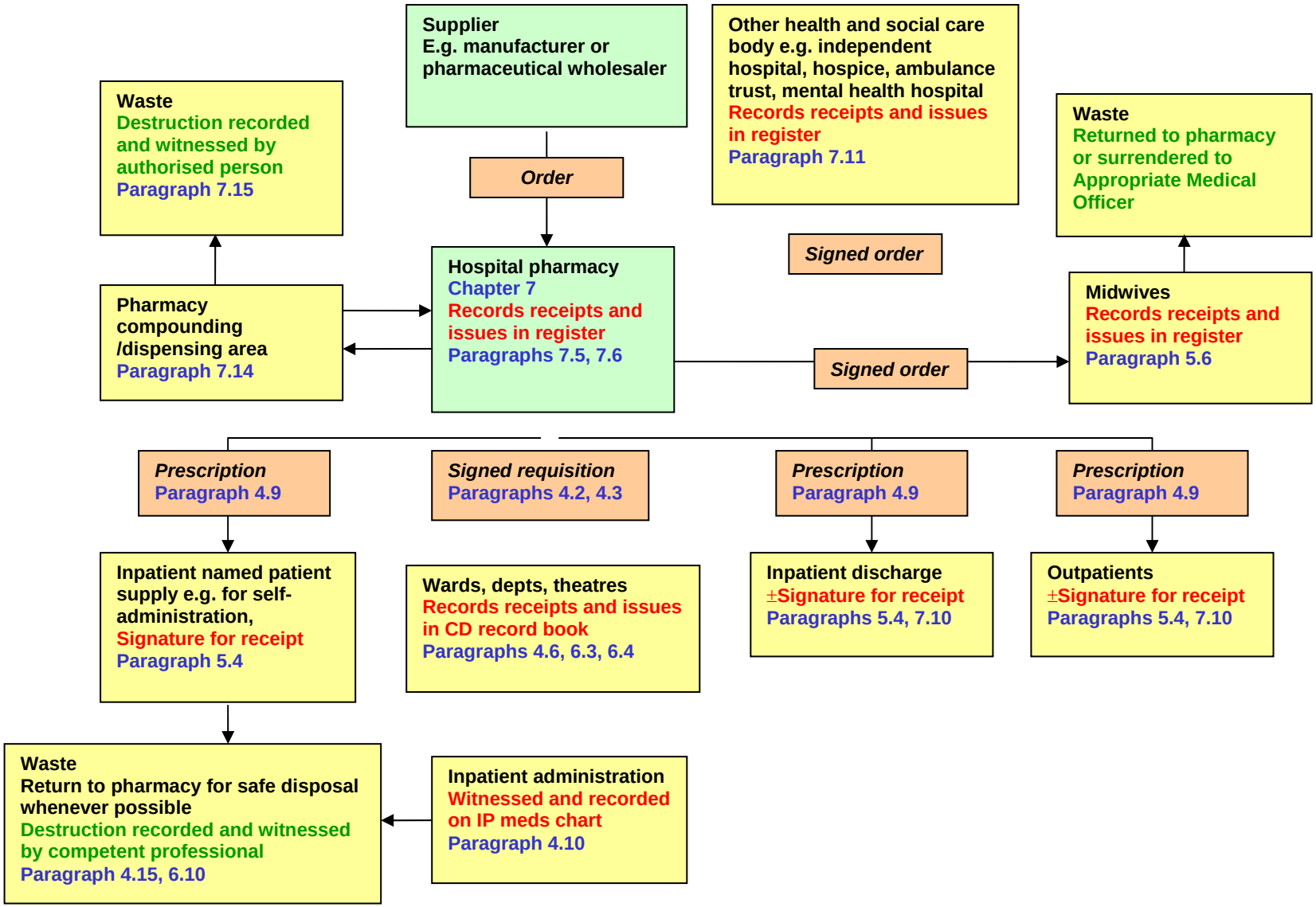
This document has been designed both for those who are involved in management of CDs in secondary care and for those who are responsible for ensuring that CDs are managed appropriately in their organisations or in their part of the organisation. It should be of value in a number of settings where CDs are used including:

- Pharmacies
- Hospital wards and departments including operating theatres
- Midwifery units
- Supply to other health and social care bodies (e.g., hospices, ambulance trusts).

This guidance should also be of value in a number of settings outside the secondary sector such as hospices, community hospitals, rehabilitation centres and other similar organisations where CDs are used and managed. It has been prepared on the basis of extensive consultation with stakeholders. A list of those who contributed to the design and content of the guidance appears at Appendix 6.

Unfortunately, the Department of Health is not in a position to answer specific individual queries relating to the management of controlled drugs. Healthcare professionals should in the first instance contact their local Medicines Information Centres. Appendix 4 lists professional organisations that provide advice for their members. The Department's website www.dh.gov.uk/controlleddrugs, the Home Office websites www.homeoffice.gov.uk and www.drugs.gov.uk/drugslaws and the Royal Pharmaceutical Society of Great Britain website www.rpsgb.org.uk should also be referred to regularly.

Figure 1 The product journey – CDs in secondary care



2 Legislation and governance arrangements

Legislation

Legislative Framework for Controlled Drugs

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

The relevant legislation and guidance is summarised briefly in Appendix 1. Readers are encouraged to refer the relevant websites for detailed, up-to-date information.

The legal requirements pertaining to the main groups of CDs are summarised in Table 1. Schedule 1 drugs have been omitted from the table as drugs in this group have virtually no therapeutic uses.

Table 1: Summary of legal requirements that apply to controlled drugs in Schedules 2,3,4 and 5 of the Misuse of Drugs Regulations

Schedule (refers to schedules of the Misuse of Drugs Regulations)	**Schedule 2** Includes – Opioids, (e.g. diamorphine, morphine, methadone), major stimulants (eg amphetamines) ,remifentanil secobarbital,	**Schedule 3** Includes minor stimulants, temazepam, diethylpropion, buprenorphine, flunitrazepam, Barbiturates except secobarbital	**Schedule 4, pt I** Includes benzo-diazepines	**Schedule 4, pt II Includes** anabolic steroids, clenbuterol, growth hormones	**Schedule 5** Includes low strength opioids
Designation	CD	CD No Reg	CD Benz	CD Anab	CD Inv
Safe custody	Yes, except quinalbarbitone	Yes, with certain exemptions (see MEP)	No	No	No
Prescription requirements (including handwriting*) – apply to OP and discharge prescriptions	Yes	Yes, except temazepam	No	No	No
Requisitions necessary?	Yes	Yes	No	No	No
Records to be kept in CD register	Yes	No	No	No	No
Pharmacist must ascertain the identity of the person collecting CD	Yes	No	No	No	No
Emergency supplies allowed	No	No, except phenobarbitone for epilepsy	Yes	Yes	Yes
Validity of prescription	28 days	28 days	28 days	28 days	6 mths (if POM)
Maximum duration that may be prescribed	30 days as good practice	30 days as good practice	30 days as good practice	30 days as good practice	

(Table adapted from the Medicines, Ethics and Practice Guide *(http://www.rpsgb.org/pdfs/MEP30s1-2b.pdf)*

* Prescriptions for schedule 2 and 3 CDs may be typed or computer generated but must be signed by the prescriber. (SI 2005 No.2864)

Further information can be found in the Medicines, Ethics and Practice Guide (MEP) and in the British National Formulary (http://www.bnf.org/bnf/)

2.1 Supply and administration of controlled drugs

There are a number of mechanisms for the supply and administration of controlled drugs in secondary care. Controlled drugs can be

- Prescribed by a doctor or nurse independent prescriber
- Supplied and administered by a midwife
- Supplied and administered under Patient Group Directions

Certain restrictions apply to each of these routes of supply

2.2.1 Supply and /or administration of controlled drugs under Patient Group Directions

A Patient Group Direction (PGD) allows a range of specified health care professionals to supply and /or administer a medicine directly to a patient with an identified clinical condition within an identified set of circumstances without the patient first seeing a prescriber. Individual professionals who are to work within a PGD must be named on it and have signed it

Named nurses, paramedics and other specified health professionals can supply and administer certain CDs in restricted circumstances in accordance with a PGD and the additional requirements of the Misuse of Drugs (Amendment) (No 3) Regulations (SI 2003 No.2429. (www.opsi.gov.uk/si/si2003/20032429.htm) (*HO circular Home Office Circular 049 / 2003. Controlled Drugs Legislation - Nurse Prescribing And Patient Group Directions*) [http://www.knowledgenetwork.gov.uk/ho/circular.nsf/79755433dd36a66980256d4f004d1514/248786ae1bb78d6180256dab003b2948?OpenDocument]

There are currently only limited circumstances in which certain CDs may be administered or supplied under a PGD by certain named heath professionals. These are:

- Registered nurses (but no other health care practitioners) in an accident and emergency departments and coronary care units in hospitals can supply or administer diamorphine for the treatment of cardiac pain in accordance with a PGD.
- Registered nurses, pharmacists, paramedics, midwives, ophthalmic opticians, chiropodists, orthoptists, physiotherapists, radiographers, occupational therapists and orthotists or prosthetists can supply or administer any schedule 4 or 5 CD in accordance with a PGD, except
    - The anabolic steroids in Schedule 4, part 2
    - Injectable formulations for the purpose of treating a person who is addicted to a drug

2.2.2 Midwive's exemptions

Registered midwives may administer parenterally, a number of specified CDs in the course of their professional practice. These are:

- Diamorphine
- Morphine
- Pentazocine lactate
- Pethidine hydrochloride

(See - The Prescription Only Medicines (Human Use) Order 1997(SI 1997 No. 1830). The Misuse of Drugs Regulations 2001] (SI 2001 No. 3998))

(See also paragraph 5.8 Controlled drugs for midwives)

Governance arrangements

2.3 Accountability and responsibility

At local level, all healthcare organisations or designated bodies (see Controlled Drugs (Supervision of Management and Use) Regulations 2006; (SI 2006 No. 3148) www.opsi.gov.uk) are accountable, through the Accountable Officer (see below), for ensuring the safe management of controlled drugs. In England, the following are designated bodies:

- A primary health care trust
- An NHS trust
- An NHS foundation trust
- An independent hospital

All designated bodies, including NHS Trusts, Foundation Trusts and independent healthcare organisations, are accountable for the monitoring of all aspects of the use and management of controlled drugs by all healthcare professionals whom they employ, with whom they contract or to whom they grant practice privileges. This will be done through normal governance arrangements such as analysing baseline data and clinical governance visits (for example by clinical governance leads).

Where one organisation provides services to another, responsibility for governance arrangements should be specified in the contract (or service level agreement). Reporting should be to the Accountable Officer for the organisation that is receiving the service. (Once the CDs have been received responsibility for them passes to receiving organisation.) In setting up and reviewing these governance arrangements, the AO will want to pay particular attention to and prioritise key areas of risk which will include the interface with other health and social care providers.

2.4 The Accountable Officer

The Accountable Officer is responsible for all aspects of the safe and secure management of CDs in his or her organisation. This includes ensuring that safe systems are in place for the management and use of CDs, monitoring and auditing the management systems and investigation of concerns and incidents related to CDs.

The regulatory requirements for Accountable Officers are set out in full in the Controlled Drugs (Supervision of Management and Use) Regulations 2006; (SI 2006 No.3148) [http://www.opsi.gov.uk/si/si2006/20063148.htm] and a summary of the main provisions is provided at Appendix 2 of this document.

2.5 Standards for monitoring and inspection

Guidelines for inspection visits have been developed. A working group of representatives from the RPSGB, Healthcare Commission, Commission for Social Care Inspection (CSCI), the police and the NHS has agreed the guidelines. They set out the core activities that should be included in an inspection and cover areas such as ensuring safe storage arrangements and proper record keeping. They also suggest a frequency for visits: a minimum ten per cent random sample of designated bodies to be inspected each year. Notice should be given of routine inspections.

The guidelines can be found at: www.dh.gov.uk/controlleddrugs. A competency framework is also available for those involved in monitoring and inspection. (See - www.npc.co.uk/pdf/CDI_Competency_Framework.pdf)

2.6 Standard operating procedures

Each of the activities that relate to CDs, regardless of where in the organisation they occur, must be described in a standard operating procedure (SOP). This is particularly important if tasks are delegated to others. For example, issue and receipt of Controlled Drugs in the pharmacy may be delegated to a pharmacy technician. However, final responsibility lies with the chief pharmacist.

SOPs should be kept up-to-date, reflecting current legal and good practice requirements for CDs, and each one should be clearly marked with the date of issue and review date.

All staff who are involved in the prescribing, supplying, administering or disposing of controlled drugs of CDs need to be familiar with the SOPs.

There is a regulatory requirement for the Accountable Officer (AO) to ensure that there are adequate and up-to-date SOPs in place in relation to the management and use of controlled drugs within their organisation.

The standard operating procedures must, in particular, cover the following matters -

(a) who has access to the controlled drugs;

(b) where the controlled drugs are stored;

(c) security in relation to the storage and transportation of controlled drugs as

required by misuse of drugs legislation;

(d) disposal and destruction of controlled drugs;

(e) who is to be alerted if complications arise; and

(f) record keeping, including:

(i) maintaining relevant controlled drugs registers under Misuse of Drugs legislation, and

(ii) maintaining a record of the controlled drugs specified in Schedule 2 to the Misuse of Drugs Regulations 2001 (specified controlled drugs to which certain provisions of the Regulations apply) that have been returned by patients.

SOPs within a health care organisation should be formally approved by the Accountable Officer for that organisation. This task may be delegated to a suitably qualified person, however, the final responsibility lies with the Accountable Officer. (See Appendix 2)

Further information about SOPs for CDs can be found in the document, *Safer Management of Controlled Drugs: Guidance on Standard Operating Procedures for Controlled Drugs* at http://www.dh.gov.uk/prod_consum_dh/idcplg?IdcService=GET_FILE&dID=122755&Rendition=Web.

2.7 Additional Information

- A comprehensive list of drugs included within these schedules is given in the 2001 Misuse of Drug Regulations and can be accessed at www.opsi.gov.uk
- The Healthcare Commission is responsible for overseeing the management of controlled drugs by healthcare organisations in England and a section of the website is dedicated to controlled drugs www.healthcarecommission.org.uk
- Home Office www.homeoffice.gov.uk
- Medicines and Healthcare Products Regulatory Agency (MHRA) www.mhra.gov.uk
- Department of Health Controlled Drugs pages www.dh.gov.uk/PolicyAndGuidance/MedicinesPharmacyAndIndustry/Prescriptions/ControlledDrugs/fs/en
- Royal Pharmaceutical Society of Great Britain. *Medicines, Ethics and Practice: A guide for pharmacists.* http://www.rpsgb.org.uk/pdfs/MEP30s1-2a.pdf
- Royal Pharmaceutical Society of Great Britain. Patient Group Directions: A resource pack for pharmacists. http://www.rpsgb.org.uk/pdfs/pgdpack.pdf.
- Pharmaceutical Services Negotiating Committee (PSNC). *Controlled Drugs – recent changes.* http://www.psnc.org.uk/index.php?type=more_news&id=2056&k=3
- National Prescribing Centre (NPC). *A guide to good practice in the management of controlled drugs in primary care (England)*. http://www.npc.co.uk/background_for_cd.htm

- Nursing and Midwifery Council (www.nmc-uk.org). NMC Circular 25/2005 *Midwives Supply Orders*; NMC Circular 1/2005, *Medicine legislation: what it means for midwives.*

3 General principles

There are a number of overarching principles that guide the use of medicines in general and CDs in particular. They underpin and inform the decisions that are made about the safe management of CDs within the current legal framework. The following principles should apply in relation to the management of CDs.

3.1 Patients have timely access to the medicines prescribed for them

3.2 Organisations and individuals comply with the current legal requirements for CDs

3.3 Patients are partners in their treatment and share decision-making with healthcare professionals about their treatment.

3.4 Patients are adequately informed about their treatment

3.5 CDs are used and managed safely and securely

3.6 There is a clear audit trail for the movement and use of all CDs

3.7 The use of CDs is audited and action is taken if necessary

3.8 CDs are prescribed by professionals who are competent to do so and who receive regular training and support on the safe management of CDs

3.9 Local procedures and protocols are designed to be as clear and accurate in operationalisation as possible and do not impose an intolerable administrative burden

3.10 The stock levels and preparations of CDs held in wards and departments match what is routinely used in that clinical area

3.11 Health care staff have access to up-to-date information about CD legislation and official (Department of Health, Home Office and other) guidance

3.12 Health care staff in the organisation work to standard operating procedures, approved by the Accountable Officer, that are appropriate to their area of work

3.13 Health care and appropriate ancillary staff receive adequate training and are competent in the management of CDs (appropriate to their sphere of activity and level of responsibility)

3.14 Access to CDs is restricted to appropriate, designated and legally authorised personnel

4 Management of CDs in wards and departments

This chapter deals with the management of CDs in wards and departments. The management of CDs in operating theatres is covered in Chapter 6.

Contents of this chapter:

This section deals with measures concerned with the management of controlled drugs that are applicable in most wards and departments, including diagnostic departments. The requirements for pharmacy departments can be found in Chapter 7.

Where additional information can be found in other paragraphs, cross-references are also included.

4.1 Accountability and responsibility

4.1.1 Accountable individuals

The registered nurse, midwife or Operating Department Practitioner (ODP) in charge of a ward or department is responsible for the safe and appropriate management CDs in that area.

The registered nurse, midwife or ODP in charge can delegate control of access (i.e. key-holding) to the CD cupboard cabinet to another, such as a registered nurse or ODP. However, legal responsibility remains with the registered nurse, midwife or ODP in charge. Whilst the task can be delegated, the responsibility cannot.

4.1.2 Standard operating procedures

There should be standard operating procedures (SOPs) covering each of the activities concerned with CDs such as requisitioning, receipt, administration etc.

SOPs should be kept up-to-date, reflecting current legal and good practice requirements for CDs, and each one should be clearly marked with the date of issue and review date.

SOPs should be discussed with and approved by the Accountable Officer or by the person to whom he has delegated this task. The AO remains finally accountable for all the systems for the safe management of CDs. (See Appendix 2)

4.2 Controlled Drug stocks

There should be a list of the CDs to be held in each ward or department as stock items. The contents of the list should reflect current patterns of usage of CDs in the ward or department and should be agreed between the pharmacist or pharmacy technician responsible for stock control of medicines on the ward and the registered nurse, midwife or ODP in charge.

4.2.1 The list should be modified if practices change and should be subject to regular review at agreed intervals.

4.3 Requisitioning of Controlled Drugs

The registered nurse, midwife or ODP in charge of a ward, department, operating theatre or theatre suite is responsible for the requisitioning of controlled drugs for use in that area.

4.3.1 The registered nurse, midwife or ODP in charge can delegate the task of preparing a requisition to another, such as a registered nurse or ODP (See Chapter 6; The management of CDs in operating theatres). However, legal responsibility remains with the registered nurse, midwife or ODP in charge.

4.3.1.1 Orders should be written on suitable stationery (e.g. a controlled drug requisition book with duplicate pages) and must be signed by an authorised signatory. (See also 4.3.5 Electronic systems)

4.3.1.2 A copy of the signature of each authorised signatory should be available in the pharmacy department for validation. Where electronic systems are in use, there should be a reliable means of validating the identity of individuals who requisition CDs.

4.3.1.3 Requisitions must contain the following:

- Name of hospital
- Ward / Department
- Drug name, form, strength, ampoule size if more than one available
- Total quantity
- Signature and printed name of registered nurse
- Date
- Signature of person issuing the item from the pharmacy

The person who receives the CDs on the ward should sign the duplicate copy of the requisition.

4.3.1.4 The person who accepts the CDs for transit should sign for receipt. This may be on the duplicate requisition (if space permits) or may be in a separate book kept for this purpose.

4.3.2 CD Top-up schemes

In some situations pharmacy-led CD top-up schemes for replenishing stocks of CDs on wards and departments are a practical and convenient mechanism of stock control. These are usually carried out by a pharmacy technician or senior assistant technical officer (SATO), but may also be carried out by other suitably-trained, competent members of the pharmacy staff.

4.3.2.1. When a CD top-up scheme is in operation, the responsibility for CDs in a ward or department remains with the registered nurse, midwife or ODP in charge.

4.3.2.2 In a top-up scheme a member of the pharmacy staff is responsible for checking the stock balances in the ward Controlled Drug Record Book against the levels in the agreed stock list and preparing the CD requisition forms in order to replenish the stock. These requisition forms should be signed by the registered nurse, midwife or ODP in charge.

4.3.3 Electronic systems

Where electronic systems for the requisitioning of CDs are introduced, safeguards in the software should be put in place to ensure that:

- Only individuals who are authorised to requisition CDs from the pharmacy can do so
- Safeguards should be incorporated in the software to ensure the author of each entry is identifiable

- Entries cannot be altered at a later date
- A log of all data entered is kept and can be recalled for audit purposes.

4.4 Receipt of controlled drugs

When CDs are delivered to a ward or department they should be handed to an appropriate individual. On no account should they be left unattended. (See paragraph 5.2 Transfer of CDs). A local procedure should define the appropriate persons who are permitted to receive CDs and the way in which messengers identify them. As a matter of good practice the receiving person should not be the same person who ordered the controlled drugs.

4.4.1 As soon as possible after delivery the registered nurse, midwife or ODP in charge should:

- Check the CDs against the requisition – including the number ordered and received. If this is correct then the duplicate sheet in the controlled drug requisition book should be signed in the "received by" section. Any tamper-evident seals on packs should be left intact when they are received from pharmacy. This will simplify and speed up routine checks. A seal should only be broken when the pack is required for administration.
- If when the tamper evident seal is broken, the contents do not match the expected amount stated on the pack, the nurse or ODP in charge should contact the pharmacy department.
- Appropriate records should be made in the CD Register and all necessary action taken to resolve the discrepancy.
- Place the CDs in the appropriate CD cupboard
- Enter the CDs into the controlled drug record book, update the running balance and check that the balance tallies with quantity that is physically present.

4.4.2 Depending on local circumstances, some health care organisations may wish to stipulate that receipt of CDs and updating of the register should be witnessed by a second competent professional

See also paragraph 6.4 Receipt of CDs in Theatre

4.5 Storage of controlled drugs

The Misuse of Drugs (Safe Custody) Regulations 1973 (SI 1973 No 798) cover the safe custody of controlled drugs in certain specified premises. The Regulations also set out certain standards for safes and cabinets used to store controlled drugs.

4.5.1 Ward CD cupboards should conform to the British Standard reference BS2881 or be otherwise approved by the pharmacy department. This is a

minimum security standard and may not be sufficient for areas where there are large amounts of drugs in stock at a given time, and/or there is not a 24-hour staff presence, or easy control of access. In this case a security cabinet that has been evaluated against the SOLD SECURE standard SS304 (See www.soldsecure.com) should be used.

4.5.2 All controlled drugs must be stored in a locked receptacle which can only be opened by a person who can lawfully be in possession, such as a pharmacist or the registered nurse, midwife or ODP in charge, or a person working under their authority e.g. a pharmacy technician.

4.5.3 In certain circumstances, for example when CD discharge medicines (TTOs) are sent to the ward several hours before the patient leaves, the medicines may be stored in the CD cupboard. These medicines should be segregated from the ward CD stock. (See paragraph 5.4 Management of CDs that are patients' property – TTOs)

4.5.4 General measures for the storage of CDs include the following:

- Cupboards must be kept locked when not in use
- The lock must not be common to any other lock in the hospital
- Keys must only be available to authorised members of staff and at any time the key-holder should be readily identifiable
- The cupboard should be dedicated to the storage of CDs.
- No other medicines or items should normally be stored in the CD cupboard. Occasionally, in response to local circumstances health care organisations may decide to allow other drugs that are not CDs to be stored in the CD cupboard. Trusts should carry out a risk assessment and have clear guidelines and SOPs in place to cover this
- CDs must be locked away when not in use
- There must be arrangements for keeping the keys secure. This is particularly important for areas such as day surgery units and five-day wards that are not operational at all times.

4.6 Key-holding and access to CDs

4.6.1 Responsibility for CD keys

The registered nurse, midwife or ODP in charge is responsible for the CD key.

4.6.1.1 Key-holding may be delegated to other suitably-trained, registered healthcare professionals but the legal responsibility rests with the registered nurse, midwife or ODP in charge.

4.6.1.2 The controlled drug key should be returned to the nurse, midwife or ODP in charge immediately after use by another registered member of staff.

4.6.1.3 On occasions, for the purpose of stock checking, the CD key may be handed to an authorised member of the pharmacy staff (e.g. the pharmacy technician responsible for stock control of medicines on the ward).

4.6.2 Missing CD keys

If the CD keys cannot be found then urgent efforts should be made to retrieve the keys as speedily as possible e.g. by contacting nursing, midwifery or ODP staff who have just gone off duty.

4.6.2.1 A procedure should be in place to ensure that the senior registered nurse, midwife or matron or the duty nurse or midwife manager is informed as soon as possible and the duty pharmacist as soon as appropriate.. The procedure should specify the arrangements for preserving the security of CD stocks and for ensuring that patient care is not impeded e.g. by issuing a spare key.

4.6.2.2. If the keys cannot be found then the Accountable Officer should be informed. Depending on the circumstances, it may also be appropriate to contact the police.

4.7 Record-keeping

Each ward or department that hold stocks of CDs should keep a record of CDs received and administered in a CD record book (CDRB).

The Registered nurse, midwife or ODP in charge is responsible for keeping the CD Record book up to date and in good order.

4.7.1. Controlled drug record books

4.7.1.1 The CDRB should be bound (not loose-leaf) with sequentially numbered pages and it should have separate pages for each drug and each strength, so that a running balance can be kept easily. Entries should be made in chronological order, in ink or be otherwise indelible.

4.7.1.2 All entries should be signed by a registered nurse, midwife or ODP and should be witnessed preferably by second registered nurse, midwife or ODP. If a second registered nurse, midwife or ODP is not available, then the transaction can be witnessed by another registered practitioner (e.g. doctor, pharmacist, pharmacy technician) or by an appropriately trained healthcare assistant.

4.7.1.3 On reaching the end of a page in the CDRB, the balance should be transferred to another page. The new page number should be added to the bottom of the finished page and the index updated. As a matter of good practice this transfer may be witnessed.

4.7.1.4 If a mistake is made it should be bracketed in such a way that the original entry is still clearly legible. This should be signed, dated and witnessed by

a second registered nurse, midwife or other registered professional or by an appropriately trained healthcare assistant. The witness should also sign the correction

4.7.2 Records of receipts

A record should be kept of all Schedule 2 CDs that are received or administered.

4.7.2.1 For CDs received, the following details should be recorded on the appropriate page in the CDRB:

- Date of entry.
- Name of pharmacy making supply and the serial number of requisition
- Quantity received
- Form (name, formulation and strength) in which received
- Name/signature of nurse/authorised person making entry
- Name/signature of witness
- Balance in stock

4.7.2.2 When recording CDs received from pharmacy, the number of units received may be recorded in words not figures (e.g. ten, not 10) to reduce the chance of entries being altered.

4.7.2.3 After every administration, the stock balance of an individual preparation should be confirmed to be correct and the balance recorded in the controlled drug record book. The entry should be signed and dated.

For records of CDs administered see paragraph 4.11 Administration of CDs

4.8 Controlled drug stock checks

The stock balance of all CDs entered in the CD record book (CDRB) should be checked and reconciled with the amounts in the cupboard with sufficient frequency to ensure that discrepancies can be identified in a timely way. The frequency of such checks should be determined locally after a risk assessment has been carried out. In addition, regular stock checks should be carried out by pharmacy staff (see paragraph 7.7.2 - Checks of CD stocks held in wards, theatres or departments).

4.8.1 The registered nurse, midwife or ODP in charge is responsible for ensuring that the regular CD stock check is carried out by staff in the ward or department

4.8.1.1 Two registered nurses, midwives or registered health professionals should perform this check. Where possible the staff undertaking this check should be rotated periodically. The check should take account of the following points:

- Checking of controlled drugs involves checking of balance in the CDRB against the contents of the CD cupboard, not the reverse, to ensure all balances are checked.
- It is not necessary to open packs with intact tamper-evident seals for stock checking purposes.
- Stock balances of liquid medicines should generally be checked by visual inspection but periodic volume checks may be helpful. The balance must be confirmed to be correct on completion of a bottle.

4.8.1.2 A record indicating that this reconciliation check has been carried out and confirming the stock is correct may be kept in a separate bound record book or in the CDRB. This record should as a minimum state the date and time of the reconciliation check and include wording such as, "check of stock level" and be signed by the registered nurse, midwife or ODP and the witness.

4.8.1.3 If a discrepancy is found it should be investigated without delay. (See paragraph 5.9 Discrepancies and diversion) The local investigation and reporting procedures should be followed

4.9 Archiving of controlled drug records

Healthcare organisations must make arrangements to store CD records for a minimum period of two years. Some health care organisations may want to keep records for longer than two years. Once electronic CD registers are in common use, the Government intends a further requirement to keep secure copies for up to eleven years.

All registers and CDRBs used in the organisation should be kept for a period of at least two years from the date when the last entry was made.

All local documents designed to track and/or monitor CD usage should also be kept for two years after the last entry/date of use

See also paragraph 7.9 - Archiving of controlled drug records

4.10 Prescribing

4.10.1 Prescribing for inpatients/discharge patients

For hospital inpatients or discharge patients, CDs can be prescribed on the inpatient medicines chart or case sheet (commonly called the inpatient prescription and administration chart) or the anaesthetics card in line with local policies and procedures.

4.10.1.1 The written requirements for controlled drugs on these charts are the same as for other medicines:

- Drug name and form

- Route
- Dose
- Frequency (if prescribed "when required" e.g. for breakthrough pain, a minimum interval for administration should be specified, e.g. every six hours, and a maximum total quantity to be administered in 24hrs)
- Include a finish date where appropriate
- Start date
- Signature of prescriber

The patient's name, unit number and allergy status should also be written on the chart.

4.10.2 Prescribing for discharge patients

Prescriptions for CDs for patients who are going home (discharge medicines) should be written on locally-approved TTA (to take home or to take out) prescription forms for dispensing by the pharmacy. These prescriptions must conform to all requirements of the Misuse of Drugs Regulations for a controlled drugs prescription (see section 4.10.3).

4.10.2.1 Medical doctors who have not achieved full registration with the GMC are permitted to prescribe CDs (and other POM medicines) on these prescription forms for in patient use so far as this is necessary for the purposes of his employment as defined in the Medical Act 1983. Further guidance is available from the GMC http://www.gmc-uk.org/education/documents/provisional_registration_prescribing.pdf

4.10.2.2 Up to a maximum of 30 days supply should be prescribed, as a matter of good practice. There may be circumstances where there is a genuine need to prescribe for more than 30 days. Where the prescriber believes that it is in the clinical interest of the patient to prescribe for more than 30 days and would not pose an unacceptable threat to patient safety, the prescriber should make a note of the reasons in the patient's notes

4.10.3. Prescribing for outpatients

Prescriptions for CDs for outpatients must be written in accordance with the requirements of the Misuse of Drugs Regulations (Regulation 15). The prescription document can either be a locally-approved outpatient prescription form for the hospital pharmacy to dispense or a hospital FP10 for the a community pharmacy to dispense.

4.10.3.1 A prescription for Schedule 2 and 3 CDs (with the exception of temazepam and preparations containing it) must contain the following details, written so as to be indelible, i.e. written by hand, typed or computer-generated (SI 2005 No.2864) [http://www.opsi.gov.uk/SI/si2005/uksi_20052864_en.pdf]

- The patient's full name, address and, where appropriate, age

- The name and form of the drug, even if only one form exists
- The strength of the preparation, where appropriate
- The dose to be taken
- The total quantity of the preparation, or the number of dose units, to
- be supplied in both words and figures

In addition, it is good practice to include the patient's NHS number on the prescription.

4.10.3.2 The prescription must be signed by the prescriber with his/her usual signature, in his own handwriting (this must be handwritten) and dated by him/her (the date does not have to be handwritten).
Amendments to the Misuse of Drugs Regulations 2001, which came into force on 14th November 2005, removed the requirement for prescriptions for Schedule 2 and 3 CDs (except temazepam) to be written in the prescriber's own handwriting (other than their signature).
CD prescriptions may be computer-generated but **do not have** to be computer-generated. Prescribers may issue computer-generated prescriptions for all CDs. Only the signature has to be in the prescriber's own handwriting. The prescriber should sign any manuscript changes.

4.10.3.3 If the prescription is prepared by someone other than the prescriber then that person should, ideally, be a registered healthcare professional.

4.10.3.4 The use of pre-printed sticky labels on prescriptions is not recommended. Technically the new legislative requirements for computer generated prescriptions for CDs do not prevent the use of preprinted sticky labels on prescriptions. If and where they are used, such sticky labels should be tamper-evident (i.e. it is obvious if an attempt has been made to remove them). If a sticky label is used, prescribers should also sign the sticky label or at least start their signature on the sticky label. This is a further safe guard to ensure sticky labels are not tampered with or another sticky label is not placed on top of the one that the prescriber signed for.

4.10.3.5 Up to a maximum of 30 days supply should be prescribed as a matter of good practice. There may be circumstances where there is a genuine need to prescribe a supply for more than 30 days. Where the prescriber believes that it is in the clinical interest of the patient to prescribe a supply for more than 30 days and would not pose an unacceptable threat to patient safety, the prescriber should make a note of the reasons in the patient's notes.

4.10.4 Supplementary prescribers

Regulations were amended in 2005 to permit a supplementary prescriber, when acting under and in accordance with the terms of an agreed individual clinical management plan (CMP) to prescribe and administer and/or supply or direct any person to administer any CD provided that the CD is included in the CMP.

4.10.4.1 If the patient takes his prescription to a community pharmacy for dispensing, then the appropriate prescription form must be used (FP10SS). Details of the prescription forms on which CDs for outpatients

can be prescribed, are provided in the RPSGB Medicines, Ethics and Practice guide. [http://www.rpsgb.org.uk/pdfs/MEP30s1-2a.pdf]

4.10.5 Non-medical independent prescribers

Community Practitioner Nurse Prescribers
Community Practitioner Nurse Prescribers may only prescribe those products and medicines specified in the Nurse Prescribers' Formulary for Community Practitioners. No CDs are included in this formulary.

Nurse Independent Prescribers (formerly Extended Formulary Nurse Prescribers)
Following amendments to the Medicines Regulations, which came into force in January 2006, the range of drugs that Nurse Independent Prescribers were able to prescribe independently has been extended. From 1st May 2006, the Nurse Prescribers' Extended Formulary was discontinued and qualified Nurse Independent Prescribers are now able to prescribe any licensed medicine for any medical condition within their competence, including some CDs for specific conditions. The 2001 Misuse of Drugs Regulations were amended, with effect from 1st May 2006, to reflect the change in terminology relating to Nurse Independent Prescribers. The condition of tonic-clonic seizures was also added as an allowable indication for the prescribing of diazepam, lorazepam and midazolam.

Nurse Independent Prescribers are permitted to prescribe, administer, or direct anyone to administer the following CDs solely for the medical conditions indicated. Details of the appropriate route of administration for these CDs can also be found in the table below.

Table 2: CDs that can be prescribed and administered for specified indications by Nurse Independent Prescribers

Drug	Schedule	Indication	Route of administration
Buprenorphine	3	Transdermal use in palliative care	Transdermal
Chlordiazepoxide hydrochloride	4	Treatment of initial or acute withdrawal symptoms caused by the withdrawal of alcohol from persons habituated to it	Oral
Codeine phosphate	5	N/A	Oral
Co-phenotrope	5	N/A	Oral
Diamorphine hydrochloride	2	Use in palliative care, pain relief in respect of suspected myocardial infarction or for relief of acute or severe pain after trauma, including in either case postoperative pain relief	Oral or parenteral
Diazepam	4	Use in palliative care, treatment of initial or acute withdrawal symptoms caused by the withdrawal of alcohol from persons habituated to it, tonic-clonic seizures	Oral, parenteral or rectal
Dihydrocodeine tartrate	5	N/A	Oral
Fentanyl	2	Transdermal use in palliative care	Transdermal
Lorazepam	4	Use in palliative care, tonic-clonic seizures	Oral or parenteral
Midazolam	4	Use in palliative care, tonic-clonic seizures	Parenteral or buccal
Morphine hydrochloride	2	Use in palliative care, pain relief in respect of suspected myocardial infarction or for relief of acute or severe pain after trauma, including in either case post-operative pain relief	Rectal
Morphine sulphate	2	Use in palliative care, pain relief in respect of suspected myocardial infarction or for relief of acute or severe pain after trauma, including in either case post-operative pain relief	Oral, parenteral or rectal
Oxycodone hydrochloride	2	Use in palliative care	Oral or parenteral administration in palliative care

4.10.6 Pharmacist Independent Prescribers

At present Pharmacist Independent Prescribers are not able to prescribe Controlled Drugs. Readers are advised to consult the DH and HO websites for up-to-date information.

The Home Office has issued a consultation for nurse and pharmacist independent prescribers to be able to prescribe any CD provided they work within their competence. The outcome of the consultation will inform any regulatory changes required.

4.11 Administration

See also paragraph 4.7 Record keeping.

The administration of Controlled Drugs should comply with all local policies and procedures for the administration of medicines.

Nurses and midwives must follow Nursing and Midwifery Council standards and guidance.

Anyone can administer any drug specified in Schedule 2,3 or 4 provided they are acting in accordance with the directions of an appropriately qualified prescriber. (MDR 2001, Regulation 7(3)). Any person can administer to another person any drug specified in Schedule 5 – MDR 2001- Regulation 7 (1)

4.11.1 Health care organisations should carry out a risk assessment to determine whether the introduction of double checking for administration of CDs as an additional risk-reduction measure is necessary, within their organisation.

4.11.1.1 Where two practitioners are involved in the administration of CDs, one of them should be a registered nurse, midwife, doctor or ODP. (The MHRA is consulting (April 2007) on potential changes to the legislation which if approved would add pharmacists to this list.) Both practitioners should be present during the whole of the administration procedure. They should both witness:

- The preparation of the CDs to be administered.
- The CD being administered to the patient.
- The destruction of any surplus drug (e.g. part of an ampoule infusion not required).

A record should be made in the ward or department CD Record Book when a CD is removed from the CD cupboard.

4.11.1.2 For CDs administered the following details should be recorded:

- Date and time when dose administered
- Name of patient
- Quantity administered
- Form (name, formulation and strength) in which administered
- Name/signature of nurse/authorised person who administered the dose
- Name/signature of witness (where there is a second person witnessing administration)
- Balance in stock

4.11.1.3 If part of a vial is administered to the patient, the registered nurse, midwife or registered health professional should record the amount given and the

amount wasted e.g. if the patient is prescribed 2.5 mg diamorphine and only a 5mg preparation is available, the record should show, "*2.5mg given and 2.5mg wasted* " This should be witnessed by a second registered nurse midwife or registered health professional who should also sign the record. If a second registered nurse midwife or registered health professional is not available, the transaction can be witnessed by another registered practitioner (e.g. doctor, pharmacist, pharmacy technician) or by an appropriately trained healthcare assistant.

4.11.1.4 Individual doses of CDs which have been prepared but not administered should be destroyed by a registered nurse midwife or registered health professional on the ward or department in the presence of a witness and the reason documented in the CD Record Book.

(For appropriate methods of destruction see paragraph 4.16 Disposal and destruction of CDs).

4.12 Management of CDs when patients are admitted

See paragraph 5.4 Management of CDs that are the patient's property

4.13 Management of CDs when patients are transferred to other wards or departments

See paragraph 5.2 Transfer of CDs

There should be a local procedure which covers all aspects of the safe management of patient-controlled analgesia. This should include:

- A description of the CD preparations available and the medical devices (for example, pumps, syringe drivers) used for administration
- Arrangements for requisitioning the appropriate medical devices
- Instructions for prescribing and requisitioning the CD preparations (for example, pre-loaded syringes, small volume infusion bags)
- Specification of the entries required in the CDRB
- Arrangements for documentation when the patient is moved from theatre to wards
- Arrangements for recording administration
- Arrangements for disposal of surplus CDs

4.14 Management of CDs when patients are discharged

See paragraph 4.10.2 Prescribing for discharge patients and 7.10 Supply to outpatients and discharge patients

4.15 Returning controlled drugs to the pharmacy

4.15.1 Unused CD stock from wards or departments may be returned to the pharmacy. Such CD stock can be re-issued by the pharmacy provided it was initially issued by that pharmacy and has at all times been under the control of that hospital. The pharmacy department should carry out a risk assessment of CDs returned to pharmacy to ensure they are fit for re-use.

Controlled Drugs that are time-expired or otherwise unfit for use (e.g. opened liquids) should also be returned to the pharmacy for safe destruction and onward disposal.

Any other controlled drug that is no longer needed on the ward should be returned to pharmacy. This should be done as soon as is practicable. Local policies may define time limits.

4.15.2 Records of CDs returned

The ward or department should keep a record of drugs returned to pharmacy. This may be in the form of a returns advice note with duplicate pages so that both the pharmacy and the ward have a record of the transaction.

The following details should be recorded when CDs are returned to the pharmacy:

- Date
- Name, form, strength and quantity of drug being returned
- Reason for return
- Name and signature of the registered nurse, midwife or ODP

The top copy will be taken from the book and transported with the drugs to the pharmacy.

In addition, an entry should be made on the relevant page of the ward CDRB, showing:

- Date
- Reason for return
- Names and signatures of the registered nurse, midwife or ODP responsible and a competent witness
- Quantity removed
- Name, form and strength of drug
- Balance remaining

The drugs should be transferred to the pharmacy in a safe and secure way. (See paragraph 5.2 transfer of CDs)

4.16 Disposal of controlled drugs in wards and departments

See also paragraph 7.15 Disposal of CDs in pharmacies

In the interests of safety and containment of environmental pollution, CDs should, as far as is practicable, be returned to the pharmacy for safe denaturing and disposal.

CDs should be destroyed in such a way that the drug is denatured or rendered irretrievable so that it cannot be reconstituted or re-used. Where denaturing is carried out on the wards, the methods used should be those currently recommended by the RPSGB [Guidance for Pharmacists on the safe destruction of Controlled Drugs: England, Scotland and Wales. www.rpsgb.org.uk/pdfs/cdsafedestructionguid.pdf]

Some health care organisations may wish to provide denaturing kits for use on wards to destroy CDs that have been used for patients. This may be appropriate on wards or departments where large quantities of CDs are used and where the volume of part-used vials, ampoules, syringes and infusion bags may be high. A risk assessment should be carried out before a decision is made whether denaturing kits should be available on the wards. Where denaturing kits are provided to wards or department, an SOP should be developed for this practice.

4.16.1 Disposal of small amounts of CDs

4.16.1.1 Only small amounts of CDs should be destroyed on wards, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or when a dose is drawn up but not used. Larger quantities of CDs, for example, discontinued infusions or patient-controlled analgesia (PCA) syringes, should be either be returned to the pharmacy for safe denaturing and disposal or denatured on the ward using denaturing kits.

4.16.1.2 All destruction must be documented in the appropriate section of the CD record book (see below). It should be witnessed by a second competent professional such as a registered nurse, midwife or ODP. Both persons should sign the CD record book.

4.16.2 Method of disposal

Small amounts of CDs, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or when a dose is drawn up but not used, should be rendered irretrievable by emptying into a sharps bin. The emptied vial or ampoule should then also be placed in the sharps bin. When the bin is sent for destruction it should be labelled "*contains mixed pharmaceutical waste and sharps – for incineration*".

5 Management of CDs – general processes and specific circumstances

Contents of this chapter:

5.1 Controlled Drug stationery

All stationery which is used to order, return or distribute controlled drugs (CD stationery) should be stored securely and access to it should be restricted. These measures are important to guard against unauthorised use of the stationery to obtain CDs for inappropriate purposes.

5.1.1 Definition of CD stationery

CD stationery includes:

- Controlled drug requisition books
- Controlled drug record books
- Local CD documents such as CD returns advice notes, pharmacy distribution documents

5.1.2 Secure storage of CD stationery

CD stationery which is kept in wards, theatres or departments should be kept in a locked cupboard or drawer.

Stocks of CD stationery held in pharmacy departments should be kept in a secure area that is locked when there is no one present.

5.1.3 Supply of CD stationery

CD stationery should be issued from the pharmacy against a written requisition signed by an appropriate member of staff. The local policy should define the groups of staff who can sign requisitions for CD stationery.

5.1.3.1 A record should be kept of the supply of CD stationery. It should include:

- Date
- Ward/department
- Name of person ordering the stationery
- Type of stationery issued
- Quantity
- The serial numbers of the stationery
- Signature of the member of pharmacy staff making the supply
- Signature of member of staff receiving the stationery

5.1.3.2 Any unused stationery returned to pharmacy will be recorded as a return, with the details above, in the supply record.

5.1.3.3 Health care organisations may wish to number CD requisition books to provide an additional means of tracking.

5.1.4 Loss or theft of CD stationery

Loss or theft of any controlled stationery which may be used to order CDs should be reported immediately to the chief pharmacist and Accountable Officer.

5.1.5 Use of CD stationery

Only one CD requisition book per ward or department should normally be in use.

5.1.5.1 When a new CD Record Book is started, the balance of CDs in stock should be written into the new book promptly by ward staff. This transfer should be witnessed by a registered nurse, midwife or operating department practitioner or authorised member of staff e.g. pharmacy technician.

5.1.5.2 Completed ward requisition books and CD record books must be retained for a minimum of two years from the date of the last entry. (See paragraphs 4.9 and 7.9 Archiving of records)

5.2 Transfer of CDs within and outside the hospital

Transfer of CDs is likely to involve the following situations:

- Collection by ward staff from the pharmacy
- Collection by porters from the pharmacy
- Delivery by pharmacy staff to wards, departments, theatres
- Collection by patient or representative for outpatient items only;
- Delivery by Trust porter/driver
- Delivery by commercial courier (for example, taxi out-of-hours)
- Delivery using recorded delivery Postal Service (The use of postal services should not be routine but should be limited to exceptional situations such as when there is an urgent clinical need.)

5.2.1 Methods of transfer

Wherever possible, CDs should be transferred or conveyed in a secure, locked or sealed, tamper-evident container.

5.2.1.1 Depending on local circumstances, some health care organisations may choose to use bags with numbered seals for delivery and require a signature for receipt of the bag with the correctly numbered seal. Whatever system is used it must be fully auditable and explicit as to who has custody of the controlled drugs at any point in time.

5.2.1.2 CDs may not be transported in pneumatic tubes.

5.2.2 Records of transfer

At each point where a controlled drug moves from the authorised possession of one person to another, a signature for receipt should be obtained by the person handing over the drug and the person receiving it.

5.2.2.1 Health care organisations may wish to design local distribution/transport documentation as a means of keeping a full audit trail.

5.2.3 Messengers

The person who conveys the CD acts as a messenger, that is to say he/she carries a sealed or locked container and is responsible for delivering the intact container.

5.2.3.1 The person acting as the messenger should:

- Ensure destination is known

- Be aware of safe storage and security, the importance of handing over the item to an authorised person and obtaining a signature for delivery on the delivery document.
- Have valid ID badge

5.2.3.2 Health care organisations may wish to stipulate that CDs should only be handed to members of staff who are wearing valid ID badges.

5.2.3.3 Where a commercial courier or taxi driver is responsible for conveying a CD he/she should be asked to show their valid company ID, as they would for any other medicine.

- Taxi drivers or commercial couriers should not be made aware that CDs are being transported as this may increase the potential for diversion or may discourage taxi drivers from carrying CDs.
- As a matter of good practice the taxi registration number may also be recorded.

5.2.3.4 Health care organisations may wish to keep a list of porters who are authorised to transfer controlled drugs. A list of their names with sample signatures may be kept in pharmacy for validation purposes.

5.2.4 Transfer from ward to ward or theatre to ward

Local procedures should define safe, secure and auditable methods to transfer CDs from ward to ward when a patient moves. The three situations in which this is most likely to arise are:

- When a patient is receiving a CD by means of syringe pump (PCA pump) or infusion
- When a patient has his/her own CDs for self-administration
- When a CD has been dispensed on a “named-patient” basis

5.2.4.1 Patients’ own Controlled Drugs should be transferred from ward to ward with the patient in line with local procedures for transferring all other medicines and properties belonging to that patient.

5.2.4.2 There should be a local procedure for all aspects of the management of patient controlled analgesia. This should include:

- A description of the CD preparations available and the medical devices (for example, pumps, syringe drivers) used for administration
- Arrangements for requisitioning the appropriate medical devices
- Instructions for prescribing and requisitioning the CD preparations (for example, pre-loaded syringes, small volume infusion bags)
- Specification of the entries required in the CDRB

- Arrangements for documentation when the patient is moved from theatre to wards
- Arrangements for recording administration
- Arrangements for disposal of surplus CDs

See also paragraph 5.4 managing CDs that are the patient's property

5.2.5 Transfer from ward to pharmacy

When CDs have to be returned to the pharmacy they should be placed in a secure container and handed to an authorised messenger. (See paragraph 4.15 Returning CDs to the pharmacy)

5.3 Clinical trials

The procedures for the use of CDs in clinical trials must comply with the MDR and with local policies governing the management of clinical trial medicines, in addition to clinical trials legislation and MHRA guidance on clinical trials.

5.3.1 Storage and records

5.3.1.1 All clinical trial CDs should be stored separately from stock CDs. They do not necessarily need to be stored in a separate CD cupboard. A separate page in the register should be used to record receipt and issues in addition to clinical trial documentation so that a running balance of trial stock can be kept.

5.3.1.2 If a discrepancy is identified then it should be reported on the internal incident reporting system in accordance with local procedures. A note to file should be stored with all the clinical trials documentation. The sponsor and investigator should be informed and also the chief pharmacist and AO. (See also paragraph 5.9 Discrepancies and diversion)

5.3.1.3 For double blind trials in which only one arm involves a CD, pharmacy staff may be unaware which packs contain CDs. In this situation, all supplies should be treated as CDs until the end of trial.

5.3.1.4 For trials that involve the use of Schedule 1 CDs, such as cannabinoids, a licence from the Home Office must be obtained before the item is received into stock or supplied. The licence should normally be held by the Chief Pharmacist and/or the AO. A copy should be kept with the trial protocol.

5.3.2. Labelling

All clinical trial CDs must be labelled and dispensed in accordance with the specific trial protocol in addition to the MDR requirements.

5.3.2 Disposal

Clinical trial CDs must be destroyed in the same way as other CDs. (See section 7. 15 Destruction of controlled drugs in pharmacies) However, this destruction may need to be carried out following the monitoring instructions with the trial sponsor. For example, the sponsor may wish to carry out an independent reconciliation (in addition to the check and reconciliation carried out by the pharmacy department) prior to any destruction.

5.3.4. Clinical trial CDs returned by patients

The pharmacy should establish secure arrangements for the storage (and destruction) of CD clinical trial medicines returned by patients. Drug accountability records should be completed promptly when a patient returns the CD clinical trial medicine and opportunities for diversion should be minimised.

5.3.5 Arrangements for research departments

If a hospital pharmacy supplies CDs to a research department, then the same governance arrangements for safe use should apply as for elsewhere in the organisation. All the activities should be covered by SOPs and the processes should be robust and auditable.

5.4 Management of CDs that are the patient's property

A local procedure should be in place for the management of CDs that are the patient's property.

5.4.1 Use of a patient's own controlled drugs on the ward

It may be appropriate to use a patient's own CDs (i.e. CDs brought into the hospital by the patient on admission) whilst they are in hospital, for example, if the patient is self-administering other medicines. On such occasions the drugs should be checked for suitability according to the local procedure for patients own drugs (PODs) to ensure that they are fit for purpose. (See paragraph 5.4.4 Self administration of CDs)

5.4.1.1 If patients' own CDs are not required for use in this way then one of the following procedures should be followed and all actions should be recorded:

- If the patient or the patient's agent agrees, medicines may be sent to the pharmacy for safe destruction. The pharmacist should take responsibility for destruction.
- If the patient wishes, the medicines may be returned home via an identified adult. Responsibility for security is given to that adult. If the medicines are not safe and/or appropriate for use, then the

patient and/or patient's agent should be advised and they should be encouraged to send them to the pharmacy for safe destruction

5.4.1.2 Patients' own CDs that are not to be used for self-administration should not routinely be stored on the ward.

5.4.1.3 Temporary storage of patients' own controlled drugs on the ward may be necessary whilst they are awaiting collection and removal to the pharmacy or to the patient's home. In this situation, they should placed in the CD cupboard but should be clearly marked and kept separate from ward stock.

5.4.1.4 Patient's own controlled drugs should never be used to treat other patients.

5.4.2 Controlled drug discharge medicines (TTOs)

When CD discharge medicines (TTOs) are sent to the ward several hours before the patient leaves, the medicines may be stored in the CD cupboard. These medicines should be segregated from the ward CD stock and clearly marked and should remain in a sealed bag.

When Schedule 2 CD TTOs are collected from the pharmacy, the person collecting them (who may be the patient, his representative, a health care professional or porter) should be asked to sign for receipt as a matter of good practice.

5.4.3 Receipt of CDs by outpatients

Patients or their representatives may be asked to provide evidence of identity when collecting CDs.

From July 2006, there has been a requirement for persons asked to supply CDs on prescription to seek to establish whether the person collecting the medicine is the patient, their representative or a healthcare professional acting in his professional capacity on behalf of the patient.

Where the person is the patient or their representative, the dispenser:

- **May** request evidence of that person's identity and
- May refuse to supply the medicine if he is not satisfied as to the identity of the person

Where it a healthcare professional acting in his professional capacity on behalf of the patient, the dispenser:

- **Must** obtain the person's name and address
- **Must,** unless he is acquainted with that person, request evidence of that person's identity; but

- **May** supply the medicine even if he is not satisfied as to the identity of the person

Any strengthening of controls has been balanced with ensuring that patients have access to medicines they need and have been prescribed for them. The new requirement placed on the dispenser therefore allows them:

- Discretion not to ask patients or patient representatives for proof of identity if, for example, they have concerns that to do so may compromise patient confidentiality or deter patients from having their medicines dispensed.

From 1st February 2008, it will be a requirement to record the following information in the CD register for Schedule 2 CDs supplied on prescription:

- 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 and address
- If the person who collected the drug was the patient or their representative, whether evidence of identity was requested (as a matter of good practice a note as to why the dispenser did not ask may be included but this is not mandatory).
- And whether evidence of identity was provided by the person collecting the drug.

Depending on local circumstances, some health care organisations may wish to stipulate that outpatients receiving CDs sign for receipt of a specified number of doses.

5.4.4 Self-administration of CDs

A local procedure should be in place for wards or departments where patient self-administer their own medicines including their CDs.

5.4.4.1 When patients who self-administer CDs require additional supplies, these should be dispensed for discharge. Health care organisations may wish to consider whether the administration of these CDs is recorded in the CDRB or they may consider having a separate book for recording of CDs that are self-administered.

5.4.4.2 Patients receiving CDs for self-administration should sign for receipt of a specified number of doses.

5.4.4.3 Health care organisations may wish to stipulate that these CDs are entered in and out of the ward CDRB so that there is an auditable record of their arrival on the ward. A daily count of the quantity of the CDs in the patient's individual medicines cabinet may be made by the registered

nurse, midwife or other healthcare professional and recorded on the medicines chart or in the CDRB

5.4.4.4 The CDs for patients who self-administer their medicines should be kept in a locked metal receptacle immediately adjacent to their bed, or in their bedside locker. The receptacle should not be easily portable. Health care organisations may wish to consider the use of electronic patient medicines lockers accessed by means of programmable transponders. Such systems provide a high level of security and a clear record who accessed the locker and when.

5.4.4.5 Useful sources of information about controlled drugs for patients are listed at Appendix 5.

5.5 Out-of-hours supply

Under the current Regulations, a ward sister (or the registered nurse, midwife or ODP in charge) can only supply CDs to a patient on that ward, theatre or department in accordance with the written instructions of an authorised prescriber.

Every effort should be made to ensure that adequate stock levels are maintained to meet likely needs.

Local arrangements for emergency issues of CDs should be discussed with the Accountable Officer and/or chief pharmacist. Where such systems exist, an SOP should be developed.

5.6 Temporary ward closure and transfer of wards

5.6.1 Temporary ward closure

There should be a local procedure for the management of CDs during short and long term ward closures. The procedure should ensure the security of the CDs and should be auditable.

5.6.1.1 The procedure should include:

- A provision for a risk assessment to be carried out
- Arrangements for removal and temporary storage of CDs by the pharmacy, if appropriate
- Arrangements for return of CDs to the pharmacy for re-use, if appropriate
- Specification of the entries required in the CDRB
- Arrangements for secure storage of current (i.e. in use) CD stationery during closure
- Arrangements for return of stocks, including reconciliation with list of CDs removed, if appropriate
- Arrangements for restocking, if appropriate

5.6.1.2 As a matter of good practice, the list of authorised signatories for the ward that is kept in the pharmacy must be annotated by the pharmacist or pharmacy technician responsible for stock control of medicines on the ward so that the pharmacy and audit staff are aware that the ward is temporarily closed. The list will need to be reviewed by the ward pharmacist when the ward reopens, to ensure that signatures are valid and up to date.

5.6.2. Transfer of wards

When a ward moves to another location, a decision must be made as to whether its CDs and CDRBs may be transferred or, where swapping of wards occurs, left on the ward. This will depend upon the appropriateness of the stock list, the periods for which ward premises will be unoccupied and the security of the drugs during this time. (See paragraph 5.6.1 Temporary ward closures).

5.6.2.1 There should be a local procedure for the management of CDs during ward moves. This procedure should ensure the security of the CDs and should be auditable.

5.6.2.3 The procedure, which should have been agreed with the pharmacy department should include:

- A provision for a risk assessment to be carried out
- Arrangements for transfer of CDs and CDRBs, if appropriate
- Arrangements for checking and reconciliation of stocks, in particular when ward staff transfer but CDs and CDRBs are left in place
- Specification of the entries required in the CDRB, in particular when ward staff transfer but CDs and CDRBs are left in place

5.6.2.4 The pharmacist or pharmacy technician responsible for stock control of medicines on the ward should ensure that the ward signatory lists and stock lists are updated to reflect the new ward location/name/number.

5.7 Paediatrics

The management of CDs in paediatrics does not differ significantly from the management in adult care and so all the general provisions apply. There are, however, a few specific situations when the management of CDs may require a slightly different approach.

5.7.1 Part vials of controlled drugs

On many occasions in paediatrics, the dose required for the patient is smaller than that which is contained in a single vial or ampoule. When a dose is given to a child, an amount may be left, which needs to be discarded. In order to minimise the opportunities for diversion, the following steps should be taken:

- When a dose is given, the nearest suitable dose volume should be selected, so that the minimum volume has to be discarded.
- When only part of the contents of a vial or ampoule are used, the entry made in the ward CD record book (CDRB) should clearly show how much was given to the patient and how much was discarded. For example, if the patient is prescribed diamorphine 2.5mg and only a 5mg preparation is available, the record should show, “2.5mg given and 2.5mg wasted “ This should be witnessed by a second registered nurse, midwife or registered health professional who should also sign the record. If a second registered nurse or midwife is not available, the transaction can be witnessed by another registered health professional (e.g. doctor, pharmacist, ODP, pharmacy technician)
- The CD to be discarded should be rendered irretrievable by emptying into a sharps bin. This should be witnessed by another person. The emptied vial or ampoule should then also be placed in the sharps bin. When the bin is sent for destruction it should be labelled “contains mixed pharmaceutical waste and sharps - for incineration”.
- Some health care organisations may wish to provide denaturing kits for use on wards to destroy CDs that have been used for patients. This may be appropriate where large quantities of CDs are used and where the volume of part-used vials, ampoules, syringes and infusion bags may be high. A risk assessment should be carried out before a decision is made whether denaturing kits should be available on the wards. This is particularly relevant within children’s services. Where denaturing kits are provided, an SOP should be developed for this practice.
- The person who administers the dose is responsible for making the entry and this must be done immediately or as soon as is practicable after administration.
- The destruction should be recorded in the CDRB by both the person who undertook the destruction and the witness.

5.7.2 Child protection

Parents who are substance misusers sometimes bring CDs on to hospital premises. Health care organisations may wish to consider whether, on a parent’s request, they may want to store the CD in the CD cupboard and the parent requests the nurse when a dose is required. These CDs should be clearly labelled and kept separate from other CDs.

Where there are concerns about potential diversion, staff should be alert that this may be a possibility and if appropriate, reference should be made to the appropriate child protection services

5.8 Controlled drugs for midwives

A registered midwife may possess diamorphine, morphine, pethidine and pentazocine in her own right so far as is necessary for the practice of her profession.

5.8.1 Acquisition of CDs by midwives

Supplies of diamorphine, morphine, pethidine and pentazocine may only be made to her on the authority of a midwife's supply order signed by the Supervisor of Midwives, or other Appropriate Medical Officer who is a doctor authorised in writing by the local supervising authority.

5.8.1.1 The Supervisor of Midwives or other Appropriate Medical Officer should be satisfied that locally agreed procedure is being followed before signing the supply order (e.g. that the amount being requested is appropriate).

5.8.1.2 The order must specify the name and occupation of the midwife, the purpose for which the controlled drug is required and the total quantity to be obtained.

5.8.1.3 Supplies of pethidine, pentazocine, morphine and diamorphine may be obtained from a hospital pharmacy. The pharmacist who makes the supply must ensure that medicines are only supplied on the instruction of an authorised person.

5.8.1.4 The pharmacist must retain the midwife's supply order for two years.

5.8.2 Storage and records

Midwives should record full details of supplies of diamorphine, morphine and pethidine received and administered in their Controlled Drugs Register. This register should be used solely for that purpose and be made available for inspection as required by the Supervisor of Midwives.

5.8.2.1 Once medicines are received by midwives working in the community or self-employed midwives, they become the responsibility of the midwife, and should be stored safely and securely.

5.8.2.2 Where it is necessary for midwives to keep medicines in their homes, the medicines should be placed in a secure, locked receptacle. If necessary, this should be provided by the employing body.

5.8.2.3 Administration of Controlled Drugs by midwives should be in accordance with locally agreed procedures.

5.8.2.4 A record of administration of the CDs should also be kept in the woman's records.

5.8.3 Returns and disposal

When a midwife is in possession of CDs that are no longer required they should be returned to the pharmacy from which they were obtained, another pharmacy or to an Appropriate Medical Officer, who should make arrangements for safe disposal. A record of the return should be made in the midwife's Controlled Drugs Register.

5.8.3.1 Surplus or expired CD stock held by a midwife may only be destroyed by the midwife in the presence of an authorised witness. (see paragraph 7.15.1.1) The method of disposal should be in accordance with current Home Office guidance, Waste Management Regulations and Environment Agency guidance. CDs for destruction should be denatured using an approved method (see 7.15.3) and sent for incineration; they should not be disposed of in the sewerage system. The midwife could also return surplus or expired stock to a pharmacy for safe destruction and onward disposal.

5.8.3.2 When a Schedule 2 CD has been prepared/drawn up but is no longer required, and/or no longer usable, it should be destroyed by the midwife, in accordance with current Regulations. Where possible a member of the family should witness the destruction. A record of the destruction should be made in the midwife's record. Some health care organisations may wish to provide denaturing kits to midwives to ensure safe destruction.

5.8.3.3 Controlled drugs that have been prescribed for a woman by her doctor for use in her home confinement are her own property and are not the midwife's responsibility. Even when no longer required they should not be removed by the midwife, but the woman should be advised to return them to the community pharmacy for destruction. Where this is not possible, the midwife should obtain the patient's agreement in writing before removing it from the patient's home and returning it to a pharmacy for safe disposal, on behalf of the woman.

5.9 Discrepancies and diversion

The balances in the Controlled Drug record books (CDRBs) should always tally with the amounts of CDs in the cupboard. If they do not, the discrepancy must be reported, investigated and resolved. It is important to remember that a discrepancy can indicate misuse.
There should be a procedure for dealing with discrepancies and this should specify the arrangements for reporting and investigation.

In the first instance the following should be carefully checked:

- All requisitions received have been entered into the correct page of the register
- All CDs administered have been entered into the CDRB
- Items have not been accidentally put into the wrong place in the cupboard
- Arithmetic to ensure that balances have been calculated correctly

If the error or omission is traced, the registered nurse, midwife or ODP in charge should make an entry in the CDRB, clearly stating the reason for the entry and the corrected balance. This entry should be witnessed by a second nurse, midwife, ODP, pharmacist, pharmacy technician or doctor. Both persons will sign the CDRB.

If no errors or omissions are detected then the discrepancy should be reported to the Chief Pharmacist and the Accountable Officer without delay and a local incident form completed in line with the health care organisation's policy or procedure for reporting incidents.

5.10 Illicit substances

The health care organisation should take advice from the local police and if necessary the Serious and Organised Crime Agency concerning appropriate procedures for dealing with patients who bring suspected illicit substances into the hospital.

6 Management of CDs in in-house operating theatres

Contents of this chapter:

This chapter describes measures for management of CDs in in-house operating theatres and departments where CDs are used primarily by anaesthetists.

6.1 Accountability and responsibility

6.1.1 Accountable individuals

The registered nurse, midwife or Operating Department Practitioner (ODP) in charge of an operating theatre or theatre suite is responsible for the safe and appropriate management of CDs.

The registered nurse, midwife or ODP in charge can delegate control of access (i.e. key-holding) to the CD cupboard to another, such as a registered nurse or an ODP. A nurse or ODP may then only remove controlled drugs from the cupboard and/or return them to the cupboard on the specific authority of either the registered nurse, midwife or ODP in charge or doctor. However, legal responsibility remains with the registered nurse, midwife or ODP in charge. Whilst the task can be delegated, the responsibility cannot. (The person to whom the task has been delegated is still professionally accountable for his/her actions)

Similar considerations apply to requisitioning and checking of CDs.

6.1.2 Standard operating procedures

The health care organisation should ensure that all the procedures for the management of CDs in in-house operating theatres and recovery wards are included in written standard operating procedures and that all staff, including anaesthetists, are aware of these procedures. It is good practice to ensure all staff who have to work in accordance with SOPs have an opportunity to comment on draft versions before the SOPs are finalised to ensure ownership. This is especially important in areas where many different staff are working perhaps for only a small part of their working week.

SOPs should be discussed with and approved by the Accountable Officer or by the person to whom he has delegated this task. The AO remains accountable for the safe management of CDs

6.2 Controlled Drug stocks

There should be a list of CDs to be held in each theatre as stock items. The contents of the list should reflect current patterns of usage of CDs in the theatre and should be agreed between the pharmacy technician or pharmacist responsible for stock control of medicines in the theatre and the Operating Department manager, appropriate medical staff and the registered nurse, midwife or ODP in charge.

The list should be modified if practices change and should be subject to regular review at agreed intervals.

6.3 Requisitioning of CDs

The registered nurse, midwife or ODP in charge is responsible for the requisitioning of controlled drugs for use in the theatre. The registered nurse, midwife or ODP in charge is not permitted to requisition controlled drugs from wholesalers.

The registered nurse, midwife or ODP in charge can delegate the task of preparing a requisition to another, such as a registered nurse or registered ODP. However, legal responsibility remains with the registered nurse, midwife or ODP in charge.

Wherever practicable different persons should be responsible for requisitioning and receipt of Controlled Drugs.

Requisitions must comply with the requirements for suitable stationery, authorised signatories and content set out in paragraph 4.3 Requisitioning of controlled drugs

Health care organisations should consider the introduction of a pharmacy-led top-up scheme as an efficient way of maintaining adequate stock levels of CDs in theatres

6.4 Receipt of controlled drugs

When CDs are delivered to a theatre or theatre suite they should be handed to an appropriate individual. On no account should they be left unattended. (See paragraph 5.2 Transfer of CDs). A local procedure should define the persons who are permitted to receive CDs and the way in which messengers identify them. As a

matter of good practice the receiving person should not normally be the same person who ordered the controlled drugs.

Receipt of CDs in theatre should follow the provisions set out in section 4.4 Receipt of controlled drugs

6.5 Storage of controlled drugs

The storage arrangements for CDs in theatres should conform to the general provisions set out in section 4.5 Storage of controlled drugs

Where robotic storage cabinets are installed in theatre areas, access should be controlled by secure passcodes and the software should provide an auditable record of transactions.

It may also be necessary to install separate, secure, CD fridges for aseptically-prepared parenteral doses of CDs.

6.6 Record-keeping

The records for CDs in theatres should conform to the general provisions set out in section 4.7 Record-keeping

There should be a separate CD record book for each theatre.

In addition to the standard CD record books, some health care organisations may wish to stipulate the use of stationery that permits more detailed records of CDs issued, administered and destroyed.

6.7 Controlled drug stock checks

The stock balance of all controlled drugs entered in the CD Record Book should be checked and reconciled with the amounts in the cupboard with sufficient frequency to ensure that discrepancies can be identified in a timely way. The frequency of such checks should be determined locally after a risk assessment has been carried out.

The registered nurse, midwife or ODP in charge is responsible for ensuring that stock checks are carried out and recorded. It may be appropriate for pharmacy staff to carry out a stock check at regular intervals but this should be at least every six months.

Controlled drug stock checks should follow the provisions set out in paragraph 4.8 Controlled drug stock checks

6.8 Archiving of controlled drug records

The archiving of CD records in theatres should conform to the general provisions set out in paragraph 4.9 Archiving of controlled drug records

6.9 Prescribing of controlled drugs

The anaesthetist on duty is usually responsible for prescribing CDs but other prescribers may also be involved. Nurse Independent Prescribers may also be responsible for prescribing or administration of diamorphine and morphine for post-operative pain. In future - subject to the outcome of public consultation and Ministerial approval - Nurse Independent Prescribers may be able to prescribe other CDs in addition to the ones they are already able to prescribe and pharmacist independent prescribers may also be able to prescribe CDs.

Where separate charts are used e.g. epidural charts, anaesthetic charts they should be cross-referenced on the patient's main medicines chart.

Prescribing of CDs should follow the general provisions set out in paragraph 4.10 Prescribing of controlled drugs.

6.10 Administration

The practice of issuing "active stock" to the anaesthetist and then returning the unused portion to stock, recording both issues and returns in the theatre CD record book, should be avoided. [See *Controlled Drugs in Perioperative Care. January 2006. www.aagbi.org*] An amount should be issued to the anaesthetist for a specific patient and any surplus drug should be destroyed and witnessed. E.g. if the patient is prescribed diamorphine 2.5mg and only a 5mg preparation is available, the record should show, "*2.5mg given and 2.5mg wasted* "

- The CD to be discarded should be rendered irretrievable by emptying the contents of the ampoule or vial into a sharps bin. The emptied vial or ampoule should then also be placed in the sharps bin. When the bin is sent for destruction it should be labelled "mixed pharmaceutical waste and sharps – for incineration".
- Injectables should be treated as intended for single use only unless the label specifically indicates that they are licensed and intended for use on more than one occasion or to provide more than a single dose on any one occasion.
- A record of administration should be made on the appropriate chart immediately after administration by the person who administered the CD. This should include the identity of the person, the dose administered and the time of administration.

6.11 Patient-controlled analgesia

There should be a local procedure for all aspects of the management of patient controlled analgesia. This should include:

- A description of the CD preparations available and the medical devices (for example, pumps, syringe drivers) used for administration
- Arrangements for requisitioning the appropriate medical devices
- Instructions for prescribing and requisitioning the CD preparations (for example, pre-loaded syringes, small volume infusion bags)
- Specification of the entries required in the CDRB

- Arrangements for documentation when the patient is moved from theatre to wards
- Arrangements for recording administration
- Arrangements for disposal of surplus CDs

6.12 Returning controlled drugs to the pharmacy

The arrangements for return of CDs to the pharmacy should conform to the provisions set out in paragraph 4.15 Returning controlled drugs to the pharmacy

In general, time-expired or CDs that are otherwise unfit for use should be returned to pharmacy for safe disposal.

Surplus stock should be returned to the pharmacy as described in section 4.15

6.13 Disposal of controlled drugs

The disposal of CDs in theatres should conform to the general provisions set out in section 4.16 Disposal of controlled drugs in wards and departments

Unused part-doses should be destroyed promptly and witnessed by a registered nurse or registered ODP.

- The CD to be discarded should be rendered irretrievable by emptying the contents of the ampoule/vial into a sharps bin. The emptied vial or ampoule should then also be placed in the sharps bin. When the bin is sent for destruction it should be labelled, “contains mixed pharmaceutical waste and sharps – for incineration”.
- If large quantities of part used CDs are being added to sharps bins, some health care organisations may wish to provide denaturing kits for use to theatres to destroy CDs that have been used for patients. A risk assessment should be carried out before a decision is made whether denaturing kits should be available in theatres. Where denaturing kits are provided to theatres, an SOP should be developed for this practice.

7 Management of CDs in hospital pharmacies

Contents of this chapter:

This chapter deals with the management of CDs in hospital pharmacies and between pharmacies and other departments or health and/or social care bodies.

7.1 Accountability and responsibility

The chief pharmacist is responsible for the safe and appropriate management of CDs in the pharmacy. Day-to-day management of CDs (for example, receipt into and issue from dispensary stock) in the pharmacy will normally be delegated to a suitably-trained, competent registered pharmacy technician or pharmacist. However, legal responsibility for CDs remains with the Chief Pharmacist.

7.2 Security of CDs

The pharmacy should have standard operating procedures (SOPs) covering each of the aspects of the safe management of CDs such as ordering, receipt, record-keeping etc.

SOPs should be kept up-to-date, reflecting current legal and good practice requirements for CDs, and each one should be clearly marked with the date of issue and review date.

SOPs should be approved by the Accountable Officer or by the person to whom he has delegated this task. The AO remains finally accountable for all the systems for the safe management of CDs. (See Appendix 2)

7.3 Ordering and receipt

Ordering of CDs from wholesalers and manufacturers and receipt of CDs should follow the principles of good procurement. Local procedures should ensure that there is a robust audit trail and that the opportunities for diversion are minimised.

7.3.1 Ordering

Routine orders to wholesalers and manufacturers for Controlled Drugs for stock are usually placed electronically. Some health care organisations may, following a risk assessment, make a decision to store paper records.

Stock levels should be determined by need and kept to a minimum, but should not be so low that there is a danger of running out at busy periods. This will normally be calculated by the pharmacy stock management system. It may be necessary to increase stock levels temporarily when it is anticipated that there may be a greater demand, for example, during long holiday breaks.

7.3.2 Receipt

There should be a local procedure for the receipt of CDs into the pharmacy department. The procedure should ensure the security of CDs and should be auditable. It should include:

- Who should sign for receipt
- How the goods should be checked (e.g. matching of the details on the delivery note to the goods) and appropriate stock control documentation completed
- Any tamper-evident seals on packs should be left intact when they are received from the supplier. This will simplify and speed up routine balance checks.
- If when the tamper evident seal is broken, the contents do not match the expected amount stated on the pack, the pharmacy should contact the supplier.
- The action to be taken if the item received is incorrect
- Arrangements for storage of incorrect items for return, if appropriate
- Specifications of the entry required in the register including who should make the register entry and whether a witness is required

7.3.2.1 It is good practice to record receipt at the first opportunity, and in any event no later than 24 hours after receipt.

7.3.2.2 As a matter of good practice the balance in stock should be checked and recorded as correct by the person making the entry

7.3.2.3 The stock must be put away into the appropriate section of the Controlled Drug cabinet promptly.

7.4 Storage

Pharmacy CD cabinets must comply with the Misuse of Drugs (Safe Custody) Regulations

This is a minimum security standard and may not be sufficient for areas where there are large amounts of CDs in stock at a given time and/or there is not a 24-hour staff presence or easy control of access. . In this case a security cabinet that has been evaluated against the SOLD SECURE standard SS304 (See www.soldsecure.com) should be used.

7.5 Issuing of CDs to wards and departments

There should be a local procedure for the issuing of CDs to wards and departments. The procedure should ensure the security of the CDs and should be auditable. It should include:

- The procedure for checking that the requisition is valid (complete and signed by an authorised signatory – names should be detailed in local SOPs)
- The mechanism for correcting an incomplete or inaccurate requisition
- Specifications of the details required on labels (see below)
- Specification of entry required in the register including who should make the register entry
- Whether a witness is required. The decision as to whether a witness is required or not should be made following a risk assessment.
- Arrangements for transfer of the CDs to the ward or department

7.5.1 Electronic systems

Where electronic systems for the requisitioning of CDs are introduced, safeguards in the software should be put in place to ensure that:

- Only individuals who are authorised to requisition CDs from the pharmacy can do so
- Entries cannot be altered at a later date
- A log of all data entered is kept and can be recalled for audit purposes.

7.5.2 Labelling of CDs

There should be a standardised procedure for labelling CDs.

The label should state:

- Drug name, form and strength
- Quantity
- “Store in CD cupboard”
- Department / ward name or number
- Date of issue
- Expiry date if dispensed from bulk. (NB: Certain preparations have a reduced expiry once opened, e.g., Oramorph).
- “Keep out of reach and sight of children”
- Address of pharmacy

Depending on local circumstances, some pharmacies may also wish to add

- The requisition number
- The batch number of a product that has been dispensed from bulk

Each carton, syringe or bottle must be labelled individually. In addition, labels may also be placed on outer wrappers or containers.

7.6 Record-keeping

7.6.1 CD registers

Pharmacy department are required to keep registers of receipts and supplies of Schedule 2 CDs.

7.6.1.1 Register entries must be made in consecutive, chronological order. The entry must be made on the day when the drug is received or supplied, or on the next day. Entries must be in ink or be otherwise indelible

7.6.1.2 If a mistake is made the entry should not be crossed out, deleted, obliterated or defaced; liquid paper must not be used. If an error is found, it must be bracketed and accompanied by a clearly recognised signature; the balance shown should be accurate and easily read. A footnote should be added to explain the alteration.

7.6.1.3 The following staff may complete the CD register:

- Any registered pharmacist under their own authority
- Any competent member of Pharmacy staff, ideally a regulated healthcare professional under the authority of the chief pharmacist, provided this is included in the SOP
- Any person who is being trained by a competent member of pharmacy staff, such as a trained technician or a pharmacist, under their supervision. The supervisor should countersign entry

7.6.1.4 Each drug form and strength should be on a different page in the register. The drug name, form and strength must be written at the top of the page. An index should be kept at the front of the register.

7.6.1.5 For CDs supplied, the register entry must also include:

- Date of transaction
- Name and address of person/department supplied
- Licence or authority of person/department supplied
- Amount supplied
- Form in which supplied
- Name of patient, if individually dispensed

7.6.1.6 For CDs received into stock the following details must be recorded in the CD register:

- The date on which the CD was received
- The name and address of the supplier, e.g. wholesaler, pharmacy
- The quantity received
- The name, form and strength of the CD

7.6.1.7 The stock balance in the register should be checked against both the quantity in the CD cabinet and the balance shown in the pharmacy stock control system. The frequency of such checks should be determined locally following a risk assessment.

7.6.1.8 The 2001 Regulations were amended in July 2006 to make clear that the record keeping requirements of the CD Regulations are a minimum and do not prevent any person required to keep a register from including additional relevant information.

7.6.1.9 The 2001 Regulations were further amended in 2007. The changes will come into force **from 1 February 2008**. The "Form of the Register" as specified in Schedule 6 of the 2001 Regulations will be removed and replaced with a requirement to maintain, where appropriate, a CD Register with specified headings/ titles by which to capture mandatory fields of information. Additionally in the CD Register or separate part of the CD Register used for each class of drug, separate pages (in paper) or sections for each strength and form of CD will be required. The name, strength and form of the drug must be entered at the top of each page or section and the mandatory fields of information recorded under the specified headings.

7.6.1.10 The headings/fields of information are largely unaltered from the previous requirements. Entries in respect of drugs supplied and drugs obtained may be made on the same page or separate pages within the CD Register as follows:

7.6.1.11 For CDs supplied the register entry must also include:

- Date supplied
- Name/address of person or firm supplied

- Details of authority to possess, prescriber or licence holder details
- Quantity supplied

7.6.1.12 For CDs obtained the following details must be recorded in the CD Register

- Date supply received
- Name and address from whom received
- Quantity received

7.6.1.13 The Misuse of Drugs And Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007 can be found at http://www.opsi.gov.uk/si/si2007/20072154.htm and Home Office guidance is available at http://www.knowledgenetwork.gov.uk/HO/circular.nsf/79755433dd36a66980256d4f004d1514/457714a5c1da7f8480257338003f2479?OpenDocument

7.6.2 Liquid preparations

Discrepancies can arise with liquids CDs as a result of manufacturer's overage, the measurement process or spillage. Such overage or losses of liquid preparations should be recorded and the running balance adjusted. Stock balances of liquid medicines may be checked by visual inspection but the balance must be confirmed to be correct on completion of a bottle. It may be appropriate to carry out volume checks at regular intervals. When spillages occur, every effort should be made to find another person who can verify that the spillage has occurred and this should be recorded and initialed by both the person making the spillage and the second person, if there is one.

7.6.3 Computerised 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. The Regulations require that entries in computerised registers must be attributable and auditable.

If the CD register is held in computerised form, the following should be put in place:

- Safeguards should be incorporated in the software to ensure the author of each entry is identifiable
- Entries cannot be altered at a later date
- All entries are attributable to an individual making the entry
- A log of all data entered is kept and can be recalled for audit purposes
- Adequate backups are made
- Systems are in place to minimize the risk of unauthorized access to the data

For further details see The Misuse of Drugs and the Misuse of Drugs (Supply to Addicts) (Amendment) Regulations 2005. (SI 2864) www.opsi.gov.uk/si/si2005/20052864.htm.

7.7 Checks of CD stocks performed by pharmacy staff

7.7.1 Checks of CD stocks held in the pharmacy

All controlled drugs in the pharmacy should be checked periodically e.g. every three months. The frequency of such checks should be determined, following a risk assessment, by the pharmacist with operational responsibility for managing CDs and this should be included in an SOP.

7.7.1.1 This check may be undertaken by any competent person approved by the pharmacist with operational responsibility for CDs, the store supervisor, or by a trainee working under their direct supervision and this should be included in an SOP.

7.7.1.2 The check should be recorded in the register by means of signature, date and an appropriate entry, for example, "*Stock checked. Balance correct*".

7.71.3 Some health care organisations may also wish to stipulate periodic checks of CDs by pharmacy managers who do not routinely work in the dispensary.

7.7.2 Checks of CD stocks held in wards, theatres or departments

All stocks of CDs held in wards and departments should be checked by a pharmacist or pharmacy technician at least every three-six months and at other times when requested by the ward or department manager.

7.7.2.1 The stock check procedure should cover the following:

- A check that the levels of drugs in stock tally 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
- Checking and updating (if required) of the list of authorised signatories for CD requisitions
- A check for exceptional usage of CDs
- A check of the physical security arrangement for the storage of CDs, CD stationery and the key-holding policy.

7.7.2.2 The procedure may also include a check of patients' own CDS held on the ward at the time

7.7.2.3 A record of the stock check should be made clearly in ink in the CD Record Book. The entry should be signed and dated by the person who carried it out.

7.7.2.4 Local documentation may be designed to record all aspects of the CD stock-check procedure (e.g. ward CD inspection report forms) for audit purposes.

7.8 Discrepancies

The balance recorded in the hardcopy register and/or, where relevant, the electronic register/pharmacy stock control system, should be reconciled against the stock of every product in the CD cupboard. If one or more of these levels does not tally, the discrepancy must be investigated and resolved without delay. It is important to remember that a discrepancy may indicate misuse. The discrepancy should be reported to a senior pharmacist within one working day.

There should be a careful check of transactions in the register and in the stock control system to trace an error or omission.

If an error is traced then a register entry should be made, clearly stating the reason for the entry, the reference of the error or the omission, the date of the error or omission and the signature of both the person carrying out the amendment and the witness.

If no error or omission can be traced the Chief Pharmacist and Accountable Officer should be informed. They should decide on what action to take.

7.9 Archiving of controlled drug records

Every requisition, order or private prescription on which a Controlled Drug is supplied must be preserved by the Pharmacy department for a minimum period of two years from the date on which the last delivery under it was made. Although the mandatory period for keeping requisitions is two years, health care organisations may wish to store them for longer periods, as cases often come to court at a much later date.

The time periods for archiving CD documentation are:

Requisitions	2 years
Registers and CDRBs	2 years from last entry
Extemporaneous preparation worksheets	13 years
Aseptic worksheets (adult)	13 years
Aseptic worksheets (paediatric)	26 years
External orders and delivery notes	2 years
Prescriptions (inpatients)	2 years
Prescriptions (outpatients)	2 years
Clinical trials	5 years minimum (may be longer for some trials)
Destruction of CDs	7 years

Future Regulations may increase the period of time for the storage of records. Readers are advised to refer to Department of Health and RPSGB websites for up-to-date information

7.10 Supply to outpatients and discharge patients

For outpatient prescriptions being given directly to the patient or their representative:

Patients or their representatives may be asked to provide evidence of identity when collecting CDs.

From July 2006, there has been a requirement for persons asked to supply CDs on prescription to seek to establish whether the person collecting the medicine is the patient, their representative or a healthcare professional acting in his professional capacity on behalf of the patient.

Where the person is the patient or their representative, the dispenser:

- May request evidence of that person's identity and
- May refuse to supply the medicine if he is not satisfied as to the identity of the person

Where it a healthcare professional acting in his professional capacity on behalf of the patient, the dispenser:

- Must obtain the person's name and address
- Must, unless he is acquainted wit that person, request evidence of that person's identity; but
- May supply the medicine even if he is not satisfied as to the identity of the person

Any strengthening of controls has been balanced with ensuring that patients have access to medicines they need and have been prescribed for them. The new requirement placed on the dispenser therefore allows them:

- Discretion not to ask patients or patient representatives for proof of identity if for example they have concerns that to do so may compromise patient confidentiality or deter patients from having their medicine dispensed.

From 1st February 2008, it will be a requirement to record the following information in the CD register for Schedule 2 CDs supplied on prescription:

- 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 and address
- If the person who collected the drug was the patient or their representative, whether evidence of identity was requested (as a matter of good practice a note as to why the dispenser did not ask may be included but this is not mandatory).

And whether evidence of identity was provided by the person collecting the drug.

The patient's date of birth may be used as a second check if necessary.

Depending on local circumstances, some health care organisations may wish to stipulate that outpatients and discharge patients should not just sign for receipt of a dispensed item but also for receipt of a specific number of doses.

7.11 Supply to external units or other health and social care bodies

A hospital pharmacy can only supply to an external organisation if it is registered with the Society or holds a wholesale dealers licence.

Before making a supply to an external unit or other health and social care body, the hospital should satisfy itself that the recipient may lawfully possess controlled drugs. A private hospital that is not maintained by voluntary funds or by a registered charity needs a Home Office Licence to hold CD stocks. The supplier should only make supply if such a licence is held. (For further information see the Home Office see Drug Laws and Licensing pages: www.drugs.gov.uk/drugs-laws/licensing/)

Where the external unit or body is a designated body as defined in the Regulations it will have an Accountable Officer and the AO must ensure that his designated body has up-to-date SOPs for the use and management of CDs.

Where a service level agreement (SLA) is drawn up for a service to supply CDs to an external body or unit, the SLA should specify the SOPs that are to be followed (i.e. those of the provider or purchaser).

If the external unit/body does not have an AO then the SLA should specify that the SOPs of the provider organisation should be followed in relation to CDs.

7.11.1 Supply to external units (i.e. other health and social care bodies)

Other health and social care bodies include community hospitals, hospices, prisons or ambulance trusts.

The other health and social care body must comply with the legislation for controlled drugs and should also follow the guidance in this document.

7.11.2 Written agreement (service level agreement)

When the hospital pharmacy is providing services to another health and social care body the details should be specified in a written agreement or contract (service level agreement).

In relation to controlled drugs the following points should be included in the written agreement (service level agreement):

- What is to be supplied; stock controlled drugs and /or patients' own controlled drugs (e.g., for external units where patients are encouraged to self-administer their own medicines including CDs).
- An outline of the ordering and supplying processes and the documentation used.

- The arrangements for obtaining supplies of CDs in emergencies and out of hours. (These should comply with DH guidance, guidance "Securing proper access to medicines in the out of hours period" and ensure that there is a complete, documented and coherent audit trail from stock room to patient. (See – www.out-of-hours.info/downloads/short_medicines_guidance.pdf)
- Specification of responsibilities and accountability in relation to controlled drugs medicines management including governance arrangements.
- A statement that the pharmacy department and receiving unit produce SOPs for the ordering and issuing processes including transit at their respective facilities. This should include the different ordering processes for stock controlled drugs and patient-specific controlled drugs (see below).
- It is good practice for the other health and social care body to ensure that its SOPs have been reviewed and agreed by a pharmacist. (Note that not all external organisations employ a pharmacist).
- That both parties review each others' SOPs to ensure a consistent, safe and auditable management process for CDs.
- If two different Accountable Officers cover the issuing and receiving units then each the Accountable Officer should take responsibility for the SOPs relating to his organisation.
- That the representatives from the issuing pharmacy and the other health and social care body meet on a regular basis to discuss any problems and agree any remedial action to resolve these and review services.
- That the issuing pharmacy and receiving unit conduct audits across the interface to ensure that process and procedures follow the SOPs and that any gaps in the systems, processes and procedures are identified and rectified. It is good practice to provide the Accountable Officer(s) with the audit reports and action plans.

Further information about the content of service level agreements can be found at http://www.nelm.nhs.uk/Record%20Viewing/viewRecord.aspx?id=573380

7.11.3 Ordering of stock controlled drugs by another health and social care body

Ordering of controlled drugs must comply with the current Misuse of Drugs Regulations.

Where a pharmacist is employed, the purchase of controlled drugs must be under his or her direct supervision and this includes authorising orders to suppliers. Where no pharmacist is employed a registered medical practitioner must countersign orders for controlled drugs raised by the senior registered nurse on duty.

All stock controlled drugs should be ordered as stock items only and contain no patient names.

7.11.3.1. Arrangements when the hospital pharmacy provides a supply service only

An authorised registered nurse who must be the person or acting person in charge of a hospital or nursing home can complete the controlled drugs requisition book and sign this order. The stock controlled drugs order must contain:

- Name, address and ward or department name from the other health and social care body,
- Name, formulation, strength and quantity (whole pack sizes) of the CD
- Date the order was made.
- Purpose for use
- Signature of the authorised registered nurse
- Countersignature of a doctor (or dentist) who is employed or engaged at the other health and social care body

The medical doctor will sign the order as an independent verification that the controlled drugs ordered are to be used within the requesting ward or department within the other health and social care body. The medical doctor who countersigns the CD order form is not responsible for management and accountability for the controlled drugs within the ward or department of the other health and social care body. This responsibility falls within the remit of the registered nurse or midwife in charge.

There are other corporate bodies where a medical doctor is requesting controlled drugs and is also responsible for the management of the controlled drugs within the department of other corporate body.

7.11.4 Requisitioning patients' own controlled drugs for patients by other health and social care body

7.11.4.1 Requisitioning from a hospital pharmacy

Patients' own controlled drugs can be ordered for either use within an inpatient unit (e.g. as part of self-administration scheme) or as discharge medication.

Where a hospital pharmacy dispenses CDs prescribed on FP10s for patients in an external facility, the same principles for maintaining an audit trail as for other controlled drugs should be followed e.g. from dispatch, during transport and on receipt at the external unit.

Note: In order to be able to dispense FP10s, a hospital pharmacy would first need to be registered with the Royal Pharmaceutical Society of Great Britain

It is acceptable for the other health and social care body to use locally designed and approved discharge (TTO, TTA) prescription forms for prescribing a patient's discharge medication. The hospital pharmacy should manage these TTA prescription forms in the same way as they would internal TTA prescription forms.

A full audit trail should be maintained when transferring the dispensed CDs to the other health and social care body.

The controlled drug prescription on the locally designed prescription forms must comply with all the legal requirements for the prescription of a controlled drug.

7.11.4.2 Requisitioning from a community pharmacy

A similar arrangement of using locally designed and approved prescription forms can be used when a community pharmacy is supplying patient-specific controlled drugs under a written agreement to an inpatient unit (or prison) such as a community hospital, prison or hospice.
(It should be noted that these prescriptions are not private prescriptions but part of a system for supplying patients/prisoners with appropriate dispensed and labelled medicines including controlled drugs on discharge from that unit or as part of a patient self-administration scheme).

The controlled drug prescription on the locally designed prescription forms must comply with all the legal requirements for the prescription of a controlled drug

7.12 Transfer of CDs

At each point where a controlled drug moves from the authorised possession of one person to another, the transfer should be recorded by means of the signatures of both parties.

Wherever possible, the drug must be transported in a secure, lockable container and a suitable delivery document completed to provide a full audit trail.

See paragraph 5.2 - Transfer of controlled drugs

7.13 Controlled drugs returned from wards

There should be a local procedure for the management of CDs returned from wards.

See also paragraph 4.17 – Returns to Pharmacy

7.14 Production and Quality Control

Where pharmacy production units are preparing products the contain CDs, then the same governance arrangements for safe use should apply as for elsewhere in the

organisation. All the activities should be covered by SOPs and the processes should be robust and auditable.

7.15 Disposal/destruction

See also section 4.16 disposal of controlled drugs in wards and departments

Unwanted CDs should be denatured and disposed of in a pharmacy.

CDs should be disposed of in such a way that the drug is denatured or rendered irretrievable so that it cannot be reconstituted or used again.

There should be a local policy for disposal of CDs and this policy must be in accordance with current Home Office guidance, Waste Management Regulations and Environment Agency guidance. The methods used for denaturing should be in accordance with RPSGB guidance.

(See - RPSGB guidance [Guidance for Pharmacists on the safe destruction of Controlled Drugs: England, Scotland and Wales. *www.rpsgb.org.uk/pdfs/cdsafedestructionguid.pdf*)

The Environment Agency (EA), which covers England and Wales, has decided that it is not in the public interest to expect pharmacies to obtain a waste management license for denaturing CDs as this is seen by the EA as a 'low risk' activity. The EA emphasises, however, that it may amend or revoke its position at any time and will continue enforcement in all circumstances where activity has or is likely to cause pollution or harm to health. It is therefore essential that local policies and procedures for destruction of CDs not only ensure effective destruction but also protect the environment and workers and others within the pharmacy.

7.15.1 Destruction of stock controlled drugs

Any pharmacy held stock of obsolete, expired or unwanted Schedule 2 CDs not returned by patients, that requires destruction can only be destroyed in the presence of an authorised person authorised by the Secretary of State for Health in England and Wales and the Secretary of State for Scotland.

7.15.1.1 Authorised witnesses in England, Scotland and Wales currently include inspectors of the Royal Pharmaceutical Society, and police constables.

Other people authorised to witness the destruction of controlled drugs in England are:

- Chief Dental Officer of the Department of Health or a Senior Dental Officer to whom authority has been delegated;
- Supervisors of Midwives appointed by the Local Supervising Authority;
- Senior officers in an NHS Trust who report directly to the Trust Chief Executive and who have responsibility for health and safety, security or risk management matters in the Trust;

- Chief Executives of NHS Trusts;
- A Primary Care Trust Chief Pharmacist or Pharmaceutical/Prescribing Adviser who reports directly to the Chief Executive or to a Director of the Primary Care Trust;
- A Registered Medical Practitioner who has been appointed to the Primary Care Trust Professional Executive Committee or equivalent;
- The Primary Care Trust Board Executive member with responsibility for Clinical Governance or Risk Management;
- Medical Director of a Primary Care Trust;

In addition, any officer of the healthcare organisation who, for this purpose, is directly accountable to an executive officer of the organisation to witness the destruction of CDs. This could include Strategic Health Authority pharmacy leads, Medical Directors, and clinical governance leads. However, these individuals must be independent of the routine supply and administration of controlled drugs.

An amendment to The Misuse of Drugs Regulation 2001 which came into force on 16 August 2007, permits the Accountable Officer to authorise people or groups of people, within their own organisations, to witness the destruction of controlled drugs in compliance with these regulations.

Accountable Officers should not be authorised to witness destruction as one of the criteria for Accountable Officers is their independence from day-to-day management of controlled drugs.

Further guidance can be found at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_078034

7.15.1.2 Until they can be destroyed, obsolete, expired and unwanted stock CDs requiring safe custody, according to arrangements appropriate to their schedule, must be kept segregated from other CDs in the CD cupboard. Stock CDs awaiting destruction should be clearly marked in order to minimise the risk of errors and inadvertent supply.

7.15.1.3 When stock Schedule 2 CDs are destroyed, the following details must be entered into the CD register:

- Drug name
- Drug form
- Drug strength
- Quantity of drug being destroyed
- Date of destruction
- Signature of the authorised person in whose presence the drug was destroyed

7.15.1.4 It is good practice for the person carrying out the destruction to also sign against this record.

7.15.2 Destruction of controlled drugs returned by patients

These are CDs that have been prescribed for, and dispensed to, a named patient and then returned unused or part-used by the patient or their representative to the pharmacy.

Controlled Drugs that have been returned by patients do not form part of the pharmacy stock and can be destroyed without the presence of an Authorised Person.

7.15.2.1 Although recording of patient-returned CDs is not a current legal requirement in relation to the Misuse of Drugs Regulations 2001, as amended, The Controlled Drugs (Supervision of Management and Use) Regulations 2006 require Standard Operating Procedures to be in place for maintaining a record of the CDs specified in Schedule 2 that have been returned by patients These Regulations came into force 1st January 2007 in England.

7.15.2.2 A record of CDs returned by patients should be kept and a record of destruction should be made. As a matter of good practice, destruction should be witnessed, preferably by a pharmacist or pharmacy technician.

7.15.2.3 The record of destruction should be made somewhere other than the CD register – for example in a separate book designated for that purpose. It is recommended that the following details are recorded:

- Date of return of the CDs
- Name, quantity, strength and form of the CDs
- Role of the person who returned the CDs (if known)
- Name and signature of the person who received the CDs
- Patient's name and address (if known)
- Names, positions and signatures of the person destroying the CDs and the witness
- Date of destruction
- Comments, for example, expiry date, name of patient and ward

A suggested recording form is available at http://www.rpsgb.org.uk/pdfs/restooldestrcd.pdf

7.15.2.4 Controlled drugs requiring safe custody awaiting destruction should be stored in the controlled drug cabinet separately from pharmacy stock controlled drugs.

7.15.2.5 Destruction of controlled drugs should occur with sufficient frequency (for example, monthly) to ensure that excessive quantities are not stored awaiting destruction. The frequency should be determined locally following a risk assessment.

7.15.3 Methods of disposal for CDs

CDs for destruction should be placed in suitable waste containers which are then sent for incineration and should not be disposed of in the sewerage system. The containers containing waste should be labelled, " *contains pharmaceutical waste – for incineration*".

All CDs in Schedule 2 and those CDs in Schedule 3 that are subject to safe custody requirements (temazepam, diethylpropion, buprenorphine and flunitrazepam) must rendered irretrievable (e.g. by denaturing) before being placed into waste containers

7.15.3.1 Wherever practicable, CD denaturing kits should be used to denature CDs. Where this is not possible or practical other methods of denaturing may be used.

7.15.3.2 Details of suitable methods for destruction of CDs in different dosage forms can be found in, *Guidance for Pharmacists on the safe destruction of Controlled Drugs: England, Scotland and Wales*. (*www.rpsgb.org.uk/pdfs/cdsafedestructionguid.pdf*) and it is strongly recommended that these methods are used. The low risk position provided by the Environment Agency is based on the use of appropriate and safe methods, which do not pose risks to the environment or human health.

7.15.3.3 Small amounts of CDs, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or when a dose is drawn up but not used, should be rendered irretrievable by emptying the contents into a sharps bin. The emptied vial or ampoule should then also be placed in the sharps bin. When the bin is sent for destruction it should be labelled "*contains mixed pharmaceutical waste and sharps – for incineration*".

The other option would be to use denaturing kits following a risk assessment. Where denaturing kits are used, their use should be included in an SOP.

This type of situation is most likely to arise when products are prepared extemporaneously. In these circumstances, the CD has already been issued to the extemporaneous preparation area or aseptic preparation area and is no longer part of the pharmacy CD stock. A full audit trail should be maintained. The worksheet should show the amount used and the amount wasted, for example: "2.5ml used 0.5ml wasted".

As a matter of good practice, the emptying of the part dose into the sharps bin should be witnessed and recorded on the worksheet. Both people should sign the worksheet.

8 Staff training for management of CDs

The Accountable Officer is responsible for ensuring that members of staff who are involved in prescribing, supplying, administering or disposing of controlled drugs receive appropriate training to enable them carry out their duties.

Staff should receive appropriate training on local standard operating procedures for controlled drugs when they first become involved in prescribing, supplying, administering or disposing of controlled drugs and then regularly thereafter. The frequency of training should be determined locally..

Staff should be informed and, if necessary receive additional training when SOPs are revised or amended and when new CD products or systems are introduced.

Glossary of terms

Accountable Officer	Officer in a health care organisation who is responsible for the safe and effective use of and management of controlled drugs. Appointment required by Controlled Drugs (Supervision and Management of Use) Regulations 2006.
Administer	To give a medicine either by introduction into the body, whether by direct contact with the body or not, (eg orally or by injection) or by external application (eg application of an impregnated dressing). There are specific definitions in meds legislation as follows: “external use" means application to the skin, hair, teeth, mucosa of the mouth, throat, nose, ear, eye, vagina or anal canal when a local action only is intended and extensive systemic absorption is unlikely to occur; and references to medicinal products for external use shall be read accordingly except that such references shall not include throat sprays, throat pastilles, throat lozenges, throat tablets, nasal drops, nasal sprays, nasal inhalations or teething preparations; "parenteral administration" means administration by breach of the skin or mucous membrane;
Controlled Drugs (CDs)	The drugs listed in schedules 1-5 of the Misuse of Drugs Regulations 2001 (as amended). Drugs listed in different schedules are subject to differing levels of control but all are Controlled Drugs.
CD record book (CDRB)	Bound book in which records are made of CDs received and administered in wards, theatres and departments.
CD register	A “register” as specified in the Misuse of Drugs Regulations 2001 (as amended) means either a bound book, which does not include any form of loose leaf register or card index, or a computerised system which is in accordance with best practice guidance endorsed by the Secretary of State under section 2 of the National Health Service Act 1977.
Designated body/bodies	Health care organisations e.g. hospital trusts defined in the Controlled Drugs (Supervision and Management of Use) Regulations 2006.
Discrepancy	Difference between the amount shown in the register or record book and the amount that is physically present.
Dispense, dispensing	Dispensing of Controlled Drugs Preparation (including compounding, dissolving, diluting, packing and labelling) and giving out of medicines for individual patients
Diversion	Removal of CDs for unauthorised use; theft
Duty Pharmacist	Senior pharmacist on duty for the time being
Health care organisations	Organisations responsible for the delivery of healthcare.

	Includes NHS Trust hospitals and independent hospitals.
Local Intelligence Network	A network established by the Accountable Officer of a Primary Care Trust for sharing information regarding the management and use of controlled drugs
"May"	Used in this document in connection with recommendations concerned with good practice if they are relevant to local circumstances
MDR	Misuse of Drugs Regulations – Regulations made under the Misuse of Drugs Act (1971)
"Must"	Used in this document in connection with legal requirements e.g. "records of schedule 2 CDs received and supplied by a pharmacy must be kept in a CD register."
Order	To order Controlled Drugs To make a formal order for Controlled Drugs. Can only be done by some one who is entitled to be in possession of CDs (as defined in current MDR). Must be addressed to a suitable pharmaceutical supplier.
Patient Group Directions (PGD).	Written directions from a senior doctor (or dentist) and a senior pharmacist and a representative of the appropriate organisation giving registered nurses, pharmacists and other specified health professionals a general authority to supply and administer specified medicines to patients, who are not individually identifiable, in specified clinical situations.
PCA	Patient-controlled analgesia
PODs	Patient's own drugs. In this context - CDs brought into the hospital by the patient on admission
Prescribe	Prescribing is the ordering of a medicine for an individual patient. In medicines legislation, certain medicines may be supplied only in accordance with a prescription by a doctor, dentist or other appropriate practitioner, and which meets the conditions specified in the Prescription Only Medicines (Human Use) Order 1997. The term has however become commonly used to describe authorising - by means of an NHS prescription - the supply of any medicine (Prescription Only Medicine, Pharmacy or General Sales List medicine) at public expense to a named patient;
Registered nurse, midwife or ODP in charge	The registered nurse, registered midwife or registered operating department practitioner (ODP) who is in charge for the time being (senior registered nurse, midwife or ODP on duty) and is therefore responsible for management of Controlled Drugs
Registered operating department practitioner	Operating Department Practitioner whose name is on the register of the Health Professions Council and should be a member of the College of Operating Department Practitioners
Registered pharmacist	Person registered in the register of pharmacists maintained by the Royal Pharmaceutical Society of Great Britain
Registered pharmacy technician	Pharmacy technician whose name is on the register held by the Royal Pharmaceutical Society of Great

	Britain
Relevant persons	People who • are directly or indirectly concerned with the provision of health care and/or • carry on activities that involve or may involve the supply or administration of controlled drugs • work for a designated body
Requisition	To requisition Controlled Drugs To make a formal, written request for a supply of a Controlled Drug for use in a ward or department. The requisition must be signed by an authorised signatory. Requisitions are usually made in stationery designed specifically for that purpose. These books are sometimes called “Controlled Drug Order books”
Responsible body	Bodies listed in regulation 22 of the Controlled Drugs (Supervision f Management and Use) Regulations 2006. Includes: PCT, NHS Trust, NHS Foundation rust, Strategic Health Authority, Healthcare Commission, Commission for Social Care Inspection.
Senior Assistant Technical Officer	In this context, a member of the pharmacy staff who has received in-house training for specific duties. Not a pharmacy technician.
Service Level Agreement (SLA)	Written agreement between two parties that specifies the service to be provided
“Should”	Used in this document in connection with recommendations concerned with good practice
Standard Operating Procedure (SOP)	A standard operating procedure specifies in writing what should be done, when, where and by whom in order to manage safely and accountably any set of processes, in this case around the total management of CDs.
Supervisor of midwives	A person appointed by the local supervising authority to exercise supervision over midwives in its area in accordance with rule 11(1) of the Nursing and Midwifery Council (Midwives) Rules 2004 (SI 2004/1764) www.hmso.gov.uk
Supply	Supply of Controlled Drugs Making a supply against a signed order or a prescription. In medicines legislation, “supply” is described as “retail sale or supply in circumstances corresponding to retail sale”.
Transcribe	To copy the details of one document on to another
TTOs (TTAs)	“To take outs” (also known as TTAs, “To take aways”). Medicines that patients take with them at the time of discharge

Appendix 1: Legislation for the management of CDs

Misuse of Drugs Act 1971

The Misuse of Drugs Act (MDA) 1971 and its Regulations provide the statutory framework for the control and regulation of controlled drugs. The primary purpose of the MDA is to prevent misuse of CDs. The MDA 1971 makes it unlawful to possess or supply a controlled drug unless an exception or exemption applies. A controlled drug is defined as any drug listed in Schedule 2 to the Act.

Misuse of Drugs Regulations 2001 (MDR)

The use of CDs in medicine is permitted by the Misuse of Drug Regulations (MDR). The MDR classify the drugs in five schedules according to the different levels of control required (see below). Schedule 1 CDs are subject to the highest level of control, whereas Schedule 5 CDs are subject to a much lower level of control.
For practical purposes, health care staff need to be aware of the current Regulations.

The MDR are periodically amended and revised. The MDR currently in force and its amendments can be found at the website for the Office of Public Information (www.opsi.gov.uk)

Schedule 1 (CD Licence)

Schedule 1 drugs include hallucinogenic drugs such as coca leaf, lysergide and mescaline. Production, possession and supply of drugs in this Schedule are limited, in the public interest, to research or other special purposes. Only certain persons can be licensed by the Home Office to possess them for research purposes. Practitioners (e.g. doctors, dentists and veterinary surgeons) and pharmacists may not lawfully possess Schedule 1 drugs except under licence from the Home Office.
The drugs listed in Schedule 1 have no recognised medicinal use although Sativex© (a cannabis based product) is currently being supplied on a named-patient basis.

Schedule 2 (CD POM)

Schedule 2 includes more than 100 drugs such as the opioids, the major stimulants, secobarbital and amphetamine.

Safe custody
Schedule 2 CDs (except secobarbital) are subject to safe custody requirements (under the Misuse of Drugs Safe Custody Regulations 1973, (see below)). They must be stored in a locked receptacle, such as an appropriate CD cabinet or approved safe, which can only be opened by the person in lawful possession of the CD or a person authorised by them**.**

Schedule 2 CDs may be manufactured or compounded by a licence holder, a practitioner, a pharmacist or a person lawfully conducting a retail pharmacy business acting in their capacity as such.

A pharmacist may supply schedule 2 CDs to a patient only on the authority of a prescription in the required form issued by an appropriate clinician.

Schedule 2 CDs may be administered to a patient by a doctor or dentist, or by any person acting in accordance with the directions of an appropriately qualified prescriber who is authorised to prescribe Schedule 2 CDs (DN - not all prescribers can prescribe Schedule 2 CDs).

Nurse Independent Prescribers are permitted to prescribe, administer, or direct anyone to administer some CDs for specific conditions and routes of administration

Record-keeping
There is a statutory requirement for pharmacy departments to keep a register for Schedule 2 CDs and this register must comply with the requirements of the Misuse of Drugs Regulations 2001.
As a matter of good practice wards and departments should also keep a register for Schedule 2 CDs
Midwives must keep register for the Schedule 2 CDs that they are allowed to carry.

A licence is required to import or export drugs in Schedule 2.

Destruction
The destruction of Schedule 2 CD stock must only take place in the presence of an appropriately authorised person. (For further information on appropriately authorised persons)

Schedule 3 (CD No Register)

Schedule 3 includes a small number of minor stimulant drugs and other drugs, which are less likely to be misused than drugs in Schedule 2, or are less harmful if misused.

Safe custody
Schedule 3 CDs are exempt from safe custody requirements and can be stored on the open dispensary shelf. Exceptions are flunitrazepam, temazepam, buprenorphine and diethylpropion, which must be stored in a locked CD receptacle within a secure environment.

Record keeping
There is no legal requirement to record transactions involving Schedule 3 CDs in a CD register.
Invoices must be retained for a minimum of two years.
Schedule 3 CDs are subject to full import and export control.

Destruction
The requirements for destruction do not apply unless the CDs are manufactured by the individual.

Schedule 4 (CD Benzodiazepines and CD Anabolic steroids)

Schedule 4 is split into two parts.

Part 1 (CD Benzodiazepines) contains most of the benzodiazepines, plus eight other substances including zolpidem, fencamfamin and mesocarb.

Part 2 (CD Anabolic steroids) contains most of the anabolic and androgenic steroids such as testosterone, together with clenbuterol (adrenoreceptor stimulant) and growth hormones (5 polypeptide hormones).

There is no restriction on the possession of a Schedule 4 Part 2 (CD Anabolic steroids) drug when it is part of a medicinal product. However, possession of a drug from Schedule 4 Part 1 (CD Benzodiazepines) is an offence without the authority of a prescription in the required form. Possession by practitioners and pharmacists acting in their professional capacities is authorised.

Drugs in Part 1 (CD Benzodiazepines) are subject to full import and export control and a Home Office licence is also required for the importation and exportation of substances in Part 2 (CD Anabolic steroids) unless the substance is in the form of a medicinal product and is for administration by a person to themselves.

All substances in Schedule 4 are exempt from safe custody requirements, with destruction requirements only applying to importers, exporters and manufacturers.

Prescription-writing requirements for these CDs do not apply, except those requirements laid out in the Medicines Act 1968. CD registers do not need to be kept for Schedule 4 drugs, although records should be kept if such CDs are compounded, or if a licensed person imports or exports such drugs (see Regulation 22 of the Misuse of Drugs Regulations 2001).

Schedule 5 (CD Invoice)

Schedule 5 contains preparations of certain CDs (e.g. codeine, pholcodine, morphine), which are exempt from full control when present in medicinal products of low strengths, as their risk of misuse is reduced.

There is no restriction on the import, export, possession, administration or destruction of these preparations and safe custody Regulations do not apply.
Preparations containing not more than 0.1% cocaine are no longer exempt from prohibitions on import, export and possession.
A practitioner or pharmacist acting in his capacity as such, or a person holding an appropriate licence, may manufacture or compound any CD in Schedule 5.
Invoices must be retained for a minimum of two years.

Misuse of Drugs (Safe Custody) Regulations 1973

The Safe Custody Regulations 1973 impose controls on the storage of controlled drugs. The degree of control depends on the premises within which the drugs are being stored.

All schedule 2 and some schedule 3 CDs should be stored securely in accordance with the Misuse of Drugs (Safe Custody) Regulations. These Regulations state that such CDs must be stored in a cabinet or 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 Regulations prohibit doctors from prescribing, administering or supplying diamorphine, cocaine or dipipanone for the treatment of addiction or suspected addiction except under Home Office licence. A licence is not required with such drugs for the treatment of organic disease or injury.

Medicines Act 1968

This Act, and Regulations made under the Act, sets out the requirements for the legal sale, supply and administration of medicines. It also allows certain exemptions from the general restrictions on the sale, supply and administration of medicines which, for example, enable midwives to supply and/or administer diamorphine, morphine, pethidine or pentazocine. A number of health care professionals are permitted to supply and/or administer medicines generally in accordance with a Patient Group Direction (PGD). Some of these professional groups, but not all, are permitted to possess, supply or administer CDs in accordance with a PGD under Misuse of Drugs legislation

Health Act 2006

The Key provisions of the Act are:

- All designated bodies such as healthcare organisations and independent hospitals are required to appoint an Accountable Officer
- A duty of collaboration placed on responsible bodies, healthcare organisations and other local and national agencies including professional regulatory bodies, police forces, the Healthcare Commission and the Commission for Social Care inspection to share intelligence on controlled drug issues
- A power of entry and inspection for the police and other nominated people to enter premises to inspect stocks and records of controlled drugs

Controlled Drugs (Supervision of Management and Use) Regulations 2006

The Controlled Drug (supervision of Management and Use Regulations) 2006 came into effect in England on the 1st January 2007.

These set out the requirements for certain NHS bodies and independent hospitals to appoint an Accountable Officer and describe the duties and responsibilities of Accountable Officers to improve the management and use of controlled drugs.

The Regulations also require specified bodies to co-operate with each other, including with regard to sharing of information, about concerns about the use and management of controlled drugs, and set out arrangements relating to powers of entry and inspection.

Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007

This Regulation amends the Misuse of Drugs Regulations 2001 and the Misuse of Drugs (Safe Custody) Regulations to:

Give authority to Accountable Officers, within their organisation, to nominate persons or groups of persons to witness the destruction of CDs.

Allow ODPs to order, possess and supply CDs.

Remove the requirement to maintain a Controlled Drugs Register in a prescribed format.

Change the record keeping requirements for CDs.

Reschedule Midazolam from Schedule 4 to Schedule 3 of the 2001 Regulations.

Appendix 2: The Accountable Officer

The regulatory requirements for Accountable Officers are set out in full in the Controlled Drugs (Supervision and Management of Use) Regulations 2006; www.opsi.gov.uk. (hyperlink to www.opsi.gov.uk/si/si2006/uksi_20063148_en.pdf). Further detail is also given in, Safer Management of Controlled Drugs: Guidance on Strengthened Governance Arrangements. January 2007 (www.dh.gov.uk) [http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4141666&chk=AtnhRu]

The following paragraphs provide a summary of the main provisions.

Persons who may be appointed as Accountable Officers

Each healthcare organisation must appoint an 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 should not be personally involved in the routine prescribing, supply, administration or disposal of controlled drugs. An organisation can have an Accountable Officer who has occasional need to handle CDs (for example, in emergencies), but if this is the case, their use of CDs should be open to the scrutiny of another senior member of the organisation or Accountable Officer of another trust. Individuals such as Chief Nurses, Medical Directors and Chief Pharmacists can be appointed as Accountable Officers if they meet these criteria. Accountable Officers should call on other Accountable Officers if a conflict of interest arises.

The organisation's controlled drugs policy should specify the person whom staff should approach if they have concerns about the practice of their Accountable Officer.

The Accountable Officer for the secondary care should liaise with the PCT Accountable Officer (or an Accountable Officer on behalf of a cluster of PCTs) who will act as the hub of the network and assist with setting up and managing the network.

Responsibilities of the Accountable Officer

In discharging his responsibilities, an Accountable Officer must have regard to best practice in relation to the management and use of controlled drugs.

The Accountable Officer must:

- Secure the safe and effective use and management of controlled drugs within local organisations subject to his/her oversight (i.e. the organisation and those with which it contracts).

- Appropriate systems for the safe management of controlled drugs must be established, operated and reviewed periodically.
- All arrangements must comply with relevant statutory requirements
- Adequate ands up-to-date standard operating procedures must be in place for the management and use of controlled drugs
- Ensure that adequate destruction and disposal arrangements are made for controlled drugs
- Appropriate arrangements for securing the safe destruction and disposal of controlled drugs must be established and operated
- Ensure monitoring and auditing of the management and use of controlled drugs within the organisation and take action where necessary. The following must be in place:
    - Systems to alert the Accountable Officer to complaints or concerns involving the management of controlled drugs
    - An incident reporting system to capture untoward incidents involving the management or use of controlled drugs
- Arrangements for analysing and responding to untoward incidents involving the management or use of controlled drugs
- Ensure that individuals involved in prescribing, supplying, administering or disposing of controlled drugs receive appropriate training. Arrangements must be in place for relevant individuals:
    - to receive information and, where appropriate, training on local standard operating procedures for controlled drugs when they first become involved in prescribing, supplying, administering or disposing of controlled drugs
    - to be informed when any local standard operating procedures for controlled drugs are subsequently reviewed or amended
- Monitor and audit the management and use of controlled drugs by relevant individuals, and to monitor and assess their performance. The Accountable Officer must, where appropriate, provide for the following
    - Recording concerns raised in relation to the management or use of controlled drugs by a relevant individual
    - Assessing and investigating concerns raised regarding the management or use of controlled drugs by a relevant individual
    - Determining whether there are concerns in relation to the management or use of controlled drugs by a relevant individual which the designated body reasonably considers should be shared with a responsible body.

The Accountable Officer should be aware that unusually high usage of some CDs or unusually high numbers of breakages could indicate misuse.

The Accountable Officer in Acute care should also monitor prescriptions that are written in hospital but dispensed in the community.

- Maintain a record of concerns regarding relevant individuals. Such records may be paper-based or electronic. The Accountable officer must:
    - Establish and operate appropriate arrangements for recording concerns expressed about incidents that involved, or may have involved, improper management or use of controlled drugs by a relevant individual. This must include a system to ensure that access to such records is limited to the Accountable Officer, his staff and others who need to have access for the purposes of ensuring the safe management or use of controlled drugs.
    - Ensure that adequate records are compiled, which must include (but not be limited to), as appropriate:
        - the date on which the concern was made known to the accountable officer;
        - dates on which the matters that led to the concern took place;
        - details regarding the nature of the concern;
        - details of the relevant individual in relation to whom the concern was expressed;
        - details of the person who, or body which, made known the concern;
        - details of any action taken by the designated body in relation to the concern;
        - the assessment of whether information in relation to the concern should be disclosed to another responsible body
        - if information regarding the concern is disclosed to another responsible body, the details of any such disclosure, including the name of the responsible body to which the disclosure was made and the nature of the information disclosed to the body.

- Assess and investigate concerns
    - Establish and operate appropriate arrangements for assessing and investigating concerns about incidents that involved, or may have involved, improper management or use of controlled drugs by a person who is, as regards his designated body, a relevant individual
    - Take appropriate action if there are well-founded concerns
    - Establish and operate appropriate arrangements for ensuring that appropriate action is taken for the purposes of protecting patients or members of the public in cases where concerns in relation to the management or use of controlled drugs by a person who is, as regards designated body, a relevant individual, appear to be well-founded.
- Establish arrangements for sharing information
    - Establish and operate appropriate arrangements for ensuring the proper sharing of information, by his designated body with other

responsible bodies regarding the management and use of controlled drugs
    - Provide a quarterly report to the PCT Accountable Officer lead for the Local Intelligence Network
    - Cooperate with other organisations including the Healthcare Commission, the Commission for Social Care Inspection, the NHS Business Service Authority and the police as circumstances require.

- Participate in the Local Intelligence Network

Appendix 3: Accountable Officer (acute care) - sample job description

Job Title: Controlled Drugs Accountable Officer

Reports to: The chief executive or an executive director (for NHS trusts) or for independent hospitals reporting to the registered manager.

Accountable for: Management of the safe and effective use and management of controlled drugs within the organisation

Key Working Relationships

- Members of the Local Intelligence Network
- Accountable officers of other organisations
- Performance management departments
- Information managers
- Chief Pharmacists and medical directors
- Local representative committees
- Organisations with statutory roles of inspection
- The Media or media officers within the organisation

Job Purpose

Statement of Job Purpose:

To safeguard patient safety by monitoring the use of controlled drugs within their organisation and take action where necessary.

Responsibilities

Ensures monitoring arrangements are in place for management and use of controlled drugs

Establishes mechanisms for the very quick sharing of intelligence and joint action in cases of urgency (where patient safety is at risk or evidence may be destroyed)

Ensures clear routes, such as the NHS complaints system, are available for any healthcare professional, patient or member of the public to raise matters of concern, within a framework of appropriate confidentiality. This includes routes for healthcare professionals to self-refer if they have concerns about their own performance.

Establishes mechanism for further investigation of causes for concern.

Determines whether a targeted inspection is required and those who should be involved (May do this as part of a decision-making group)

Determines remedial action to be taken (e.g. no action required, support to healthcare professional or organisation, referral to regulatory body, RPSGB, Healthcare Commission, CSCI, police) (May do this as part of a decision-making group)

Ensures remedial action is followed through (though police services retain responsibility for determining whether the evidence for possible criminal behaviour warrants a criminal investigation with a view to subsequent prosecution)

Plays full part in intelligence network (bearing in mind the need to separate the investigative and decision-making functions).

Encourages good practice and development in management of controlled drugs

Key Tasks

Data analysis – prescribing data, supply details etc
Analysis of organisational self-assessment

Determines remedial action to be taken

Maintains a record of remedial actions that have been instigated with expected dates of completion. Contacts people concerned to check actions are on target. Refers poor progress back into the review mechanism.
Approves all policies and procedures within the organisation covering controlled drugs to ensure compliance with legislations, centrally issued guidance and governance.

Regularly review internally reported incidents involving controlled drugs to identify any specific trends or additional requirement for control measures within the organisation.

Personnel Specification

Title of Post:	**Accountable Officer**

Category	**Essential/Desirable[2]**	**Description[1]**
Knowledge and Experience	Essential	
	Desirable	• Have previous experience in the handling of CDs. • Knowledge of controlled drugs legislation
Skills and Abilities	Essential	
	Desirable	• Be familiar with organisational processes for clinical governance and performance management
Training and Education	Essential	• Be a registered doctor, pharmacist or nurse with no restrictions placed upon them by their regulatory body with regards to controlled drugs Or • Be a senior manager with experience of clinical governance
	Desirable	
Other Requirements	Essential	
	Desirable	• Be remote from current practice involving CDs (except in emergencies) including, prescribing, administering or disposing of CDs

Appendix 4: Useful contacts

British Medical Association
BMA House
Tavistock Square
London
WC1H 9JP

Tel: 0207 387 4499
Fax: 0207 383 6400
Website: www.bma.org.uk

Commission for Social Care Inspection
33 Greycoat Street
London
SW1P 2QF

Tel: 0207 979 2000
Fax: 0207 979 2111
Website: www.csci.org.uk

Community Practitioners' and Health Visitors Association
33-37 Moreland Street
London
EC1V 8HA

Tel: 0207 505 3000
Website:
www.amicustheunion.org/cphva/

Council for Healthcare Regulatory Excellence
1st Floor, Kierran Cross
11 Strand
London
WC2N 5HR

Tel: 0207 389 8030
Fax: 0207 389 8040
Website: www.chre.org.uk

Department of Health
Richmond House
79 Whitehall
London
SW1A 2NS

Tel: 0207 210 4850
Website: www.dh.gov.uk

Dispensing Doctors' Association
Low Hagg Farm
Starfitts Lane
Kirbymoorside
North Yorkshire
YO62 7JF

Tel: 01751 430835
Fax: 01751 430836
Website: www.dispensingdoctor.org

General Medical Council
Regent's Place
350 Euston Road
London
NW1 3JN

Tel: 0845 357 3456
Website: www.gmc-uk.org

Healthcare Commission
Finsbury Tower
103-105 Bunhill Row
London
EC1Y 8TG

Tel: 0207 448 9200
Website:
www.healthcarecommission.org.uk

Home Office Drugs Licensing Branch
2 Marsham Street

Tel: 0207 035 0483

Safer Management of Controlled Drugs: a guide to good practice in secondary care (England)

London
SW1P 4DF
Website: www.drugs.gov.uk

Home Office Drugs Legislation and Enforcement Unit
2 Marsham Street
London
SW1P 4DF
Tel: 0207 035 0464
Website: www.homeoffice.gov.uk

Medicines and Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London
SW8 5NQ
Tel: 0207 084 2000
Fax: 0207 084 2353
Website: www.mhra.gov.uk

National Clinical Assessment Service (part of the National Patient Safety Agency)
Market Towers
1 Nine Elms Lane
London
SW8 5NQ
Tel: 0207 062 1620
Fax: 0207 084 3851
Website: www.ncas.npsa.nhs.uk

National Patient Safety Agency
4-8 Maple Street
London
W1T 5HD
Tel: 0207 927 9500
Website: www.npsa.nhs.uk

National Pharmacy Association
Mallinson House
38-42 St Peter's Street
St Albans
Hertfordshire
AL1 3NP
Tel: 01727 832161
Fax: 01727 840858
Website: www.npa.co.uk

National Prescribing Centre
The Infirmary
70 Pembroke Place
Liverpool
L69 3GF
Tel: 0151 794 8134
Fax: 0151 794 8139
Website: www.npc.co.uk (Internet)
www.npc.nhs.uk (NHSNet)

National Treatment Agency
8th Floor, Hercules House
Hercules Road
London
SE1 7DU
Tel: 020 7261 8801
Fax: 020 7261 8883
Website: www.nta.nhs.uk

NHS Clinical Governance Support Team
1st Floor
St. Johns House
30 East Street
Leicester
LE1 6NB
Tel: 0116 295 2000
Fax: 0116 295 2001
Website: www.cgsupport.nhs.uk

Nursing and Midwifery Council

23 Portland Place
London
W1B 1PZ

Tel: 020 7637 7181
Fax: 020 7436 2924
Website: www.nmc-uk.org

Pharmaceutical Services Negotiating Committee

59 Buckingham Street
Aylesbury
Buckinghamshire
HP20 2PJ

Tel: 01296 432 823
Fax: 01296 438 427
Website: www.psnc.org.uk

Prescription Pricing Division

Bridge House
152 Pilgrim Street
Newcastle-upon-Tyne
NE1 6SN

Tel: 0191 232 5371
Fax: 0191 232 2480
Website: www.ppa.org.uk

Prescribing Support Unit

The Health and Social Care
Information Centre
1 Trevelyan Square
Boar Lane
Leeds
LS1 6AE

Tel: 0113 254 7041
Fax: 0113 254 7097
Website**:** www.psu.nhs.uk

Appendix 5: Patient information

NHS Direct

The NHS Direct website has developed a Common Health Question about CDs specifically to inform the public. It is entitled 'What is a controlled drug (medicine)?' and is available at **www.nhsdirect.nhs.uk/articles/article.aspx?articleId=1391.** The text defines a CD in legal terms, how the Regulations apply to them and directs patients to information about requirements for traveling abroad.

Embedded in the text of this Common Health Question is a template leaflet with supporting information that has been agreed with the DH as suitable text for a leaflet available at the time of dispensing. The leaflet can be downloaded and used to prepare local practice leaflets.

If patients require further information about travel or other general health advice they can be advised to contact NHS Direct by telephone on 0845 4647 or visit the NHS Direct website at **ww.nhsdirect.nhs.uk**.

Medicines Guides

Medicine Guides provide a source of information for members of the public who are looking for information about individual medicines that is up-to-date, reliable and easy to understand. Medicine Guides are being developed as part of the Medicines Information Project which aims to provide people with information about medicines, conditions and the different treatment options available.

The Medicine Guides on CDs can be found on the www.medicines.org.uk website which is published by Datapharm Communications. There is a link to the NHS Direct Common Health Question within each Guide. Guides for the CDs that have been published to date can be accessed at http://medguides.medicines.org.uk/cd.

The current list available is:

- Cyclimorph
- Cyclizine / Morphine
- Diamorphine
- Filanarine
- Minijet morphine
- Morphgesic
- Morphine
- MST
- MXL
- Oramorph
- Sevredol
- Zomorph

Appendix 6: Contributors

The following individuals and organisations contributed to the design and content of this guidance:

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