Primary and Community Care Directorate
Pharmacy Division

The Scottish Government

CEL 7 (2008)

12 February 2008

Dear Colleague

SAFER MANAGEMENT OF CONTROLLED DRUGS:

A Guide to Good Practice in Secondary Care (Scotland)

Action
NHS Boards are asked to copy this letter and guidance document to:

- **all healthcare professionals in secondary care involved in the management and use of controlled drugs. The guidance must also be copied to the Board's Accountable Officer.**

Purpose

1. The document attached to this letter provides guidance on good practice in the management and use of controlled drugs in secondary care.

Background

2. The fourth report of the Shipman Inquiry "*The Regulation of Controlled Drugs in the Community*" made recommendations to strengthen and improve current systems for the management and use of controlled drugs. The Government's response to the report set out a programme of work to address the shortcomings identified by the Inquiry. The Health Act 2006 and Regulations made under the Act – the Controlled Drugs (Supervision of Management and Use) Regulations 2006 – introduced new governance arrangements for controlled drugs.

3. The 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 covers 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.

Addresses
For action
Chief Executives, NHS Boards
Chief Executive, Scottish Ambulance Service Board
Chief Executive, State Hospitals Board for Scotland
Chief Executive, National Waiting Times Centre Board
Medical Directors, NHS Boards
Directors of Nursing, NHS Boards
Directors of Pharmacy, NHS Boards

For information
Chief Executive, NHS QIS
Chief Executive, NHS NSS
Chief Executive, NHS NES
Scottish Commission for the Regulation of Care
Royal Pharmaceutical Society of Great Britain, Scottish Division

Email Enquires to:
cdenquiries@scotland.gsi.gov.uk

Pharmacy Division
Room 1E.01
St Andrew's House
EDINBURGH
EH1 3DG

4. A copy of this letter is being sent separately to Accountable Officers in the independent sector.

Yours sincerely

Bill Scott
PROFESSOR BILL SCOTT
Chief Pharmaceutical Officer

SAFER MANAGEMENT OF CONTROLLED DRUGS : A guide to good practice in secondary care (Scotland)

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Introduction

1. The fourth report of the Shipman Inquiry, "The Regulation of Controlled Drugs in the Community"[1] made recommendations to strengthen and improve systems for the use and management of controlled drugs for human use. The UK Government's response to the fourth report, "Safer Management of Controlled Drugs"[2] agreed that the systems should be improved and strengthened and set out a programme of work to address the shortcomings identified by the Inquiry. This has included amendments to the Misuse of Drugs Regulations 2001 and new governance arrangements introduced in the Health Act 2006 and Regulations made under the Act – the Controlled Drugs (Supervision of Management and Use) Regulations 2006[3].

2. 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 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.

3. In recent years developments have taken place to modernise working practices. For example, 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, e.g. Operating Department Practitioners. This guidance seeks to clarify how these developments fit within the existing legal framework for controlled drugs. It builds on and augments the advice provided in *The Safe and secure handling of medicines: A team approach* (the Revised Duthie Report)[4] and readers are encouraged to refer to the Revised Duthie Report for guidance on more general aspects of medicines' management.

4. In this document 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. Although the guidance includes most of the commonly-encountered situations, inevitably, as practice continues to develop, users will on occasion find gaps or points which fit uneasily with their situation. In such cases the principles listed in Chapter 4 will provide a basis for policy formulation.

5. Legislation relating to Controlled Drugs is reserved. The Scottish Government is therefore 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 Health Board's Accountable Officer.

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[1] www.the-shipman-inquiry.org.uk
[2] www.dh.gov.uk/assetRoot/04/09/79/06/04097906.pdf
[3] www.opsi.gov.uk/si/si2006/20063148.htm
[4] www.rpsgb.org.uk/pdfs/safsechanmeds.pdf

6. This guidance is based on *"Safer Management of Controlled Drugs: a guide to good practice in secondary care (England)"* published by the Department of Health in October 2007, which was developed following widespread consultation with key stakeholders chaired by the Royal Pharmaceutical Society of Great Britain. In Scotland, at the request of the Chief Pharmaceutical Officer, a working group from the Directors of Pharmacy Group reviewed and developed the guidance for the Scottish healthcare system.

7. Appendix 1 lists professional organisations that provide advice for their members. 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.

2 Legislation

Misuse of Drugs Act 1971

1. The legislation relating to Controlled Drugs is reserved and the Misuse of Drugs Act (MDA) 1971 and its associated Regulations provide the statutory framework for the control and regulation of CDs. The primary purpose of the MDA is to prevent misuse of CDs. The Act makes it unlawful to possess or supply a CD unless an exception or exemption applies. (Additional statutory measures for the use and management of CDs are laid down in the Health Act 2006 and its associated Regulations).

Misuse of Drugs Regulations

2. The Misuse of Drugs Regulations (MDR) enable certain classes of persons to possess, produce, supply, prescribe or administer CDs in the practice of their professions. The MDR classify the drugs in five schedules according to the different level of control required. Schedule 1 CDs contains the most strictly controlled, whereas Schedule 5 CDs are subject to a much lower level of control. For practical purposes, healthcare staff need to be aware of the current Regulations. The MDR are periodically amended and revised and can be found at the website of the Office of Public Information (www.opsi.gov.uk).

Schedule 1: includes 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 and other special purposes. Only certain persons can be licensed by the Home Office to possess them for research purposes. Practitioners, for example, doctors, dentists and veterinary surgeons and pharmacists may not lawfully possess Schedule 1 CDs except under a license 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: includes more than 100 drugs such as the opioids, the major stimulants, secobarbital and amphetamine. Schedule 2 drugs (except secobarbital) are subject to safe custody requirements under the Misuse of Drugs (Safe Custody) Regulations 1973. 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. These drugs 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 practitioner. Not all prescribers can currently prescribe CDs but the position may change in the future.

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.

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 amended. As a matter of good practice, wards and departments should also keep a register for Schedule 2 CDs. Midwives must keep a register for the Schedule 2 CDs that they are allowed to carry.

The destruction of unused or unwanted Schedule 2 CD stock must only take place in the presence of an appropriately authorised person.

A licence is required to import or export Schedule 2 CDs.

Schedule 3: includes a small number of minor stimulant and other drugs, which are less likely to be misused than drugs in Schedule 2, or are less harmful if misused. With a few exceptions, Schedule 3 CDs are exempt from the safe custody requirements and can be stored on the open dispensary shelf. The exceptions are flunitrazepam, temazepam, buprenorphine and diethylpropion, which must be stored in a locked CD receptacle within a secure environment.

There is no legal requirement to record transactions involving Schedule 3 CDs in a CD register. Invoices must be kept for two years.

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

Schedule 3 CDs are subject to full import and export control.

Schedule 4: is spilt into two parts. Part 1 (CD benzodiazepines) contains most of the benzodiazepines, plus 8 other substances including zolpidem, fencamfamin and mescarb. 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 Schedule 4 Part 2 drugs when it is part of a medicinal product. However, possession of a CD from Schedule 4 Part 1 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 Schedule 4, Part 1 are subject to full import and export control. A Home Office license is required for the importation and exportation of substances in Part 2 unless the substance is in the form of a medicinal product and is for administration to 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 Schedule 4 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 CDs although records should be kept if such CDs are compounded, or if a licensed person imports or exports the CDs (see regulation 22 of the Misuse of Drugs Regulations 2001).

Schedule 5: includes preparations of certain low strength CDs which are exempt from full control when present in medicinal products, as their risk of misuse is reduced.

There is no restriction on the import, export, possession, administration or destruction of Schedule 5 CDs and the 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/her 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

3. The regulations impose controls on the storage of CDs and the degree of control depends on the premises where the CDs are being stored. All Schedule 2 and 3 CDs should be stored securely 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

4. These regulations prohibit practitioners 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 if the drugs are being used for the treatment of organic disease or injury.

Health Act 2006

5. The Controlled Drugs (Supervision of Management and Use) Regulations 2006, made under the Health Act, came into effect in Scotland on 1 March 2007. The regulations set out requirements for certain NHS and independent organisations for the safe management and use of CDs.

Medicines Act 1968

6. The Medicines Act and regulations made under the Act govern the sale, supply and administration of medicines. It also allows certain exemptions from the general restrictions for e.g. midwives. A number of healthcare professionals are permitted to supply and/or administer medicines in accordance with Patient Group Directions (PGDs). More information about the Medicines Act and PGDs can be found on the website of the Medicines and Healthcare products Regulatory Agency (MHRA). www.mhra.gov.uk

Supply and administration of controlled drugs

7. 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, dentist 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.

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

8. A Patient Group Direction (PGD) allows a range of specified health care professionals, who may not be prescribers in their own right, 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.

9. 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.[5] The limited circumstances are:

- Registered nurses (but no other healthcare practitioners) in 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.

Midwife exemptions

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

- Diamorphine
- Morphine

[5] SI 2003 No.2429. www.opsi.gov.uk/si/si2003/20032429.htm
Home Office Circular 049 / 2003. Controlled Drugs Legislation - Nurse Prescribing And Patient Group Directions
www.knowledgenetwork.gov.uk/ho/circular.nsf/79755433dd36a66980256d4f004d1514/248786ae1bb78d6180256dab003b2948?OpenDocument

- 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 Chapter 6, paragraphs 70-84 Controlled Drugs for Midwives)

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/)

3. Governance arrangements

Accountability and responsibility

1. At local level, Accountable Officers in designated bodies (see Controlled Drugs (Supervision of Management and Use) Regulations 2006) must ensure the safe management and use of controlled drugs within their organisation. In Scotland, NHS Boards, the State Hospitals Board for Scotland, the National Waiting Times Centre Board, the Scottish Ambulance Service, and independent hospitals (including hospices) are designated bodies.

2. Full guidance on the new governance arrangements including monitoring and inspection arrangements for controlled drugs can be found in HDL (2007)12 dated 14 February 2007[6].

3. 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 the receiving organisation.) In setting up and reviewing these governance arrangements, the Accountable Officer 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.

Standard Operating Procedures

4. Full guidance on the development of standard operating procedures can be found in CEL (2007)14 dated 17 October 2007.[7]

Additional Information

- A comprehensive list of drugs included in Schedules 1-5 is given in the 2001 Misuse of Drug Regulations and can be accessed at www.opsi.gov.uk
- Home Office www.homeoffice.gov.uk
- 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.

[6] www.show.scot.nhs.uk/publicationsindex.htm
[7] www.sehd.scot.nhs/mels/CEL2007_14.pdf

4. General principles

1. 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.

- Patients have timely access to the medicines prescribed for them.
- Organisations and individuals comply with the current legal requirements for CDs.
- Patients are partners in their treatment and share decision-making with healthcare professionals about their treatment.
- Patients are adequately informed about their treatment.
- CDs are used and managed safely and securely.
- There is a clear audit trail for the movement and use of CDs.
- The use of CDs is audited and action is taken if necessary.
- CDs are prescribed by professionals who are competent to do so and who receive regular training and support on the safe management of CDs.
- Local procedures and protocols are designed to be as clear and accurate as possible and do not impose an intolerable administrative burden.
- The stock levels and preparations of CDs held in wards and departments match what is routinely used in that clinical area.
- Healthcare staff have access to up-to-date information about CD legislation and official (e.g. Home Office) guidance.
- Healthcare staff in the organisation work to standard operating procedures, approved by the Accountable Officer.
- Healthcare 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).
- Access to CDs is restricted to appropriate, designated and legally authorised personnel.

5. Management of CDs in wards and departments

Management of CDs in operating theatres is covered in Chapter 7. The requirements for pharmacy departments can be found in Chapter 8.

Accountable individuals

1. 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.

2. 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.

Standard Operating Procedures

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

4. 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 work. SOPs must comply with local policies and systems.

5. The Accountable Officer remains finally accountable for systems for the safe management and use of CDs.

CD stocks

6. 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.

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

Requisitioning of CDs

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

9. 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 7; The management of CDs in operating theatres). However, legal responsibility remains with the registered nurse, midwife or ODP in charge.

10. Orders should be written on suitable stationery (e.g. a CD requisition book with duplicate pages) and must be signed by an authorised signatory. (See also paragraph 18 Electronic systems)

11. The registered nurse, midwife or ODP in charge of a ward, department, operating theatre or theatre suite is responsible for ensuring access to ordering stationery is restricted to those staff authorised to order CDs. Where electronic systems are in use, there should be a reliable means of validating the identity of individuals who requisition CDs.

12. 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, midwife or operating department practitioner authorised to order controlled drugs for that ward/department.
- 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.

13. On occasion it may be necessary for pharmacy staff to alter the quantity supplied to that of a complete pack or blister strip. Where this happens the quantity stated must be altered, signed and dated by the member of pharmacy staff on both copies on the requisition.

14. The person who accepts CDs for transit/delivery from the pharmacy should sign for receipt. This may be on separate documentation kept for this purpose.

CD Top-up schemes

15. 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.

16. 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.

17. 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.

Electronic systems

18. 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.

Receipt of CDs

19. 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 Chapter 6 paragraphs 14 - 27 Transfer of CDs). A local procedure should define the appropriate persons who are permitted to receive CDs, the way in which messengers identify them and how the CDs are to be handled immediately thereafter. As a matter of good practice the receiving person should not be the same person who ordered the CDs.

20. The person permitted to receive CDs should sign for receipt of the sealed delivery package confirming that it was received intact. The package should be held in a secure place as defined by local policy.

21. 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 CD 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 person 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 CD record book, update the running balance and check that the balance tallies with the quantity that is physically present.

22. The healthcare organisation may wish to stipulate that receipt of CDs and updating of the register should be witnessed by a second competent person.

(See also Chapter 7 paragraph 14 Receipt of CDs in Theatre)

Storage of CDs

23. The Misuse of Drugs (Safe Custody) Regulations 1973 cover the safe custody of CDs in certain specified premises. The Regulations also set out certain standards for safes and cabinets used to store CDs.

24. 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.

25. All CDs 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.

26. In certain circumstances, for example when CD discharge medicines 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 Chapter 6 paragraph 37 Management of CDs that are patients' property)

27. 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, healthcare organisations may decide to allow other drugs that are not CDs to be stored in the CD cupboard. This should be covered in a SOP.
- 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.

Responsibility for CD keys

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

29. On occasion, 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).

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

31. There should be a local policy for storage of spare CD keys. This policy must ensure that they are secure at all times and can only be accessed by authorised staff.

Missing CD keys

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

33. If the keys cannot be located, 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.

34. 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. Local systems should be in place for recording and handling of incidents regarding lost CD keys. This should form part of the SOP approved by the Accountable Officer.

Record-keeping

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

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

37. The CD record book should be bound (not loose-leaf) with sequentially numbered pages and it should have separate pages for each drug, each form 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.

38. All entries should be signed by a registered nurse, midwife or ODP and should be witnessed preferably by a 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.

39. On reaching the end of a page in the CD record book, 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.

40. 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, ODP or other registered professional or by an appropriately trained healthcare assistant. The witness should also sign the correction.

Records of receipts

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

42. For CDs received, the following details should be recorded on the appropriate page in the CD record book:

- Date of entry.
- 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.

43. When recording CDs received from pharmacy, the number of units received must be recorded in words not figures (e.g. ten, not “10”) to reduce the chance of entries being deleted.

44. After every administration, the stock balance of an individual preparation should be confirmed to be correct and the balance recorded in the CD record book. The entry should be signed and dated. (For records of CDs administered see paragraphs 70 - 77 Administration of CDs.)

Ward/Department CD stock checks

45. The stock balance of all CDs 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. In addition, regular stock checks should be carried out by pharmacy staff. (See Chapter 8 paragraphs 37 - 41 Checks of CD stocks held in wards, theatres or departments.)

46. 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.

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

- Checking of the balance in the CD record book 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, e.g. manufacturer's complete sealed packs.
- 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.

48. A record indicating that this reconciliation check has been carried out and confirming the stock is correct should be kept. This record should include as a minimum 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.

49. If a discrepancy is found it should be investigated without delay (see paragraphs 92 -95 Discrepancies and diversion). The local investigation and reporting procedures should be followed.

Archiving of CD records

50. Healthcare organisations must make arrangements to store CD records for a minimum period of two years. Some healthcare organisations may want to keep records for longer and once electronic CD registers are in common use, the Government intend a further requirement to keep secure copies for up to eleven years.

51. 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.

Prescribing for inpatients

52. CDs can be prescribed on the inpatient medicines form or other approved prescription form including electronic records in line with local policies and procedures. CDs may only be prescribed by a suitably qualified practitioner who is recognised and authorised by the organisation to undertake this function.

53. The written requirements for CDs 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).
- Start date.

- Include a finish date where appropriate.
- Signature of prescriber.

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

Prescribing for discharge patients

54. Prescriptions for CDs for patients who are going home (discharge medicines) should be written on locally-approved prescription forms for dispensing by the hospital pharmacy. These prescriptions must conform to all requirements of the Misuse of Drugs Regulations for a CD prescription (see paragraph 58).

55. 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[8].

56. 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 a prescriber considers it clinically appropriate to supply more than a 30-day quantity and this does not pose an unacceptable risk to patient safety, the patient's notes should be annotated to that effect. Prescribers who prescribe more than a 30-day supply should be prepared to justify their decision.

Prescribing for outpatients

57. CD prescriptions 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 HPB10 for a community pharmacy to dispense. Paragraph 56 also applies to such prescriptions.

58. 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:[9]

- 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.

[8] http://www.gmc.uk.org/education/documents/provisional_registration_prescribing.pdf
[9] (SI 2005 No.2864) [http://www.opsi.gov.uk/SI/si2005/uksi_20052864_en.pdf]

In addition the patient's CHI number must be included on the prescription.

59. The prescription must be signed by the prescriber with his/her usual signature, in his/her own handwriting 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).

60. CD prescriptions may be computer-generated. Only the signature has to be in the prescriber's own handwriting. The prescriber is also required to sign any manuscript changes. If an electronic solution exists, local polices should describe how this operates within the supply system.

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

62. The use of pre-printed sticky labels on prescriptions is not good practice. Technically the new legislative requirements for computer generated prescriptions for CDs do not prevent the use of preprinted sticky labels on prescriptions. If they are used, such sticky labels should be non-peelable and 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 safeguard 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.

63. Sticky labels should not be used on CD prescriptions to be dispensed in the community. The scanning systems in use at Practitioner Services Division cannot process such prescriptions.

Supplementary prescribers

64. 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.

65. If the supplementary prescriber is a pharmacist good practice requires that there is a separation of duties, i.e. prescribing and supply.

66. If the patient takes his prescription to a community pharmacy for dispensing, then the appropriate prescription form must be used. Details of the prescription forms on which CDs for outpatients can be prescribed, are provided in the RPSGB Medicines, Ethics and Practice guide[10].

[10] http://www.rpsgb.org.uk/pdfs/MEP30s1-2a.pdf

Community Practitioner Nurse Prescribers

67. 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 and Pharmacist Independent Prescribers (formerly Extended Formulary Nurse Prescribers)

68. Following amendments to 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 Misuse of Drugs Regulations 2001 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.

69. At the time of writing, Pharmacist Independent Prescribers cannot prescribe CDs. The Home Office has consulted on proposals to enable Nurse and Pharmacist Independent Prescribers to prescribe CDs. The Advisory Council on the Misuse of Drugs (ACMD) will make recommendations to Ministers based on the outcome of the consultation. Any changes to the Misuse of Drugs legislation will be made available on www.opsi.gov.uk and the Home Office website.

Administration

70. The administration of CDs 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.

71. 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)).

72. The administration of CDs within secondary care should normally be done via two-person administration process. Any departure from the double check process should be considered exceptional and carry with it a specific risk assessment to support this practice.

73. Where two practitioners are involved in the administration of CDs, one of them should be a registered nurse, midwife, doctor or ODP. Both practitioners should be present during the whole of the administration procedure or, in the case of an infusion or patient-controlled analgesia device, for the set-up and start. 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).

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

75. 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.
- Name and status of the prescriber.

76. 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 discarded 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 discarded".* 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.

77. 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 paragraphs 87-91.

Management of CDs when patients are admitted

78. See Chapter 6 paragraph 37 Management of CDs that are the patient's property.

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

79. A local procedure is required to ensure that appropriate records are maintained when patients are transferred between wards/departments with CDs physically attached to them, e.g. patient-controlled analgesia or patches etc. This should include:

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

See also Chapter 6 paragraphs 14 - 27 Transfer of CDs.

Management of CDs when patients are discharged

80. See paragraphs 54-56 Prescribing for discharge patients.

Returning CDs to the pharmacy

81. There should be local polices that specify the circumstances and procedures to be followed when CDs are returned to the pharmacy.

82. Unused CD stock from wards or departments may be returned to the pharmacy for re-issue 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 returned CDs to ensure they are fit for re-use.

83. The drugs should be transferred to the pharmacy in a safe and secure way (see Chapter 6 paragraphs 14 - 27 Transfer of CDs).

Records of CDs returned: Ward or Department

84. The ward or department should keep a record of drugs returned to the pharmacy in the CD record book. The entry should be made on the relevant page of the CD record book and should show:

- 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.

85. Local policy should ensure that there is a fully auditable trail of the CD movement back to the pharmacy and the pharmacy register. It is appropriate for the ward/department CD drug requisition book to be used to record the details of CDs being returned to the pharmacy.

Records of CDs returned: Pharmacy

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

- Date.
- Name, form, strength and quantity of drug returned.
- Reason for return.

- Name and signature of the registered nurse, midwife or ODP.

Disposal of CDs in wards and departments

87. 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[11]

88. Some healthcare organisations may wish to provide denaturing kits for use on wards. 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 departments, a SOP should be developed for this practice. **(**See also Chapter 8 for information on disposal of CDs in pharmacies.)

Disposal of small amounts of CDs

89. 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. For larger quantities of partly used doses of CDs, e.g. patient-controlled analgesics, epidurals etc. There should be local systems in place to allow the drug to be denatured and disposed of appropriately and safely at ward/department level.

90. All destruction must be documented. It should be witnessed by a second competent person such as a registered nurse, midwife or ODP. Both persons should sign the destruction record. A separate page of the ward/department CDRB can be used for this purpose.

Method of disposal

91. 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*".

Discrepancies and diversion

92. The balances in the CD record books should always tally with the amounts of CDs in the cupboard. If they do not, the discrepancy must be reported, investigated and resolved.

93. There should be a local 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:

[11] Guidance for Pharmacists on the safe destruction of Controlled Drugs: England, Scotland and Wales. www.rpsgb.org.uk/pdfs/cdsafedestructionguid.pdf

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

94. If the error or omission is traced, the registered nurse, midwife or ODP in charge should make an entry in the CD record book 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 should sign the CD record book.

95. If no errors or omissions are detected then the discrepancy should be reported to the Pharmacist in Charge. If the discrepancy cannot be resolved it must be reported to the Accountable Officer without delay and a local incident form completed in line with the healthcare organisation's policy or procedure for reporting incidents. Further guidance is given in HDL(2007)12 dated 14 February 2007.

6. Management of CDs – general processes and specific circumstances

CD Stationery

1. The registered nurse, midwife or ODP in charge of a ward, department, operating theatre or theatre suite is responsible for the requisitioning of CDs for use in that area and for ensuring that all CD stationery used to order, return or distribute CDs is stored securely and that access to the stationery is restricted to those staff authorised to order CDs. .

Definition of CD stationery

2. CD stationery includes:

- CD requisition books.
- CD record books.
- Local CD documents such as CD returns advice notes, pharmacy distribution documents, Midwives Supply Order etc.

Secure storage of CD stationery

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

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

Supply of CD stationery

5. 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 such requisitions.

6. 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.

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

8. Healthcare organisations may wish to number CD requisition books to provide an additional means of tracking.

Use of CD stationery

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

10. 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, ODP or authorised member of staff e.g. pharmacy technician.

11. 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 Chapter 5 paragraph 51 and Chapter 8 paragraph 47 Archiving of records).

Loss or theft of CD stationery

12. Loss or theft of any CD stationery which may be used to order CDs should be reported immediately to the Pharmacist in Charge and Accountable Officer. There should be a local procedure to deal with the loss or theft of CD stationery.

Movement/Distribution of CDs within and outside the hospital

13. Movement/distribution 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 hospital 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.)

Methods of transfer

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

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

16. CDs may not be transported in pneumatic tubes.

Records of transfer

17. At each point where a CD moves from the authorised possession of one person to another, a signature for receipt should be obtained.

18. Healthcare organisations may wish to design local distribution/transport documentation as a means of keeping a full audit trail.

Messengers

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

20. 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 a valid ID badge.

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

22. Where a commercial courier or taxi driver is responsible for conveying a CD he/she should be asked to show their valid company ID.

23. 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.

Transfer of CDs from ward to ward or theatre to ward

24. Local procedures should define safe, secure and auditable methods to transfer CDs from ward to ward. 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.

25. Patients’ own CDs 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.

26. 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 paragraphs 37 - 42 Management CDs that are the patient's property.

Return/Transfer of CDs from ward to pharmacy

27. When CDs have to be returned to the pharmacy this should follow local procedures and ensure appropriate security precautions. The registered nurse, midwife or ODP in charge is responsible for their return.

Clinical trials

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

29. All clinical trial CDs should be stored separately from stock CDs. However, 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.

30. 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 Pharmacist in Charge and Accountable Officer. (See also Chapter 5 paragraphs 92 - 95 Discrepancies and diversion)

31. 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.

32. 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 Pharmacist in Charge and/or the Accountable Officer. A copy should be kept with the trial protocol.

Labelling

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

Disposal

34. The clinical trial protocol should stipulate requirements for disposal of CDs. Clinical trial CDs must be destroyed in the same way as other CDs (see Chapter 8 Destruction of CDs 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.

Clinical trial CDs returned by patients

35. The clinical trial protocol should stipulate requirements for handling of 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.

Arrangements for research departments

36. 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.

Management of CDs that are the patient's property

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

Use of a patient's own CDs on the ward

38. 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 to ensure that they are fit for purpose (see paragraphs 51 - 56 Self administration of CDs).

39. If patients' own CDs are not required for use in this way then, if the patient or the patient's representative agrees, medicines may be designated for destruction.

40. Patients' own CDs that are not to be used for self-administration should not routinely be stored on the ward. If they are accepted into the hospital they must be recorded in the ward's CDRB.

41. Temporary storage of patients' own CDs on the ward may be necessary whilst they are awaiting collection and removal to the pharmacy or to the patient's home. All CDs on the ward must be stored securely and recorded in the ward CDRB and be subject to same procedures as all other CD stocks.

42. Patient's own CDs should never be used to treat other patients.

CD discharge medicines

43. When CD discharge medicines 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.

44. When Schedule 2 CDs are collected from the pharmacy, the person collecting them (who may be the patient, his representative, a healthcare professional or porter) must sign for receipt.

Receipt of CDs by outpatients

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

46. 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/her professional capacity on behalf of the patient.

47. 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.

48. Where the person collecting the medicine is 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.

49. Any strengthening of controls has been balanced with ensuring that patients have access to the 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 is 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 healthcare professional acting on behalf of the patient;
- if the person who collected the drug was a healthcare professional acting on behalf of the patient, that person's name and address;
- if the person who collected 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.

Further information on these requirements is set out in CEL(2007)21[12].

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

Self-administration of CDs

51. A local procedure should be in place for wards or departments where patient self-administer their own medicines, including their CDs. This procedure should specify arrangements for the dispensing, recording of receipt of any additional supplies, storage and stock checking of these medicines.

52. When patients who self-administer CDs require additional supplies, these should be dispensed for discharge. Healthcare 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.

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

54. Healthcare 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.

55. The CDs for patients who self-administer 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. Healthcare 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 of who accessed the locker and when.

56. Useful sources of information about CDs for patients are listed at Appendix 2.

Out-of-hours supply

57. 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.

[12] www.sehd.scot.nhs.uk/mels/CEL2007_21.pdf

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

59. Local arrangements for emergency issue of CDs should be discussed with the pharmacy. Where such systems exist, a SOP should be developed.

Temporary ward closure

60. 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.

61. 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.

Transfer of wards

62. 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 occur, 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 paragraphs 60 - 61 Temporary ward closure).

63. 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.

64. 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.

65. 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.

Paediatrics

66. The general provisions apply equally to the management of CDs in paediatrics. There are, however, a few specific situations when the management of CDs may require a slightly different approach.

Part vials of CDs

67. On many occasions, the dose required for the patient is smaller than that which is contained in a single vial or ampoule and an amount may be left. 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 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 discarded". This should be witnessed by a second registered nurse, midwife or registered healthcare 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 healthcare 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 healthcare 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, a 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.

CDs Brought into Hospital belonging to Parents/Carers

68. Parents/carers who are substance misusers sometimes bring CDs prescribed and supplied for their own use on to hospital premises. There requires to be a local policy that addresses this. Healthcare organisations

may wish to consider whether they may want to store these CDs in the CD cupboard and the person then requests a dose from the nurse when required. These CDs should be clearly labelled and kept separate from other CDs and full records and controls maintained.

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

CDs for midwives

70. 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. There should be SOPs in place to cover acquisition, storage, recording, return and disposal of CDs.

Acquisition of CDs by midwives

71. 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.

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

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

74. 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.

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

Storage and records

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

77. 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.

78. 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.

79. Administration of CDs by midwives should be in accordance with locally agreed procedures.

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

Returns and disposal

81. When a midwife is in possession of opiates that are no longer required they should be surrendered to the Supervisor of Midwives or other Appropriate Medical Officer, who should make arrangements for safe disposal. A record of the return should be made in the midwife's CD Register.

82. Surplus or expired CD stock held by a midwife may only be destroyed by the midwife in the presence of an authorised witness (see Chapter 8 paragraph 79), The method of disposal should be in accordance with current Home Office guidance, Waste Management Regulations and SEPA guidance. CDs for destruction should be denatured using an approved method (see Chapter 8 paragraphs 91 - 98) and sent for incineration; they should not be disposed of in the sewerage system.

83. 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 second health professional should witness the destruction. If this is not possible then a member of the family may do so. A record of the destruction should be made in the midwife's record. Some healthcare organisations may wish to provide denaturing kits to midwives to ensure safe destruction.

84. CDs 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 woman's agreement in writing before removing the CD from her home and returning it to a pharmacy for safe disposal, on behalf of the woman.

Illicit substances

85. Healthcare organisations should take advice from their local police and if necessary the Serious and Organised Crime Agency concerning appropriate procedures for dealing with patients who bring suspected illicit substances into hospital.

7. Management of CDs in in-house operating theatres

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

Accountable individuals

2. 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.

3. 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 CDs 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)

4. Similar considerations apply to requisitioning and checking of CDs.

Standard Operating Procedures (SOPs)

5. The healthcare organisation should ensure that all the procedures for the management of CDs in in-house operating theatres and recovery wards are included in written SOPs 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. This is especially important in areas where many different staff are working perhaps for only a small part of their working week.

6. SOPs should be discussed with pharmacy and approved by the Accountable Officer or by the person to whom this task has been delegated.

CD stocks

7. There should be a list of stock item CDs to be held in each theatre. The contents of the list should reflect current patterns of usage of CDs in the theatre and should be agreed between the pharmacist or pharmacy technician 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.

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

Requisitioning of CDs

9. The registered nurse, midwife or ODP in charge of an operating theatre or theatre suite is responsible for the requisitioning of CDs for use in the theatre.

10. 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.

11. Wherever practicable different persons should be responsible for requisitioning and receipt of CDs.

12. Requisitions must comply with the requirements for suitable stationery, authorised signatories and content set out in Chapter 5 paragraphs 8 – 14 Requisitioning of CDs.

13. Healthcare 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.

Receipt of CDs

14. 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. 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 CDs.

15. Receipt of CDs in theatre should follow the provisions set out in Chapter 5 paragraphs 19 – 22 Receipt of CDs.

Storage of CDs

16. The storage arrangements for CDs in theatres should conform to the general provisions set out in Chapter 5 paragraphs 23 – 27 Storage of CDs.

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

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

Record-keeping

19. The records for CDs in theatres should conform to the general provisions set out in Chapter 5 paragraphs 35 – 40 Record-keeping.

20. In addition to the standard CD record books, some healthcare organisations may wish to stipulate the use of stationery that permits the

recording of more detailed records of CDs issued, administered and destroyed.

CD stock checks

21. The stock balance of all CDs 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.

22. 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.

23. CD stock checks should follow the provisions set out in Chapter 5 paragraphs 45 – 49 CD stock checks.

Archiving of CD records

24. The archiving of CD records in theatres should conform to the general provisions set out in Chapter 5 paragraphs 50 – 51 Archiving of CD records.

Prescribing of CDs

25. 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. Pharmacist Independent Prescribers may also be able to prescribe CDs.

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

27. Prescribing of CDs should follow the general provisions set out in Chapter 5 paragraphs 52 – 69 Prescribing of CDs.

28. There requires to be a record of:

- all CDs issued.
- CDs administered to each named patient.
- CDs returned to stock.

Administration

29. 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. 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 discarded* "

30. 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*".

31. 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.

32. 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.

Patient-controlled analgesia

33. 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.

Returning CDs to the pharmacy

34. The arrangements for returning CDs to the pharmacy should conform to the provisions set out in Chapter 5 paragraphs 81 – 83 Returning controlled drugs to the pharmacy.

35. Surplus stock should be returned to the pharmacy as described in Chapter 5 paragraphs 81 – 85.

Disposal of CDs

36. The disposal of CDs in theatres should conform to the general provisions set out in Chapter 5 paragraphs 87 - 88 Disposal of controlled drugs in wards and departments.

37. 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*".

38. If large quantities of part-used CDs are being added to sharps bins, some healthcare organisations may wish to provide denaturing kits for use in theatres. A risk assessment should be carried out before a decision is made. Where denaturing kits are provided to theatres, a SOP should be developed for this practice.

8. Management of CDs in hospital pharmacies

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

Accountability and responsibility

2. The Pharmacist in Charge 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 Pharmacist in Charge.

Security of CDs

3. The pharmacy should have SOPs covering each of the aspects of the safe management of CDs such as ordering, receipt, record-keeping etc.

4. 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.

5. SOPs should be approved by the Accountable Officer or by the person to whom he/she has delegated this task. The AO is accountable for all the systems for the safe management of CDs.

Ordering and receipt

6. 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.

Ordering

7. Routine orders to wholesalers and manufacturers for CDs for stock are usually placed electronically. Some healthcare organisations may, following a risk assessment, make a decision to store paper records.

8. 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.

Receipt

9. 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.
- specifications of the entry required in the register, including who should make the register entry and whether a witness is required.

10. It is good practice to record receipt at the first opportunity, and in any event no later than 24 hours after receipt. See paragraph 20 for receipt of Schedule 2 CDs.

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

12. The stock must be put away into the appropriate section of the CD cabinet promptly.

Storage

13. 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.

Issuing of CDs to wards and departments

14. 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).
- 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 the transfer of the CDs to the ward or department.

Electronic systems

15. 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.

Labelling of CDs

16. There should be a standardised procedure for labelling CDs issued from the pharmacy. The CD pack should clearly 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 the pharmacy.

17. 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.

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

CD registers

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

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

21. 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.

22. 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 Pharmacist in Charge, 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.

23. 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.

24. 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.

In addition, the serial number of indent/requisition number may be recorded as a matter of good practice.

25. 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.

26. 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.

27. 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. See also CEL(2007)21[13].

28. 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

[13] www.sehd.scot.nhs.uk/mels/CEL2007_21.pdf

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.

29. 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:

For CDs supplied the 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

For CDs obtained the following details must be recorded:

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

Liquid preparations

30. Discrepancies can arise with liquid CDs as a result of e.g. 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.

Computerised registers

31. 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.

32. 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 the 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 minimise 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.[14]

Checks of CD stocks held in the pharmacy

33. All CDs in the pharmacy should be checked periodically e.g. every month. Following a risk assessment, the frequency of such checks should be determined by the pharmacist with operational responsibility for managing CDs. This should be included in a SOP.

34. The check may be undertaken by any competent person approved by the pharmacist with operational responsibility for CDs. The system should enable CD registers to be reconciled with issues to wards/departments. The routine check should include sample reconciliations of the register against requisitions received in the pharmacy, plus checks of any exceptional usage. Exception issue or usage of CDs should be queried.

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

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

Checks of CD stocks held in wards, theatres or departments

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

38. 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.
- a check for exceptional usage of CDs.
- a check of the physical security arrangements for the storage of CDs, CD stationery and the key-holding policy.

39. The procedure may also include a check of patients' own CDs held on the ward at the time.

40. 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.

[14] SI 2864 www.opsi.gov.uk/si/si2005/20052864.htm

41. 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.

Discrepancies

42. 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 as soon as possible.

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

44. 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.

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

Archiving of CD records

46. Every requisition, order or private prescription on which a CD 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, healthcare organisations may wish to store them for longer periods, as cases often come to court at a much later date.

47. 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

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

Supply to outpatients and discharge patients

49. When outpatient prescriptions are being given directly to patients or their representatives, the patients or their representatives may be asked to provide evidence of identity when collecting Schedule 2 CDs.

50. 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. For information about the legal requirement please refer to HDL (2006)27[15].

51. Any strengthening of controls has been balanced with ensuring that patients have access to the medicines they clinically 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.

52. **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 healthcare professional acting on behalf of the patient;
- if the person who collected the drug was a healthcare professional acting on behalf of the patient, that person's name and address;
- if the person who collected 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.

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

54. Depending on local circumstances, some healthcare 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.

Supply to external units or other health and social care bodies

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

[15] www.sehd.scot.nhs.uk/mels/HDL2006_27.pdf

56. 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 CDs. 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 a supply if such a licence is held. (For further information see the Home Office Drug Laws and Licensing pages: www.drugs.gov.uk/drugs-laws/licensing/)

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

58. 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).

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

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

60. Other health and social care bodies include community hospitals and hospices. These bodies must comply with the legislation for CDs and should also follow the guidance in this document.

Written agreement (service level agreement)

61. 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).

62. In relation to CDs the following points should be included in the written agreement (service level agreement):

- What is to be supplied; stock CDs and /or patients' own CDs (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 guidance document "*Securing proper access to medicines in the out of hours period*"[16] and ensure that there is a complete, documented and coherent audit trail from stock room to patient.)
- Specification of responsibilities and accountability in relation to CD 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

[16] www.out-of-hours.info/downloads/ short_medicines_guidance.pdf

respective facilities. This should include the different ordering processes for stock CDs and patient-specific CDs (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/her 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 processes 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.

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

Ordering of stock CDs by another health and social care body

64. Ordering of CDs must comply with the current Misuse of Drugs Regulations.

65. Where a pharmacist is employed, the purchase of CDs 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 CDs raised by the senior registered nurse on duty.

66. All stock CDs should be ordered as stock items only and contain no patient names.

Arrangements when the hospital pharmacy provides a supply service only

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

68. The medical doctor will sign the order as an independent verification that the CDs so 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 CDs 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.

69. There are other corporate bodies where a medical doctor requests CDs and is responsible for the management of the CDs within the department of the other corporate body.

Requisitioning from a hospital pharmacy

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

Transfer of CDs

71. At each point where a CD moves from the authorised possession of one person to another, a signature for receipt should be obtained.

72. Wherever possible, the drug must be transported in a secure, tamper evident container and a suitable delivery document completed to provide a full audit trail. (See Chapter 6 paragraphs 14 - 27 Transfer of CDs.)

CDs returned from wards

73. There should be a local procedure for the management of CDs returned from wards. (See also Chapter 5 paragraph 81 Returns to Pharmacy.)

Production and Quality Control

74. Where pharmacy production units are preparing products that 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.

Disposal/destruction

75. 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.

76. 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 SEPA guidance. The methods used for denaturing should be in accordance with RPSGB guidance[17].

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

77. In Scotland, pharmacies should register an exemption under paragraph 39 of Schedule 3 to the Waste Management Licensing Regulations 1994 (as amended) with SEPA. The exemption covers the secure storage of CDs at a pharmacy prior to subsequent collection and disposal. SEPA is willing, at the present time, to accept that the denaturing of CDs forms part of the exempt activity of secure storage. However, SEPA may reconsider this position and pursue enforcement action if the denaturing activity causes, or is likely to cause, pollution of the environment or harm to human health.

78. See also Chapter 5 paragraphs 87 - 88 Disposal of CDs in wards and departments

Destruction of stock CDs

79. Any pharmacy held stock of obsolete, expired or unwanted Schedule 2 CDs not returned by patients that require destruction can only be destroyed in the presence of an authorised person. For further information on the destruction of CDs please refer to CEL(2007)21[18].

80. An amendment to the Misuse of Drugs Regulations which came into force on 16 August 2007, permits Accountable Officers to authorise people or groups of people to witness the destruction of CDs in compliance with these Regulations. Accountable Officers should not themselves be authorised to witness destruction as they must be independent from day-to-day management of controlled drugs.

81. 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.

82. 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

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

[18] www.sehd.scot.nhs.uk/mels/CEL2007_21.pdf

Destruction of CDs returned by patients

84. 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 must be kept securely and separate from pharmacy stock. When destroyed their destruction should be recorded appropriately.

85. 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 SOPs 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 in Scotland on 1 March 2007.

86. A record of CDs returned by patients should be kept and a record of destruction should be made.

87. 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.

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

89. CDs requiring safe custody awaiting destruction should be stored in the CD cabinet separately from pharmacy stock CDs.

90. Destruction of CDs 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.

Methods of disposal for CDs

91. 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*".

92. All CDs in Schedule 2 and those CDs in Schedule 3 that are subject to safe custody requirements (temazepam, diethylpropion, buprenorphine and

flunitrazepam) must be rendered irretrievable (e.g. by denaturing) before being placed into waste containers.

93. 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.

94. 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.

95. 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*".

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

97. 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*".

98. 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.

9. Staff training for management of CDs

1. Within designated bodies, the Accountable Officer is responsible for ensuring that members of staff who are involved in prescribing, supplying, administering or disposing of CDs receive appropriate training to enable them carry out their duties.

2. Staff should receive appropriate training on local SOPs for CDs when they first become involved in prescribing, supplying, administering or disposing of CDs and then regularly thereafter. The frequency of training should be determined locally.

3. 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 designated body who is responsible for the safe and effective management and use of CDs. 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, (e.g. orally or by injection) or by external application (e.g. application of an impregnated dressing). There are specific definitions in medicines 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.
CD record book (CDRB)	Bound book in which records are made of CDs received and administered in wards, theatres and departments.
CD register	Bound book, as specified in the Misuse of Drugs Regulations 2001 (as amended), in which records are made of CDs received and issued by pharmacies.
Designated body/bodies	Organisations 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 CDs 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 at a particular time.
Healthcare organisations	Organisations responsible for the delivery of healthcare, includes NHS hospitals and independent hospitals.
Local Intelligence Network	A network established by the Accountable Officer of an NHS Board for sharing information about CDs.
"May"	Used in this document in connection with recommendations concerned with good practice if they are relevant to local circumstances.
Midwives Exemptions	Exemptions from the requirements of the Medicines Act 1968 which allow registered midwives to sell, or supply specified medicines in the course of their professional practice. In addition, midwives are alloed to administer certain parenteral medicines in the course of their professional practice.
MDR	Misuse of Drugs Regulations made under the Misuse of Drugs Act (1971).
"Must"	Used in this document in connection with legal requirements.
Order	To make a formal order for CDs. Can only be done by a person 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 developed by a senior doctor (or dentist) and a senior pharmacist and authorised by a representative of the appropriate organisation giving registered nurses, pharmacists and other specified healthcare professionals a general authority to supply and administer specified medicines to patients, who may not be 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 or midwife in charge	The registered nurse or registered midwife who is in charge for the time being (senior registered nurse or midwife on duty) and is therefore responsible for the management of CDs.

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	Defined under the Controlled Drugs (Supervision of Management and Use) Regulations 2006.
Requisition	To make a formal, written request for a supply of a CD 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 Sometimes known as “Controlled Drug Order Books”.
Responsible body	Bodies listed in regulation 22 of the Controlled Drugs (Supervision of Management and Use) Regulations 2006.
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.
SEPA	Scottish Environmental Protection Agency
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. Full guidance is given in CEL(2007)14.
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	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.

Appendix 1: Useful contacts

British Medical Association Scotland
14 Queen Street
Edinburgh
EH2 1LL

Tel: 0131 247 3000
Fax: 0131 247 3001
Website: www.bma.org.uk

Community Practitioners' and Health Visitors Association Scotland
Unite
145-165 West Regent Street
Glasgow
G2 4RZ

Tel: 0141 248 7131
Website: www.amicustheunion.org/cphva/

General Medical Council Scotland
5th Floor, The Tun
4 Jackson's Entry
Holyrood Road
Edinburgh
EH8 8AE

Tel: 0131 525 8700
Fax: 0131 525 8701
Website: www.gmc-uk.org

Home Office Drugs Licensing Branch
2 Marsham Street
London
SW1P 4DF

Tel: 0207 035 0483
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

Nursing and Midwifery Council
23 Portland Place
London
W1B 1PZ

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

Information Services Division
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB

Tel: 0131 275 7777
Website: www.isdscotland.org

Royal Pharmaceutical Society
Scottish Directorate
36 York Place
Edinburgh
EH1 3HU

Tel: 0131 556 4386
Fax: 0131 558 8850
Website: www.rpsgb.org/scotland/

SEPA
Erskine Court
Castle Business Park
Stirling
FK9 4TR

Tel: 01786 457700
Fax: 01786 446885
Website: www.sepa.org.uk

Appendix 2: Information sources

NHS 24

The NHS 24 website has developed information about CDs including the legal definition of a CD, the Regulations and traveling abroad. This information can be accessed at www.nhs24.com .

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