

A guide to good practice in the management of controlled drugs in primary care (England)

Second Edition

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1 Introduction

This second edition of the guide takes into account significant legislative changes, introduced by the Government to strengthen the governance arrangements for controlled drugs (CDs) since publication of the first edition in December 2005. A number of changes affecting the prescribing, record keeping and destruction of CDs have been introduced as a result of amendments to the Misuse of Drugs Regulations 2001. The Health Act, which received Royal assent in July 2006, enabled Regulations to be laid relating to governance and monitoring of CDs which came into effect in England on the 1st January 2007.

Changes to primary legislation and the Misuse of Drug Regulations 2001 will apply to Scotland, England and Wales. Northern Ireland has its own misuse of drugs Regulations — Misuse of Drugs Regulations (Northern Ireland) 2002 — although these largely mirror the 2001 Regulations. However, arrangements for the new requirements may differ between each of the countries.

This guide is primarily aimed at developing good practice for the management of CDs in primary care in England, but also encompasses issues raised at the interfaces between primary, secondary and social care. Although this document is not aimed at the hospital setting, much of the content will have relevance to the management of CDs across all NHS and non-NHS settings.

The guide aims to identify robust systems for obtaining, storing, supplying, recording, monitoring and disposing safely of CDs, whilst at the same time helping to ensure appropriate and convenient access for those patients that require them. It does not advise on the clinical choice and application of CDs — the focus being directed towards defining processes for their appropriate and safe use once selected. References for the clinical use of CDs in a variety of settings are provided on page 6.

Implementation of the recommendations within the guide will require a systematic approach to improvement in the management and control of CDs, enhancing patient and public safety, whilst at the same time ensuring that health care professionals are not overburdened with additional bureaucracy resulting in reluctance to prescribe CDs. The emphasis, therefore, is predominantly on the roles and responsibilities of health care professionals commonly involved in the management of CDs, especially in primary care. The development and use of standard operating procedures (SOPs) are an important means of enshrining good practice into everyday health care activities.

The guide should be of value in a wide range of settings where CDs are used, including:

- GP and dental practices
- Pharmacies
- Midwifery services
- Out-of-hours services
- Patients' own homes
- Care homes
- Community nursing services
- Community palliative care services
- Substance misuse services
- Hospices
- Prison services.

When Primary Care Trusts (PCTs), including Care Trusts, are commissioning services involving CDs, either within the NHS or from non-NHS organisations, they should ensure that the same standards and good practice frameworks apply in these settings.

Each of the main sections of this guide has been formatted, where appropriate, into two categories. The first identifies and clarifies the current key legal and regulatory frameworks, and the second provides good practice recommendations within these frameworks. Planned regulatory and other changes are also now highlighted.

Whilst every care has been taken to ensure the accuracy of this guide, the National Prescribing Centre (NPC) cannot accept liability for any errors or omissions. The contents of this guide will be updated over time to reflect proposed and potential legislative / regulatory changes under consideration. Therefore, individuals looking for guidance and support should ensure that they refer to the most recent edition of this guide, plus any other national guidance, legislation and directions that may have been published.

Unfortunately, the NPC is not in a position to be able to answer specific individual queries relating to the management of CDs. However, individual professional organisations provide a range of advisory services to their members (see Appendix 3 — Useful contacts).

The NPC website www.npc.co.uk, the Department of Health (DH) website www.dh.gov.uk/controlleddrugs, the Home Office websites www.homeoffice.gov.uk and www.drugs.gov.uk/drugs-laws/ and the Royal Pharmaceutical Society of Great Britain (RPSGB) website www.rpsgb.org.uk should be referred to regularly, amongst others.

Examples of guidelines in a variety of settings

- British Pain Society www.britishpainsociety.org
Pain and substance misuse: improving the patient experience August 2006
Recommended guidelines for pain management programmes for adults
- Joint Royal Colleges Ambulance Liaison Committee Clinical Practice Guidelines
www.asancep.org.uk/JRCALC/guidelines
- Royal College of General Practitioners (RCGP) runs a training programme specifically for the management of drug users www.rcgp.org.uk/drugindex.aspl.
- British National Formulary www.bnf.org

2 Relevant Acts of Parliament and Regulations

Misuse of Drugs Legislation

The Misuse of Drugs Act 1971 and its Regulations control the availability of drugs that are considered sufficiently 'dangerous or otherwise harmful', with the potential for diversion and misuse. The drugs which are subject to the control of the Misuse of Drugs Act 1971 and are listed in Schedule 2 of the Act and are termed CDs. The Act establishes a series of criminal offences for their unauthorised, and therefore unlawful, possession, possession with intent to supply, supply, importation and unlawful production.

As many CDs have legitimate medical purpose, the Regulations made under the Misuse of Drugs Act 1971, authorise and govern certain activities which would otherwise be illegal under the Act. The Regulations identify those health care professionals who may legitimately possess and supply CDs. They also establish a regime of control around prescribing, administering, safe custody, dispensing, record keeping and destruction or disposal.

Misuse of Drugs Act 1971

Drugs controlled under the Misuse of Drugs Act 1971 are divided into three classes — Classes A, B and C — for the purposes of establishing the maximum penalties which can be imposed in criminal law on persons convicted of any of the offences under the Act. The class of a drug reflects its relative harm to the individual and to society when misused, in a descending order of severity, from A–C. The maximum penalties for offences of possession and supply of the main CDs within each class are outlined in the table below (summary provided by the Home Office).

Drug class	Penalties for possession	Penalties for supply
Class A — diamorphine (Heroin), cocaine (Crack), MDMA (Ecstasy), lysergic acid diethylamide (LSD), Methamphetamine, cocaine, more potent opioid analgesics, e.g. methadone	Up to seven years imprisonment or an unlimited fine or both	Up to life imprisonment or an unlimited fine or both
Class B — amphetamine, barbiturates, less potent opioid analgesics, e.g. codeine	Up to five years imprisonment or an unlimited fine or both	Up to 14 years imprisonment or an unlimited fine or both
Class C — cannabis, benzodiazepines (and zolpidem) ketamine, anabolic steroids, and gamma-hydroxybutyrate (GHB)	Up to two years imprisonment or an unlimited fine or both	Up to 14 years imprisonment or an unlimited fine or both

NB: Any Class B drug in injectable form is treated as Class A. Some Class C drugs are legal to possess — for example, anabolic steroids are Schedule 4 Part II and may be possessed in medicinal form without a prescription

The Act establishes the Advisory Council on the Misuse of Drugs (ACMD) as a statutory committee, which has a duty to keep under review the misuse of drugs in the United Kingdom and to advise Ministers on measures that deal with social problems caused by drug misuse.

Misuse of Drugs Regulations 2001 (2001 Regulations)

The current version of the Regulations made under the Misuse of Drugs Act 1971 are the Misuse of Drugs Regulations 2001 (2001 Regulations) which came into operation on the 1st February 2002. (The first Regulations were made in 1973, were amended on many occasions and replaced by the Misuse of Drug Regulations 1985, which in turn were amended several times before being replaced by the Regulations currently in force, the 2001 Regulations).

The 2001 Regulations have been subject to a number of amendments since 2001. For details of the more recent amendments, links to the Home Office Circulars — which set out summaries of the changes — are as follows:

- 14th November 2005: Home Office Circular 48/2005
www.knowledgenetwork.gov.uk/HO/circular.nsf/79755433dd36a66980256d4f004d1514/e36f3a7e7c6e8119802570b400565d0a?OpenDocument
- 7th July 2006: Home Office Circular 20/2006
www.knowledgenetwork.gov.uk/HO/circular.nsf/79755433dd36a66980256d4f004d1514/b4889f1eb47a8e9f802571aa005b1ced?OpenDocument
- 1st September 2006: Home Office Circular 27/2006
www.knowledgenetwork.gov.uk/HO/circular.nsf/79755433dd36a66980256d4f004d1514/2462fd7b73736929802571dc0048efe5?OpenDocument.

You should check the Office of Public Sector information website (www.opsi.gov.uk) on a regular basis to ensure you are up-to-date with amendments.

The 2001 Regulations divide CDs into five Schedules, which dictate the degree to which a CD's use is regulated. The Schedule in which a CD is placed depends upon its medicinal or therapeutic benefit balanced against its harm when misused. Schedule 1 CDs are subject to the highest level of control, whereas Schedule 5 CDs are subject to a much lower level of control.

Schedule 1 (CD Licence)

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 under Home Office licence. Other Schedule 1 drugs include hallucinogenic drugs such as coca leaf, lysergide and mescaline. Production, possession and supply of drugs in this Schedule are limited to research or other special purposes that are considered to be in the public interest. Only certain persons can be licensed by the Home Office to possess them for these purposes. Practitioners ('practitioner' is defined in s.37 Misuse of Drugs Act 1971 as a doctor, dentist, veterinary practitioner or veterinary surgeon) and pharmacists may not lawfully possess Schedule 1 drugs except under licence from the Home Office.

Schedule 2 (CD)

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

Schedule 2 CDs (except quinalbarbitone) 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.

A licence is required to import or export drugs in Schedule 2. They 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 them to a patient only on the authority of a prescription in the required form (see page 27) issued by an appropriate prescriber. 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. Nurse independent prescribers are permitted to prescribe, administer, or direct anyone to administer some CDs for specific conditions and routes of administration (Refer to page 24).

A register must be kept for Schedule 2 CDs and this register must comply with the requirements of the 2001 Regulations.

The destruction of Schedule 2 **stock** CDs must only take place in the presence of an appropriately authorised person. (For further information on appropriately authorised person, see page 49). Patient returns do not currently have to be witnessed by an authorised person but good practice would deem that another person witnesses it. (For further information on patient returns, see page 51).

Schedule 3 (CD No Register)

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

The majority of Schedule 3 CDs are exempt from safe custody requirements and can be stored on the open dispensary shelf. Exceptions are flunitrazepam, temazepam, buprenorphine and diethylpropion, which must be stored in a locked 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.

There is no legal requirement to record transactions involving Schedule 3 CDs in a CD register. 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 (CD Benzodiazepines and CD Anabolic steroids)

Schedule 4 is split into two parts.

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

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

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

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

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

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

Schedule 5 (CD Invoice)

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

There is no restriction on the import, export, possession, administration or destruction of these preparations and safe custody Regulations do not apply. The Misuse of Drugs Regulations 2001 have been amended so that preparations containing not more than 0.1% cocaine are no longer exempt from prohibitions on import, export and possession. This change came into force on 14th November 2005. A practitioner or pharmacist acting in his capacity as such, or a person holding an appropriate licence, may manufacture or compound any CD in Schedule 5. Invoices must be retained for a minimum of two years.

Misuse of Drugs (Safe Custody) Regulations 1973

The Misuse of Drugs (Safe Custody) Regulations 1973 (the Safe Custody Regulations) imposes controls on the storage of CDs. The degree of control depends on the premises within which the drugs are being stored.

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

Misuse of Drugs (Supply to Addicts) Regulations 1997

These Regulations prohibit doctors from prescribing, administering or supplying diamorphine, cocaine or dipipanone for the treatment of addiction or suspected addiction except under Home Office licence. A licence is not required with such drugs for the treatment of organic disease or injury.

Medicines Act 1968

This Act sets out the requirements for a valid prescription. It also allows midwives to possess and administer diamorphine, morphine, pethidine or pentazocine.

A number of health care professionals are permitted to supply or administer medicines in accordance with a Patient Group Direction (PGD) under Medicines Act legislation. Some of these professional groups, but not all, are permitted to supply or administer CDs in accordance with a PGD under Misuse of Drugs legislation (See page 11).

Health Act 2006

The key provisions of the Act are:

- All designated bodies such as health care organisations and independent hospitals are required to appoint an accountable officer
- A duty of collaboration placed on responsible bodies, health care organisations and other local and national agencies including professional regulatory bodies, police forces, (in England) the Healthcare Commission and the Commission for Social Care Inspection (CSCI) to share intelligence on CD issues
- A power of entry and inspection for the police and other nominated people to enter premises to inspect stocks and records of CDs.

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

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

These Regulations set out the requirements for certain NHS bodies and independent health care bodies to appoint an accountable officer and describe the duties and responsibilities of accountable officers to improve the safe management and use of CDs.

The Regulations also require specified bodies to co-operate with each other, including with regard to sharing of information, about concerns about the use and management of CDs, and set out arrangements relating to powers of entry and inspection. (Further details are provided in section 20 — Governance, inspections and monitoring, see page 78).

Additional information

- A comprehensive list of drugs included within these Schedules is given in the Misuse of Drug Regulations 2001 and can be accessed at www.opsi.gov.uk
- A summary of the legal requirements is provided in Appendix One (see page 84)
- A summary produced by the National Pharmacy Association (NPA) can also be accessed via the NPA website at www.npa.co.uk
- The Healthcare Commission is responsible for overseeing the Regulation of the management of CDs by health care organisations in England at www.healthcarecommission.org.uk
- Home Office website at www.homeoffice.gov.uk
- Medicines and Healthcare products Regulatory Agency (MHRA) website at www.mhra.gov.uk
- RPSGB website at www.rpsgb.org.uk

3 Possession of controlled drugs

Legal framework

The Misuse of Drugs Act 1971 states, that a person may not legally have a CD in their possession unless the Regulations allow them to do so. Unlawful possession of any CD in Schedules 2 to 4 (Part 1) is a criminal offence.

Persons who can legally **possess CDs include:**

- Medical practitioners (this includes doctors, dentists and veterinary surgeons)
- Pharmacists or a person lawfully conducting a retail pharmacy business
- Supplementary prescribers where CDs form part of an agreed Clinical Management Plan
- Nurse independent prescribers, but restricted to a specified range of CDs for specific medical conditions
- Any person administering under the direction of a doctor or dentist
- Midwives acting in their capacity as such (only those CDs that she / he may administer in accordance with Medicines Act)
- Paramedics acting in their capacity as such (Only those CDs which are the subject of the Group Authority issued by the Secretary of State under the 2001 Regulations)
- Health professionals supplying or administering certain categories of CDs under a PGD
- Individuals and bodies corporate licensed by the Home Office Drugs Branch
- Persons in charge of a hospital or care home with nursing
- Someone who is transferring, with permission, a CD to another person who is lawfully allowed to have it in their possession. This permission may be granted by the person authorised to possess and should be in writing
- Someone who has legally been prescribed a CD
- Constables when acting in the course of their duty as such
- Persons engaged in the business of a carrier when acting in the course of that business
- Persons engaged in the business of a postal operator when acting in the course of that business
- Customs and excise officers when acting in the course of their duty as such
- Persons engaged in the work of any laboratory to which the drug has been sent for forensic examination when acting in the course of their duty as a person so engaged
- Someone who has found a CD and is immediately taking it to a person who may lawfully possess it, e.g. a pharmacist for a medicinal product, a police officer for illicit drugs
- Someone who has removed a CD from someone else to stop them offending and is immediately taking it to a person who may lawfully possess it.

The following health care professionals are authorised under the Misuse of Drugs Regulations 2001 to **possess, supply and compound** CDs in Schedules 2, 3, 4 and 5:

- Doctors
- Dentists
- Pharmacists.

These people may only supply CDs to those who may lawfully possess them, including patients for whom a drug is prescribed.

Controlled drugs declaration statement and self-assessment

All organisations providing clinical services and relevant social care organisations who hold CDs are required to carry out a self assessment, which will inform other monitoring and inspection activities. (For further information see section 20 — Governance, inspections and monitoring, page 80).

All health care organisations providing clinical services, and relevant social care organisations, will need to:

- Complete a periodic declaration on whether or not their organisation keeps stocks of CDs
- Those that do hold stocks of CDs will be required to complete a self assessment of their management of CDs.

A declaration and self-assessment questionnaire will be sent to organisations by the relevant agency (see page 80 for details), and may be included in other assessments or planning tools, e.g. The Healthcare Commission will use existing methodologies such as the Annual Health Check Core Standards Assessment for Trusts.

The relevant agency can determine the frequency of self-assessment. A model declaration and assessment form for use in primary care is available at www.dh.gov.uk/PolicyAndGuidance/MedicinesPharmacyAndIndustry/Prescriptions/ControlledDrugs/fs/en.

Standard Operating Procedures

- All health care providers holding stocks of CDs should have SOPs, which will be monitored as part of the strengthened governance arrangements for CDs
- Minimum requirements for SOPs are outlined in Controlled Drugs (Supervision of Management and Use) Regulations 2006
- Refer to page 74 for further guidance.

4 Purchasing and supply of controlled drugs

Requisitions

Legal framework (general)

It is important to distinguish between supplies of CDs prescribed for individual patients on a prescription and those obtained by practitioners for stock or bags for home visits, etc. Medicines prescribed for an individual patient must be supplied to, and used by, that patient only. The prescribing of CDs is covered in full (page 24).

Practitioners must NOT use patient-specific CD prescriptions to replace or 'top-up' their bags for home visits, etc. or practice stock, even if the stock was used for that patient initially. This could be considered as a potential offence under the Theft Act 1968 and might be seen as a means of obtaining CDs by deception.

The following can obtain supplies of Schedule 2 or 3 CDs for use in their practice, business or profession:

- A practitioner (this includes doctors, dentists, and veterinarians)
- A person in charge of a laboratory, which carries out scientific research or education and is attached to a university, university college, hospital or approved institution
- The owner or master of a ship, which does not carry a doctor on board
- Requisitions supplied by the master of a foreign ship must contain a statement, signed by the appropriate authority (Port health authority officer in England and Wales or Medical officer in Scotland and Northern Ireland), indicating that the quantity of the drug is necessary for the equipment of the ship
- The installation manager of an offshore installation (such as an oil-rig)
- Schedule 2 drugs may be possessed by the person or acting person in charge of a hospital or nursing home which is wholly or mainly maintained by a public authority out of public funds or by a charity or by voluntary subscriptions. In other such circumstances, a licence is required. (With Schedule 3 and 4 drugs, the basis of the funding makes no difference at all and the person in charge may supply and possess under the authority of the Regulations). Such requisitions must be countersigned by a doctor or dentist who work there.

Good practice (general)

Any person or organisation that holds stocks of CDs should keep stock levels to a minimum but enough to meet clinical need. CD usage, for example, over the last two years, should be reviewed when assessing current stock requirements. The level of stock held should then be reviewed on an appropriate / annual basis.

Requisitions and invoices for CDs should ideally be kept for longer than the mandatory two years, as cases often come to court at a much later date, by which time the evidence would have been destroyed.

Potential change

The Government is considering changing the Regulations for CD requisitions for Schedule 2 and 3 CDs. Any changes will be subject to consultation.

Purchasing by practitioners from wholesalers or pharmacies for practice use or stock purposes

Legal framework

Schedule 2 and 3 controlled drugs

Practitioners (doctors and dentists) may obtain CDs from pharmacies or wholesalers for practice use or stock upon the production of a written requisition.

Schedule 4 and 5 controlled drugs

A requisition is not required before supplying or obtaining Schedule 4 or 5 CDs.

Requisition requirements

Requisitions for Schedule 2 and 3 CDs have to be in writing not computer generated. They do not need to be written in the recipient's own handwriting, and may be written by a receptionist or secretary, etc. However, the recipient must sign the requisition.

Requisitions must:

- Be signed by the prescriber
- State the prescriber's name and address
- State the prescriber's profession or occupation
- Specify the total quantity of the drug (this does not have to be in words and figures)
- Specify the purpose for which it is required, such as 'for practice use'.

A wholesaler or pharmacy supplying CDs to a prescriber must be reasonably satisfied that the requisition is a genuine document. This means that it should be the original document, hence faxed or other electronically transmitted requisitions are not currently permitted.

If a messenger is sent to collect the CD they must carry a bearer's note, signed and dated by the prescriber, stating that they are authorised to collect the CD.

Retention of requisitions

Suppliers must keep all requisitions for a minimum of two years. The 2001 Regulations have been amended to allow the information contained in orders, requisitions and private prescriptions to be preserved as a copy on computer. Safeguards must be in place to ensure the following:

- Data cannot be altered at a later date
- All entries are attributable to an individual making the entry
- That all data can be recallable for audit purposes
- That adequate backups are made
- Those systems are in place to minimise the risk of unauthorised access to the data.

Emergency supply

Urgent supplies to practitioners

A practitioner who requires a Schedule 2 or 3 CD urgently and who is unable to supply a signed order can request the drugs to be supplied in an emergency. The practitioner may be supplied with the CD provided he or she gives an undertaking to supply a written, signed requisition **within 24 hours**. Failure to do this is a criminal offence on the part of the practitioner.

Good practice

- The prescriber's identification number (i.e. their professional registration number) should be included on the requisition
- Suppliers of CDs should provide a delivery note for the purchaser to sign. The person signing the delivery note should be authorised to receive CDs by the prescriber. A copy of the signed delivery note should be retained by the supplier
- Any bearer's note should be retained by the pharmacy for a minimum of two years.

(For emergency supply of Schedule 2 and 3 CDs to patients, see page 33).

Purchasing by pharmacists and doctors from wholesalers

In addition to the legal requirements and good practice described previously in this chapter, the following applies when purchasing **from wholesalers**.

Note that pharmacists do not need to issue a signed order when purchasing Schedule 2 or 3 CDs from a pharmaceutical wholesaler. However, this does not apply to ordering wholesale supplies to support a pharmacist's supplementary prescriber function.

Legal framework

Pharmacists or doctors, when purchasing CDs from wholesalers for their dispensary, can already order them electronically. Doctors, however, must provide the wholesaler with a requisition, as described on page 16, on receipt of the CDs.

It is the responsibility of the pharmacist or doctor, when receiving a supply of CDs from the wholesaler, to ensure that the correct item is delivered and that all appropriate entries are made in the CD register on the day of supply, or the day following the day of supply. The task of completing the register can be delegated, but the pharmacist or doctor retains full accountability for this process.

Good practice

Any tamper-evident seals on packs of CDs should be left intact when they are received from the supplier. This will simplify and speed up routine balance checks, as sealed containers can be assumed to contain the full amount as stated on the pack. A seal should only be broken when the pack is required for dispensing / administration.

If, when the tamper-evident seal is broken, the contents do not match the expected amount stated on the manufacturer's pack, the following action should be taken:

- Wherever possible the pack and contents should be kept as evidence to present to the manufacturer and the CD should be dispensed from an alternative pack to the patient
- Where this is not possible because patient care will be compromised, the professional should assure themselves that the contents are suitable for dispensing and then appropriately repackage them for the patient, keeping the original packaging for evidence and action
- Appropriate records should be made in the CD register and all necessary action taken to resolve the discrepancy.

The person receiving CDs from the wholesaler should be authorised in writing in advance to do so by the pharmacist or doctor, and should sign the supplier's delivery note on receipt of these CDs.

Where CDs are transferred between pharmacies, the pharmacist requesting the supply should provide a requisition, and the pharmacist providing the supply should retain this. Both pharmacists must ensure that the correct entries are made in their respective CD registers within 24 hours.

Acquisition of controlled drugs by other health care professionals

In addition to the legal requirements and good practice described previously in this chapter, the following applies when other health care professionals acquire CDs.

Legal framework

Midwives

A Registered midwife who has, in accordance with the provisions of the nurses, midwives and Health Visitors Acts (1979 and 1992), notified her intention to practice to the Local Supervising Authority is authorised to possess and administer specified CDs as far as is necessary for his / her professional practice.

The Misuse of Drug Regulations 2001 covers the possession and administration of CDs by midwives. Certified midwives are authorised to possess and administer certain medicines including diamorphine, morphine, pentazocine and pethidine in the course of their practice.

Community practice

Midwives Supply Order

Local Supervising Authorities (LSA) determine their own systems for providing midwives with supply orders in their area.

Midwives may obtain specified CDs from a community pharmacy by a Midwives Supply Order, signed by the 'appropriate medical officer' who is authorised in writing by the local supervising authority (i.e. Health Authority).

The Midwives Supply Order must state:

- The name and occupation of the midwife
- The purpose for which the CD is required
- The total quantity required.

Supplies from Midwifery Unit / Trust

Midwives can also obtain CDs for an individual patient from stock held within a Midwifery Unit / Trust. If stock is used in this way, then the midwife must record the usage in the CD register. If the CD is not subsequently used for that patient, it can be returned into stock and entered as such, back into the CD register. This practice should be defined by a local SOP.

Midwives must also make all relevant entries in their own CD registers.

[Individual patient prescription](#)

Alternatively, a prescription can be written by a doctor, e.g. a GP if that patient is under their care. The patient obtains the prescribed CD from a pharmacy and keeps it in their home until it is required for administration by the midwife.

Hospital

Drug Supply Orders are only issued to community midwives, and not to midwives operating in the hospital setting. The administration of CDs by midwives working in a hospital or institution should be in accordance with locally agreed policies and procedures.

Paramedics

Ambulance paramedics serving at any approved ambulance station are able to administer diazepam and / or morphine sulphate injection (to a maximum of 20mg) for immediate necessary treatment of sick or injured persons.

Hospices, community hospitals and independent hospitals

Where a hospice, community hospital or private hospital does not employ a pharmacist, the person or acting person in charge may obtain CDs via a requisition signed by a doctor (or dentist) employed or engaged there. This requisition may be presented to a wholesaler, community pharmacy or the pharmacy department of an NHS Trust with whom a service level agreement (SLA) is in place. Establishments with employed pharmacists can obtain CD stocks via a requisition, which complies with the Regulations described earlier.

Out-of-hours premises

At out-of-hours premises, as long as the ordering, supply or dispensing of CDs is undertaken by a doctor or pharmacist, CD stock can be ordered via a requisition, as described earlier. However, if these duties are undertaken by anyone else, e.g. an office manager the out-of-hours provider requires a Home Office licence.

Good practice

Midwives

Where a CD has been prescribed for a patient, but not used during a home birth, then that patient should normally return it to a pharmacy for safe destruction and disposal, as it is no longer required for the purpose for which it was prescribed. Midwives should recommend to patients that they should return unused CDs to the pharmacy. Where this is not practical, midwives should obtain the patient's agreement before removing the CD from the patient's home and returning it to a pharmacy or GP dispensing practice for destruction, but this practice is not recommended by the Royal College of Nursing.

Out-of-hours premises

In terms of good practice when managing CDs out-of-hours, reference should be made to the following DH guidance 'Securing proper access to medicines in the out-of-hours period' www.out-of-hours.info/downloads/short_medicines_guidance.pdf and the accompanying practical guide www.out-of-hours.info/downloads/medicines_supply_guidance__a_practical_guide.pdf.

To strengthen governance arrangements a SOP should be drawn up to define who requisitions the CDs (normally the person in charge), what documentation is required and how stock movements are audited, etc.

Potential change

The Government is piloting Patient Drug Record Cards (PDRCs) for injectable Schedule 2 CDs. Following this pilot and consultation, the Government may consider regulatory change by the Home Office.

5 Preparation and administration of controlled drugs

Legal framework

- Any person may legally administer a Schedule 5 CD to any other person
- When administration of a Schedule 5 CD is defined in a PGD only those health care professionals specified in the PGD can supply / administer in this circumstance as they cannot delegate this function
- For more information about administration of CDs under PGDs (see page 26)
- A doctor, dentist or any person acting in accordance with the directions of a doctor or dentist may administer any Schedule 2, 3 or 4 CD from stock
- Nurse independent prescribers or any person acting in accordance with their directions can administer a limited range of CDs (see page 24)
- Some professional groups, but not all, are permitted to supply or administer CDs in accordance with a PGD (see page 26)
- A carer / relative can, with consent, administer a CD that has been individually prescribed for a third party. As CDs are included within the legal category of prescription-only medicines (POMs), home carers who are competent to administer medicines should also be competent to administer CDs
- Midwives may possess those CDs, which they may lawfully administer under the Medicines Act (i.e. diamorphine, morphine, pethidine and pentazocine)
- Ambulance paramedics can supply and / or administer under PGD all drugs listed in Schedules 4 and 5 with the exception of anabolic steroids. Under separate exemptions to medicines legislation and more specifically by a group authority issued under the 2001 Regulations by the Secretary of State (Reg 8 (3)), NHS employed ambulance paramedics serving at any approved ambulance station are able to administer diazepam 5mg/ml emulsion for injection and / or morphine sulphate injection (to a maximum of 20mg) for immediate necessary treatment of sick or injured persons.

Good practice

Except in exceptional circumstances, the person prescribing the CD should not also personally undertake all of the following tasks: preparation, dispensing, transportation and administration of the CD. For safety reasons it is always good practice to ensure that wherever possible another appropriate competent individual is involved in, and thus can reflect on, the process. There will be occasions, such as the initial treatment of acute myocardial infarction, where this separation of tasks is not possible. Where this is the case, it is important that accurate records are kept.

Depending on the environment of care that the patient is in, a record of each administration should be kept in the relevant patient clinical notes. This record should specify the date, time, strength, presentation and form of administration, dose administered as well as the name and occupation of the person administering it.

Safeguards must be in place when any prescribed medicine is given to residents of Care Homes by care workers. A procedure for giving CDs to residents should be in place to minimise the potential for a drug error. This should include a witness to the administration of CDs unless this is not practical.

Refer to 'CSCI — Safe management of CDs in care homes' for further guidance www.csci.org.uk.

Serious medication errors have been reported as a result of process errors during the preparation and administration of injections, including CDs. Health care organisations should publish policies and procedures that define safe medication practice for the preparation and administration of injections, including CDs.

- National Patient Safety Agency (NPSA) alert letter 25th May 2006
www.npsa.nhs.uk/health/display?contentId=5065
- ‘Good practice statement for the preparation of injections in near-patient areas, including clinical and home environments’, published by the Scottish Executive and available at
www.scotland.gov.uk/resource/doc/46932/0013922.pdf
- ‘Building a safer NHS for patients’, published by the DH, January 2004 and available at
www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4006525&chk=wLMQjJ.

Any such procedures should include references to information on the following:

- Aseptic preparation
- Manufacture
- Mixing two or more medicines in a syringe — drug compatibility
- Expiry dating and labelling of prepared medicines
- Single-checking, versus double-checking with another practitioner or carer
- Safe administration of bolus doses
- Programming and safe use of syringe-driver pumps
- Warnings about the danger of confusing different strengths and types of CDs during preparation and administration.

Extemporaneous preparation of methadone

The RPSGB issued guidance on the extemporaneous preparation of methadone mixture in February 2006.

- If a licensed product is available, methadone mixture should only be prepared extemporaneously if the quantity of methadone dispensed on a regular basis is large enough to preclude storage of sufficient quantities of the licensed product
- SOPs must be in place for the extemporaneous preparation of methadone
- It is essential that robust standards and systems are in place to ensure the quality of extemporaneously prepared methadone so that patient care is not compromised.

Full guidance is available at www.rpsgb.org/pdfs/extprepmethmixtguid.pdf.

Potential change

The Government is piloting PDRCs for injectable Schedule 2 CDs. Following this pilot and consultation, it will consider regulatory change by the Home Office.

6 Prescribing of controlled drugs

Legal framework

Medical practitioners

Doctors and dentists may prescribe all CDs in Schedules 2 to 5 for organic disease. Doctors are only able to prescribe diamorphine, dipipanone and cocaine to substance misusers for the treatment of addiction if they hold a licence issued by the Home Office. All doctors may prescribe such drugs for patients, including substance misusers, for the relief of pain due to organic disease or injury without a specific licence. (Note: supplementary prescribers working within agreed patient specific management plans who prescribe for substance misusers for the treatment of addiction are not currently able to apply for a licence from the Home Office; licences are restricted to doctors).

Potential policy change

In early 2007, the Home Office is issuing a public consultation on the expansion of those professionals entitled under the Misuse of Drugs (Supply to Addicts) Regulations 1997 to apply for a licence.

Non-medical prescribers

Community practitioner nurse prescribers

Community practitioner nurse prescribers may only prescribe those products and medicines specified in the Nurse Prescribers' Formulary for community practitioners. No CDs are included in this formulary.

Nurse independent prescribers (formerly extended formulary nurse prescribers)

From 1st May 2006, the Nurse Prescribers' Extended Formulary was discontinued and qualified nurse independent prescribers are now able to prescribe any licensed medicines for any medical condition within their competence, including some CDs for specific conditions. The 2001 Regulations were amended, with effect from 1st May 2006, to reflect the change in terminology relating to nurse independent prescribers. The condition of tonic-clonic seizures was also added as an allowable indication for the prescribing of diazepam, lorazepam and midazolam.

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

Drug	Schedule ¹	Indication	Route of administration
Buprenorphine	3	Transdermal use in palliative care	Transdermal
Chlordiazepoxide hydrochloride	4	Treatment of initial or acute withdrawal symptoms caused by the withdrawal of alcohol from persons habituated to it	Oral
Codeine phosphate	5	N/A	Oral
Co-phenotrope	5	N/A	Oral
Diamorphine hydrochloride	2	Use in palliative care, pain relief in respect of suspected myocardial infarction or for relief of acute or severe pain after trauma, including in either case post-operative pain relief	Oral or parenteral
Diazepam	4	Use in palliative care, treatment of initial or acute withdrawal symptoms caused by the withdrawal of alcohol from persons habituated to it, tonic-clonic seizures	Oral, parenteral or rectal
Dihydrocodeine tartrate	5	N/A	Oral
Fentanyl	2	Transdermal use in palliative care	Transdermal
Lorazepam	4	Use in palliative care, tonic-clonic seizures	Oral or parenteral
Midazolam	4	Use in palliative care, tonic-clonic seizures	Parenteral or buccal
Morphine hydrochloride	2	Use in palliative care, pain relief in respect of suspected myocardial infarction or for relief of acute or severe pain after trauma, including in either case post-operative pain relief	Rectal
Morphine sulphate	2	Use in palliative care, pain relief in respect of suspected myocardial infarction or for relief of acute or severe pain after trauma, including in either case post-operative pain relief	Oral, parenteral or rectal
Oxycodone hydrochloride	2	Use in palliative care	Oral or parenteral administration in palliative care

1 Schedule 1–5 of the Misuse of Drugs Regulations 2001

For the purposes of nurse independent prescribing, palliative care means the care of patients with advanced, progressive illness.

Pharmacist independent prescribers

Pharmacist independent prescribers cannot currently prescribe any CDs, although community pharmacists can advise on and sell Schedule 5 CDs from a pharmacy.

Potential policy change

In early 2007, the Home Office is issuing a public consultation on the expansion of nurse independent prescribing of CDs and to allow prescribing of CDs by pharmacist independent prescribers.

Supplementary prescribers

The 2001 Regulations were amended in March 2005 to add supplementary prescribers to the list of people authorised to write prescriptions for CDs, providing they are acting in accordance with a Clinical Management Plan. From 14th April 2005, amendments to the General Medical Service / Personal Medical Service Regulations enabled the prescribing of CDs by supplementary prescribers.

Registered nurses, pharmacists and Registered midwives, chiropodist / podiatrist, physiotherapist, radiographer and optometrist supplementary prescribers may now prescribe any CD as long as it is within the Clinical Management Plan specific to that patient and agreed between the independent prescriber (doctor or dentist), supplementary prescriber and the patient.

Midwives

Midwives may also train as nurse independent prescribers. Midwives who are not trained as nurse independent prescribers may administer CDs under Exemption Orders under medicines regulations.

Patient Group Directions

From October 2003, the supply and administration of the following CDs was allowed under PGDs:

- Diamorphine, but only for the treatment of cardiac pain by nurses working in coronary care units or hospital accident and emergency departments
- All drugs listed in Schedule 4 of the Regulations except:
 - The anabolic steroids in part 2 of that Schedule
 - Injectable formulations for the purpose of treating a person who is addicted to a drug
- All drugs listed in Schedule 5 of the Regulations.

It is important to note that most but **not** all registered health care professionals who are permitted to supply or administer medicines generally in accordance with a PGD under Medicines Act legislation are permitted to supply or administer CDs in accordance with a PGD under 2001 Regulations.

The amended Regulations allow nurses, midwives, pharmacists, optometrists, chiropodists, radiographers, orthoptists, physiotherapists, ambulance paramedics, occupational therapists, orthotists and prosthetists to supply or administer CDs in Schedule 4 and 5.

Exemptions

Midwives, who are not trained as nurse independent prescribers may administer some specific named CDs under Exemption Orders under medicines legislation.

Prescription requirements

Legal framework

Details and handwriting

Amendments to the Misuse of Drugs Regulations 2001, which came into force on 14th November 2005, removed the requirement for prescriptions for Schedule 2 and 3 CDs (except temazepam) to be written in the prescriber's own handwriting (other than their signature).

CD prescriptions may be computer-generated but **do not have** to be computer-generated. Prescribers may issue computer-generated prescriptions for all CDs. Only the signature has to be in the prescriber's own handwriting. The prescriber should sign any manuscript changes.

It is a legal requirement under the Medicines Act 1968 that all prescriptions for POMs contain '*Such particulars as indicate whether the appropriate practitioner is a doctor, dentist, supplementary prescriber, etc.*' (Regulation 15 of *The Prescription Only Medicines (Human Use) Order 1997*).

Good practice

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

Whilst a new legal requirement allows all other details except the signature on the prescription to be 'written in any form', if these other details on the prescription are handwritten, good practice would indicate that they are hand written by the prescriber but if not, only by an appropriate health care professional.

Schedule 2 and 3 controlled drugs (except temazepam)

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, e.g. written by hand, typed or computer-generated:
 - 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 figure
- Be signed by the prescriber with their usual signature (this must be handwritten) and dated by them (the date does not have to be handwritten)
- The address of the prescriber must be stated on the prescription and must be within the UK. (NB: the UK does NOT include the Channel Islands or the Isle of Man)
- Dentists: prescriptions issued by a dentist must contain the words 'for dental treatment only'.

(See section on private prescribing for additional requirements, page 34).

Temazepam and Schedule 4 and 5 controlled drugs

Prescriptions for temazepam and for Schedule 4 and 5 CDs are exempt from the specific prescription requirements of the Misuse of Drugs Regulations 2001. However, they must still comply with the general prescription requirements as specified under the Medicines Act.

Validity of prescriptions

In order to reduce the likelihood of CDs being dispensed beyond their clinical need and stored or diverted inappropriately the maximum validity of a prescription form was amended in July 2006. The validity period of NHS and private prescriptions for Schedule 1, 2, 3 and 4 CDs has been restricted to 28 days. This means that the prescription should not be dispensed if more than 28 days have elapsed since it was signed and dated by the prescriber, or if the prescription has a later start date, not more than 28 days from this date.

In the case of a prescription containing a Schedule 2 or 3 CD, which directs that specified instalments of the total amount may be supplied at stated intervals, the first instalment must be supplied no later than 28 days after the 'appropriate date'.

See the following website for further details www.opsi.gov.uk/si/si2006/20061450.htm.

Technical errors on a prescription

pharmacists are able to supply Schedule 2 and 3 CDs except temazepam (which is exempt from CD prescription requirements), against some prescriptions that have a minor technical error but where the prescribers intention is clear.

The only errors that pharmacists may amend are:

- Minor typographical errors or spelling mistakes
- Where the total quantity of the preparation of the CD or the number of dosage units as the case may be is specified in either words or figures but not both (i.e. they may add the words or the figures to the CD prescription if they have been omitted).

As a safeguard to these changes the pharmacist must satisfy two pre-conditions before amending the prescription and supplying the CD:

- He must be satisfied on reasonable grounds, having exercised due diligence that the prescription is genuine and that he is supplying the drug in accordance with the intention of the prescriber
- Any correction must be marked so as to be attributable to the pharmacist to ensure it is readily identifiable, for the purpose of the audit.

Additional guidance is available at www.rpsgb.org.uk

Good practice (general)

- All prescriptions for Schedule 2 and 3 CDs should include the patients NHS number where possible so that the usage of CDs by individual patients can be audited
- The professional registration number and the profession of the person who signs the prescription should be added to the CD prescriptions they write, to assist with any future audit. The prescriber's full name, address, telephone number and the PCT in which they are working should also be included on the prescription. This information is generally pre-printed on the prescription
- Dosages and frequencies for all CDs should normally be presented in full by the prescriber, to aid administration by nurses and carers. Particular care should be taken to ensure clarity of dosage instructions where systems such as syringe drivers are being used
- Any space on the prescription form that has not been written on must be blanked off, e.g. by drawing a line through it to reduce the opportunity for fraud
- Computer systems should be used, wherever feasible, as an additional method to record and audit the prescribing of CDs. If a prescriber makes a domiciliary visit, and a CD is administered or a handwritten prescription for a CD is issued, it is good practice to make a note of this on the patient's computer record as soon as possible after the event. The doctor should also record the administration of a CD to a patient in his or her own CD register for that bag

- CDs have the potential to be diverted to the illicit market. For this reason, when a patient presents a CD prescription for an acute condition, more than two / three weeks after the prescription was issued, it would be prudent to check with the patient and / or prescriber that the supply of the CD is still warranted before dispensing the item
- For private prescribing (see page 34).

Good practice

Quantity supplied on prescription

The quantity of drug prescribed on each prescription should be appropriate for the clinical need of the patient. Careful consideration should be given to the quantities prescribed, both to anticipate requirements, e.g. over a weekend, and to reduce the amount of excess CDs stored in the patient's home.

Although not a legal requirement, there is a strong recommendation that prescriptions for Schedule 1, 2, 3 and 4 CDs are limited to a quantity necessary for up to 30 days clinical need.

This is a good practice requirement and not a legal requirement because there may be circumstances where there is a genuine need to prescribe more than 30 days supply.

Prescribing more than 30 days supply

In exceptional circumstances where the prescriber believes a supply of more than 30 days medication is clinically indicated and would not pose an unacceptable threat to patient safety the prescriber.

- Should make a note of the reasons for this in the patient's notes
- Be ready to justify his / her decision if required.

Dispensing more than 30 days supply

- It is not illegal for a pharmacist to dispense a prescription for more than 30 days supply, but they must satisfy themselves as to the clinical appropriateness of the prescription before doing so
- A pharmacist does not need to contact the prescriber each time they receive a prescription requesting a supply in excess of 30 days of a Schedule 2–4 CD. There may be circumstances where there is a genuine need to prescribe more than 30 days supply and pharmacists should exercise their professional judgement and assess both the prescription and the situation to check the suitability for the patient. Where there is concern that the prescription is not appropriate the prescriber should be contacted.

Prescribing in instalments

Some CDs can be dispensed to substance misusers in instalments providing they are prescribed using specific NHS prescription forms.

A prescriber writing a private prescription can also ask for the prescription to be dispensed in instalments.

FP10 (MDA)

In **England**, GPs must use the form FP10 (MDA) to prescribe in instalments Schedule 2 CDs, buprenorphine (Schedule 3) or diazepam (Schedule 4) for drug addiction. This form must not be used for any other purpose, e.g. when the total quantity needs to be dispensed at one time — in this case the normal FP10 form must be used.

Hospital or clinic-based prescribers use a variation of this form — FP10 (MDA) SS that is overprinted with the words ‘HOSPITAL PRESCRIBER’. The SS forms are intended to be used for computer-generated prescriptions although they can be handwritten as well.

Details to be specified

If a CD prescription is to be dispensed in instalments, e.g. daily, then the prescription must specify the following details:

1. The number of instalments
2. The intervals to be observed between instalments; if necessary, instructions for supplies at weekends or bank holidays should be included
3. The total quantity of CD that will provide treatment for a period not exceeding **14 days**
4. The quantity to be supplied in each instalment.

Points 1, 2 and 3 are required by the NHS (General Medical Services Contract) Regulations 2004. Points 2, and 4 are required under the Misuse of Drugs Regulations 2001, Regulation 15.

Collection of instalments

The prescription must be dispensed on the date on which it is due. If the client does not collect an instalment when it is due that supply is no longer valid. The client cannot collect that supply the following day.

If a prescriber has ordered several days’ instalments to be collected on one day and the client does not come in on the specified day, then he loses the complete instalment; he cannot have the remainder of the instalment. pharmacists should endorse the prescription ‘NOT DISPENSED’ for that instalment and, if possible, notify the prescriber.

However, guidance from the Home Office has indicated that the use of specific wording will enable those supplying CDs to issue the remainder of an instalment prescription when the person has failed to collect the instalment on the specified day.

This wording below can be used by those prescribing CDs by instalment in accordance with the Misuse of Drugs Regulations 2001. If a prescription does not contain such wording the Regulations only permit the supply to be made in accordance with the prescribers instalment direction. Further guidance can be found at www.pharmj.com/Editorial/20050430/society/ethics.html.

'Supervised consumption of daily dose specified days; the remainder of supply to take home. If an instalment prescription covers more than one day and is not collected on the specified day, the total amount prescribed less the amount prescribed for the days used may be supplied.'

'Unsupervised consumption; instalment prescriptions covering more than one day should be collected on the specified day; if this collection is missed the remainder of the instalment (i.e. the instalment less the amount prescribed for the days missed) may be supplied.'

NHS forms issued to substance misusers

Issued by / in	Type of form	Region	What is allowed
GPs	FP10 (MDA) or FP10 (MDA) SS	England	Schedule 2 CDs, buprenorphine diazepam, plus single supplies of water for injection as necessary
Hospital or clinic based prescribers	FP10 (MDA) SS	England	Schedule 2 CDs, buprenorphine, diazepam, plus single supplies of any other medication allowed on FP10
Nurse independent prescribers	FP10 (MDA) or FP10 (MDA) SS	England	Diazepam for treatment of initial or acute withdrawal symptoms caused by the withdrawal of alcohol from persons habituated to it
Supplementary prescribers	FP10 (MDA) SS FP10 (MDA) SP	England	Schedule 2 CDs, provided this is agreed by a doctor in the patient's Clinical Management Plan

Good practice

On FP10 (MDA) prescriptions, it is good practice for the duration of the instalments to be set out on the prescription, e.g. dispense daily for five days starting on x date.

The client should collect the CD in person. If he or she is unable to collect prescriptions personally, the client may arrange for a representative to collect it. The representative should bring a suitable note on each occasion to ensure they have authority to collect.

The requirements to see identification on collection only apply to the first dispensing of an instalment prescription.

Prescribing controlled drugs for addiction

Only doctors are able to prescribe diamorphine, dipipanone or cocaine to substance misusers for treatment of addiction, but only if they hold a licence, issued by the Home Office. Prescribers can prescribe such drugs for patients, including substance misusers, for relief of pain due to organic disease or injury, without a specific licence.

Repeat prescribing

Current legislation does not allow Schedule 2 and 3 CDs to be prescribed as repeat prescriptions (i.e. to be part of the repeat prescribing system within a practice, or part of a repeat dispensing system).

NHS repeat dispensing scheme

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

Potential change

The Government will consider proposals to allow repeat dispensing of CDs subject to the development of satisfactory controls and safeguards.

Emergency supplies

Emergency supplies (as defined in the Medicines Act) of Schedule 2 and 3 CDs, for a specific patient, are not permitted either at the request of the patient or a practitioner. The only exception to this rule is phenobarbital for the treatment of epilepsy.

If a Schedule 2 CD from a bag for home visits, etc. has been used for a patient, the prescriber should write the equivalent of a 'prescription' for the item used. GPs are remunerated through the basic practice allowance to purchase drugs necessary for immediate treatment. In the case of injections, which are personally administered, the cost can be reclaimed by sending the relevant details of what has been used to the Prescription Pricing Division (PPD), e.g. on an FP10 written purely for the purposes of reimbursement.

Prescribing to self and family

Good practice

Other than in emergencies, no prescriber should prescribe any drug for themselves or anyone with whom they have a close personal or emotional relationship.

There may be some cases, such as in an emergency situation in which prescribing for family, friends or self is immediately necessary to:

- Save life
- Avoid significant deterioration in the patients health
- Alleviate uncontrollable pain.

And that no other person with the legal right to prescribe is available to assess the patients clinical condition and to delay prescribing would put the patients health at risk, or cause unacceptable pain.

The British Medical Association (BMA) and the General Medical Council (GMC) advise doctors against prescribing for themselves, family, friends and colleagues. There is a risk that doctors who self-treat may ignore or deny serious health problems. There is also a risk that self-prescribing could lead to drug abuse or addiction.

The RPSGB and Nursing and Midwifery Council (NMC) also advise against self prescribing, and prescribing for friends, family and colleagues. See NMC 'Standards of Proficiency to prescribe' www.nmc-uk.org and RPSGB 'Code of Ethics' www.rpsgb.org.uk.

Private prescribing

Besides reviewing the current legal framework, this document helps to establish good practice for the management of CDs. Although this is presented in the form of guidance for the NHS, this is equally applicable to professionals providing health care in non-NHS settings. The law relating to prescribing applies to all NHS and Non NHS settings and good governance is equally applicable to Non NHS organisations.

The term 'private prescriber' is used to describe the situation when a private prescription is written, either by NHS or non-NHS practitioners, in either NHS or non-NHS settings.

Legal framework

When writing private prescriptions, prescribers must comply with all legal requirements, including appropriate record keeping, when ordering, prescribing, dispensing, administering and destroying CDs.

Registerable private doctors and independent clinics, as defined under section 2 of the Care Standards Act 2000, are required to be registered with the Healthcare Commission, as laid out in the Health and Social Care (Community Health and Standards) Act (2003) and Private and Voluntary Health Care (England) Regulations 2001.* There is a need to demonstrate safe systems of handling and prescribing CDs in meeting the National Minimum Standards for Independent Healthcare www.dh.gov.uk/assetRoot/04/07/83/67/04078367.pdf.

Normally, private prescriptions can allow a prescriber to request that the prescription is repeatable** for a specified number of times. However, this is not permitted for Schedule 2 and 3 CDs. It is possible to prescribe Schedule 4 and 5 CDs on a repeat basis, both privately and under NHS repeat dispensing arrangements.

* It is an offence under the Care Standards Act 2000 section 11 to carry on or manage a registerable service without first being registered to do so. Failure to apply for registration could render the practitioner liable to prosecution and could lead to the refusal of the application to register.

** The repeat method is where a private prescription is written for a specified quantity of drugs and the prescriber endorses the prescription with the number of times the prescription should be repeated. The pharmacist is then able to make the specified number of dispensing transactions from that prescription.

Standardised private prescription form

All private prescriptions for human use of Schedule 1, 2 and 3 CDs (including temazepam) that are presented for dispensing in the community (not the hospital) must be written on a standard prescription form which must include the private prescriber's unique (six digit) identification number issued specifically for their private prescribing activity.

There are two types of forms available:

Personalised FP10 (PCD) NC — These contain the prescribers details already printed.

Non personalised forms FP10 (PCD) SS — These allow private prescribers to print private CD prescriptions, including their private prescriber details, using their practice computer systems.

Private prescribers should obtain stocks of private prescription forms via their designated PCT.

Private prescriber identification number

Prescribers who issue private prescriptions for Schedule 2 and 3 CDs that will be dispensed by community pharmacists must have a unique prescriber identification number. Any prescriber requiring a private prescriber identification number should apply via their local PCT. A number will then be issued by the PPD of the NHS Business Services Authority. It will be different from the prescriber's NHS prescriber code if they have one. A prescriber who practices in the NHS and privately will, therefore have two identifier numbers (one NHS and one private).

Prescribers working in private practice in a hospital should inform patients that private prescriptions not written on the standard form can only be dispensed in a hospital pharmacy.

Submission of prescription

The original or a copy of each prescription for a Schedule 1,2 or 3 CD should be submitted after dispensing (community pharmacists or dispensing doctors) to the relevant National Health Service Agency (NHS Business Services Authority for England) along with a CD submission form (FP34PCD). Until the Miscellaneous Provisions Regulations are amended a copy needs to be submitted.

Prescriptions for prisoners and other agency agreements for NHS services

In England, the NHS provides prescriptions for prisoners and some other patients under SLAs with other organisations. Traditionally, this has been treated for administrative convenience in the same way as private work in order to prevent submission to and reimbursement by the relevant NHS agency. However, the new standardised private prescription forms should not be used for such patients as this is classed as NHS activity.

Good practice

The National Clinical Assessment Service (NCAS) and the NHS Clinical Governance Support Team have suggested the following good practice for private prescribers:

Private prescribers should produce their own guidance for use in their services with respect to:

- Treatment, prescribing and review policies
- Clinical governance systems
- Training and continuing professional development (CPD)
- This guidance should be rooted in any relevant national good practice guidance, including 'Drug misuse and dependence: guidelines on clinical management' published by the DH.

Private prescribers should, in most circumstances and with the patient's agreement, contact the patient's private or NHS GP before initiating treatment and during the course of treatment.

Private prescribers should, in most circumstances, liaise as appropriate with other health care professionals involved in the care of the patient. This should include the pharmacist / dispensing doctor.

Private prescribers should indicate on the prescription when prescribing for a non-UK resident. Several of the points here are included in Regulation under the Health and Social Care (Community Health and Standards) Act (2003), and Private and Voluntary Health Care (England) Regulations 2001.

7 Dispensing of controlled drugs

In this context, the term 'dispense' means to assemble and to supply a medicine (please note 'dispense' is not defined in legislation).

Legal framework

Details of supplies of Schedule 2 CDs must be entered into the CD register as soon as possible and at the latest the next day following the day of supply.

The date entered in the CD register should be the date of supply (i.e. the date on which the CD is handed to the patient / carer / representative) and not the date when it is assembled.

The pharmacist / dispensing doctor must endorse prescriptions for Schedule 2 and 3 CDs with the date of supply to the patient.

As with all dispensed medicinal products (except unlicensed medicines), it is a legal requirement to provide a manufacturer's patient information leaflet.

Good practice

Signing the back of the CD form

From the 7th July 2006 there has been a best practice requirement (not a legal requirement) for patients, or other people collecting Schedule 2 and 3 drugs on their behalf, to sign for them. This applies to both NHS and private prescriptions. Patients or their representative will be asked to sign the back of the prescription on collection of the above dispensed medicines.

If a prescription for a CD is handed in for dispensing, but is not due to be collected until a future date or time, the prescription can be assembled in advance. However, details should not be entered in the CD register until after the CD has been supplied to the patient / carer / representative.

It is good practice for a second person to check the quantity / volume and strength of a CD being dispensed, although this may not be practical in all situations.

As with all prescribed medicines, dispensers should ensure that CDs are normally dispensed in child-resistant containers, or with child-resistant closures. Advice to patients, their representatives or carers should include safe and secure storage at home, especially out of sight and reach of children, and safe disposal by returning any unused CDs to a pharmacy.

Potential change

The Government is piloting PDRCs for injectable Schedule 2 CDs. Following this pilot and consultation, it may consider regulatory change by the Home Office.

Dispensing against instalment prescriptions FP10 (MDA)

Legal framework

For instalment prescriptions of Schedule 2 CDs, each supply must be entered, on the day of supply, into the relevant section of the CD register. This task must not be left until the end of the prescription period or carried out in advance.

Instalments must only be supplied on the day that they are due, as specified on the prescription.

NHS (General Medical Services Contract) Regulations 2004 specify only a sufficient quantity of drugs as will provide treatment for not more than 14 days can be prescribed on NHS instalment prescriptions.

Validity

Prescriptions are valid for 28 days. The 28 day period starts on the applicable date entered on the prescription form. This date will be the date of signing or a start date specified by the prescriber on the form. The first instalment must be dispensed within the 28-day limit, with the remainder instalments dispensed in accordance with instructions.

Good practice

- Where appropriate, shared care arrangements for the prescribing and dispensing of CDs for substance misusers, should be developed
- If an instalment prescription for a CD is presented, then it should be stamped with the pharmacy / dispensing practice address at the time of the first dispensing. This is to prevent the possibility of future misdirection of the prescription
- In practice, methadone prescriptions are often made up in advance, to ensure substance misusers can be dealt with in a proactive and timely manner when they present for their medicine. The pre-assembled methadone must be stored in a cabinet which meets the legal requirements (see page 53), or be under the direct personal supervision of the pharmacist / doctor. If the patient does not collect the instalment, it can be returned to stock, provided it is labelled appropriately as stock, e.g. with batch number and expiry date. Where CDs are assembled in advance for instalment dispensing and not collected, the patient medication record should be amended and the prescription annotated to reflect the fact that the supply was not collected
- Guidance on instalments prescribing and pharmacy closures can be found at www.rpsgb.org.uk/pdfs/LEBapprovwordinginstalprescs.pdf
- Pharmacists dispensing CDs to substance misusers should liaise with the prescriber regarding collection / non-collection of the CDs by these clients
- Patients receiving methadone, diazepam and buprenorphine may require supervision of consumption by a pharmacist. This should ideally be carried out in a quiet area of the pharmacy. This area should not normally be the dispensary, or involve taking the patient through the dispensary
- Particular care should be exercised when a third party collects a CD for a patient being treated for addiction. RPSGB guidance states that third party collection of CDs for addicts should only occur in exceptional circumstances. A letter of authority from the patient should be obtained on every occasion that the representative collects the prescription and this letter should be retained in the pharmacy. If a patient regularly sends a third party to collect the supply, it may be necessary for the pharmacist to notify either the clinic where the substance misuser is being treated, or the prescriber.

'Owing' prescriptions for controlled drugs

Legal framework

If the pharmacist / dispensing doctor is unable to supply the total quantity of the drug requested, the entry made in the CD register must only be for the quantity of drug actually supplied. A further entry must be made when the balance is supplied. If the patient no longer requires the balance of the prescription, the prescription should be endorsed with the amount dispensed. It is good practice to record the reason why the remainder was not dispensed, e.g. the patient has died.

Dispensed items or owings for Schedule 2, 3 or 4 CDs cannot be supplied more than 28 days after the appropriate date on the prescription.

Where the prescriber has written on the prescription that it must be supplied on a specific date, as in the case for instalment prescriptions, those instructions must be complied with. Where a prescription requires a specific quantity of CDs to be dispensed on a specific date, the dispenser may not dispense a part of this quantity and then the rest at a later date, as this would deviate from the prescriber's instructions. The stock initially held in the dispensary, plus the balance remaining, can be dispensed to the patient, as long as it is done during the same calendar day.

Dispensing doctors

Legal framework

It is lawful for a dispensing doctor to delegate the act of dispensing medicines for their patients to employed staff.

Good practice

Practice and partners carry vicarious liability for errors made, or for any breach of the law. A dispenser or other dispensing doctor employee would not normally be expected to dispense a Schedule 2 or 3 CD without first checking the dispensed items with a doctor. The Dispensing Doctor's Association's Guidelines for dispensing doctors state that 'the doctor should check all prescriptions for CDs'.

Updated guidance on managing the use of CDs is available from the Dispensing Doctor's Association www.dispensingdoctor.org/.

8 Recording of controlled drugs

This section applies to all CD registers, whether held by a doctor, a pharmacist or other health care professional (personally or as part of the activities of an organisation).

Legal framework

Records for Schedule 2 CDs must be kept in a CD register. This is not a legal requirement for Schedule 3, 4 or 5 CDs.

All health care professionals who hold personal CD stock must keep their own CD register, and they are personally responsible for keeping this accurate and up-to-date.

The format and requirements for CD registers are specified in Regulations 19, 20 and Schedule 6 of the Misuse of Drugs Regulations 2001 as amended.

Currently the register must:

- Be bound (not loose-leaved) or a computerised system which is in accordance with best practice guidance
- Contain class sections for each individual drug
- Have the name of the drug specified at the top of each page
- Have the entries in chronological order and made on the day of the transaction or the next day
- Have the entries made in ink or otherwise so as to be indelible or in a computerised form in which every such entry is attributable and capable of being audited and is in accordance with best practice guidance endorsed by the Secretary of State under section 2 of the NHS Act 1977
- Not have cancellations, obliterations or alterations; corrections must be made by a signed and dated entry in the margin or at the bottom of the page
- Be kept at the premises to which it relates and be available for inspection at any time. A separate register must be kept for each set of premises (for example, not just the main surgery)
- Be kept for a minimum of two years after the date of the last entry, once completed
- Not be used for any other purpose.

Computerised controlled drug registers

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

Full details see www.opsi.gov.uk/si/si2005/20052864.htm.

Good practice

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
- A log of all data entered is kept and can be recalled for audit purposes.

Record keeping requirements

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.

For CDs supplied to patients (via prescriptions), or to practitioners (via requisitions), the following details must be recorded in the CD register:

- The date on which the supply was made
- The name and address of the patient or practitioner receiving the CD
- Particulars of the authority of person who prescribed or ordered the CD
- The quantity supplied
- The name, form and strength in which the CD was supplied.

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 CD register from including additional related information.

Prescriber and dispenser details

CD registers are allowed but not required to include:

- The prescriber identification number (six digit private prescriber code or the NHS prescriber code) and or professional registration number of the prescriber where known
- The name and professional registration number of the pharmacist or dispensing doctor.

As the dispensing of a prescription can involve several pharmacists, it should be the pharmacist who makes the supply of CDs to a patient or his / her representative whose name and professional number are entered in the CD register.

Dealing with discrepancies

SOPs should clearly define the action to be taken if a discrepancy arises. Once resolved, a note should be made in the CD register correcting the discrepancy in the balance. It is also advisable to keep appropriate records of the action taken when discrepancies arise.

If the source of the discrepancy cannot be identified during the stock check, then a nominated member of the relevant organisation should be informed and a formal internal investigation undertaken. This process may include discussion with the relevant professional body, or other inspectors. If this still does not resolve the issue satisfactorily then the police should be informed. The accountable officer should be informed of any concerns in relation to the management and use of CDs (see page 73).

Good practice

The aim of maintaining running balances in CD registers is to ensure irregularities are identified as quickly as possible. More information on running balances can be found on the RPSGB's website www.rpsgb.org.uk/pdfs/cdrunningbalanceguid.pdf.

Maintaining a running balance of stock

Pharmacists and other health care professionals who supply CDs should maintain a running balance of stock in their CD registers as a matter of good practice.

The running balance of drug remaining should be calculated and recorded after each transaction and balances should be checked with the physical amount of stock at regular intervals. Guidance on this can be found on the RPSGB website www.rpsgb.org.uk/pdfs/cdrunningbalanceguid.pdf.

Accountability for maintaining the running balance of CD stock and dealing with any discrepancies lies with the health care professional in charge and not with the person to whom they may delegate day-to-day responsibility under defined SOPs.

Physical reconciliation with stock levels

The running balance recorded in the CD register should be checked with the physical amounts of stock at regular intervals. The decision on how often to carry out stock checks should be in line with any guidance from professional representative bodies and undertaken after a risk assessment has been carried out. Frequency of reconciliation may alter according to local circumstances but should form part of SOPs.

Wherever possible, two members of staff should check all stock received or removed, and both individuals should initial the entry in the CD registers, where the format of the register allows this.

It is good practice for a health care professional / registered manager or registered provider, when first taking over accountability for premises that hold CD stock, and where they will be in regular attendance, to ensure the CD stock levels are correct. This primarily applies to:

- GP practices holding CD stock in the surgery
- Pharmacies
- Dispensing doctor practices
- Care homes, community hospitals and hospices
- Independent health care establishments, hospitals and community hospitals without a pharmacy.

Where changeover of responsibility occurs very frequently, e.g. when multiple locums are required within community pharmacies, out-of-hours providers or GP practices, it would be impractical to carry out stock checks at every changeover. SOPs for the reconciliation of physical stock with balances should define how often this takes place; as a minimum it should take place weekly. If usage of CDs is high, e.g. in drug and alcohol units, palliative care establishments, etc., then stock checks should be carried out more frequently and by different, suitably trained members of staff. The day-to-day responsibility for this task can be delegated under SOPs, to another appropriate, suitably trained, member of staff who is routinely present at the premises.

Ultimately, the decision on how often to carry out stock checks should be undertaken after a risk assessment has been carried out. The decision should also be in line with any guidance from the professional representative bodies. The accountability for maintaining the correct balance of CD stock lies with the professional in charge and not with the person to whom they may delegate the day-to-day responsibility.

Preservation of records

Registers, requisitions and orders for CDs must be preserved for two years. The 2001 Regulations have been amended to allow the information contained in these records to be preserved in the original paper form, or in computerised form.

Potential changes

Subject to parliamentary approval, the Government intends to mandate the additional entries once electronic registers are in widespread use and electronic systems which automatically capture the data are in common use.

Once electronic registers are in common use, subject to Parliamentary approval at the time, the Government intends to make the inclusion of a running balance in the register a mandatory requirement.

Once electronic drug records are in common use, the Government intends to require anyone to keep a CD register to keep secure copies for up to eleven years.

The Government will be carrying out a root and branch review of the CD register. It has not changed since it was first introduced in 1973. This review will bring together all the changes to the CD register, including the additional columns required to record information concerning the person collecting a Schedule 2 CD to be included — and allow for a revised format. These changes will be set out in the Regulation in the Summer 2007, with a delayed mandating date of 1st January 2008 to enable those maintaining a CD register to make the necessary preparations. This will provide greater clarity for those required to maintain a CD register.

Potential change

The Government intends to amend NHS Contract Regulations to require all health care providers holding stocks of CDs to comply with an agreed SOP, where this is not already the case.

Proof of identity: prescriptions for Schedule 2 controlled drugs

Legal framework

Patients or their representatives may require evidence of identity when collecting CDs medication.

From July 2006, there has been a new requirement for persons asked to supply Schedule 2 CDs on prescription to seek to establish whether the person collecting the drug is the patient, the patient's representative or a health care professional acting in his professional capacity on behalf of the patient.

Patient or patient representative

Where the person is the patient or the patient's representative, e.g. a friend, neighbour, etc., **the dispenser:**

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

Health care professional

Where the person collecting the prescription is a health care professional acting in his professional capacity on behalf of the patient, **the dispenser:**

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

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

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

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

- Whether the person who collected the drug was the patient, the patient's representative or a health care professional acting on behalf of the patient
- If the person who collected the drug was a health care professional acting on behalf of the patient, that person's name and address
- If the person who collected the drug was the patient or their representative, whether evidence of identity was requested (as a matter of good practice a note as to why the dispenser did not ask may be included but this is not mandatory).

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

Good practice

RPSGB have issued professional guidance 'Changes in the management of CDs affecting pharmacists (England, Scotland and Wales)' for their members on what forms of identification may be considered suitable and advice on circumstances where discretion should be exercised. This guidance is available from the following website www.rpsgb.org.uk/pdfs/cdmanagechguid.pdf.

It is good practice to record information to support the proof of identity requirements outlined.

As a matter of good practice, the form of identification for health care professionals should be their professional registration number.

Potential changes

Once electronic CD registers are in common use, the Government intends a further requirement to keep secure copies for up to eleven years.

GP practices and pharmacists will be required to send information on movements of stock into and out of their CD registers to the PPD, or equivalent.

'Doctor's bag'

Good practice

Where a practitioner carries a bag for home visits, etc. containing CDs, a separate CD register should be kept for the CD stock held within that bag. Each doctor is responsible for the receipt and supply of CDs from their own bag.

Restocking of a bag for home visits, etc. from practice stock should be witnessed by another member of the practice staff, as should the appropriate entries into the practice's CD register.

Where a prescription is written by a doctor following the administration of a CD to a patient, the doctor should endorse the prescription form with the word 'administered' and then date it. This aims to avoid unauthorised individuals attempting to reuse such 'prescriptions' to obtain CDs illegally. Information should also be entered into the patients record as soon as practicable.

Recording of 'patient-returned' controlled drugs

'Patient-returned' CDs are those that have been prescribed for, and dispensed to, a named patient, and then returned unused or part-used for destruction.

Legal framework

Controlled Drugs (Supervision of Management and Use) Regulations 2006 require SOPs to be in place for maintaining a record of Schedule 2 drugs that have been returned by patients.

Good practice

It is good practice for pharmacists and doctors to keep a separate book to record all CDs returned by patients. Although it is not a legal requirement to witness destruction of 'patient-returned' CDs by an authorised witness, good practice would recommend that they are witnessed by another member of staff and the signature of both the person witnessing and the person destroying should be entered in a separate book set aside for this purpose (see section on 'patient-returned' CDs, page 51).

Potential change

The Government is proposing to amend the Misuse of Drugs Regulations 2001 to impose a new requirement to witness destruction of returns of CDs from patients. This requirement will not be introduced until the pilot of the concept of a PDRC has been evaluated. At this point, further consultation will take place.

Recording of expired controlled drugs stock

If CDs kept in a bag for home visits, etc. expire, they should be returned to the central practice stock for future destruction in the presence of an authorised individual. If the practice does not hold central stock, then the CDs need to be destroyed directly from the bag, witnessed by an authorised individual and appropriate records made in the CD register.

9 Destruction of controlled drugs

Legal framework

Stock controlled drugs

Stock refers to CDs that have not been issued / dispensed to a patient. The possession, storage and destruction of CDs stocks are governed by the Misuse of Drugs Act 1971 and Misuse of Drugs Regulations 2001 as amended.

Those health care professionals and service providers required by law to maintain a CD register are not allowed to destroy expired Schedule 2 (or 1) CDs from their stock without destruction being witnessed by an authorised person.

Recording

When a CD is destroyed, details of the drug must be entered into the CD register. This should include: the name of the drug; form; strength and quantity; the date it was destroyed; and the signature of the authorised person who witnessed the destruction and the professional destroying it (i.e. two signatures).

Persons currently authorised to witness the destruction of controlled drugs

The Misuse of Drugs Regulations 2001 Regulation 27 enables the Secretary of State for Health and the Home Secretary to specify groups of people who are authorised to witness the destruction of stock.

The Secretary of State for Health currently authorises the following groups in England:

- Chief dental officer of the DH or a senior dental officer to whom authority has been delegated
- Supervisors of midwives appointed by the Local Supervising Authority
- Senior officers in an NHS Trust who report directly to the Trust chief executive and who have responsibility for health and safety, security or risk management matters in the Trust
- Chief executives of NHS Trusts
- A PCT chief pharmacist or pharmaceutical / prescribing adviser who reports directly to the chief executive or to a director of the PCT
- A registered medical practitioner who has been appointed to the PCT Professional Executive Committee or equivalent
- The PCT board executive member with responsibility for clinical governance or risk management
- Medical director of a PCT.

The Home Secretary also authorises:

- Inspectors of the RPSGB
- Police constables
- Holders of specific roles within the independent health care sector, for example, registered managers of independent hospitals.

An authorised person cannot witness the destruction of CDs that have been supplied to them or by them — there must be an appropriate separation of roles and responsibilities. Anyone directly involved with a GP practice, or who is authorised to supply CDs from the GP practice, e.g. a PCT clinical governance lead working in their own practice, or practice based pharmacists, must not be asked to witness the destruction of CDs in that GP practice, even if they are included within the authorised groups.

Home Office Drugs Licensing is responsible for the processing of applications for authorisation to witness the destruction of CDs under Regulation 27(1) of the Misuse of Drugs Regulations 2001. These authorisations cover the holders of specified jobs and locations within the private sector, e.g. regional managers of major retail pharmacy chains. For further information, contact the Home Office Drugs Licensing on 0207 035 0483 or email Licensing_enquiry.aadu@homeoffice.gsi.gov.uk.

Additional groups authorised to witness the destruction of controlled drugs

The DH has, as an interim measure, extended the groups who are authorised to witness the destruction of CDs.

The DH had issued an authority in September 2006 stating that all those currently authorised to witness retain that authorisation and in addition, authorising any officer of the health care organisation who, for this purpose, is directly accountable to an executive officer of the organisation to witness the destruction.

The authorised groups include: SHA pharmacy leads; medical directors; and clinical governance leads. However, these individuals must be independent of the routine supply and administration of CDs. Accountable officers should not be authorised people to witness destruction as one of the criteria for accountable officers is their independence from day-to-day management of CDs.

Sufficient witnesses

Accountable officers in PCTs, who oversee community pharmacy and dispensing practices, will need to ensure they have sufficient authorised witnesses to avoid build-up of expired or unwanted CDs stock. This can quickly become a crime prevention issue and breach Waste Management Regulations.

When the Misuse of Drugs Regulations allow any person authorised to witness destruction by an accountable officer should be subject to a professional code of ethics and / or have been the subject of Criminal Records Bureau checks and should have appropriate training. They should also be independent of day-to-day use or management of CDs.

Methods of destruction

The RPSGB issues guidance on the methods of destruction / denaturing that meet the requirements of the Misuse of Drugs Regulations 2001 and the health and safety needs of people undertaking the role. This can be accessed from the RPSGB website at www.rpsgb.org.uk/pdfs/cdsafedestructionguid.pdf.

Environment Agency Regulations and permissions on waste

The destruction and disposal of CDs are also subject to Waste Management Licensing Regulations 1994. Having considered the risks posed by destruction of CDs in a pharmacy, the Environment Agency (EA), which covers England and Wales, has decided that it does not believe it is in the public interest to expect pharmacies to obtain a waste management licence for denaturing CDs and this is seen by the EA as a ‘low risk’ activity. The EA emphasises, however, that it may amend or revoke its position at any time and will continue enforcement in all circumstances where activity has or is likely to cause pollution or harm to health.

For further information on Waste Management Regulation visit the following website www.environment-agency.gov.uk.

Good practice

When Schedule 2 CDs plus temazepam, flunitrazepam, buprenorphine and diethylpropion pass their expiry date, they should be stored in the CD cabinet / safe until destruction. They should be segregated and clearly marked as ‘date-expired’ stock to prevent them being issued in error to patients.

When signing the CD register, it would be good practice for the authorised person to state their authority, e.g. PCT medical director, RPSGB inspector.

‘Patient-returned’ controlled drugs

Patient’s drugs

These are often known as ‘patient returns’ and are CDs that have been prescribed for patients in the hospital or community which are no longer wanted and may be returned to a doctor or pharmacist for destruction.

Health care professionals should be aware that professional guidance strongly recommends that medicines returned from patient stocks should NOT be re-issued or used to treat other patients.

For pharmacists, the RPSGB Code of Ethics prevents pharmacists reusing patient returns. A breach of this requirement could form the basis of disciplinary action.

Legal framework

While there is no requirement currently that ‘patient-returned’ Schedule 2 and 3 CDs should be destroyed in the presence of an authorised witness, it is good practice and strongly recommended that doctors and pharmacists have the destruction of these returns witnessed by another member of staff (preferably by a registered health care professional) and to make a record of the destruction in a separate book set aside for this purpose. It is also good practice for both the person denaturing and the person witnessing to sign that this has taken place.

Good practice

Community pharmacies can accept CDs returned by patients from their own homes and from care homes (personal care) for safe destruction and onward disposal even if they did not originally dispense them.

However, pharmacists are not able to accept waste medicines, including CDs, from care homes (nursing), unless the pharmacy holds a waste management licence.

Under the Waste Management Regulations, a pharmacy does not require a Waste Management Licence to store its own unwanted expired stock, pending disposal. There is also an exemption in the Waste Management Licence Regulations for the secure storage at a pharmacy, pending disposal, of waste medicines, which have been returned to the pharmacy from households or by individuals. This includes waste medicines from a patient's own home or a care home providing residential care, but NOT from a care home providing nursing care (this is classed as industrial waste).

CDs can be placed into waste containers only after the CD has been rendered irretrievable (i.e. by denaturing). The RPSGB has produced guidance in conjunction with the EA on the safe destruction of CDs, which is available at www.rpsgb.org.uk/pdfs/cdsafedestructionguid.pdf.

The EA has, however agreed that where CDs are denatured using one of the specially designed CD denaturing kits, e.g. those that use resin mixtures to render the CD irretrievable, or the methods included in the RPSGB guidance would be seen as low risk activity, this activity would not normally be regulated as licensable waste treatment.

Guidance on The Hazardous Waste Regulations 2005 can be found on the RPSGB website www.rpsgb.org/pdfs/hazwastehospguid.pdf. Since the guidance was published, the EA has agreed that pharmacists may deblist and otherwise treat waste CDs in a pharmacy without the need to obtain a licence. Further information on this may be found on the EA website www.environment-agency.gov.uk.

Further information can be found in the document 'Guidance for pharmacists on the safe destruction of controlled drugs England, Scotland and Wales' which can be found on the RPSGB website at www.rpsgb.org.uk/pdfs/cdsafedestructionguid.pdf.

Potential change

The Government is piloting PDRCs for injectable Schedule 2 CDs. One issue for consideration is the responsibilities for recovery and safe disposal of any unwanted CDs after a patient's death or at the end of a course of treatment. Following this pilot and consultation, it may consider regulatory change by the Home Office.

10 Storage of controlled drugs

This section covers the legal and good practice issues for the storage of CDs. It does not cover any clinical or drug stability issues, which should be addressed separately.

Legal framework

The Misuse of Drugs (Safe Custody) Regulations 1973 imposes controls on the storage of Schedule 1, 2 and Schedule 3 CDs. The Regulations apply to all Schedule 2 medicines (except quinalbarbitone) and the Schedule 3 drugs Buprenorphine, Diethylpropion, Flunitrazepam and Temazepam.

Schedule 2 of these Regulations fully applies to the storage of CDs at retail pharmacies but has not been amended to take account of the change in status of nursing and residential homes to care homes. In residential and healthcare settings it is recommended that the specifications of cabinets and safes set out in Schedule 2 of the Safe Custody Regulations should be regarded as a minimum standard for the storage of CDs.

Regulation 5 of the Safe Custody Regulations requires CDs (other than those specified in Schedule 1 of that Regulation) to be kept in a locked receptacle which can only be opened by the person to whom the Regulation applies (or a person authorised by him / her). The exceptions to this are drugs prescribed to persons for treatment purposes and carriers (including the Post Office).

The Controlled Drugs (Supervision of Management and Use) Regulations 2006 specify that storage arrangements for CD storage must be covered within SOPs.

Good practice

If a safe is used to store CDs, then there should be a separate receptacle within the safe that keeps the CDs apart from other items, e.g. money, valuables, etc. Nothing should be displayed outside to indicate that CDs are kept within the container.

The room housing this container should be lockable and tidy, to avoid drugs being misplaced. This room should not normally be accessible to patients, nor should the keys required for access. However, if patients do have to enter the area where CDs are stored, it is good practice that they should be continuously supervised until such time as they leave the area.

One designated person within the premises should take overall responsibility for the keys / codes. The number of sets of keys to the container, and who holds them, or who has access codes for digital key pads, must be known at all times by the designated person. The keys should always be kept separate from the container and should never be accessible to unauthorised persons. The container should only be opened by the designated person, or by a person authorised by them, e.g. a locum. The designated person remains ultimately accountable for the management of the CDs.

Other drugs that are liable to misuse can be locked in the container if this is deemed appropriate by the relevant health care professional.

Drugs in Schedules 4 and 5 can also be a target for substance misusers. Dispensary areas are required to be secure enough to prevent unauthorised access, but additional precautions, such as keeping these items out of sight of patients, may be advisable.

For CD stock held within any types of premises, the CD register should be stored safely outside the CD container but near to it but not easily visible or accessible.

All CDs should be stored out of sight and reach of children.

For further information on care homes please refer to the care homes section on page 62.

Controlled drugs in a 'doctor's bag'

Legal framework

A 'doctor's bag' is a locked bag, box or case for home visits, etc. which should be kept locked at all times, except when in immediate use. The person in lawful possession of this bag, or an individual authorised by them, must always retain the keys. Legal precedent holds that such a bag is regarded, once locked, as a suitable receptacle for storing CDs, but a locked car is not.

Good practice

For a bag for home visits, etc., a digital combination lock on a case is often the most practical and convenient solution and avoids problems with keys. Bags containing CDs should not be left in a vehicle overnight, or in a vehicle left unattended for long periods of time.

Many doctors only use the CD stock carried in their bag on rare occasions. The stock levels held in this bag should be kept to a minimum and informed by previous requirements.

Normally, only one strength of each CD should be kept in a bag for home visits, etc. in order to minimise the risk of confusion, error and inappropriate administration. Oral preparations of CDs would not routinely be considered essential items to be carried in such a bag.

A formulary for all medicines (including CDs), that might normally be required out-of-hours, has been developed by the DH and is available in the practical guide that accompanies 'Securing proper access to medicines in the out-of-hours period' www.out-of-hours.info/downloads/medicines_supply_guidance_a_practical_guide.pdf.

It is good practice for the doctor, or a delegated member of staff, to undertake a monthly stock check of CDs held within each bag for home visits. This process also provides a good opportunity to check for any out-of-date (or 'soon to expire') stock. This needs to be included in an SOP.

When a bag for home visits, etc. containing CDs is in the practice, it should be stored in a safe place away from patient areas in a locked room. This location should be determined by carrying out a risk assessment.

Each professional should also assess the risks and benefits in relation to where they store CDs and registers in relation to each other. A balance has to be achieved between having the CD register readily available to make an entry at the time of administration, and the possibility of the bag and the register both being stolen, with the consequent loss of both the CDs and the audit trail.

A small number of GPs continue to provide their own personal service in the out-of-hours period, and would therefore use their own bag in the same way as they do during normal hours. However, the majority of GPs delegate responsibility to an organised provider of out-of-hours services, e.g. a GP co-operative or a deputising service.

In terms of good practice when managing CDs out-of-hours, reference should be made to the following DH guidance 'Securing proper access to medicines in the out-of-hours period' www.out-of-hours.info/downloads/short_medicines_guidance.pdf and the accompanying practical guide www.out-of-hours.info/downloads/medicines_supply_guidance__a_practical_guide.pdf.

11 Transportation of controlled drugs

Legal framework

All health care professionals in legal possession of a CD have a professional duty of care to take all reasonable steps to maintain safe custody of that CD at all times.

Nurses, midwives, doctors, pharmacists, pharmacy staff and other health care professionals, plus formal carers and patients' representatives, are legally allowed to transport CDs to a patient, provided the CDs have been prescribed, by an appropriate prescriber, for that patient. Any nominated individual is also allowed to return CDs from the patient to the pharmacy, or the practice, for destruction. The person authorised to possess may grant permission, and it should be in writing. It should be noted that community pharmacies and GP practices must not accept waste medicines, including CDs, from care homes providing nursing care (see page 13).

Good practice

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

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

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

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

12 Nurses working in the community

Transportation

Legal framework

Nurses may transport CDs, where patients or their carers / representatives are unable to collect them, provided the nurse is conveying the CD to a patient for whom the medicine has been prescribed, e.g. from a pharmacy to the patient's home. Nurse independent prescribers, or nurses acting under the direction of a nurse independent prescriber, can administer the CDs listed in the table on page 25 — but solely for the specified medical conditions.

Good practice

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

Administration

Legal framework

Nurses may administer CDs to a patient in their care, as long as they are acting in accordance with the directions of a doctor or dentist. Nurse independent prescribers, or nurses acting under the direction of a nurse independent prescriber, can administer the CDs listed in the table on page 25 but solely for the medical conditions specified.

Midwives may administer diamorphine, morphine, pentazocine and pethidine to their patients, acting on their own professional judgement.

Any CD that is administered by a nurse must be recorded in the nurse's and patient's notes, stating the medicine and dose administered, the date of administration, the method of administration and the person who administered it.

Good practice

Administration on a verbal instruction

The NMC has published 'Guidelines for the administration of medicines', which includes guidance on CDs, and is available at www.nmc-uk.org/aFrameDisplay.aspx?DocumentID=610.

Disposal / destruction of controlled drugs

Good practice

CDs no longer required

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

It should not normally be the responsibility of community nurses to become involved in the disposal of unwanted CDs. However, there may be occasions when it is appropriate for nursing staff to become involved in recovery / disposal of CDs.

A possible staged approach would be:

- If return by relatives / next of kin is not practical or possible then the following action could be taken
- Nurse with another member of the nursing team acting as a witness disposes of CD in an appropriate and safe manner. This should be within an agreed local SOP and should include appropriate record keeping in patients notes.

Or

- Nurse could take CDs to local community pharmacy who would be asked to countersign patient nursing record.

13 Palliative care

Good practice

It is good practice to only prescribe quantities of CDs that are needed by the patient for effective symptom control. This can include CDs for regular dosage, plus a quick-acting CD at an appropriate dose for breakthrough pain. The good practice principles for managing CDs described earlier in these guidelines apply equally to the palliative care situation.

Where prescribers are prescribing high doses of CDs for palliative care, it is recommended that the specialist palliative care team are contacted for advice and support, wherever feasible. Any actions resulting from such a contact should be recorded in the patient's notes.

If a prescriber is prescribing high doses of CDs for a patient, particularly where prolonged use is expected, then it is recommended that this is reported to the PCT (probably to the senior prescribing adviser) to aid the interpretation of routine PACT data.

Palliative care patients may obtain CD prescriptions from more than one source, e.g. GPs, hospices, hospitals, out-of-hours services and specialist palliative care teams. In such circumstances, one professional in the locality, could take on a co-ordinating role to avoid over-supply and to help maintain patient and public safety.

Additional sources of information:

- Liverpool Care Pathway www.lcp-mariecurie.org.uk
- NHS End of Life Programme www.endoflifecare.nhs.uk
- National Council for Palliative Care www.ncpc.org.uk

Out-of-hours palliative care

Good practice

There are sometimes problems encountered with the availability of medicines for palliative care patients in the community during the out-of-hours period. To maintain effective symptom control in patients choosing to be treated at home, or in other care environments, it is important that health care professionals ensure sufficient quantities of appropriate palliative care drugs, including CDs, are available to anticipate deterioration in the patient's condition. The potential needs of deteriorating conditions need to be balanced with the safety risk of increased quantities of CDs left in the domiciliary / care setting. For specific recommendations about the manner in which a patient-centred, high quality palliative care service can be provided out-of-hours, please refer to 'Securing proper access to medicines in the out-of-hours period' www.out-of-hours.info/downloads/short_medicines_guidance.pdf and the accompanying practical guide www.out-of-hours.info/downloads/medicines_supply_guidance_a_practical_guide.pdf.

Self-medication

Good practice

If patients are self-medicating, whether in a hospice or hospital, their CDs should be kept in a locked metal receptacle immediately adjacent to their bed, or in their bedside locker. The receptacle should not be readily portable. In order to prevent unauthorised access, each receptacle should have an individual key, with a master key kept by the person in charge (on duty).

Where a patient is being treated in their own home, professional advice and supporting information should be provided in a timely way, by the most appropriate professional, to ensure safety and efficacy is maintained.

14 Care homes

Legislation governing nursing homes and residential homes changed in April 2002 with the implementation of the Care Standards Act 2000. Nursing homes and residential homes are now both categorised as care homes.

There are two main types of care home:

- Care homes (personal care): These homes are residential and they usually provide accommodation, meals and personal care
- Care home (nursing): Have registered nursing staff who can provide care for more complex health needs.

Although this section primarily applies to registered care homes, much of the good practice also applies to other social care environments for example children's homes.

Legal framework

Regulation 13 of the Care Homes Regulations (2001) requires registered providers to make arrangements for the recording, handling and, safe keeping, safe administration and disposal of medicines received into the care home. This applies to all medicines including CDs.

The National Minimum Standards specifically include the handling of CDs in care homes for older people and care homes for adults (18–65). www.dh.gov.uk.

Supply

- The usual method of supply is a prescription for individual residents
- The Medicines Act 1968 does permit a care home (nursing) to purchase and use stocks of CDs so long as they have a licence from the Home Office or are mainly maintained by charitable funds. (This may be the case in some drug and alcohol rehabilitation units)
- A Home Office licence must be obtained for each type of Schedule 2 drug required to be held as stock
- Care homes (personal care) are prohibited from purchasing and holding stocks of any prescription only medicine including CDs
- A supply can be obtained via a requisition supplied by a person (or acting person) in charge of a care home signed by a doctor or dentist who works there and the requisition must comply with the usual requirements for requisitions (see page 16)
- A practitioner who urgently requires a Schedule 2 CD for use in the care home and who is unable to supply a signed order may request the drugs to be supplied in an emergency (see page 33).

Good practice

CDs are usually individually prescribed for residents in care homes. It is recommended that care homes only keep CDs prescribed for individual residents unless there are exceptional circumstances, e.g. if the care home is registered for drug and alcohol rehabilitation or provides 'End of Life' care.

Reference should be made to guidance produced by the CSCI 'Safe management of CDs in care homes' www.csci.org.uk.

Receipt, storage and recording

Legal framework

- The Misuse of Drugs (Safe Custody) Regulations 1973 have not been amended to take account of the change in the status of nursing and residential homes to care homes
- It is recommended that the specifications of cabinets and safes set out in Schedule 2 of the Safe Custody Regulations should be regarded as a minimum standard for the storage of CDs in all care homes (personal care and nursing) for all residents' CDs that are held in a central location within the care home
- In all types of care home, residents who are responsible for storing and administering their own medication (as they would in their own home) do not need to use a CD cabinet.

Good practice

For residents who are self-medicating, the CDs should be stored in a locked, non-portable receptacle in the resident's room. This also applies to any monitored dosage systems containing CDs.

All care homes should keep a record of residents' own CDs, in addition to the records maintained on medicine administration record charts. This CD register should contain separate pages for each resident's medicines and should have a column for recording running balances in order to maintain effective control and identify any discrepancies. In addition:

- The CD register should be used to record the receipt, administration and disposal of CDs held in the care home. Each drug, for each resident, should be recorded on a separate page, with the name, dose and strength of the drug written clearly at the top of the page. Where residents are self-administering, each individual dose taken does not need to be recorded
- On receipt of the CD from the pharmacist / dispensing doctor, the date, quantity and source should be entered into the CD register and initialled by the receiving nurse or authorised member of staff, with a second person as a witness. The correct balance should be verified each time

- When transferring the drug record to a new page in the CD register, the amount remaining should be identified with 'brought forward from page x' written clearly on the new page
- It is good practice to keep CD registers for longer than the mandatory two years, as cases often come to court at a much later date, by which time the paper evidence would have been destroyed. This will become more practical as the legal framework and IT systems allow information to be stored electronically.
- The CD register must include details of disposal of CDs by return to the supplier (care homes providing personal care only) or through a licensed waste management company (care homes with nursing).

Administration of controlled drugs

Good practice

- Where residents are not able to self-administer in a care home providing nursing care, a medical practitioner or a Registered nurse should administer the CDs. In care homes providing personal care, CDs should be administered by appropriately trained care staff, and this should be witnessed by another appropriate member of staff
- The resident's name, plus time and dose given, should be recorded in the CD register after carefully checking the administration sheet. Once the Registered nurse / trained carer has witnessed the resident taking the medication, the resident's administration chart also can be initialled by that nurse / trained carer
- Before administering the medicine, the nurse / trained carer should measure and check the dose with a competent witness
- The nurse / trained carer and the witness should then initial the CD register, after verifying that the remaining balance is correct
- The administration process should be fully completed for each resident, before moving on to the next resident.

Disposal of controlled drugs

Legal framework

Community pharmacists cannot accept waste medicines, including CDs, from care homes registered to provide nursing care (including those registered for both personal and nursing care). Waste medicines from care homes WITH nursing input is regarded as industrial waste and is therefore not exempt from the Waste Management Licence Regulations. Waste medicines from care homes with NO nursing input is regarded as 'household waste' and is exempt. A care home with nursing input should dispose of its special / hazardous waste by consigning it to a suitably authorised facility, and transfer non-hazardous waste to a suitably authorised person for transport to a suitably authorised site.

Good practice

These points only apply to care homes providing personal care:

- When CDs have passed their expiry date, the need for the prescription has ceased, or the resident has died, the CDs should be returned to the relevant pharmacist or dispensing doctor at the earliest opportunity for appropriate destruction. Even when still in date, such drugs should not be reused for other residents
- Care homes should record the forms and quantities of CDs they are returning, and the pharmacist / dispensing doctor should sign for them on receipt. If pharmacy staff collect the CDs they should sign for them in the CD register at the time of collection
- Relevant details of any such transfer for disposal should be entered into the CD register and signed by the nurse, or authorised member of staff, returning the drug.

The CSCI has produced guidance for care homes providing nursing care:

- The care home will need to make arrangements for the collection of waste medication with a licensed waste disposal company
- CDs should be denatured before being handed to the waste disposal company, e.g. in specially designed denaturing kits
- A registered nurse and an appropriate witness should sign the record of disposal in the CD register.

More detailed guidance can be found in 'Safe disposal of waste medicines from care homes (nursing)', published by the CSCI at www.csci.org.uk.

Dealing with discrepancies

Good practice

- Routine checks of all CDs held, and the recorded running balances, should be carried out by two nurses, or other authorised members of staff, on a regular basis, e.g. monthly, and a record kept
- Where a discrepancy is found, it should be reported immediately to the registered manager who should investigate promptly
- If the discrepancy cannot be resolved, the advice of the local pharmacist should be sought and the CSCI local office informed. CSCI will then share information as needed with the accountable officer
- If the discrepancy is found to be an error of subtraction or addition in the calculation of stock balance, the following procedure should be followed:
 - Do not change the balance column or use correction fluid. Under the last entry, details of the following should be made:
 - The date
 - The error in subtraction / addition (indicated with an asterisk)
 - The correct balance
 - The signature of the nurse / member of staff and the witnessing nurse / member of staff.

In care homes providing nursing care where a dose is given but the administering nurse fails to complete the CD register at the time of administration, the following procedure should be followed:

- Under the last entry, details of the following should be made:
 - The current day's date
 - 'Dose administered but not recorded at the time' followed by the resident details
 - The signature of the administering nurse and that of a witness
 - The correct balance.

If neither of the above discrepancies can be identified, the pharmacist who is providing a service to the home should be contacted to establish whether there were any unrecorded returns of CDs. If confirmed by the pharmacist, full details of such returns should be entered into the CD register together with the signature of the person who returned the drugs and that of the pharmacist who received them. The correct date and the words 'entered in retrospect' should also be added.

If the reason for the discrepancy cannot be found, and the CDs appear to have gone missing, then all relevant people, including the police, should be notified.

15 Ambulance services

Currently there is wide variation in how CDs are obtained, stored and recorded by qualified paramedics working in the ambulance service.

Legal framework

Qualified paramedics, serving at an NHS ambulance station, are legally allowed to possess and supply, under a group authority issued under the 2001 Regulations morphine sulphate injection (upto a maximum ampoule size of 20mg) and diazepam and administer it for immediate necessary treatment of sick or injured persons. They must comply with all storage and recording Regulations for CDs.

They can also act under PGDs.

Good practice

Individual ambulance organisations are not allowed to stock CDs unless they have been licensed by the Home Office to do so.*

* Some ambulance services allow the carriage of other CDs on ambulances for use by doctors who accompany crews. In such circumstances, the ambulance service has to be licensed to possess the drugs and must comply with all the usual safe custody and record keeping requirements.

16 Educational establishments

There is a need to manage more effectively the administration and safekeeping of CDs for individual pupils in educational establishments, e.g. methylphenidate. Any policies pertaining to CDs taken into educational establishments should aim to minimise the risk to children and staff, whilst allowing for pupils' medication requirements to be met with minimum bureaucracy and fuss.

Good practice

Wherever possible, dosing regimens should be designed to allow medicines to be taken outside school hours. This may have some financial consequences for the drugs bill, as modified-release formulations of CDs are often significantly more expensive than standard ones. For some patients, there may be valid clinical reasons for medicines being taken during school hours, so arrangements need to be in place to allow this to happen.

The Department for Education and Skills has produced guidance entitled 'Managing medicines in schools and early years settings' (March 2005). This guidance includes a specific section on CDs, with the following points:

- Any member of staff may administer a CD to the child for whom it has been prescribed. Staff administering medicine should do so in accordance with the prescriber's instructions
- It is permissible for schools to look after a CD, where it is agreed that it will be administered to the child for whom it has been prescribed
- Schools should keep CDs in a locked non-portable container and only named staff should have access. A record should be kept for audit and safety purposes
- A CD, as with all medicines, should be returned to the parent when no longer required, to arrange for safe disposal. If this is not possible, it should be returned to the dispensing pharmacy.

The full guidance can be found at <http://publications.teachernet.gov.uk/eOrderingDownload/1448-2005DCL-ENv3final.pdf>.

CDs are also prescribed for young people in boarding schools, residential special schools and secure children's units. As well as the guidance above, these educational establishments have additional guidance in the National Minimum Standards, published by the DH.

17 Overseas travel

Legal framework

With effect from the 1st January 2007 only those persons travelling for 28 days or more and carrying CDs will require a personal licence. A list of the most commonly held CDs can be found at www.drugs.gov.uk.

Licence

Personal import / export licences will only be issued to travellers carrying CDs abroad (or in the case of an import licence into the UK) for periods exceeding one month.

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

Licences are normally issued with an expiry date of one week after the expected return to the UK (or one week after the expected date of departure from the UK in the case of an import licence).

A personal licence has no legal standing outside the UK and is intended to allow travellers to pass through UK customs unhindered.

Some countries have their own importation regulations for CDs. It is recommended that travellers contact the countries Embassy to check these regulations.

Personal licence application forms can be downloaded from www.drugs.gov.uk. Completed application forms should be completed and sent with a letter from the prescribing doctor, nurse or drug worker confirming the following details.

- The patient's name, address and date of birth
- Country of destination (if travelling out of the UK)
- Dates of departure and return
- Details of the medicine(s) — name, form, e.g. tablets, strength and total quantity to be carried.

Home Office contact details regarding overseas travel licenses:

Licensing Section
Drugs Licensing Enforcement Unit
Home Office
6th Floor, Peel Building
2 Marsham Street
London SW1P 4DF

Direct Line: 0207 035 0472
Fax: 0207 035 6161
Email: licensing_enquiry.aadu@homeoffice.gsi.gov.uk

Full guidance on personal exports is available at www.drugs.gov.uk/publication-search/drug-licences/personal-guidance.pdf?view=Binary.

Good practice

CDs should be:

- Carried in original packaging
- Carried in hand luggage
- Carried with a letter from the prescribing doctor confirming the carriers name, destination, drug details / amounts
- Checked with the relevant embassy / consulate to enquire of any restrictions in the country visited.

18 Out-of-hours

Good practice

'Securing proper access to medicines in the out-of-hours period' www.out-of-hours.info/downloads/short_medicines_guidance.pdf and the accompanying practical guide www.out-of-hours.info/downloads/medicines_supply_guidance_a_practical_guide.pdf were published by the DH in December 2004. They set out a framework to support PCTs in their commissioning of out-of-hours medicines supply arrangements, including CDs. They include specific examples of ways in which local health communities can develop a patient-centred, effective service, which meets the urgent needs of patients in the out-of-hours period.

Many areas across the country have, or are now setting up, schemes where pharmacists are formally commissioned to supply appropriate CDs, and other medicines, out-of-hours, and where they also provide a source of advice.

More information pertinent to out-of-hours services can be found elsewhere in this document:

- Ordering CDs (see page 20)
- Recording of CDs (see page 41)
- Storage of CDs (see page 53)
- 'Doctors' bags' (see page 54)
- Palliative care (see page 59).

19 Patient information

NHS Direct

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

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

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

Medicines Guides

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

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

The current list available is:

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

20 Governance, inspections and monitoring

Overall governance

Legal framework

The Health Act (1999) placed a duty on PCTs and Trusts to implement and maintain arrangements for the purpose of monitoring and improving the quality of the health care that it provides to individuals. Chief executives of these organisations are accountable for the quality of care provided in their locality.

Controlled drugs and governance

Overview

- New arrangements for CDs have been established to encourage good practice in the management of CDs as well as help to detect unusual or poor clinical practice systems, criminal activity or risk to patients
- All PCTs, NHS Trusts, Foundation Trusts, the independent health care sector, and care homes now have a responsibility to assure the quality of their CDs management as an integral part of their clinical governance processes, with external inspection where appropriate as an additional safeguard. This is supplemented by new arrangements for collaboration and information sharing between NHS and partner organisations
- The Healthcare Commission will provide external assurance of the new systems
- The DH has provided comprehensive guidance on strengthened governance arrangements www.dh.gov.uk.

Legal framework

The Health Act 2006

The Health Act 2006 received royal assent in June 2006 and provides for a number of key provisions relating to CDs.

Controlled Drugs (Supervision of Management and Use) Regulations 2006

These Regulations apply in England from 1st January 2007 and 1st March 2007 in Scotland.

Implications of Regulations

Appointment of accountable officer

There is a requirement for certain NHS and independent health care bodies to appoint an accountable officer.

In England the following organisations (designated bodies) are required to appoint an accountable officer:

- PCTs
- NHS Trust
- NHS Foundation Trusts
- Independent hospitals.

The Regulations specify who may be appointed as an accountable officer. Irrespective of the designated body the accountable officer cannot be a person who routinely supplies, administers or disposes of CDs as part of his duties.

Designated bodies must notify the Head of Operations at the Healthcare Commission of the nomination or appointment of their accountable officer, and also the removal of an accountable officer. There is a web form on the Healthcare Commission website to make these notifications at <http://healthcarecommission.org.uk/serviceproviderinformation/controlleddrugs.cfm>.

The Healthcare Commission is required to publish a list of accountable officers in England.

Overview of responsibilities of accountable officers

- Responsible for ensuring the safe and effective use and management of CDs within local organisations subject to their oversight
- Accountable officers must have regard to best practice in relation to the management of CDs.

In particular:

- Secure the safe management and use of CDs, in particular:
 - Establish and ensure appropriate arrangements to comply with Misuse of Drugs legislation
 - Ensure adequate and up-to-date SOPs are in place in relation to the management and use of CDs
- Ensure adequate destruction and disposal arrangements for CDs
- Ensure monitoring and auditing of the management and use of CDs
- Ensure relevant individuals receive appropriate training
- Maintain a record of concerns regarding relevant individuals
- Assess and investigate concerns
- To take appropriate action if there are well founded concerns
- To establish arrangements for sharing information.

Standard Operating Procedures

Legal:

- All health care providers will have and comply with an approved SOP
- SOPs for organisations will be agreed by the relevant accountable officer
- Each GP practice or pharmacy should have clear, written SOPs in place that are known, understood and followed by practitioners and their staff
- Every PCT should have SOPs for handling CDs for all of its directly managed services and staff.

The Regulations state that SOPs must cover the following:

- Who has access to CDs
- Where the CDs are stored
- Security in relation to storage, and transportation, of CDs as required by Misuse of Drugs legislation
- Disposal and destruction of CDs
- Who is to be alerted if complications arise
- Record keeping including:
 - Maintaining relevant CD registers under Misuse of Drugs legislation
 - Maintaining a record of Schedule 2 drugs that have been returned by patients.

Good practice

SOPs should cover all aspects of risk management and they should include audit trails for ordering, storing, prescribing, dispensing, recording, supplying, administering and destruction of CDs, appropriate to the setting and the team.

SOPs should highlight the accountabilities and roles of all members of the relevant health care teams.

The DH document published in January 2007 'Safer management of controlled drugs: guidance on standard operating procedures for controlled drugs' provides advice on the areas that might be considered for inclusion in an SOP, see DH website www.dh.gov.uk/assetRoot/04/14/25/63/04142563.pdf.

Monitoring and auditing of the management and use of controlled drugs

Legal framework

Regulations specify that arrangements must provide for the following:

- Monitoring and analysing health service and private prescribing of CDs through the use of Epact (Electronic Prescribing Analysis and Costs) data and analysis tools available from PPD of the NHS Business Services Authority
- Ensuring systems are in place to alert the accountable officer of any complaints or concerns involving the management and use of CDs
- Ensuring an incident reporting system is in place for untoward incidents
- Ensuring appropriate arrangements are in place for analysing and responding to untoward incidents.

Good practice

Assessing CDs practice

- Good practice would suggest that a systematic audit of the processes for managing CDs in primary care is carried out.
- Results from local audits should be analysed to identify any areas where systems could be improved and better co-ordinated. All audit results should be kept, preferably electronically, for up to eleven years
- It is the responsibility of PCTs to ensure that national and local good practice guidance is routinely followed by practitioners working in their locality.

The NHS Clinical Governance Support Team, the NCAS, NPSA and RPSGB have produced a toolkit to provide support in routinely monitoring the use of CDs and taking action. ‘Clinical governance toolkit for controlled drug management in primary care in the NHS: guidance for accountable officers and their staff’ can be found at www.cgsupport.nhs.uk/downloads/Primary_Care/CG_toolkit_for_controlled_drug_management.pdf.

Using quality indicators

This list is not comprehensive, but gives a series of indicators that will help PCTs, GP practices and pharmacies identify and demonstrate they have systems in place to minimise risk when managing CDs.

1. All staff and practitioners should be trained to ensure they have the relevant knowledge and skills to undertake the tasks required of them for managing CDs safely
2. practitioners and staff who work with CDs should demonstrate reflective learning by relevant inclusions in their CPD portfolio
3. Risk management systems should be used to help minimise risks in the management of CDs. Such systems should be written and readily accessible to all relevant practitioners and staff. They must include:
 - Assessment of risks arising from managing CDs
 - Procedures for training new members of staff or locums in management of CDs
 - Identification of tasks, which have to be undertaken in the presence of a witness
 - Handling of all records relating to CDs including requisitions, invoices, private and NHS prescriptions, transport and delivery notes, and CD registers
 - Procedures for monitoring and recording stock reconciliation (in CD cupboards, ‘doctors’ bags’, etc.), including action to be taken if a problem is identified
 - Procedures for checking expiry dates of CDs and what to do with CDs that have expired
 - Recording of critical incidents, errors and near misses with CDs through local systems and the confidential National Reporting and Learning System from the NPSA
 - Procedures for reporting loss or suspected theft of CDs
 - Complaint procedures for NHS employees and employers, as appropriate
 - How to report suspected cases of NHS fraud
 - Copies of the PCT’s policy and processes for raising concerns
 - Systems for recording and destroying CDs returned from practitioners, patients or their representatives.

Managers, staff and health care professionals should know which member of staff at the PCT to contact if they have a concern regarding the performance or practice of health care professionals, or their staff, involving CDs.

Routine monitoring

Accountable officers should ensure that the use of CDs is monitored through routine processes such as data analysis, audit and clinical governance, as an integral part of normal governance arrangements. One example is the use of prescribing data.

Prescribing data

Prescription data collected by the PPD at the NHS Business Services Authority to reimburse dispensing contractors can be used to monitor and examine the prescribing of CDs. This is limited to data from prescriptions dispensed in primary care and excludes prescriptions prescribed and dispensed in secondary care. The data does not contain any patient information, or any diagnosis or dosage information.

The data is distributed to a defined distribution list within the NHS, by means of paper reports and two electronic prescribing information systems — Prescribing Toolkit and ePACT.net.

Prescribing Toolkit provides a series of prescribing indicators using predefined reports and graphs. PCTs can compare their prescribing performance with a number of suitable comparators.

ePACT.net is a sophisticated analytical system that gives users access to prescribing data relevant to their specific organisation. PCTs can access data at practice and individual prescriber level, SHAs can access the data for their constituent PCTs and national users can access data at SHA and PCT level. Hospital Trusts have access to prescribing data for NHS FP10 prescribing by cost centre (clinic or department) but not individual prescriber. Users have access to 60 months' historical data and can analyse and report on prescribing at any British National Formulary level, from total prescribing to individual formulations.

The Prescribing Support Unit (PSU) has audit toolkits to help with monitoring www.ic.nhs.uk/psu/cds.

The ePACT.net service from the PPD provides an electronic tool for auditing prescribing data. This will include NHS and private prescriptions for CDs.

Additional detail on PSU initiatives to support monitoring of CDs is provided in Appendix 2 (see page 85).

Education and training

Regulations state that accountable officer are to ensure in relation to the management of CDs that relevant individuals receive appropriate training, for example:

- Relevant individuals involved in prescribing, supplying, administering or disposing of CDs receive from time to time, appropriate training to carry out their responsibilities
- Receive information and where appropriate training on local SOPs for CDs when they first become involved in prescribing, supplying, administering or disposing of CDs.

Good practice

Initial and continuing education and CPD for health care professionals should include appropriate material on the need for safe storage, possession and return of all medicines, and on the legal status of CDs. All individuals working in NHS and non-NHS settings, who are involved in CD supply, administration, storage, prescribing, dispensing and destruction, should ensure they have appropriate, timely and up-to-date knowledge of the processes involved in managing CDs.

The Government, in its response to the Fourth Report of the Shipman Inquiry, recommends that all health care professionals who prescribe, dispense or administer CDs should be required to demonstrate, in meeting their CPD requirements, that they keep up-to-date on all aspects of CD management, including safe custody, safe storage, record keeping, supply and disposal of CDs and the legal requirements of CDs. They should have at least an annual appraisal to identify gaps in knowledge and skills in discussion with their employer, resulting in an agreed personal development plan and access to development mechanisms that will meet the agreed needs. For those professions that have formal revalidation processes, this appraisal should form an integral part of revalidation.

It is the responsibility of care homes to ensure that their formal carers are adequately trained in effective management of all medicines, including CDs.

Good practice in the management of medicines in secondary care, including CDs, is set out in the March 2005 revision of the Duthie Report (1988), 'The safe and secure handling of medicines: a team approach'. All care staff, especially those in secondary care who are involved in the prescribing, supply or administration of medicines should be familiar with its contents.

Finally, consideration should be given by the appropriate national authorities to ensuring that undergraduate and pre-registration courses for health care professionals contain more details on the prescribing, administering, supplying, destruction and recording of CDs. The Government's response to the Fourth Report of the Shipman Inquiry sets out those areas that the undergraduate education for health care professionals who prescribe, dispense or administer CDs needs to cover.

Sharing information

An accountable officer must establish and operate, or ensure his designated body establishes and operates appropriate arrangements for ensuring the proper sharing of information regarding the management of CDs.

Intelligence network

Responsibility for establishing networks lies with PCT accountable officers. The networks will ideally be based on locally recognised health communities and may span a number of PCTs. The network will enable agencies that have cause for concern about the activities of any health care professional to share them as soon as possible with other local agencies who may be affected or who may have complimentary information.

A number of bodies that can be included in the network are listed in the Controlled Drugs (Supervision of Management and Use) Regulations 2006 This list is not exhaustive and it is for the local network to consider which bodies would be involved.

Networks should include as defined by the Regulations (although it need not be limited to) the following types of bodies as appropriate:

- PCT
- NHS Trust
- NHS Foundation Trust
- SHA
- Healthcare Commission
- CSCI
- Counter Fraud and Security Management Service Division of the NHS Business Services Authority.

Entering premises, periodic inspections

Periodic inspections

- PCT accountable officers are responsible for arranging periodic inspections of premises which are used in connections with management or use of CDs and not subject to inspection by the Healthcare Commission, the CSCI or the RPSGB Inspectors
- Advanced notification of inspection does not have to be provided.

Co-operation between health bodies and other organisations

- Regulations places a statutory duty of co-operation on responsible bodies to share information about concerns with respect to the management of CDs
- Each organisation will be separately accountable for action within its own remit. The appropriate accountable officer will be responsible overall for ensuring appropriate action is being taken in response to concerns that have been raised
- PCT accountable officers will be responsible for establishing local intelligence networks. The network will enable agencies that have cause for concern about the activities of any health care professional to share them as soon as possible with other local agencies who may be affected or who may have complimentary information.

Responsible bodies

Responsible bodies are specified in regulations:

- PCT
- NHS Trust
- NHS Foundation Trust
- SHA
- Independent Hospital
- Healthcare Commission
- CSCI
- NHS Business Services Authority (Counter Fraud and Security Management Service and PPD Divisions)
- A Police Force
- A Local Authority
- A Regulatory body.

Good practice

PCTs should ensure that GP practices and pharmacies have ready access to information about local:

- Practitioners prohibited from prescribing CDs or with restrictions on their prescribing. A medical practitioner convicted or cautioned in connection with a CD offence should report the conviction or caution to the GMC, which should then report the facts and its own action to the practitioner's employer or PCT. The GMC is planning to hold all current restrictions on a doctor's clinical practice on the online version of the GMC Register
- Practitioners with a Home Office licence to prescribe diamorphine, cocaine and dipipanone for the treatment of substance misuse.

PCTs should ensure that all GP practices and pharmacies are informed in a timely manner about lost or stolen prescriptions or prescription forms, especially FP10 (MDA) forms, which may be used to acquire CDs unlawfully.

Self-assessment and controlled drugs declaration statement

- All health care organisations providing clinical services and relevant social care organisations will need to complete a periodic declaration (at least every two years) on whether or not their organisation keeps stocks of CDs and whether there are any special circumstances that might explain any seemingly unusual patterns of prescribing or supply
- The declaration and self assessment questionnaire will be sent to organisations by the relevant agency, and may be included in other assessments or planning tool, for example the Healthcare Commissions core standards assessment or where PCTs request practice development plans
- The relevant agency can determine the frequency of self-assessment. A model declaration and assessment form for primary care is available at www.dh.gov.uk/controlledrugs
- Organisations should return their declaration and self-assessment to the agency responsible for monitoring their use of CDs
- These assessments will inform inspections on a risk assessed basis to provide an additional check that CDs are managed safely.

The following bodies may request an appropriate periodic declaration and an appropriate self assessment from the organisation listed.

PCT accountable officers	A general medical practitioner on its medical performers list
Healthcare Commission	NHS Trust , NHS Foundation Trust or a organisation registered with them that provides health care
CSCI	Care home
RPSGB	Registered pharmacy

Controlled drugs review

Overview

- Information from declaration and self-assessment, routine monitoring and other sources will be reviewed to decide whether any further action is needed
- The review will assess the organisations clinical standards in the prescribing, supply, administration, storage, record keeping and disposal of CDs and assure compliance with the Misuse of Drugs Act 2001 and associated Regulations, medicines legislation and any relevant professional codes of practice.

Routine inspections

Legal framework

- The Health Act 2006 contains a provisions for a power of entry and inspection for certain designated persons which will facilitate the inspection of CDs
- Inspection remains a useful tool to check physical arrangements for the storage, record keeping and management of CDs, to support individual and organisational development and to identify and investigate concerns
- Inspections will comply with the ten principles of inspection set out in the Government's policy on Inspection of Public Services <http://archive.cabinetoffice.gov.uk/opsr/documents/pdf/policy.pdf>.

Inspection responsibilities

Controlled drug liaison officers

The Health Act 2006 has created a power of entry and inspection for the police and other nominated people to enter premises to inspect stocks and records of CDs. Prior to the Health Act 2000, the Police only had right of entry to pharmacies (but not to GP surgeries) to inspect CDs and CD registers, except if there was evidence that an offence might have been committed.

Area	Inspecting body
GP practices	PCTs will arrange a small number of routine inspections of a random sample. Inspections will be announced and can be combined with other visits (i.e. QOF and clinical governance)
Community pharmacies	The RPSGB will include inspection of CDs in their routine inspections of community pharmacies. Inspections will be informed by self-assessment, CD reviews and other monitoring
PCTs	Healthcare Commission
NHS Trusts	The Healthcare Commission will report specifically on any points of concern about CDs in all Trusts. This will be carried out as part of the routine assessment of whether a Trust is meeting core standards and through their clinical audit programme
Independent Health care sector	The Healthcare Commission will include an assessment of the adequacy of arrangements for the management of CDs within their existing regulatory frameworks for the independent sector The Healthcare Commission will also assess standard operating procedures for GPs in private practice and ensure compliance
Care homes	CSCI will include CDs within their existing regulatory frameworks for care homes. Targeted controlled drug inspections will be undertaken by CSCI pharmacist inspectors

Standards for inspection

To ensure consistency common guidelines for inspection visits have been developed. The guidelines can be found at www.dh.gov.uk/controlled drugs.

A competency framework setting out the competencies that those involved in monitoring and inspection will need is available on the NPC website at www.npc.co.uk/pdf/CDI_Competency_Framework.pdf.

Good practice

Information sharing

- In sharing information, organisations must have regard to the Data Protection Act 1998 and the codes of practice on confidentiality, in particular the Caldicott principles
- NHS organisations, those contracted to provide NHS services and the independent sector may find the Confidentiality and Disclosure of Information: General Medical Services (GMS), Personal Medical Services (PMS), and Alternative Provider Medical Services (APMS) Code of Practice helpful
- Intelligence networks may wish to agree a code on information sharing and nominate a person responsible for ensuring the code is followed
- Information should be anonymised where possible. In exceptional circumstances, an organisation may determine that it is in the public interest to share patient identifiable information, or that they are required to do so by statute. The patients consent should be sought or they should be notified of the disclosure unless such action would prejudice an investigation.

Reporting concerns

In addition to concerns arising from routine monitoring and inspection, concerns may be raised by individuals. The Public Interest Disclosure Act 1998 was introduced to protect employees who are worried about wrongdoing in their place of work and want to raise concerns. The Act applies to all NHS employees and includes all self-employed NHS professionals (i.e. doctors, dentists, opticians, optometrists and pharmacists). For the purposes of the Act, the employer of self-employed NHS professionals is deemed to be the relevant PCT or SHA. The Healthcare Commission will oversee the new arrangements.

Investigating concerns

The accountable officer will need to ensure that robust systems are in place to enable concerns about CDs to be raised, to log these concerns, to alert themselves where appropriate and to initiate investigations.

Good practice

Useful guides to establishing appropriate reporting arrangements

- The Healthcare Commission website contains more information on raising concerns about wrongdoing in the workplace www.healthcarecommission.org.uk/
- The RPSGB has produced guidance for pharmacists and Registered technicians on raising concerns www.rpsgb.org.uk/pdfs/raisingconcernsguid.pdf.

Useful tools for investigating concerns

- Clinical Governance Toolkit for CD management in primary care may be a useful toolkit for investigating concerns www.cgsupport.nhs.uk/downloads/Primary_Care/CG_toolkit_for_controlled_drug_management.pdf.
- In analysing the reasons underlying an event and determining next steps the NPSA Incident Decision Tree will be helpful in many cases www.npsa.nhs.uk/health/resources/root_cause_analysis.

Appendix 1: Summary of legal requirements or the possession and supply of controlled drugs

	Schedule 2: CD		Schedule 3: CD No Reg					Schedule 4: CD Benz and CD Anab	Schedule 5: CD Inv
		Secobarbital		Phenobarbital	Temazepam	Diethylpropion, Flunitrazepam (Rohypnol)	Buprenorphine (Subutex)		
Prescription requirements	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No
Handwriting requirements	No	No	No	No	No	No	No	No	No
Requisitions necessary	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No
Records to be kept in CD register	Yes	Yes	No	No	No	No	No	No	No
Emergency supplies allowed	No	No	No	Yes	No	No	No	Yes	Yes
Safe Custody	Yes	No	No	No	Yes	Yes	Yes	No	No
Date of supply to marked on prescription	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No
Address of prescriber to be within the UK	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No
Stock destruction to be witnessed	Yes	Yes	No	No	No	No	No	No	No
Validity of prescription	28 days	28 days	28 days	28 days	28 days	28 days	28 days	28 days	6 months
Invoices to be kept for 2 years	No	No	Yes	Yes	Yes	Yes	Yes	Yes ¹	Yes
Import / export licence required	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

1 Invoices relating to import / export transactions only

Appendix 2: Monitoring prescribing

The PSU has worked on two initiatives relating to prescribing of CDs:

Technique to monitor controlled drug prescribing

A technique to allow PCT advisers to monitor the prescribing of CDs and, in particular, analgesic injections, has been devised and is available to all PCTs via the NHSNet website www.ic.nhs.uk/psu/cds. The technique is also a component of all PPD ePACT.net training courses. The technique uses the ePACT.net system using predefined reports and drug selections to allow advisers to identify GP practices with a higher than average cost or frequency of prescribing of CDs compared with the PCT average. The technique demonstrates how advisers can focus on prescribing patterns for these practices to determine specific medicines and quantities prescribed, and produce trend graphs to see if the prescribing patterns are typical of palliative care.

Enhancements to the ePACT.net system have enabled this task to be semi-automated by providing advisers with custom reports that will automatically apply CD drug selections for Schedule 2 and Schedule 3 drugs. Recent upgrades to the system allow additional reports to be provided which enable advisers to monitor prescribing of excessive quantities of CDs on individual prescription forms, monitor prescribing for drug addicts on FP10 (MDA) forms and identify where CD prescriptions were dispensed.

The recently introduced ePACT.net monitor system also allows users to monitor private CD prescribing within their PCT.

Secondary care users can also use ePACT.net to monitor CD prescriptions prescribed on FP10 forms by their Trusts.

It must be stressed that these techniques do not detect inappropriate, fraudulent or criminal behaviour, as the PPD data it uses has no link to individual patients. It simply identifies prescribers with unusual prescribing patterns for these drugs. The adviser can use this information, together with data from other sources and their local knowledge of practices, to decide if further investigation is warranted.

It is recommended that advisers use this tool as part of their monitoring and management of CDs and PCT accountable officers should ensure that staff using ePACT.net to obtain CD information are competent users of the system and are aware its latest enhancements. In addition, advisers may need guidance and expert help to enable them to deal with some abnormal prescribing patterns. They should work with their clinical governance leads if anomalies are picked up that raise concerns. ePACT.net data is provided for a rolling 60-month historical period only, and it is important that historical data are locally archived and stored securely, as this information may be required as evidence by other bodies.

Appendix 3: Useful contacts

British Medical Association

BMA House
Tavistock Square
London
WC1H 9JP

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

Commission for Social Care Inspection

33 Greycoat Street
London
SW1P 2QF

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

Community practitioners' and Health Visitors Association

33-37 Moreland Street
London
EC1V 8HA

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

Council for Healthcare Regulatory Excellence

1st Floor, Kierran Cross
11 Strand
London
WC2N 5HR

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

Department of Health

Richmond House
79 Whitehall
London
SW1A 2NS

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

Dispensing Doctors' Association

Low Hagg Farm
Starfitts Lane
Kirbymoorside
North Yorkshire
YO62 7JF

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

Environment Agency

Millbank Tower
25th Floor
21 / 24 Millbank
London
SW1P 4XL

Tel: 08708 506 506
Website: www.environment-agency.gov.uk

General Medical Council

Regent's Place
350 Euston Road
London
NW1 3JN

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

Healthcare Commission

Finsbury Tower
103-105 Bunhill Row
London
EC1Y 8TG

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

Home Office Drugs Licensing Branch

2 Marsham Street
London
SW1P 4DF

Tel: 0207 035 0483
Website: www.homeoffice.gov.uk

Home Office Drugs Legislation and Enforcement Unit

2 Marsham Street
London
SW1P 4DF

Tel: 0207 035 0464
Website: www.homeoffice.gov.uk

Medicines and Healthcare products Regulatory Agency

Market Towers
1 Nine Elms Lane
London
SW8 5NQ

Tel: 0207 084 2000
Fax: 0207 084 2353
Website: www.mhra.gov.uk

National Clinical Assessment Service (part of the National Patient Safety Agency)

Market Towers
1 Nine Elms Lane
London
SW8 5NQ

Tel: 0207 062 1620
Fax: 0207 084 3851
Website: www.ncas.npsa.nhs.uk

National Patient Safety Agency

4-8 Maple Street
London
W1T 5HD

Tel: 0207 927 9500
Website: www.npsa.nhs.uk

National Pharmacy Association

Mallinson House
38-42 St Peter's Street
St Albans
Hertfordshire
AL1 3NP

Tel: 01727 832161
Fax: 01727 840858
Website: www.npa.co.uk

National Prescribing Centre

The Infirmary
70 Pembroke Place
Liverpool
L69 3GF

Tel: 0151 794 8134
Fax: 0151 794 8139
Website: www.npc.co.uk (Internet)
www.npc.nhs.uk (NHSNet)

National Treatment Agency

8th Floor
Hercules House
Hercules Road
London
SE1 7DU

Tel: 020 7261 8801
Fax: 020 7261 8883
Website: www.nta.nhs.uk

NHS Clinical Governance Support Team

1st Floor
St. Johns House
30 East Street
Leicester
LE1 6NB

Tel: 0116 295 2000
Fax: 0116 295 2001
Website: www.cgsupport.nhs.uk

NHS Direct

Headquarters
207 Old Street
London
EC1V 9PS

Tel: 0207 599 4200
Fax: 0207 599 4299
Website: www.nhsdirect.nhs.uk

Nursing and Midwifery Council

23 Portland Place
London
W1B 1PZ

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

Pharmaceutical Services Negotiating Committee

59 Buckingham Street
Aylesbury
Buckinghamshire
HP20 2PJ

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

Prescription Pricing Division of the NHS Business Services Authority

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

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

Prescribing Support Unit

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

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

Royal College of General Practitioners

RCGP Substance Misuse Unit
14 Princes Gate
Hyde Park
London
SW7 1PU

Tel: 0845 4564041 Ext. 217
Fax: 0207 225 3047
Website: www.rcgp.org.uk/substance_misuse/substance_misuse_home.aspx

Royal College of Nursing

Head Office
20 Cavendish Square
London
W1G 0RN

Tel: 0207 409 3333
Website: www.rcn.org.uk

Royal Pharmaceutical Society of Great Britain

1 Lambeth High Street
London
SE1 7JN

Tel: 0207 735 9141
Fax: 0207 735 7629
Website: www.rpsgb.org.uk

UK Home Care Association

42b Banstead Road
Carshalton Beeches
Surrey
SM5 3NW

Tel: 0208 288 1551
Fax: 0208 288 1550
Website: www.ukhca.co.uk

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- NHS (General Medical Service Contract) Regulations 2004 www.opsi.gov.uk/si/si2004/20040291.htm
- Hazardous Waste (England and Wales) Regulations 2005 www.opsi.gov.uk/si/si2005/20050894.htm
- Health Act 1999 www.opsi.gov.uk/acts/acts1999/19990008.htm
- Health Act 2006 <http://www.opsi.gov.uk/acts/acts2006/20060028.htm>
- Health and Social Care (Community Health and Standards) Act (2003) www.opsi.gov.uk/acts/acts2003/20030043.htm
- Medicines Act 1968
- Misuse of Drugs Act 1971
- Misuse of Drugs (Safe Custody) Regulations 1973
- Misuse of Drugs (Supply to Addicts) Regulations 1997 www.opsi.gov.uk/si/si1997/97100101.htm
- Misuse of Drugs Regulations 2001 www.opsi.gov.uk/si/si2001/20013998.htm
- Misuse of Drugs (Amendment) Regulations 2005 www.legislation.hmso.gov.uk/si/si2005/20050271.htm
- NHS (General Medical Services) Regulations 1992 www.opsi.gov.uk/si/si1992/uksi_19920635_en_1.htm
- Private and voluntary health care (England) Regulations 2001 www.opsi.gov.uk/si/si2001/20013968.htm
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www.rpsgb.org.uk/pdfs/cdsafedestructionguid.pdf
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www.pjonline.com/pdf/society/pj_20061209_inspectors.pdf
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www.csci.org.uk/information_for_service_providers/national_minimum_standards/default.htm

- National Minimum Standards on DH website, links to each provided here www.csci.org.uk/information_for_service_providers/national_minimum_standards/default.htm
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Appendix 5: Glossary

ACMD	Advisory Council on the Misuse of Drugs
BMA	British Medical Association
British National Formulary (BNF)	A reference providing UK health care professionals with authoritative and practical information on the selection and clinical use of medicines
Care home	A home providing either residential and / or nursing care to residents
CDs	Controlled drugs — drugs that are controlled under Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001
CD register	Legally binding register in which the movement of CDs into and out of the premises / ‘doctor’s bag’ is recorded
CPD	Continuing professional development
CSCI	Commission for Social Care Inspection
Deputising service	An organisation that provides medical services out-of-hours
DH	Department of Health
Dispensing doctors	doctors who provide a dispensing service to some or all of their patients
‘doctor’s bag’	A lockable bag containing medicines and medical equipment, occasionally including CDs, that doctors use when outside, and sometimes inside, their surgeries
Domicillary visit	A visit made by a health care professional to a patient at home
Drug and Alcohol Unit	A unit set up to deal with the treatment of drug and / or alcohol misuse / dependence
EA	Environment Agency
Educational establishments	Premises where people can access education
ePACT.net	Electronic analysis of prescribing
Formal / home carer	A carer who is paid for the purpose
FP10	Prescription form used by professionals, in primary care, within the NHS
FP10 (MDA)	Prescription form (blue) used to prescribe specific CDs by instalments
GP co-operative	A group of local GPs who set up a system to provide care to local patients out-of-hours
GMC	General Medical Council
Informal carer	A carer who is not employed for the purpose
Local educational authorities	Council-owned authorities with a responsibility for education within their locality

MHRA	Medicines and Healthcare products Regulatory Agency
NCAS	National Clinical Assessment Service
NMC	Nursing and Midwifery Council
NPA	National Pharmacy Association
NPC	National Prescribing Centre
NPSA	National Patient Safety Agency
Out-of-hours	Out-of-hours services provided to patients outside of the normal working hours
Patient information leaflets	Information leaflets supplied with medicines, required to be provided by law, which give information to patients about various aspects of the medicine including side effects, storage, dosing, etc.
'Patient-returned' CDs	CDs that have been prescribed and dispensed to a named patient, and then returned unused or part-used
PCTs	Primary Care Trusts or Care Trusts
PDRC	Patient Drug Record Card
PGDs	Patient group directions
PMR	Patient medication record — computer record containing personal patient details and medicines supplied to them
PPD	Prescription Pricing Division of the NHS Business Services Authority
Practice stock	Stock of drugs held centrally within a practice to which all partners in the practice have access and can use
Prescribing number	The number allocated to the prescriber when they become registered as such
POMs	Prescription-only medicines
Private prescribers	Professionals who prescribe medication outside of the NHS
Professional registration number	The number allocated to the professional upon registration with their professional body
PSU	Prescribing Support Unit of the Information Centre
RCA	Root cause analysis
RCGP	Royal College of General practitioners
RPSGB	Royal Pharmaceutical Society of Great Britain
RPSGB inspectors	Inspectors employed by the RPSGB to inspect retail pharmacies
Running balance	The total quantity at any point in time, of any particular CD that is deemed to be held at the premises

SHA	Strategic Health Authority
SLA	Service level agreement — an agreement drawn up by two or more parties detailing the specifics of the service to be provided
SOPs	Standard operating procedures
Supplementary prescriber	A health care professional who has successfully undertaken the training required to become a supplementary prescriber to provide continuing care to patients
Syringe driver	A mechanism by which patients can self-administer pain relief (and associated medication)

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