

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

Third edition

2009





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# Section 1

## Introduction



## Background

This third edition of the controlled drugs guide (CDG) takes into account the 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 were introduced as a result of amendments to the Misuse of Drugs Regulations (MDRs) 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 1 January 2007. Since then further changes have been introduced which have been included in this third edition of the CDG.

Changes to primary legislation and the MDRs 2001 apply to Scotland, England and Wales. Northern Ireland has its own MDRs - MDRs (Northern Ireland) 2002 - although these largely mirror the MDRs 2001. However, arrangements for delivering new requirements may differ between each of the countries.

## Purpose of the guide

This CDG 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 Department of Health (DH) has issued specific guidance on the management of CDs in secondary care (updated following changes to the MDR 2001 made in July 2007). This guidance also reflects the recent changes that have taken place to update working practices: the developing roles of healthcare professionals, the need to optimise skill mix and the role of pharmacy technicians and other healthcare professionals, including operating department practitioners. It describes how these changes work within the existing legal framework for CDs.

This CDG aims to identify robust systems for obtaining, storing, supplying, recording, monitoring and disposing safely of CDs, while at the same time helping to ensure appropriate and convenient access for those patients that require CDs. 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.

Since the publication of the second edition of this Controlled Drugs Guide in February 2007, work should have been undertaken towards full implementation of the recommendations within the CDG. In many cases it will have required a systematic approach to improve the management and control of CDs, enhancing patient and public safety, whilst at the same time ensuring that healthcare professionals are not overburdened with additional bureaucracy resulting in reluctance to prescribe CDs. The Care Quality Commission Annual Report (2008), *'The safer management of controlled drugs'*, concluded that there had been significant activity to help ensure that CDs are managed safely and effectively. However, ongoing activity and vigilance is required to sustain the positive developments that have been achieved in the last two years.

## Key audiences

The CDG 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
- Ambulance services/paramedics
- Intermediate care services

When an organisation commissions services involving CDs, either within the NHS or from non-NHS organisations, they should ensure that the same standards and good practice frameworks for the management of CDs apply in these settings. It is strongly recommended that these standards and good practice frameworks should be included in all contracts or service level agreements (SLAs) for provider services. These standards should then be monitored by the commissioning organisation as part of the contract monitoring process.

## How to use this guide

Each of the main sections of this CDG 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 highlighted.

While every care has been taken to ensure the accuracy of this CDG, the National Prescribing Centre (NPC) cannot accept liability for any errors or omissions. The contents of this CDG 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 CDG, plus any other national guidance, legislation and directions that may have been published since this edition of the CDG was produced.

## Additional resources

### Controlled drugs website

[www.npci.org.uk/cd/](http://www.npci.org.uk/cd/)

The NPC have produced a dedicated website to support the safe and effective use of CDs. The website contains resources and information which should be of value to all those involved in the management and prescribing of CDs. In addition, Accountable Officers (AOs) and individuals nominated by AOs can log into a protected area of the website to access additional resources and a dedicated discussion forum.

Unfortunately, the NPC is not in a position to be able to answer specific individual queries relating to the management of CDs. The CDs website [www.npci.org.uk/cd/](http://www.npci.org.uk/cd/) contains a section dealing with frequently asked questions (FAQs) and individual professional organisations provide a range of advisory services to their members (see Appendix 4 - Useful contacts).

## Key websites

NPC Controlled drugs website

[www.npci.org.uk/cd](http://www.npci.org.uk/cd)

Care Quality Commission (CQC)

[www.cqc.org.uk](http://www.cqc.org.uk)

The Department of Health (DH)

[www.dh.gov.uk/controlleddrugs](http://www.dh.gov.uk/controlleddrugs)

Home Office

[www.drugs.homeoffice.gov.uk](http://www.drugs.homeoffice.gov.uk)

National Patient Safety Agency (NPSA)

[www.npsa.nhs.uk](http://www.npsa.nhs.uk)

National Treatment Agency for Substance Misuse (NTA)

[www.nta.nhs.uk](http://www.nta.nhs.uk)

Royal Pharmaceutical Society of Great Britain (RPSGB)

[www.rpsgb.org](http://www.rpsgb.org)

## Guidance

British National Formulary

[www.bnf.org/bnf/](http://www.bnf.org/bnf/)

The British Pain Society: Pain and substance misuse: improving the patient experience. Recommended guidelines for pain management programmes for adults

[www.britishpainsociety.org](http://www.britishpainsociety.org)

Joint Royal Colleges Ambulance Liaison

Committee: Clinical Practice Guidelines

[www.jrcalc.org.uk/guidelines.html](http://www.jrcalc.org.uk/guidelines.html)

NICE: Drug misuse - methadone and buprenorphine

[www.nice.org.uk/Guidance/TA114](http://www.nice.org.uk/Guidance/TA114)

NPSA: Reducing dosing errors with opioid medicines

[www.npsa.nhs.uk/nrls/alerts-and-directives/rapidrr/reducing-dosing-errors-with-opioid-medicines/](http://www.npsa.nhs.uk/nrls/alerts-and-directives/rapidrr/reducing-dosing-errors-with-opioid-medicines/)

NPSA: Ensuring safer practice with higher dose ampoules of morphine and diamorphine

[www.npsa.nhs.uk/nrls/alerts-and-directives/notices/morphine-diamorphine/](http://www.npsa.nhs.uk/nrls/alerts-and-directives/notices/morphine-diamorphine/)

NPSA: Patient safety alert - safer practice with epidural injections and infusions

[www.npsa.nhs.uk/nrls/alerts-and-directives/alerts/epidural-injections-and-infusions](http://www.npsa.nhs.uk/nrls/alerts-and-directives/alerts/epidural-injections-and-infusions)

National Treatment Agency: Drug Misuse and Dependence

UK guidelines on clinical management is produced by the Departments of Health (England), the Scottish Government, Welsh Assembly Government and Northern Ireland Executive

[www.nta.nhs.uk/publications](http://www.nta.nhs.uk/publications)

Royal College of General Practitioners (RCGP) runs training programmes specifically for the management of substance misusers

[www.rcgp.org.uk](http://www.rcgp.org.uk)

# Section 2

## Legislation



## Misuse of drugs legislation

The overall legislative framework, which applies to all medicines, is the Medicines Act 1968 and its associated legislation - principally the Prescription Only Medicines (Human Use) Order 1997, which is managed by the MHRA (Medicines and Healthcare Products Regulatory Agency). Controlled drugs are additionally defined and governed by the Misuse of Drugs Act (MDA) 1971 and associated regulations - principally the Misuse of Drugs Regulations (MDR) 2001, which fall within the remit of the Home Office. The Health Act 2006 and its associated regulations - principally the Controlled Drugs (Supervision of Management and Use) Regulations 2006, which set out the requirements for the governance and monitoring of CDs, is the responsibility of the Department of Health.

### Medicines Act 1968

This Act, and regulations made under the Act, sets out the requirements for the legal sale, supply and administration of medicines. It also allows certain exemptions from the general restrictions on the sale, supply and administration of medicines which, for example, enable midwives to supply and/or administer diamorphine, morphine, pethidine or pentazocine.

A number of healthcare professionals are permitted to supply and/or administer medicines generally in accordance with a Patient Group Direction (PGD). Some of these professional groups, but not all, are permitted to possess, supply or administer CDs in accordance with a PGD under Misuse of Drugs legislation (see page 46).

A list of drugs controlled under the misuse of drugs legislation, showing each drug's classifications under both the MDA 1971 and the MDR 2001, is held on the Home Office website.

### Misuse of Drugs Act (MDA) 1971

The MDA 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 that are subject to the control of the MDA 1971, are listed in Schedule 2 of the Act and are termed CDs. The MDA controls the export, import, supply and possession of dangerous or otherwise harmful drugs. In effect, the Act largely renders unlawful all activities involving the drugs controlled under the Act, except where provided for under the regulations made under the Act.

Drugs controlled under the MDA 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

Drug class	Penalties for possession	Penalties for supply
<b>Class A</b> - diamorphine (Heroin), cocaine and crack cocaine, MDMA (Ecstasy), lysergic acid diethylamide (LSD), methamphetamine, more potent opioid analgesics, e.g. methadone	Up to 7 years imprisonment or an unlimited fine or both	Up to life imprisonment or an unlimited fine or both
<b>Class B</b> - amphetamine, barbiturates, cannabis, cannabis resin, cannabinal, methylphenidate, less potent opioid analgesics, e.g. codeine	Up to 5 years imprisonment or an unlimited fine or both	Up to 14 years imprisonment or an unlimited fine or both
<b>Class C</b> - buprenorphine, benzodiazepines (and zolpidem) ketamine, anabolic steroids, and gamma-hydroxybutyrate (GHB)	Up to 2 years imprisonment or an unlimited fine or both	Up to 14 years imprisonment or an unlimited fine or both
<b>Note:</b> 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 2 and may be possessed in medicinal form without a prescription.		
<b>Note:</b> Cannabis, cannabis resin, cannabinal and its derivatives were reclassified from Class C to Class B on 26 January 2009.		

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 to C. The maximum penalties for offences of possession and supply of the main CDs within each class are outlined in the table on page 14 (summary provided by the Home Office).

## Misuse of Drugs Regulations (MDRs) 2001

The use of CDs in medicine is permitted by the MDRs. The current version of the Regulations made under the MDA 1971 are the MDRs 2001, which came into operation in February 2002. The MDRs are periodically amended and revised and the 2001 MDRs have been subject to a number of amendments. The MDRs currently in force and amendments can be found at the website of the Office for Public Sector Information [www.opsi.gov.uk](http://www.opsi.gov.uk), which should be checked on a regular basis. For details of the more recent amendments, links to the Home Office Circulars - which set out summaries of the changes - are available from [www.homeoffice.gov.uk/about-us/publications/home-office-circulars](http://www.homeoffice.gov.uk/about-us/publications/home-office-circulars)

The MDRs 2001 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. A comprehensive list of drugs included within the Schedules is given in the MDRs 2001 [www.opsi.gov.uk](http://www.opsi.gov.uk). A summary of legal requirements that apply to CDs is included in Appendix 1 (page 100).

## Schedule 1 (Controlled drugs-licence)

Whilst virtually all drugs listed in Schedule 1 have no recognised medicinal use, Sativex® (Cannabis Sativa L.Extract) is an unlicensed medicine in the UK and is being used in the treatment of multiple sclerosis. Other Schedule 1 drugs include hallucinogenic drugs such as 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 MDA 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.

## Sativex®

The Home Office has issued an open general licence for Sativex® which allows pharmacists to dispense the product as an unlicensed medicine under certain conditions. There is no longer the requirement for a prescribing doctor or dispensing pharmacist to contact the Home Office in relation to obtaining a licence to prescribe or supply Sativex®.

The Home Office have lifted the record-keeping requirements and therefore pharmacists do not need to record Sativex® in their controlled drug registers (CDRs).

The Home Office have advised that, where a lockable refrigerator is available, Sativex® should be stored in it prior to dispensing. Otherwise it should be kept in a refrigerator not visible to the general public.

Prescription requirements still apply - prescriptions must be written in the same way as they are for Schedule 2 drugs with prescriptions including the dose, form, strength and total quantity of the preparation in both words and figures. Private prescriptions for Sativex® should be on the private form FP10PCD.

Sativex® remains a CD in Schedule 1 of the MDR 2001 and will remain so until such time as it has been approved by the MHRA, and consideration will then be given to its scheduling under the MDR.

## Schedule 2 (Controlled drugs)

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, amended 2007). They must be stored in a locked receptacle, such as an appropriate CDs cabinet or approved safe, which can only be opened by the person in lawful possession of the CD or a person authorised by them.

**Supply:** Supply is restricted to licensed wholesalers, practitioners, hospitals and registered pharmacies. Wholesalers are permitted to supply only to a person authorised to possess. Practitioners are restricted to supplying their patients. Hospitals (in so far as it represents the business of the hospital) may supply patients, wards and practitioners. Pharmacies may supply on receipt of a valid prescription or signed order. Additional prescription writing requirements exist.



**Record:** A record of all Schedule 2 controlled drugs obtained and supplied must be kept in a register, the form of which must comply with the relevant regulations.

**Storage:** Schedule 2 controlled drugs are subject to safe custody requirements (The Misuse of Drugs [Safe Custody] Regulations 1973, amended 2007). They must be stored in a locked receptacle, usually in an appropriate controlled drug cabinet or approved safe, which can only be opened by a person in possession of the controlled drug or a person authorised by that person.

**Destruction:** The destruction of Schedule 2 controlled drugs must be appropriately authorised and the person witnessing the destruction must be authorised to do so.

### Schedule 3 (Controlled drugs - no register)

Schedule 3 contains a number of substances that are perceived as being open to abuse, but less likely to be so than schedule 2 CDs. It contains a number of synthetic opioids together with other substances including temazepam.

From 1 January 2008, midazolam was reclassified from a Schedule 4 Part 1 to a Schedule 3. Midazolam is exempt from the requirements relating to safe custody. Midazolam must be prescribed and ordered as a CD. Dentists will have to order midazolam on a CDs form (see page 36). Midazolam is the only Schedule 3 CD that, in certain circumstances, can be included in a Patient Group Direction (PGD).

**Supply:** The regulations concerning supply (and the additional prescription writing requirements) are similar to Schedule 2 controlled drugs.

**Record:** There is no statutory requirement to record the supply of Schedule 3 controlled drugs.

**Storage:** The majority of Schedule 3 CDs are exempt from safe custody requirements and can be stored on the open dispensary shelf. Exceptions are temazepam, flunitrazepam, 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.

**Destruction:** The requirements relating to destruction do not apply to Schedule 3 controlled drugs (unless the controlled drugs are manufactured by the individual).

### Schedule 4 (Controlled drugs - benzodiazepines and anabolic steroids)

**Schedule 4 is split into two parts.**

Part 1 (CDs - benzodiazepines) contains most of the benzodiazepines (with the exception of flunitrazepam, midazolam and temazepam which are Schedule 3), plus eight other substances including zolpidem, fencamfamin and mesocarb.

Part 2 (CDs - 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 (CDs - anabolic steroids) drug when it is in the form of a medicinal product. However, possession of a drug from Schedule 4 Part 1 (CDs - 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.

**Supply:** Supply is restricted to supplies against practitioners' prescriptions or in accordance with Patient Group Directions (PGDs) but there are no additional requirements as to the form of prescription other than those that apply to all Prescription Only Medicines (POMs).

**Record:** There is no statutory requirement to record the supply of Schedule 4 controlled drugs.

**Storage:** Schedule 4 controlled drugs are exempt from safe custody requirements and can be stored on the open dispensary shelf.

**Destruction:** The requirements relating to destruction do not apply to Schedule 4 controlled drugs (unless the controlled drugs are manufactured by the individual).



## Schedule 5 (Controlled drugs-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.

**Supply:** Some of the controlled drugs in Schedule 5 are available for over-the-counter sale in registered pharmacies. It is for the pharmacist to use their professional judgement to determine the appropriateness of any supply and be alert to potential misuse of products.

The Schedule 5 controlled drugs that are prescription only medicines (including codeine, dextropropoxyphene and dihydrocodeine tablets) can only be supplied in accordance with a valid prescription or Patient Group Direction.

**Record:** There is no statutory requirement to record the supply of Schedule 5 controlled drugs.

**Storage:** Schedule 5 controlled drugs are exempt from safe custody requirements and can be stored on the open dispensary shelf.

**Destruction:** The requirements relating to destruction do not apply to Schedule 5 controlled drugs.

## 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. The 1973 Regulations specifically apply to the following:

- Any premises occupied by a retail dealer for purpose of his business
- A care home (as defined in Care Standards Act 2000)

The 1973 Regulations refer to nursing homes, a term which is now obsolete. The appropriate terminology is now "care home" as defined within the Care Standards Act 2000. The change in terminology with the introduction of the Care Standards Act 2000 did not exclude care homes from the provisions of the 1973 Regulations as the Interpretation Act 1978 operated to update the reference. The Misuse of Drugs and Misuse of Drugs (Safe Custody) Regulations replaced the term nursing home with that of care home.

The Regulations also require that in other settings the CDs to which the provisions apply should be kept in a locked receptacle that can only be accessed by the person authorised to possess them (or a person authorised by that person to access them).

All Schedule 2 and some Schedule 3 CDs (buprenorphine, diethylpropion, flunitrazepam and temazepam) 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 and Misuse of Drugs (Safe Custody) (amendment) Regulations 2007

These Regulations amend the Misuse of Drugs Regulations 2001 and (Safe Custody) Regulations to enable the following:

- Give authority to AOs, within their organisations to nominate persons or groups of persons to witness the destruction of CDs
- Allow Operating Department Practitioners to order, possess and supply CDs within their hospital
- Remove the requirement to maintain a CDR in a prescribed format
- Change the record keeping requirements for CDs
- Reschedule midazolam from Schedule 4 to Schedule 3 of the MDRs 2001
- All care homes, whether providing nursing or personal care, must now keep CDs in a CD cupboard

## Misuse of Drugs (Supply to Addicts) Regulations 1997

The 1997 Regulations prohibited doctors from prescribing, administering or supplying diamorphine, cocaine or dipipanone for the treatment of addiction or suspected addiction except under Home Office licence. However an amendment was introduced in June 2007. Doctors no longer need individual Home Office licences to prescribe diamorphine, cocaine, dipipanone [www.drugs.homeoffice.gov.uk/drugs-laws/licensing/domestic-licences/doctors](http://www.drugs.homeoffice.gov.uk/drugs-laws/licensing/domestic-licences/doctors) A general licence has been issued to cover those doctors who have been approved by the DH.

A licence is not required for such drugs for the treatment of organic disease or injury.

## Health Act 2006

The Health Act 2006 provided for regulations to be laid relating to strengthened governance and monitoring arrangements for CDs. The Health Act is primary legislation and applies to the whole of the UK.

## 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 1 January 2007. These Regulations set out the requirements for certain NHS bodies, and independent healthcare bodies, to appoint an Accountable Officer (AO) and describe the duties and responsibilities of AOs to secure the safe management and use of CDs for their organisation. The regulations also require bodies to co-operate with each other, including with regard to sharing information, relating to concerns about use and management of CDs and set out arrangements for powers of entry and inspection.

## Section 3

# Governance, inspections and monitoring



## 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. One of the guiding principles of the new arrangements was that they should not interfere with the appropriate use of CDs and good clinical care. Another was that the safer governance principles should apply to all health and social care settings and individual practices where CDs are prescribed, stored, administered or transported.

All NHS trusts and independent health and social care providers have a responsibility to assure the quality of their CDs management as an integral part of their clinical governance processes. CD management being specifically identified for risk requirements. New requirements for collaboration and information sharing between all health and social care providers and relevant regulators and agencies have also been introduced. On 1 April 2009 the Care Quality Commission (CQC) took over the responsibility for overseeing these new arrangements (previously held by the Healthcare Commission). The DH has provided comprehensive guidance on strengthened governance arrangements [www.dh.gov.uk](http://www.dh.gov.uk)

**Figure 1** (opposite) summarises the agencies involved in the management and use of CDs.

## The Health Act 2006

The Health Act 2006 provided for regulations to be laid down relating to strengthened governance and monitoring arrangements for CDs. The Health Act is primary legislation and applies to the whole of the UK.

The Key provisions of the Act are:

- All designated bodies such as NHS healthcare organisations and independent hospitals are required to appoint an AO
- A duty of collaboration placed on responsible bodies, healthcare organisations and other local and national agencies including professional regulatory bodies, police forces, the Healthcare Commission and the Commission for Social Care Inspection (CSCI) (both now absorbed into the Care Quality Commission) 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

## Controlled Drugs (Supervision of Management and Use) Regulations 2006

These Regulations came into effect in England from 1 January 2007 and 1 March 2007 in Scotland [www.opsi.gov.uk/si/si2006/20063148.htm](http://www.opsi.gov.uk/si/si2006/20063148.htm) A summary of the governance arrangements for specific sites is provided in Appendix 2.

## Implications of Regulations

### Requirement to appoint an Accountable Officer

The Controlled Drugs (Supervision of Management and Use) Regulations 2006 require that all designated bodies **must** appoint an AO. Organisations who are designated bodies but do not administer or hold CDs are still required to appoint an AO, although their responsibilities will be reduced accordingly. CD designated bodies include the following:

- PCTs
- NHS trusts
- NHS foundation trusts
- Independent hospitals\*

\* Independent hospitals: Establishments registered with the CQC under one or more of the service user categories listed below fall under the definition of 'An English independent hospital' for the purpose of the CD regulations, and hence are controlled drug designated bodies (CDDBs) and are required to appoint an AO. Acute hospitals (with overnight beds), acute hospitals (day surgery only), hospice for adults, hospice for children, mental health establishments where people are not liable to be detained, mental health establishments taking people liable to be detained.

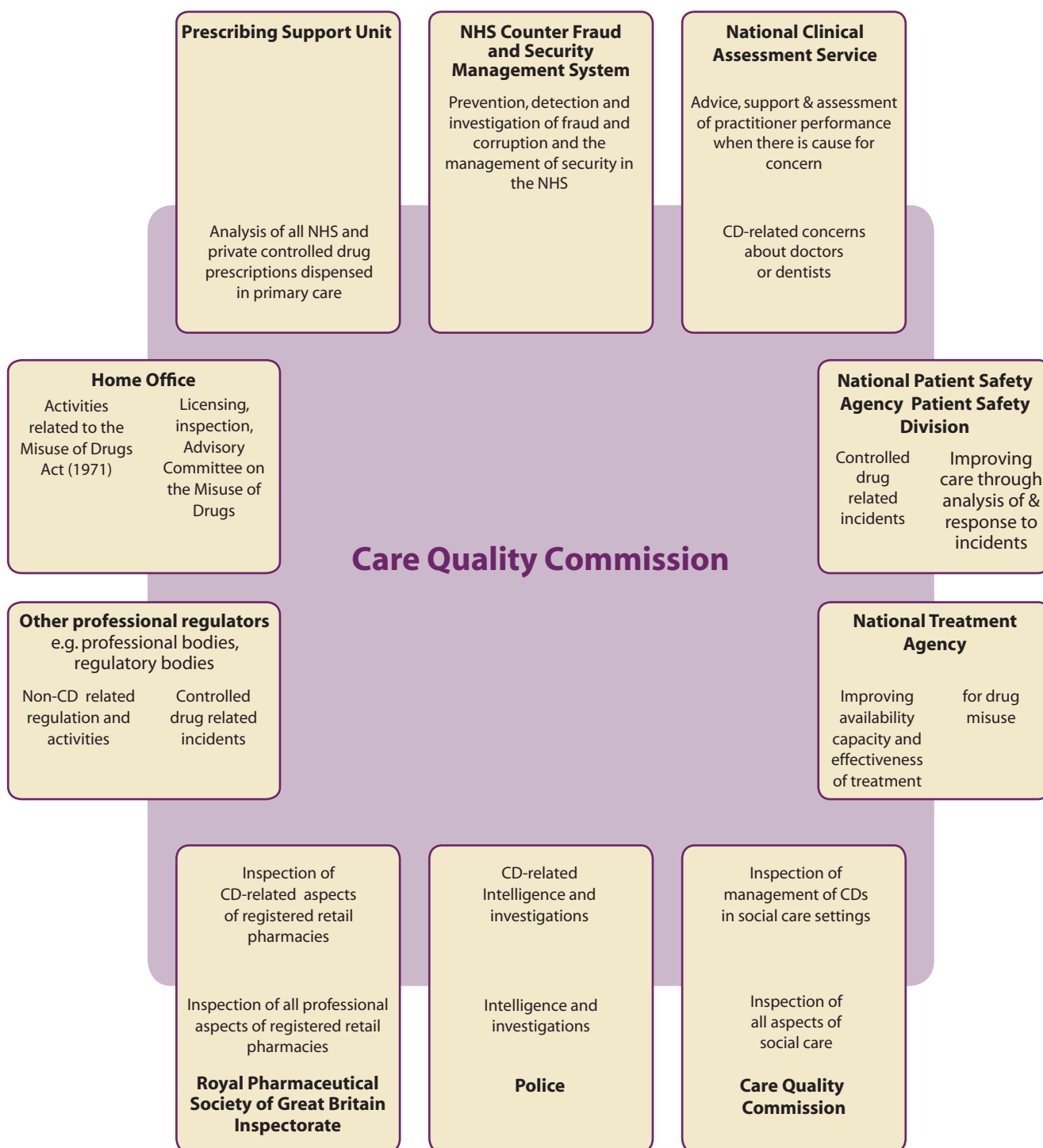
### Characteristics of an Accountable Officer

The Regulations specify who may be appointed as an AO. Irrespective of the designated body, the AO cannot be a person who routinely supplies, administers or disposes of CDs as part of his duties. They must be a senior person in the organisation.

### Notification of Accountable Officer

Designated bodies must notify the CQC of the nomination or appointment of their AO, and also the removal of an AO. There is a web form on the CQC website to make these notifications. The CQC is required to publish a list of AOs

Figure 1: The agencies that are involved in different aspects of the regulation and control of controlled drugs



in England, which it does on its website with updates, approximately monthly.

### Responsibilities of Accountable Officers

The responsibilities of AOs are specified in the Regulations.

The NPC will be producing a Handbook for AOs which outlines in more detail their responsibilities.

Responsibilities of all AOs:

- Ensure the safe and effective use and management of CDs within their own organisations and by any body or person providing services to their organisation
- Establish and ensure appropriate arrangements to comply with Misuse of Drugs legislation
- Ensure adequate and up-to-date Standard Operating Procedures (SOP) are in place in relation to the management and use of CDs
- AOs must also have regard to best practice in relation to the management 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
  - Take appropriate action if there are well founded concerns
  - Establish arrangements for sharing information
- Produce quarterly reports of their CD occurrences and give them to the AO leading the Local Intelligence Network of which their organisation is a member. The occurrence report must describe details of any concerns that the organisation has regarding the management of CDs or confirmation that there have not been any concerns in the required timeframe.

### Additional responsibilities of Accountable Officers in PCTs

- Establishing the Local Intelligence Network (LIN). Networks will normally be established on the basis of a health community, and may include more than one PCT

- Convening Incident Panels. It is a requirement [Reg 17 (2) (g)] on PCT AOs that the LIN has a process for establishing an incident panel if serious concerns are raised. The process should outline the responsibilities of key individuals and how the panel should be called together
- Analysing NHS and private prescribing of CDs using electronic Prescribing Analysis and Cost (ePACT) [Reg 11(2)(a)]
- Requesting a periodic declaration and a self assessment from a general medical practitioner on its medical performers list regarding their CD management and use [Reg 12(1)]
- Ensuring their organisation operates arrangements for periodic inspections of premises used in connection with management or use of CDs which may not be subject to inspection by CQC or RPSGB [Reg 19]
- The PCT leading a LIN must take steps to protect patient and public if there are concerns about inappropriate or unsafe use of CDs by a person who is not providing services for any designated body, but who lives or provides services in the LIN area [Reg 30(2)]

## Specific areas of Accountable Officer responsibility

### Standard operating procedures

### Legal requirements

Regulations made under the Health Act 2006 require each healthcare organisation to have SOPs for the use and management of CDs. The regulations require AOs to ensure that their organisation and those providing services to the organisation has adequate and up-to-date SOPs in relation to the use of CDs.

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 CDRs 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 healthcare 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

[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_064824](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_064824)

## Monitoring and auditing the management and use of controlled drugs by PCTs

### Legal framework

Regulations specify that arrangements must provide for the following:

- Monitoring and analysing health service, private CD and hospital prescribing dispensed in the community through the use of electronic Prescribing Analysis and Costs (ePACT) data analysis tools available from the Prescription Pricing Division (PPD) of the NHS Business Service Authority (NHSBSA)  
Requests to access ePACT.net can be made by completing the registration form available on the NHSBSA website at [www.nhsbsa.nhs.uk/PrescriptionServices/960.aspx](http://www.nhsbsa.nhs.uk/PrescriptionServices/960.aspx)  
Note that N3 network connection is required to access ePACT.net and that dental prescriptions and out-of-hours non FP10 forms are not included in the data analysis
- Ensuring systems are in place to alert the AO 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



### CQC Self-assessment for PCTs

The CQC have developed a tool to help PCTs check whether they are meeting the guidance and legal requirements regarding the governance of CDs. The self-assessment tool is not a data collection tool, but a recommended resource to help PCTs measure their performance and identify ways in which they can improve. It includes a series of detailed questions around the safe management of CDs, against which PCTs can score their current practices [www.cqc.org.uk](http://www.cqc.org.uk)

### Assessing CD 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 11 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

### 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 should include the following:
  - Assessment of risks arising from managing CDs
  - Procedures for training new members of staff or locums in management of CDs



## Good Practice (continued)



- 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 CDRs
  - 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
  - Audit trails for CD prescriptions
  - Procedures for missing/stolen/lost prescription forms
  - Procedures for the storage and distribution of prescription forms
  - Refer to the NHS Counter Fraud and Security Management Service (CFSMS) *Security of Prescription Form* guidance document available at [www.nhsbsa.nhs.uk/security](http://www.nhsbsa.nhs.uk/security)
- 4** Managers, staff and healthcare professionals should know which member of staff at the PCT to contact if they have a concern regarding the performance or practice of healthcare professionals, or their staff, involving CDs. This would normally be the AO.

## Routine monitoring

AOs 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 set out below is the use of prescribing data.

## Prescribing data

Prescription data collected by Prescription Services 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 two electronic prescribing information systems - Prescribing Toolkit and ePACT.net.

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

A report is available, to all users of the PCT Reports System of the NHSBSA, that shows all Schedule 1, 2 and 3 CD requisitions written in a PCT and supplied from community pharmacies.

This can be accessed at [www.nhsbsa.nhs.uk/prescriptionservices/815.aspx](http://www.nhsbsa.nhs.uk/prescriptionservices/815.aspx)

The Prescribing Support Unit (PSU) has audit toolkits to help with monitoring [www.ic.nhs.uk/services/prescribing-support-unit-psu/controlled-drugs](http://www.ic.nhs.uk/services/prescribing-support-unit-psu/controlled-drugs)

Prescription processing errors can occur due to the complexity and variability of information contained on prescription forms and the manual processes involved. In determining if further investigation is warranted, the NHSBSA Prescription Services can provide assistance through the prescription search request process. If the request is made within five months of the prescription being dispensed the NHS Prescription Services Helpdesk (Tel: 0845 610 1171 or email [prescriptionpricinghelpdesk@ppa.nhs.uk](mailto:prescriptionpricinghelpdesk@ppa.nhs.uk)) have the facility to access the scanned image of the prescription form. Initial contact should be made via the helpdesk.

Additional detail on PSU initiatives to support monitoring of CDs is provided in Appendix 3 (see page 102).



## Sharing information

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

### Information sharing

- There are requirements to share information on concerns about relevant individuals [Reg 25 and 26]
- 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

Confidential information which relates to, and can identify a patient [Reg 25(2)], 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 patient's consent should be sought or they should be notified of the disclosure unless such action would prejudice an investigation.

## Local Intelligence Network

Responsibility for establishing networks lies with PCT AOs. 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 healthcare professional to share them as soon as possible with other local agencies who may be affected or who may have complementary information.

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
- Care Quality Commission

- Counter Fraud and Security Management Service Division of the NHS Business Services Authority
- Regulatory body
- Police Force
- Local Authority

## Co-operation between health bodies and other organisations

- Regulations place 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 AO will be responsible overall for ensuring appropriate action is being taken in response to concerns that have been raised
- PCT AOs will be responsible for establishing LINs. The network will enable agencies that have cause for concern about the activities of any healthcare professional to share them as soon as possible with other local agencies who may be affected or who may have complimentary information

[See figure 2 - Functional relationships of the LIN](#)

### Good Practice



PCT AOs should regularly check the CQC list of AOs to ensure all of those operating in the area of the local LIN are included in the membership of the LIN

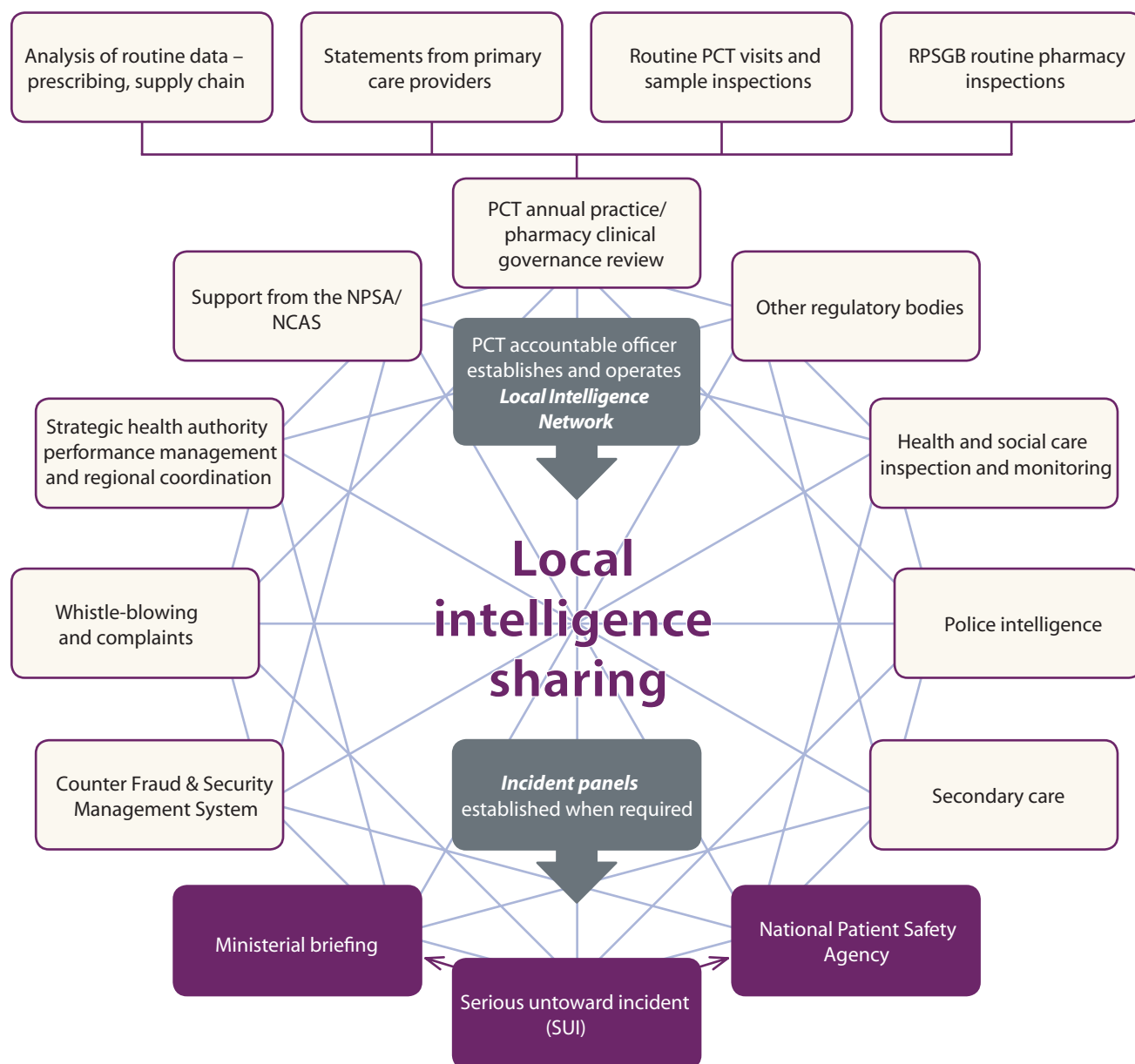
PCT AOs and the NHS Prescription Services should work collaboratively to build a communication network for the sharing of information to continually improve good practice

## Responsible bodies

Responsible bodies specified in regulation are:

- PCT
- NHS Trust
- NHS Foundation Trust
- SHA
- Independent hospital
- CQC
- NHS Business Services Authority (Counter Fraud and Security Management Service and PPD Divisions)

Figure 2: The management and functional relationships of the local intelligence network



- A Police Force
- A Local Authority
- A regulatory body (could be GMA/NMA/RPSGB etc.)

They have the following responsibilities:

- A general duty to co-operate with each other as regards relevant persons
- Duty to co-operate by disclosing information as regards relevant persons
- Have a right to request additional information be disclosed about relevant persons

### Good Practice



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

- 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 General Medical Council (GMC), which should then report the facts and its own action to the practitioner's employer or PCT. The GMC holds 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 alerted in a timely manner about lost or stolen prescriptions or prescription forms, especially FP10 (MDA) forms, which may be used to acquire CDs unlawfully. Further guidance on action to be taken in the event of prescription forms being lost or stolen can be found within NHS CFSMS Security of Prescription Form guidance document available at [www.nhs.uk/nhsbsa.nhs.uk/security](http://www.nhs.uk/nhsbsa.nhs.uk/security)

## Self-assessment and controlled drugs declaration statement

- All healthcare organisations providing clinical services and relevant social care organisations must complete a periodic declaration (at least every 2 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. **PCT AOs should send the request for a declaration to all those listed on the PCT's Performers' List**

- The declaration request and self-assessment questionnaire will be sent to organisations by the relevant agency, and may be included in other assessments or planning tools; for example the CQC's 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/en/Healthcare/Medicinespharmacyandindustry/Prescriptions/ControlledDrugs/DH\\_4131849](http://www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/Prescriptions/ControlledDrugs/DH_4131849)
- 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
- 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 standards in the prescribing, supply, administration, storage, record keeping and disposal of CDs and assure compliance with the MDA 2001 and associated Regulations, medicines legislation and any relevant professional codes of practice

## Routine monitoring and inspection arrangements

Figures 3 and 3a (overleaf) provide an overview of monitoring and inspection arrangements.

### Routine inspections

#### Legal framework

- The Health Act 2006 contains 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>

Figure 3: Routine monitoring and inspection arrangements for controlled drugs

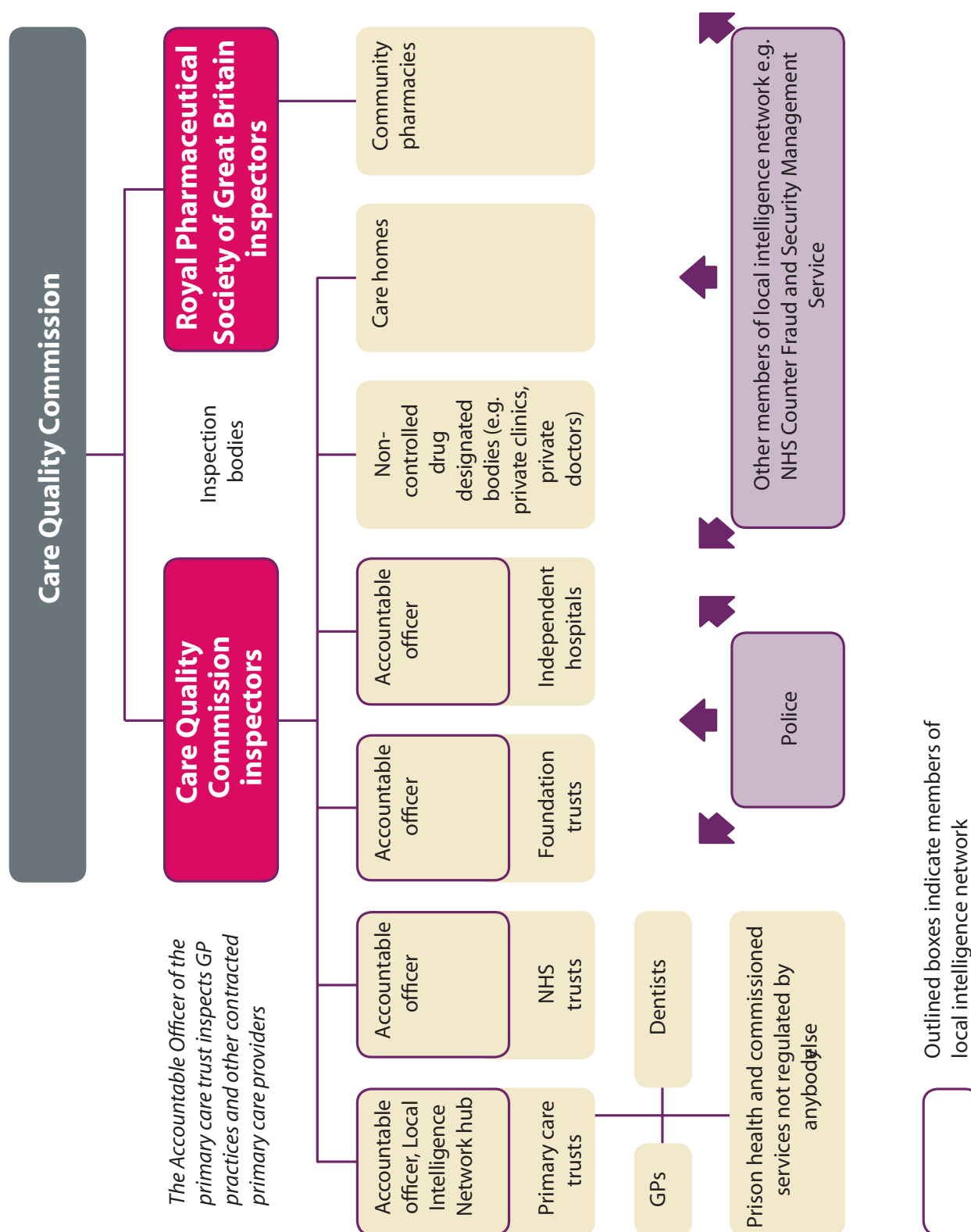


Figure 3a: Routine monitoring and inspection arrangements for controlled drugs

Body	Role
PCT	AO responsible for: <ul style="list-style-type: none"> <li>• Overseeing management of CDs</li> <li>• Leading LIN</li> <li>• Premises used in conjunction with management or use of CDs</li> </ul>
CQC	<b>NHS Trusts</b> <ul style="list-style-type: none"> <li>• CD incorporated into existing C4d medicines management standard so that compliance with the standard reflects satisfactory management of both CDs and other medicines</li> <li>• Routine and targeted inspection</li> </ul> <b>Independent healthcare</b> <ul style="list-style-type: none"> <li>• Routine and targeted inspection</li> </ul> <b>Care Homes</b> <ul style="list-style-type: none"> <li>• Routine and targeted inspection</li> </ul>
RPSGB	<ul style="list-style-type: none"> <li>• RPSGB inspect registered pharmacy premises to monitor compliance with legal requirements, professional standards and guidance, including those relating to CDs</li> </ul>
Police	<ul style="list-style-type: none"> <li>• Police available for wider support with information gathering and investigation</li> <li>• Member of LIN</li> </ul>

### 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 Controlled Drugs Registers (CDRs), except if there was evidence that an offence might have been committed.

### Standards for inspection

To ensure consistency, common guidelines for inspection visits to primary care settings have been developed [www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/Prescriptions/ControlledDrugs/DH\\_4131849](http://www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/Prescriptions/ControlledDrugs/DH_4131849)

A competency framework setting out the competencies that those involved in monitoring and inspection will need is available on the NPC website [www.npc.co.uk/prescribers/resources/cdi\\_comptetency\\_framework.pdf](http://www.npc.co.uk/prescribers/resources/cdi_comptetency_framework.pdf)

### 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.

### Investigating concerns

The AO will need to ensure that robust systems are in place to enable concerns about CDs to be raised, to log these concerns, and where appropriate to initiate investigations. The AO may request an investigation by the NHS CFSMS, solely or jointly with another responsible body. The Local Counter Fraud Specialist (LCFS) and Local Security

Management Specialist (LSMS), as the nominated advocates for the NHS CFSMS, would be responsible for conducting such an investigation on behalf of the NHS CFSMS.

### Good Practice



Useful guides to establishing appropriate reporting arrangements:

- The CQC website contains more information on raising concerns about wrongdoing in the workplace  
<http://www.cqc.org.uk/guidanceforprofessionals/socialcare/careproviders/guidance.cfm>
- The RPSGB has produced guidance for pharmacists and registered technicians on raising concerns  
[www.rpsgb.org.uk/pdfs/raisingconcernsguid.pdf](http://www.rpsgb.org.uk/pdfs/raisingconcernsguid.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/patientsafety/improvingpatientsafety/incidentdecisiontree/](http://www.npsa.nhs.uk/patientsafety/improvingpatientsafety/incidentdecisiontree/)

## Education and training

Regulations state that AOs are to ensure that relevant individuals involved in prescribing, supplying, administering or disposing of CDs receive appropriate training in relation to the management of CDs, in particular:

- 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 healthcare 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.

### Good Practice (continued)



The Government, in its response to the Fourth Report of the Shipman Inquiry, recommends that all healthcare 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'. [www.rpsgb.org.uk/pdfs/safsechandmeds.pdf](http://www.rpsgb.org.uk/pdfs/safsechandmeds.pdf) 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.

The DH has also issued useful guidance [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_079618](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079618)

Finally, consideration should be given by the appropriate national authorities to ensuring that undergraduate and pre-registration courses for healthcare 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 healthcare professionals who prescribe, dispense or administer CDs needs to cover.

## Section 4

# 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 permitted as outlined in Regulations. Unlawful possession of any CD in Schedules 2–4 (Part 1) is a criminal offence.

Persons who can legally possess CDs include the following. This list is not exhaustive, but provides an overview of who may lawfully possess CDs and in what circumstances.

- Medical practitioners (this includes doctors, dentists and veterinary surgeons)
- Pharmacists or a person lawfully conducting a retail pharmacy business
- Supplementary prescribers
- Nurse independent prescribers, but currently 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 MDRs 2001)
- Healthcare professionals supplying or administering certain categories of CDs under a PGD
- Individuals and bodies corporate, licensed by the Home Office Drug Licensing and Compliance Unit
- Persons in charge of a hospital or care home with nursing services
- 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
- Police officers 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 healthcare professionals are (only when acting in their capacities as such) authorised under the MDRs 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.

## Compounding

Pharmacists may not supply CD ingredients to patients to allow them to compound CDs themselves. Pharmacists who choose to compound a CD must ensure that they act in accordance with the Code of Ethics and Section 4 of the 'Professional Standards and Guidance for the Sale and Supply of Medicines' document [www.rpsgb.org/pdfs/coepsgssmeds.pdf](http://www.rpsgb.org/pdfs/coepsgssmeds.pdf)

They must also ensure that such activities are adequately covered by professional indemnity insurance. Guidance issued by the RPSGB is available at [www.rpsgb.org/pdfs/LEBpatlegalextempcompd.pdf](http://www.rpsgb.org/pdfs/LEBpatlegalextempcompd.pdf)



## 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 3 - Governance, inspections and monitoring (page 19).

## Standard Operating Procedures

- All healthcare providers should have SOPs for management and handling of all CDs, 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.



## Section 5

# Purchasing and supply of controlled drugs



## Overview

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 detail later (section 7).

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

## Requisitions

### Legal framework (general)

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)
- The person in charge or acting person in charge of a hospital or care home. The requisition should be signed by a doctor or a dentist who is employed or engaged in that hospital or care home
- 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)
- Authorised practitioners
- Operating Department Practitioners (ODPs)
- Schedule 2 drugs may be possessed by the person or acting person in charge of a hospital or care 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 works there.

### Good Practice



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 2 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 2 years, as cases often come to court at a much later date, by which time any evidence would have been destroyed.

## Purchasing by practitioners from wholesalers, or pharmacies with premises registered with the RPSGB, for practice use or stock purposes

### Legal framework

#### Schedule 2 and 3 controlled drugs

Practitioners (doctors and dentists) may obtain CDs from pharmacies with premises registered with the RPSGB, or wholesalers, for practice use or stock upon the production of a written requisition. Prescribers who wish to requisition a controlled drug must have a unique prescriber ID. Any prescriber without a unique prescriber ID should apply to their PCT.

#### Schedule 4 and 5 controlled drugs

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

### Requisition requirements

A further change was made to the MDRs 2001 in January 2008. A dedicated requisition form is now available (FP10CDF) which it is good practice to use. These forms are available from the PCT or the agency which supplies prescription forms on behalf of the PCT. However, there is no legal requirement to use this form.

## Completing a controlled drug requisition form (Customer)

The regulations permit requisitions for CDs to be computer generated or hand written. The person raising the requisition (customer) should complete Parts B, C and D of the requisition form.

### Part B

The customer should complete the name of the CD to be requisitioned including the form, strength and quantity. The signature should be hand-written in ink.

### Part C

The organisation code can be either the individual's NHS or private prescription code for the prescriber or the account code of the pharmacy raising the requisition. Non-medical prescribers (e.g. nurse and pharmacist prescribers) must also include the relevant practice code (which will be on their normal prescriptions) and the PCT code. The person raising the requisition should also complete the form with their name, occupation/professional qualification (e.g. GP, pharmacist) and the address of the premises that they are working out of.

### Part D

In order to satisfy the legal requirements, the customer should indicate in Part D the purpose for which the drugs are required by ticking the relevant box and, if applicable, providing further details.

## Completing the requisition form (Supplier)

### Part A

The name and address of the supplier must be recorded indelibly. The use of a pharmacy stamp which includes the full address of the pharmacy from where the supply is made is acceptable so long as the information is clear and legible. This information must be added by the supplier of the CD at the time the supply is made.

The account number should be the private CD submission F code of the pharmacy supplying the CDs. The supplier should ensure that the customer has completed their relevant sections with the correct data.

In exceptional circumstances where, for example, an individual may have difficulty in obtaining the standard form, a CD can be supplied in response to an order written on a non-standard form, provided all the legal requirements are met.

The requisition must contain the following information:

- The name, address and profession/occupation of the recipient
- The purpose for which the drug is required
- The total quantity to be supplied
- The signature of the recipient

The regulations allow requisitions for Schedule 2 and 3 CDs to be handwritten or 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 (the person ordering the CDs) must sign the requisition. Where appropriate it will include the practitioner's prescriber or dispenser identifier code or the unique prescriber identification number for private prescribers.

The name and address of the supplier must be recorded indelibly. Pharmacists are required to submit the original requisitions (not a copy) to the NHSBSA Prescription Services using their private submission F code. AOs are able to access the new reporting system available through the NHSBSA Prescription Services website to allow them to monitor CDs supplied via this route.

Although not a legal requirement, it is good practice, where one pharmacy orders a CD from another pharmacy, for written requisitions to be used. The pharmacy supplying the CD and submitting the requisition to the NHSBSA Prescription Services (and its equivalent), will use their submission code. This will be their private submission F code (Organisation Data Service [ODS] code).

Dispensing doctors should not supply CDs against requisition as they are not permitted to carry out a wholesale function unless they have a wholesaler's licence.

If a messenger is sent to collect the CD, Reg 14(1) requires a person collecting on behalf of the recipient to produce to the supplier a statement in writing signed by the recipient to the effect that he is empowered by the recipient to receive the drug on their behalf. The supplier needs to be reasonably satisfied that the document is genuine. Further guidance is available at:

[www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_079571](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079571)

[www.nhsbsa.nhs.uk/PrescriptionServices/Documents/PrescriptionServices/Safer\\_Management\\_of\\_Controlled\\_Drugs\\_requisitions.doc](http://www.nhsbsa.nhs.uk/PrescriptionServices/Documents/PrescriptionServices/Safer_Management_of_Controlled_Drugs_requisitions.doc)

### Retention of requisitions

Suppliers must keep copies of all requisitions for Schedule 2 and 3 CDs for a minimum of 2 years. The MDRs 2001 have been amended to allow the information contained in orders, requisitions and private prescriptions to be preserved as a copy on computer. The original requisition must be sent to the NHSBSA Prescription Services.

Safeguards must be in place in any computer system 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
- That systems are in place to minimise the risk of unauthorised access to the data

### Urgent supplies to practitioners

A practitioner who requires a Schedule 2 or 3 CD urgently and who is unable to supply a signed requisition 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



- 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 2 years

(For emergency supply of Schedule 2 and 3 CDs to patients, see page 53).

## 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.

To ensure good clinical governance a prescriber should not both purchase and prescribe a Controlled Drug, wherever possible.

### Legal framework

Pharmacists or doctors, who are 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 36, 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 CDR on the day of supply, or the day following the day of supply. The task of completing the CDR 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 healthcare 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 CDR 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 as described above (FP10CDF) and the supplier should submit the original to the PPD. Both pharmacists must ensure that the correct entries are made in their respective CDRs within 24 hours.

### Acquisition of controlled drugs by other healthcare professionals

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

## Midwives

### Legal framework

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 (LSA) is authorised to possess and administer specified CDs as far as is necessary for his/her professional practice.

The MDRs 2001 covers the possession and administration of specified 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

LSAs 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 LSA.

The Midwives Supply Order must state the following:

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

### 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 CDR. If the CD is not subsequently used for that patient, it can be returned into stock and entered as such, back into the CDR. This practice should be defined by a local SOP.

Midwives must also make all relevant entries in their own CDRs.

### Individual patient prescription

Alternatively, a prescription can be written by a prescriber. The patient obtains the prescribed CD from a pharmacy and keeps it in their home until it is required for administration by the midwife.



## 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. However, this practice is not recommended by the Royal College of Nursing.

### 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. See also Safer Management of Controlled Drugs - A guide to good practice in secondary care [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_079618](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079618)

### Paramedics

Ambulance paramedics serving at any approved ambulance station are able to administer diazepam and/or morphine sulphate injection (to a maximum of 20 mg) or morphine sulphate oral for immediate necessary treatment of sick or injured persons. NHS Ambulance Trusts and their paramedics have, since 8 July 2008, been covered by a Group Authority and do not need to apply individually to the Home Office for a licence to possess and supply CDs (see section 16) [www.drugs.homeoffice.gov.uk/publication-search/drug-licences/NHS-AMBULANCE-PARAMED-GRP-AUTH?view=Binary](http://www.drugs.homeoffice.gov.uk/publication-search/drug-licences/NHS-AMBULANCE-PARAMED-GRP-AUTH?view=Binary)

### 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, or pharmacy with their premises registered with the RPSGB. Establishments with

employed pharmacists can obtain CD stocks via a requisition, which complies with the Regulations described on page 36 (see also Safer Management of Controlled Drugs - A guide to good practice in secondary care).

### Out-of-hours premises

Guidance from the Home Office indicates that where practitioners are involved in management and/or handling of CDs for OOH/bodies corporate, the ability of the practitioner to operate will not require licensing when:

- they provide a public/voluntary/charity funded service to the general public
- their non-clinicians have no involvement in CD ordering, receipt or supply of CDs
- they are regulated by the AO in the PCT in which they operate

## Good Practice



### 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](http://www.out-of-hours.info/downloads/short_medicines_guidance.pdf) and the accompanying practical guide [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4134235](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4134235)



## Section 6

# Administration of controlled drugs



## Legal framework

- Any person may administer to another any drug specified in Schedule 5
- When administration of a Schedule 5 CD is defined in a PGD only those healthcare professionals specified in the PGD can supply/administer in this circumstance as they cannot delegate this function
- Some professional groups, but not all, are permitted to supply or administer CDs in accordance with a PGD
- For more information about administration of CDs under PGDs see page 46
- A doctor or dentist may administer to a patient any drug specified in Schedule 2, 3 or 4
- Any person other than a doctor or dentist may administer to a patient, in accordance with the directions of a doctor or dentist, any drug specified in Schedule 2, 3 or 4
- Nurse independent prescribers or any person acting in accordance with their directions can administer a limited range of CDs (see page 46)
- 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 administer those CDs, which they may lawfully possess under the Medicines Act (i.e. diamorphine, morphine, pethidine and pentazocine)
- NHS employed ambulance paramedics serving at any approved ambulance station are able to administer diazepam 5 mg/mL injection and/or morphine sulphate injection (to a maximum of 20 mg) and morphine sulphate oral 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 separation of tasks is not possible. Where this is the case, it is essential 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 and the diversion of CDs. This should normally include a witness to the administration of CDs.

Refer to 'CSCI - Safe management of CDs in care homes'. For further guidance see [www.cqc.org.uk](http://www.cqc.org.uk)

CDs given by domiciliary care workers in a person's own home should be treated in the same way as for all other prescribed medicines.

## Good Practice



### Preparation and administration of injections

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

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

See also:

'Good practice statement for the preparation of injections in near-patient areas, including clinical and home environments', published by the Scottish Executive [www.scotland.gov.uk/Publications/2002/12/16049/15913](http://www.scotland.gov.uk/Publications/2002/12/16049/15913)

'Building a safer NHS for patients', published by the DH, January 2004 [www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4071443](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4071443)

Patient Safety First  
[www.patientsafetyfirst.nhs.uk/](http://www.patientsafetyfirst.nhs.uk/)

## Good Practice



### Extemporaneous preparation of methadone

The RPSGB issued guidance on the extemporaneous preparation of methadone oral solution 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/coun0512-C-69.pdf](http://www.rpsgb.org/pdfs/coun0512-C-69.pdf)

#### Supervised consumption

The pharmacist should separate the dispensing process from the supervised consumption process. Patients should be invited to check the label, but the pharmacist should retain the bottle and destroy the label.

Pharmacists should ensure the patient can measure the dose, if more than one day's supply is dispensed at once. A prescriber can add the words 'Dispense daily doses in separate containers and in advance' to ensure the pharmacist will do this. (Without this wording the pharmacist will not be reimbursed for dispensing in individual containers and so it may result in the patient getting several days' dosage in one container and no means of measuring the dose accurately and safely).

## NPSA Guidance

Guidance to protect patients from harm in respect of prescribing, dispensing and administering opioid and opiate (hereafter opioid) medicines has been issued by the National Patient Safety Agency (NPSA). These specify actions that are designed to reduce human-factor error.

In England organisations are required to notify the implementation status of NPSA guidance to the Department of Health Central Alerting System (CAS) by a specified date.

See Appendix 6 (page 107) for further details

# Section 7

## Prescribing



## Legal framework

### Medical practitioners

#### **Doctors and dentists may prescribe all CDs in Schedules 2–5 for organic disease.**

Doctors no longer need individual Home Office licences to prescribe diamorphine, cocaine, dipipanone for substance misusers. A general licence has been issued to cover those doctors who have been approved by the DH

[www.drugs.homeoffice.gov.uk/drugs-laws/licensing/domestic-licences/doctors](http://www.drugs.homeoffice.gov.uk/drugs-laws/licensing/domestic-licences/doctors)

**Note:** Supplementary prescribers working within agreed patient specific clinical management plans who prescribe for substance misusers for the treatment of addiction are not able to apply for a licence from the Home Office; licences are restricted to doctors. Supplementary prescribers are able to prescribe for substance misuse, with the exception of dipipanone, diamorphine and cocaine for addicts. Supplementary prescribers are able to prescribe any CD for organic disease.

## 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 and pharmacist independent prescribers

Currently, nurse independent prescribers can prescribe from the CDs listed in the table in Appendix 7, for the medical conditions specified.

The Misuse of Drugs Regulations 2001 will be amended to come into force soon to allow nurse and pharmacist independent prescribers to prescribe, possess, supply, offer to supply, administer and give directions for the administration of any controlled drug specified in Schedules 2 to 5 of the 2001 Regulations. However, they will not be authorised to prescribe, possess, supply, offer to supply, administer or give directions for the administration of cocaine, diamorphine or dipipanone to addicts, save for the purpose of treating organic disease or injury.

## Supplementary prescribers

The MDRs 2001 were amended in 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 2005,

amendments to the General Medical Service/ Personal Medical Service Regulations enabled the prescribing of CDs by supplementary prescribers.

Registered nurses, pharmacists, 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 specified CDs under Exemption Orders of the 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:
  - 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
- Midazolam. The legal classification of midazolam changed in January 2008 from a Schedule 4 Part I CD to a Schedule 3 CD. Midazolam is the only Schedule 3 CD that, in certain circumstances, can be included in a PGD. Under no circumstances can any other Schedule 3 CD be legally included in a PGD

It is important to note that most, but not all, registered healthcare 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 MDRs 2001.

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.

The MDRs 2001 will be amended to come into force soon to allow nurses and pharmacists to possess, supply and

offer to supply morphine and diamorphine in accordance with a PGD where it is necessary to administer such drugs as a matter of urgency. The Regulations will also be amended to ensure that those acting in accordance with patient group directions have authority to possess certain controlled drugs for those purposes, and that people possessing controlled drugs, having failed to disclose a previous supply of such drugs under a patient group direction, will be committing an offence.

## Prescription requirements Legal framework

### Details and handwriting

Amendments to the MDRs 2001, which came into force in 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.

Alterations are best avoided but if any are made, they should be clear and unambiguous. The NHS Security Management Service recommends that if an error is made, best practice is for the prescriber to cross out the error, initial and date the error then write the correct information. Please see the Security of Prescription Form guidance for reference at [www.nhsbsa.nhs.uk/security](http://www.nhsbsa.nhs.uk/security)

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).

## Potential change in legislation

The use of pre-printed adhesive 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 adhesive 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 an adhesive label is used, prescribers should also sign the sticky label or at least start their signature on the sticky label. This is a further safeguard to ensure sticky labels are not tampered with or that another adhesive label is not placed on top of the one 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 handwritten by the prescriber but if not, only by an appropriate healthcare professional.

Refer to NPSA guidance at [www.npsa.nhs.uk/](http://www.npsa.nhs.uk/)

### 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. handwritten in ink, typed or computer-generated).

- The patient's full name, address and, where appropriate, age. An email address or PO Box is not acceptable. 'No fixed abode' is acceptable as an address for homeless people
- The name and form of the drug, even if only one form exists
- The strength of the preparation, where appropriate (if more than one strength exists)
- The dose to be taken
- The total quantity of the preparation, or the number of dose units to be supplied, in both words and figures
- Signed by the prescriber with their usual signature (this must be handwritten) and dated by them (the date does not have to be handwritten).



### Note:

The date can be either the date of signing OR the date the prescriber wishes the prescription to start. The address of the prescriber must be stated on the prescription and must be within the UK. The UK does NOT include the Channel Islands or the Isle of Man.

Prescriptions issued by a dentist must contain the words 'for dental treatment only'.

See sections on private prescribing (page 54) and instalment prescribing (page 49) for additional requirements.

### 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 MDRs 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'. However, if the prescription specifies a start date, the prescription can only be dispensed in accordance with the prescriber's directions. See the following website for further details [www.opsi.gov.uk/si/si2006/20061450.htm](http://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 prescriber's intention is clear. The only errors that pharmacists may amend are listed below.

- 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.

- S/He must be satisfied beyond reasonable doubt, having exercised due diligence, that the prescription is genuine and that s/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](http://www.rpsgb.org)

### Good Practice (general)



- All prescriptions for Schedule 2 and 3 CDs should include the patient's NHS number where possible
- 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 (this is the address and telephone number where the prescriber can usually be contacted - it is not necessary to have the address of the premises where the prescription was written), and the PCT in which they are working should also be included on the prescription. This information is generally pre-printed on the prescription pad
- 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 must also record the administration of a CD to a patient in his or her own CDR for that bag



## Good Practice (continued)



- 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 2–3 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
- Separate guidance is available relating to substance misuse. When patients present more than 3 days after either the date the prescription was written or the start date on the prescription, the pharmacist should check with the prescriber before dispensing. This is because the patient's tolerance to the opioid may have reduced and the same dose taken after 3 days break in treatment could result in the patient overdosing. Pharmacists are advised to inform the prescriber or key worker and agree the most appropriate course of treatment for the patient (e.g. the patient may have to return to the prescriber for reassessment and retitration of their dose)
- Prescribers should ensure that pharmacists are part of any local scheme with protocols that include the scenario of delayed pick up by more than 3 days.

Drug misuse and dependence - UK guidelines on clinical management [www.nta.nhs.uk/publications/documents/clinical\\_guidelines\\_2007.pdf](http://www.nta.nhs.uk/publications/documents/clinical_guidelines_2007.pdf)

For private prescribing see page 54.

## 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 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 person for whom the medicine has been prescribed as well as the specific situation to check the suitability for the patient
- Where there is concern that the length of the prescription is not appropriate the prescriber should be contacted
- The AO monitoring checks are likely to pick up large prescribing amounts

## Prescribing in instalments

Some CDs can be dispensed to substance misusers in instalments provided 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) or FP10MDA-SS to prescribe in instalments for Schedule 2 CDs, buprenorphine (Schedule 3), buprenorphine with naloxone (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.

FP10MDA instalment prescriptions are intended for no more than 14 days supply. Prescribers requesting more than 14 days on one instalment prescription may have the prescription refused by the dispensing pharmacist or, if

dispensed, the Prescription Pricing Division may refuse to reimburse the pharmacist for more than 14 days.

- FP10(MDA) is a glued pad of pre-printed forms for GPs, hospitals and supplementary prescribers
- FP10(MDA) - SS are single sheet blank forms that are printed with prescriber details by the prescriber's own computer system

Hospital prescribers also use an FP10(MDA) form which will be overprinted with the words 'Hospital Prescriber' and 'AD'. These forms can either be provided from the prescription supplier as a personalised pad with unit details (product order code FP10 HMDA-S) or as forms to be overprinted by the hospital prescribing system (product order code FP10 MDA-SS). If prescribing costs are to be attributed to primary care, cost centres can be set up by NHS Prescription Services and these FP10(MDA) forms would not have 'Hospital Prescriber' nor 'AD' printed on them.

If any prescription forms are lost or cannot be accounted for, the matter should be reported to the designated person with overall responsibility for prescription forms in the health body, the Accountable Officer and police as necessary. The health body's Local Security Management Specialist should also be notified.

See table 2 for the various types of FP10(MDA) forms.

### Details to be specified - legal requirements

To be legally valid, an instalment prescription for a Schedule 2 or 3 CD (except temazepam) must include the following:

- The signature of the appropriate practitioner issuing the prescription
- The date
- The address of the appropriate practitioner issuing the prescription
- The dose to be taken ('as directed' is not acceptable, but 'one as directed' is acceptable)
- The form of the preparation (e.g. mixture/tablets/capsules/ampoules)
- The strength of the preparation (if more than one different strength is available). In the case of methadone, there is more than one strength available, therefore this must be specified on the prescription
- The total quantity of the preparation in words and figures. This must be in dosage units (that is ml for a liquid, or number of tablets, capsules, ampoules and not the total mg of the drug)
- The name and address of the patient

- The instalment amount and the intervals to be observed:

- 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 MDRs 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.

More than one day's supply can be prescribed to be collected e.g. twice a week or three times a week. Good practice recommends that no more than one week's supply is prescribed in a single instalment when prescribing substitute opiate treatment.

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/she loses the complete instalment; he/she 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 overleaf can be used by those prescribing CDs by instalment in accordance with the MDRs 2001 (see table 1). If a prescription does not contain such wording the Regulations only permit the supply to be made in accordance with the prescriber's instalment direction. Further guidance can be found at [www.pharmj.com/Editorial/20050430/society/ethics.html](http://www.pharmj.com/Editorial/20050430/society/ethics.html) and [www.nta.nhs.uk/areas/Clinical\\_guidance/clinical\\_guidelines/docs/clinical\\_guidelines\\_2007.pdf](http://www.nta.nhs.uk/areas/Clinical_guidance/clinical_guidelines/docs/clinical_guidelines_2007.pdf)

Table 1: Summary of approved wording (From drug misuse and dependence - UK guidelines on clinical management)  
[www.nta.nhs.uk/publications/documents/clinical\\_guidelines\\_2007.pdf](http://www.nta.nhs.uk/publications/documents/clinical_guidelines_2007.pdf)

What prescriber intends	Wording required on prescription
If you want methadone to be measured in individual bottles for the patient (otherwise patient will be supplied with multiple take home doses in a single container).	Dispense daily doses in separate containers and in advance. <i>A rubber stamp may be used for this.</i>
If you want patients who pick up their medicine less frequently than daily to be able to collect a part instalment as soon as possible after they miss a dose.	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 missed may be supplied. <b>Or alternative wording permitted:</b> 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.
If you want the patient to be supervised consuming their dose on the days that they collect from the pharmacy but still want them to be able to obtain a part instalment of their medicine if they miss their prescribed collection day.	Supervised consumption of daily dose on specified days; the remainder of the supply to take home. If an instalment prescription covers more than 1 day and is not collected on the specified day, the total amount prescribed less the amount prescribed for the days missed may be supplied.
For unsupervised consumption, if you want to ensure that the patient is not supplied with their dose if they have missed collecting for 3 days.	Instalment prescriptions covering more than 1 day should be collected on the specified day. If this collection is missed, the remainder of the instalment (i.e. the total amount less the instalments for the days missed) may continue to be supplied in the specified instalments at the stated intervals, provided no more than 3 days are missed.
For bank holidays when unsure which days the pharmacy is closed.	Instalments due on days when the pharmacy is closed should be dispensed on the day immediately prior to closure.

Table 2: Various types of FP10(MDA) form

Issued by/in	Type of form	Region	What is allowed
<b>GPs</b>	FP10(MDA) or FP10(MDA)-SS	England	Schedule 2 CDs, buprenorphine diazepam, plus single supplies of water for injection as necessary
<b>Hospital or clinic based prescribers</b>	FP10(MDA)-SS	England	Schedule 2 CDs, buprenorphine, diazepam, plus single supplies of any other medication allowed on FP10
<b>Nurse and pharmacist independent prescribers</b>	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
<b>Supplementary prescribers</b>	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 5 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 pharmacist should be convinced beyond reasonable doubt that the note is valid.

The requirement to see identification on collection only applies to the first dispensing of an instalment prescription.

## Repeat prescribing

It is clear under the current legislation that repeat prescribing of CDs in Schedule 2 and 3 is not permitted. However, management systems which allow the patient to receive a prescription (hand signed by a practitioner) without a consultation is not subject to legislation, but is a clinical decision made on a case by case basis. It is good practice that patients should be reviewed before prescribing Schedule 2 and 3 CDs.

## 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 and the frequency of instalments the pharmacist can dispense before going back to the GP for a review. Repeatable prescriptions can be written for up to 1 year. 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 developments

The Government will be considering 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.

In National Emergency Situations special legislation may be introduced. Special legislation in the event of a pandemic will allow emergency supply of controlled drugs in specific circumstances.

GPs are remunerated through the basic practice allowance to purchase drugs necessary for immediate treatment, however, where a Schedule 2 CD injection has been personally administered the GP may claim payment by submitting an FP10 to NHS Prescription Services.

## Prescribing to self and family

### Good Practice



Other than in emergencies, no prescriber should prescribe a 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 in order to:

- save life
- avoid significant deterioration in the patients health
- alleviate uncontrollable pain.

where no other person with the legal right to prescribe is available to assess the patient's clinical condition and take the appropriate action.

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](http://www.nmc-uk.org) and RPSGB 'Code of Ethics' [www.rpsgb.org.uk](http://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, it 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 relevant 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 CQC (formerly the Healthcare Commission). There is a need to demonstrate safe systems of managing and prescribing CDs in meeting the national minimum standards for independent healthcare [www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4085259](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4085259)

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 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, or agency acting on behalf of the 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 private prescriptions

The original prescription (not a copy) for a Schedule 2 or 3 CD should be submitted after dispensing (by 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). All prescriptions dispensed in England should be submitted to NHS Prescription Services; all prescriptions dispensed in Wales to Health Solutions Wales and in Scotland to NHS National Services Scotland.

## 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 now 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 procedures for use in their services with respect to the following.

- Treatment, prescribing and review policies
- Clinical governance systems
- Training and continuing professional development (CPD)
- These 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 healthcare 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.





## Section 8

# Dispensing of controlled drugs



## Overview

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 CDR as soon as possible and at the latest the next day following the day of supply. The date entered in the CDR 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 when medicines are dispensed.

### Good Practice



#### Signing the back of the CD form

From 7 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 CDR 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 Fourth Report of the Shipman Inquiry recommended the introduction of a patient drug record card (now known as a Controlled Drug Record Card [CDRC]) to complete the audit trail for Schedule 2 injectible controlled drugs. The DH, following a number of pilots, are considering the feasibility of implementation.

## 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 CDR. 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 unless specific wording is included 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. When a start date is included, the pharmacist must follow the directions of the prescriber as to the specific days that the medicine should be dispensed.

## 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 72), 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 instalment prescribing and pharmacy closures can be found at [www.rpsgb.org.uk/pdfs/LEBapprovwor dinginstalprescs.pdf](http://www.rpsgb.org.uk/pdfs/LEBapprovwor dinginstalprescs.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, or a member of staff who has undergone appropriate PCT approved training. 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
- The requirement for signing the prescription and identification on collection does not apply to instalment prescriptions, except the first time the patient presents. It is at the discretion of the pharmacist who, in special circumstances, may dispense without these requirements.

## Good Practice (continued)



- Patients should collect the CD in person. If they are unable to collect prescriptions in person, they may arrange for a representative to collect it. In such circumstances, pharmacists will require a letter on each occasion from patients, stating that a named person is authorised to collect the medicine on their behalf. The pharmacist will keep the letter
- Such authorisation is also recommended, for example when a patient is in custody, to authorise a named police officer to collect an instalment from the pharmacy. Authorisation letters are necessary to allow people to carry CDs, since they are not the person for whom it was intended – otherwise they are in unlawful possession. It may also prevent misunderstandings or deceit. The person collecting may then be asked to sign in a record book. It is at the pharmacist's discretion whether to supply to another person, if for any reason the pharmacist is concerned the request is not genuine
- 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
- Pharmacists should ensure the patient can measure their daily dose accurately and safely when more than one day's supply is prescribed to be dispensed. Prescribers should add the words 'Dispense daily doses in separate containers and in advance' to ensure the pharmacist will dispense in separate bottles

## ‘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 CDR 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 had 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. However accountability remains with the dispensing doctor.

### Good Practice



The 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’, states 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/](http://www.dispensingdoctor.org/)

See also NPSA guidance [www.npsa.nhs.uk/](http://www.npsa.nhs.uk/)

## Section 9

# Recording of controlled drugs



## Overview

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

## Legal framework

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

All healthcare professionals who hold personal CD stock must keep their own CDR, and they are personally responsible for keeping this accurate and up-to-date. If a GP does not carry CDs in his bag, but occasionally takes stock from the surgery to a patient's home, the GP should transfer the stock from the surgery's CDR into his own register whilst he is carrying the CD in his bag. If the CD is not used the stock should be re-entered into the main surgery register and out of his own register.

The Government has carried out a review of the CDR to allow for a revised format. This also brings together all the changes to the CDR, including the additional columns required to record information concerning the person collecting a Schedule 2 CD.

These changes were introduced on 1 February 2008 and the fixed format of the CDR was removed from legislation. It is no longer a legal requirement to maintain a CDR as described in Schedule 6 of the MDRs. Instead of the previously prescribed format, the Regulations now require that certain headings must appear in the CDR and certain fields of information must be completed.

In the CDR, (or separate part of the register used for each class of drug), a separate page must be used for each strength and form of that drug. Entries made in respect of drugs obtained and drugs supplied may be made on the same page or on separate pages in the register. In support of these changes in Regulations, DH published guidance "Safer Management of Controlled Drugs: Changes to Record Keeping Requirements" which confirms that when CDs are obtained the following information must be recorded in the CDR:

- Date supply obtained
- Name and address from whom obtained (e.g. wholesaler, pharmacy)
- Quantity obtained

When CDs are supplied to patients (in response to prescriptions) or to practitioners (in response to requisitions), the following information must be recorded in the CDR:

- Date supplied
- Name and address of person or firm supplied
- Detail of authority to possess – prescriber or licence holder's details
- Quantity and form in which supplied
- The person collecting Schedule 2 CD (patient/patient's representative/healthcare professional) and, if healthcare professional, name and address. Plus:
  - Was proof of identity requested of patient/patient's representative? (Yes/No)
  - Was proof of identity of person collecting provided? (Yes/No)

These particulars are the minimum fields of information that must be recorded in the CDR. The regulations do not prevent additional related information being recorded that will help guarantee the integrity and accuracy of the audit trail. The following may (not must) be recorded:

- Running balances
- Prescriber identification number and/or the professional registration number of the prescriber (where known) and also the name and professional registration number of the healthcare professional supplying the CD

The following rules apply to the CDR. It must:

- Be kept at the premises to which it relates and be available for inspection at any time. A separate CDR must be kept for each set of premises (for example, not just the main surgery)
- Be kept for a minimum of 2 years after the date of the last entry, once completed
- Not be used for any other purpose

### Electronic controlled drugs registers

As an alternative to a bound book, an electronic CDR may be used. The regulations require that entries made in computerised CDs must be attributable and capable of being audited. Electronic CDRs must be capable of printing or displaying the name, form and strength of the drug in such a way that the details appear at the top of each display or printout to comply with the new requirements.

We strongly recommend that the electronic CDRs also comply with best practice highlighted in the current edition of the RPSGB Medicines, Ethics and Practice (MEP) guide.

Full details of the requirements for computerised CDRs are set out in SR005/2864, available from the following weblink [www.opsi.gov.uk/si/si2005/20052864.htm](http://www.opsi.gov.uk/si/si2005/20052864.htm)

### Good Practice



If the CDR 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

## Dealing with discrepancies in the controlled drugs register

SOPs should clearly define the action to be taken if a discrepancy arises in relation to CD balances. Once resolved, a note should be made in the CDR 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. The AO should be informed of any concerns in relation to the management and use of CDs.

### Good Practice



The aim of maintaining running balances in CDRs is to ensure irregularities are identified as quickly as possible.

#### Maintaining a running balance of stock

Pharmacists and other healthcare professionals who supply CDs should maintain a running balance of stock in their CDRs as a matter of good practice.

The running balance of drugs 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](http://www.rpsgb.org.uk/pdfs/cdrunningbalanceguid.pdf) This guidance also covers dealing with 'overage' in liquid preparations.

Accountability for maintaining the running balance of CD stock and dealing with any discrepancies lies with the healthcare 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 CDR 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 CDR, where the format of the register allows this.

It is good practice for a healthcare 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 the following:

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



## Good Practice (continued)



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 relevant professional bodies.

## Preservation of records

Registers, requisitions and orders for CDs must be preserved for a minimum of 2 years. The MDR 2001 has been amended to allow the information contained in these records to be preserved in the original paper form, or in computerised form.

## Standard operating procedures

The regulations require AOs to ensure that his or her organisation (or a body or person acting on behalf of, or providing services under contract with, his or her organisation) has adequate and up-to-date SOPs in relation to the use of CDs, including record keeping requirements. The DH has produced guidance to support this requirement [www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_064824](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_064824)

## 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 healthcare professional acting in his/her 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
- May refuse to supply the drug if he/she is not satisfied as to the identity of that person

The requirements for signing the prescription and identification on collection do not apply to instalment prescriptions, except the first time the patient presents.

It is at the discretion of the pharmacist who, in special circumstances, may dispense without these requirements

Patients should collect the CD in person. If they are unable to collect prescriptions in person, they may arrange for a representative to collect it. In such circumstances, pharmacists will require a letter on each occasion from patients, stating that a named person is authorised to collect the medicine on their behalf. The pharmacist will keep the letter.

Such authorisation is also recommended, for example, when a patient is in custody, to authorise a named police officer to collect an instalment from the pharmacy. Authorisation letters are necessary to allow people to carry CDs, since they are not the person for whom it was intended - otherwise they are in unlawful possession. It may also prevent misunderstandings or deceit. The person collecting may then be asked to sign in a record book. It is at the pharmacist's discretion whether to supply to another person, if for any reason the pharmacist is concerned the request is not genuine.

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 patient is being treated, or the prescriber.



## Healthcare professional

Where the person collecting the prescription is a healthcare professional, acting in their 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

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 1 February 2008, it is a requirement to record the following information in the CDR for Schedule 2 CDs supplied on prescription:

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

## Delivery schemes

RPSGB Factsheet 1 [www.rpsgb.org/pdfs/factsheet1.pdf](http://www.rpsgb.org/pdfs/factsheet1.pdf) provides guidance on documentation appropriate where the person collecting the medicine is a delivery driver. It is recommended that, as with any other delivery scheme, a robust audit trail should be in place, so that when the driver hands over the medicine to the patient/patient's representative or carer, this is documented. Wherever possible a signature should be obtained indicating safe delivery of medicines.

## 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 RPSGB website [www.rpsgb.org.uk/pdfs/cdmanagechguid.pdf](http://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 healthcare professionals should be their professional registration number.

## 'Doctor's bag'

Where a practitioner carries a bag containing CDs for home visits, etc., a separate CDR must 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 the bag from practice stock should be witnessed by another member of the practice staff, as should the appropriate entries into the practice's CDR.

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 patient's 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 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 the separate book set aside for this purpose (see section on 'patient- returned' CDs, page 69).

## 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 CDR.

## Potential Change

The Government is proposing to amend the MDRs 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 controlled drug record card (CDRC) has been evaluated. At this point, further consultation will take place.

## Section 10

# Destruction of controlled drugs



## Legal framework

### Controlled drugs held in stock

The term 'stock' refers to CDs that have not been issued/dispensed to a patient. The possession, storage and destruction of CD stocks are governed by the MDA 1971 and MDRs 2001 as amended. Those healthcare professionals and service providers required by law to maintain a CDR 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 destruction must be recorded. 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

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

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

- Chief Dental Officer of the Department of Health or a Senior Dental Officer to whom authority has been delegated
- Supervisors of Midwives appointed by the Local Supervising Authority
- Senior officers in an NHS Trust who report directly to the Trust Chief Executive and who have responsibility for health and safety, security or risk management matters in the Trust
- Chief Executives of NHS Trusts
- A Primary Care Trust Chief Pharmacist or Pharmaceutical/Prescribing Adviser who reports directly to the Chief Executive or to a Director of the Primary Care Trust
- A Registered Medical Practitioner who has been appointed to the Primary Care Trust Professional Executive Committee or equivalent
- The Primary Care Trust Board Executive member

with responsibility for Clinical Governance or Risk Management

- Medical Director of a Primary Care Trust

The Home Secretary also authorises:

- Inspectors of the Royal Pharmaceutical Society of Great Britain
- Compliance Officers of the Drug Licensing and Compliance Unit of the Home Office
- Police Constables
- Holders of specific roles within the independent healthcare sector, for example, registered managers of independent hospitals

In addition, from September 2006, those authorised include any person who is directly accountable to a director of an NHS Primary Care Trust, NHS Trust or NHS Foundation Trust in England. This also includes Strategic Health Authority pharmacy leads, Medical Directors and clinical governance leads. However, these individuals must be independent of the routine supply and administration of controlled drugs.

From 16 August 2007, an amendment to the Misuse of Drugs Regulations 2001 gave Accountable Officers the power to authorise people to witness destruction. This authorisation is in addition to the existing authorisations listed above. The Regulations prevent Accountable Officers from undertaking the role of witnessing themselves.

Any person nominated to witness destruction should have appropriate training, governance arrangements, be subject to a professional code of ethics and/or have been subject to Criminal Records Bureau (CRB) checks.

Practitioners who are actively involved in the day-to-day management of CDs or, for example, anyone directly involved with GP practices (e.g. practice pharmacists who have access to CDs in GP practices) or an individual who is authorised to supply CDs from the GP practice (e.g. clinical governance lead working in their own GP practice) should not be asked to witness the destruction of CDs in that GP practice.

### Sufficient witnesses

AOs 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.

Any person authorised to witness destruction by an AO 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

CDs must be rendered irretrievable prior to onward safe disposal. The RPSGB issues guidance on the methods of destruction/denaturing that meet the requirements of the MDRs 2001 and the health and safety needs of people undertaking the role. This can be accessed from the RPSGB website [www.rpsgb.org/pdfs/cdsafedestructionguid.pdf](http://www.rpsgb.org/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 and the Hazardous Waste Regulations 2005. 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](http://www.environment-agency.gov.uk)

### Good Practice



#### Storage of expired controlled drugs

When Schedule 2 CDs, plus temazepam, flunitrazepam, buprenorphine and diethylpropion, pass their expiry date, they must 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 CDR on destruction, it is good practice for the authorised person to state their authority, e.g. PCT medical director, RPSGB inspector.

## 'Patient-returned' controlled drugs

### 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 healthcare professional) and to make a record of the destruction in a separate book set aside for this purpose. It is good practice to record the date of receipt of patient-returned CDs and the date they are destroyed. 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 Licensing 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 Licensing 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 classified as industrial waste).

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](http://www.rpsgb.org.uk/pdfs/cdsafedestructionguid.pdf)

The EA has 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, that this would be seen as low risk activity and would not normally be regulated as licensable waste treatment.

### Good Practice (continued)



Guidance on the Hazardous Waste Regulations 2005 can be found on the RPSGB website

[www.rpsgb.org/pdfs/hazwastehospghguid.pdf](http://www.rpsgb.org/pdfs/hazwastehospghguid.pdf)

Since the guidance was published, the EA has agreed that pharmacists may deblister, 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](http://www.environment-agency.gov.uk)

# Section 11

## Storage of controlled drugs





## Overview

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 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 community 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 (including GP surgeries) 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. This is good practice rather than legislation.

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 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 on 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 healthcare 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 CDR should be stored safely outside the CD container, 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 81.

## NPSA Guidance

Guidance to protect patients from harm in respect of prescribing, dispensing and administering opioid and opiate (hereafter opioid) medicines has been issued by the National Patient Safety Agency (NPSA). These specify actions that are designed to reduce human-factor error.

In England, organisations are required to notify the implementation status of NPSA guidance to the Department of Health Central Alerting System (CAS) by a specified date.

See Appendix 6 (page 107) for further details.



## Section 12

# Transportation of controlled drugs



## Legal framework

All healthcare 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 healthcare 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 83).

Although it is recommended that healthcare professionals do not routinely return CDs that are no longer required to a pharmacy on behalf of patients, there may be certain circumstances where this is considered appropriate, for example, when there is a greater risk by leaving the CDs in the patient's home. In this type of situation it is recommended that this is documented in the patient's notes and is preferably witnessed.

## Good Practice



Healthcare 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 household and other needy patients, it is good practice to keep 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 patient's pharmacy via the postal system, but should be collected from the surgery by a healthcare 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 practical 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.

The NHSBSA guidance document on the security of prescription forms can be accessed via the NHSBSA website at [www.nhsbsa.nhs.uk](http://www.nhsbsa.nhs.uk)

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

## Section 13

# Nurses working in the community



## 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, dentist, supplementary prescriber acting within the terms of a clinical management plan, or a nurse independent prescriber prescribing from the CDs listed in the table in Appendix 7 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 'Standards for Medicines Management', which includes guidance on CDs [www.nmc-uk.org/aArticle.aspx?ArticleID=2995](http://www.nmc-uk.org/aArticle.aspx?ArticleID=2995)

## 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. The NMC provide guidance for nurses and this is covered in Standard 7 in their Standards for Medicines Management [www.nmc-uk.org/aArticle.aspx?ArticleID=2995](http://www.nmc-uk.org/aArticle.aspx?ArticleID=2995) SOPs should be developed locally to cover this activity.

### Good Practice



Nurses should not normally 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. Information on personal security measures is available in the NHS CFSMS document 'Not Alone – A guide for the better protection of lone workers in the NHS' at [www.nhsbsa.nhs.uk/security](http://www.nhsbsa.nhs.uk/security)

## 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 for a person to possess CDs that have not been prescribed for them. In the first instance the patient/patient's relatives should be advised that all CDs no longer required should be returned to a pharmacy for safe destruction.

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

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 the patient's notes
- Nurse takes CDs to local community pharmacy, who would be asked to countersign patient nursing record



# Section 14

## Palliative

## care



## Overview

Palliative care has been described as the active total care of patients whose disease is not responsive to curative treatment. Prescribing and supply of CDs can take place across a number of care settings and it's important that robust governance systems are maintained whilst ensuring that patients have appropriate access to medicines.

### 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 palliative care, particularly where prolonged use is expected, then it is recommended that this is reported to the PCT (probably to the senior prescribing adviser and the Accountable Officer) to aid the interpretation of routine ePACT data.

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

#### Additional sources of information:

Liverpool Care Pathway [www.mariecurie.org.uk/forhealthcareprofessionals/liverpoolcarepathway.htm](http://www.mariecurie.org.uk/forhealthcareprofessionals/liverpoolcarepathway.htm)

Marie Curie Palliative Care Institute [www.mcpcil.org.uk](http://www.mcpcil.org.uk)

End of life care pathway [www.endoflifecare.nhs.uk](http://www.endoflifecare.nhs.uk)

National Council for Palliative Care [www.ncpc.org.uk](http://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 the healthcare 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 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, please refer to 'Securing proper access to medicines in the out-of-hours period' [www.out-of-hours.info/downloads/short\\_medicines\\_guidance.pdf](http://www.out-of-hours.info/downloads/short_medicines_guidance.pdf) and the accompanying practical guide [www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4134235](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4134235)

Delivering urgent access to medicines outside 'normal hours' – Notes for Commissioners and Providers [www.mmnetwork.nhs.uk/Delivering\\_urgent\\_access\\_to\\_medicines\\_outside\\_normal\\_hours.pdf](http://www.mmnetwork.nhs.uk/Delivering_urgent_access_to_medicines_outside_normal_hours.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.

# Section 15

## Care homes



## Legal framework

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.

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) [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4005819](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005819)

## 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 and care homes providing 'end of life' care
- 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 POM, 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 36)

- 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 38)

### 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.

Reference should be made to guidance produced by CQC - "The safe management of controlled drugs in care homes" available from [www.cqc.org.uk](http://www.cqc.org.uk)

In addition, the RPSGB has produced guidance on the 'Handling of medicines in social care' (includes CD guidance)

<http://www.rpsgb.org.uk/pdfs/handlingmedsocialcare.pdf>

## Receipt, storage and recording

### Legal framework

- The Misuse Of Drugs And Misuse Of Drugs (Safe Custody) (Amendment) Regulations 2007, amended the MDRs 2001 in order to change the term 'nursing home' as previously referred to in the 1973 and 2001 MDRs to that of 'care home'. The change is an administrative one, as 'nursing home' as previously defined is now obsolete. It is to be noted that the change in terminology that came into force with the Care Standards Act 2000 did not mean that nursing/care homes were no longer covered under the 1973 Regulations. They still applied due to the National Minimum Standards for Care Homes for Older People that came into effect in 2002 as this made specific reference to the fact that CDs administered by staff must be stored in a metal security cupboard that complied with the 1973 Regulations
- 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

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 a resident's own CDs, in addition to the records maintained on the medicine administration record charts. There is no need to keep a record in the CDR when the person is wholly independent and is responsible for requesting a prescription and collecting the CDs personally from the pharmacy.

If the person does not arrange the supply and collection of CDs but relies on the care workers to do so, there should be clear records made in the CDR, including:

- Receipt from the pharmacy
- Supply to the person
- Any subsequent disposal of unwanted CDs

The CDR 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 CDR 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 CDR 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 CDR, the amount remaining should be identified with 'brought forward from page x' written clearly on the new page
- It is good practice to keep CDRs for longer than the mandatory 2 years, as cases often come to court at a much later date, by which time the records would have been destroyed
- The CDR 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
- Reference should be made to relevant NPSA safety alerts relating to the administration of medicines (see appendix 6)
- Staff administering medicines should do so in full accordance with the prescriber's instructions
- The resident's name, plus time and dose given, should be recorded in the CDR after carefully checking the administration sheet. Once the registered nurse/trained carer has witnessed the resident taking the medication, the resident's administration chart 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 CDR, 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 Licensing 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.

For 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 CDR at the time of collection
  - Relevant details of any such transfer for disposal should be entered into the CDR and signed by the nurse, or authorised member of staff, returning the drug

The CQC has produced guidance for care homes providing nursing care. This states:

- 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 CDR

More detailed guidance can be found in 'Safe disposal of waste medicines from care homes (nursing)'; published by the CQC

[www.cqc.org.uk/guidanceforprofessionals.cfm](http://www.cqc.org.uk/guidanceforprofessionals.cfm)

## 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. weekly, 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 CQC local

### Good Practice (continued)



office informed. CQC will then share information as needed with the AO

- If the discrepancy is found to be an error of subtraction or addition in the calculation of stock balance:

Do not change the balance column or use correction fluid. Under the last entry, details of the following should be recorded:

- 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 CDR at the time of administration:  
Under the last entry, details of the following should be recorded:
    - 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 CDR, 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.



# Section 16

## Ambulance services





## Legal framework

An ambulance trust's AO is responsible for safe storage, supply and destruction of any unused and/or expired CDs.

NHS ambulance trusts and their paramedics have, since July 2008, been covered by a Group Authority and do not need to apply individually to the Home Office for a licence to possess and supply CDs to registered paramedics.

- The Group Authority covers all NHS ambulance trusts and their registered paramedics
- A separate Group Authority covers all other registered paramedics

Further information can be found on:

Group Authority (NHS ambulance trusts and paramedics employed) [www.drugs.homeoffice.gov.uk/publication-search/drug-licences/NHS-AMBULANCE-PARAMED-GRP-AUTH?view=Binary](http://www.drugs.homeoffice.gov.uk/publication-search/drug-licences/NHS-AMBULANCE-PARAMED-GRP-AUTH?view=Binary)

Group Authority (registered paramedics) [www.drugs.homeoffice.gov.uk/publication-search/drug-licences/Paramedics\\_\(Registered\)\\_-\\_G1.pdf?view=Binary](http://www.drugs.homeoffice.gov.uk/publication-search/drug-licences/Paramedics_(Registered)_-_G1.pdf?view=Binary)

The person in charge, or the acting person in charge, of any NHS ambulance trust is authorised to supply, or offer to supply, diazepam and/or morphine sulphate (to a maximum strength of 20 mg), and/or morphine sulphate oral, to any registered paramedic serving with, or employed by, that trust.

Registered paramedics serving or employed at any approved ambulance station are authorised to supply, or offer to supply, diazepam and/or morphine sulphate (to a maximum strength of 20 mg), and/or morphine sulphate oral, to any person who may lawfully have these drugs in their possession for the purpose of administration for the immediate necessary treatment of sick or injured persons.

Registered paramedics serving or employed at any approved ambulance station are authorised to possess diazepam and/or morphine sulphate (to a maximum strength of 20 mg), and/or morphine sulphate oral, for the purpose of that service or employment, for the purpose of administration for the immediate necessary treatment of sick or injured persons.

All storage and recording regulations for CDs must be complied with.

## Section 17

# 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



All schools should have a medicines policy. It is the responsibility of the education authority to ensure that these are in place.

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 key 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

The full guidance can be found at [www.standards.dfes.gov.uk/eyfs/resources/downloads/1448-2005dcl-env3final.pdf](http://www.standards.dfes.gov.uk/eyfs/resources/downloads/1448-2005dcl-env3final.pdf)

Whenever possible, dosing regimens should be designed to allow medicines to be taken outside school hours.

Any increase in costs associated with longer acting formulations should be balanced against potential benefits related to the safer management of CDs.

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.

Medicines prescribed for an individual must not be administered to another child.

A CD, as with all medicines, should be returned to the parent when no longer required, to arrange for safe disposal. Residential schools should have policies in place for the safe management of CDs prescribed for their residents.

## Section 18

# Overseas travel



## Legal framework

With effect from 1 January 2008, only those persons travelling overseas/to this country for 3 months 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](http://www.drugs.gov.uk)

### Licence

Personal import/export licences will only be issued to travellers carrying CDs abroad (or into the UK) for periods exceeding 3 months.

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

Licences are normally issued with an expiry date of 1 week after the expected return to the UK (or 1 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 each country's embassy to check these regulations.

Personal licence application forms can be downloaded from [http://drugs.homeoffice.gov.uk/publication-search/drug-licences/Personal\\_import\\_export\\_appl2.doc](http://drugs.homeoffice.gov.uk/publication-search/drug-licences/Personal_import_export_appl2.doc)

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) and countries being visited
- Dates of departure and return
- Details of the medicine(s) - name, daily dose prescribed, form, e.g. tablets, strength and total quantity to be carried

### Home Office contact details regarding overseas travel licences:

Licensing Section, Drug Licensing and Compliance Unit, 4th Floor Peel Building, 2 Marsham Street, London SW1P 4DF.

Direct Line: 0207 035 0475

Fax: 0207 035 6161

Email: [licensing\\_enquiry.aadu@homeoffice.gsi.gov.uk](mailto:licensing_enquiry.aadu@homeoffice.gsi.gov.uk)

Full guidance on personal exports is available at

[www.drugs.homeoffice.gov.uk/drugs-laws/licensing/personal/](http://www.drugs.homeoffice.gov.uk/drugs-laws/licensing/personal/)

### Good Practice



CDs should be transported as follows:

- Carried in original packaging
- Carried in hand luggage
- Carried with a letter from the prescribing doctor confirming the carrier's name, destination, drug details / amounts

Check with the relevant embassy/consulate to enquire of any restrictions in the country visited. It is recommended that patients check with the airline and airport prior to travel as security arrangements may change at any time; for example, restriction on volume of liquids.

- The BMA have also issued guidance around prescribing of all medicines for patients going abroad
- The NHS accepts responsibility for supplying ongoing medication for temporary periods abroad of up to 3 months
- If a person is going to be abroad for more than 3 months, then all that the patient is entitled to at NHS expense is a sufficient supply of his/her regular medication to get to the destination and find an alternative supply of that medication

See: [www.bma.org.uk/health\\_promotion\\_ethics/drugs\\_prescribing/InfoOnPrescrib0904.jsp?page=2](http://www.bma.org.uk/health_promotion_ethics/drugs_prescribing/InfoOnPrescrib0904.jsp?page=2)

## Section 19

### Out of hours



## Good Practice



Refer to:

Securing proper access to medicines in the out-of-hours period [www.out-of-hours.info/downloads/short\\_medicines\\_guidance.pdf](http://www.out-of-hours.info/downloads/short_medicines_guidance.pdf) and the accompanying practical guide [www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/DH\\_4134235](http://www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/DH_4134235) which were published by the DH in December 2004. They set out a framework to support PCTs in the 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.

Out-of-hours services should liaise with local substance misuse prescribing services, shared care monitoring groups and/or local Drug Action Teams, plus PCT commissioners, to confirm and agree arrangements for drug misusers who contact the out-of-hours service requesting a prescription for an opiate substitute, such as methadone or buprenorphine. In such circumstances, it is generally inappropriate and potentially dangerous to commence prescribing an opiate substitute drug or to replace a lost, stolen or broken bottle or supply. A local SOP should be produced, in liaison with local specialist prescribers, as to how out-of-hours services should respond to ensure a consistent and fair treatment of patients.

NPSA guidance applies to all sectors including out-of-hours provision.

PCTs can access out-of-hours FP10 prescribing data through ePACT.net, and non-FP10 out-of-hours information can be accessed through the NHSBSA website at [www.nhsbsa.nhs.uk/prescriptionservices/815.aspx](http://www.nhsbsa.nhs.uk/prescriptionservices/815.aspx)

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

- Ordering CDs (see page 35)
- Recording of CDs (see page 61)
- Storage of CDs (see page 71)
- 'Doctor's bags' (see page 65)
- Palliative care (see page 79)



information



## General information

To support patients and the public with information about the legal status of a CD, the NHS Choices website contains some general information that could be provided directly to the public. The text defines a CD in legal terms, how the regulations apply to them and directs patients to information about requirements for travelling abroad

[www.nhs.uk/chq/Pages/1391.aspx](http://www.nhs.uk/chq/Pages/1391.aspx)

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 Choices website [www.nhs.uk](http://www.nhs.uk)

## Medicines guides

Medicines guides provide a source of information for members of the public who are looking for up-to-date, reliable and easy to understand information. The information is provided through a collaboration between NHS Choices, the medicines information provider Datapharm, and other health organisations.

Guides for those CDs that have been published to date can be accessed at: [www.medguides.medicines.org.uk](http://www.medguides.medicines.org.uk) or [www.nhs.uk](http://www.nhs.uk)

# Section 21

## Controlled drugs in prisons



## Legal Position

Prisons are not Designated Bodies in regulation and so are not required to appoint an Accountable Officer.

As with Prison Health, where making suitable arrangements is the responsibility of the local PCT, the PCT Accountable Officer also has the responsibility to assure that the prison has suitable arrangements in place for the safer management of CDs. How this happens in practice is for local determination.

### Local arrangements

Although the responsibility to assure that CD arrangements are safe, and all concerns are fully reported, documented, and managed or investigated, remains with the PCT AO, most current arrangements involve there being an appropriate lead in the prison. This could be, for example, the Prison Health Lead or the Lead for a commissioned service. Their remit for CD safe handling should include appropriate dialogue and a feedback mechanism to the PCT AO.

## Inspection

Prisons / Prison Health are subject to inspection by Her Majesty's Inspectorate of Prisons (HMIP). HMIP have an SLA with the RPSGB who undertake the medicines inspection on their behalf. This includes CDs, and the CD element of the inspection report is now sent as a matter of routine to the PCT AO. The PCT AO has no need to carry out routine CD inspection, but should have some mechanism for regular feedback on assurance, and be informed about concerns.

### Good Practice



#### Purchasing and supply of CDs

As prisons are not mentioned in legislation, the good practice guidance suggests that the healthcare professional in charge of the Healthcare Department in the prison takes responsibility for the day to day management of CDs and that any requisitions for stock CDs are countersigned by a medical prescriber employed or engaged at that prison.

For CD management in prison settings, we point toward the DH/RPSGB Guidance 'Safer management of Controlled Drugs: a guide to good practice in secondary care (England)'. Here there is reference to regulations only applying to certain settings and, for some situations, these may now only be considered to be a minimum standard

### Good Practice (continued)



and risk assessment may indicate a higher level of security is more appropriate. For those settings not included in the regulations, the same principles of risk assessment and safe and secure management apply. In the prison service, there are detailed requirements for all areas where Controlled Drugs and other medication is stored. The security aspects of the building requirements state that such rooms must have walls, floors and ceiling of solid construction and all doors must be gated and all treatment hatches/windows barred. In areas where large amounts of Controlled Drugs are stored, or where there is not a 24-hour staff presence, it is recommended that the Controlled Drugs cabinets meet the 'sold secure' (silver) standard of construction. For further information see the website [www.soldsecure.com](http://www.soldsecure.com)

#### Receipt of CDs

For prisons, where there is no pharmacy on site, the relevant doctor should sign a written letter of authorisation for specified members of the nursing staff to accept the delivery and sign for the CDs on receipt.

#### Administration

Good practice guidance in prisons – clinical guidance (Integrated Drug Treatment System in prisons (IDTS)- Clinical Guidelines) specifies that the administration of CDs should be undertaken by at least one healthcare professional, with a 'competent' other to witness administration and sign the register as witness. The competence of the witness, if not a healthcare professional, should be determined by local competency training. Furthermore, all CDs prescribed for substance misuse treatment, or maintenance, should be only administered by supervised consumption (designated as 'Not In Possession' in prisons), taking into account the National Treatment Agency (NTA) guidelines for administration.

Where buprenorphine is prescribed, this is often administered under a locally determined protocol, being crushed prior to supervised consumption. This crushing renders the medication 'off-licence' and needs to be with the agreement of the prescriber and patient (patient compact). Such protocols should also specify that the patient should be continuously observed throughout the administration process by the healthcare professional administering the dose, with safeguards so that diversion is minimised.

## Good Practice (continued)



### Prescriptions in prisons

The drug administration charts used in prisons should be completed as per prescription guidelines above, with the additional identifier of the prison number as the unique patient identifier. Ensuring that the prescription is legally complete will enable the patient to have their medication continued if they are suddenly moved to another prison, until the new prescriber can review and renew their medication (until after a Bank Holiday or weekend, for example).

Where a CD prescription is not intended to be initiated on the day the prescription is written, it is suggested that the date of commencement of treatment is stated on the prescription to ensure there is no ambiguity over the date administration is commenced.

FP10s or FP10(MDA) prescriptions can be used in the prison setting for patients on discharge, if the discharge is such that it is not possible to obtain a "To Take Out" (TTO) supply of medicines for the patient in time. Or, in the case of substance misuse medication, if it has not been possible to arrange a prescribing appointment with the drug treatment agency or GP on the day, or day after discharge to ensure continuation of treatment. In these cases, the Healthcare Department at the prison will endeavour to contact the pharmacy in advance. In some circumstances, the patient may present at the pharmacy with an FP10 or FP10(MDA) with HMP as the address. Such prescriptions are exempt from payment. If any confirmation of authenticity is needed, the pharmacist can contact the prison Healthcare Department.

### Additional information for discharged prisoners

Information on provision of FP10 and FP10(MDA) prescription forms, by HM Prison Service, for released prisoners is available on the DH website [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_083474](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_083474)

Additional information relating to prescription charges and discharged prisoners is available from the Pharmaceutical Services Negotiating Committee (PSNC) website [www.psnc.org.uk/pages/points\\_of\\_dispensing\\_checks\\_guidance.html](http://www.psnc.org.uk/pages/points_of_dispensing_checks_guidance.html)

## Good Practice (continued)



### Dispensing

Although prescriptions are written for all CD medicines, those for substance misuse medication will usually be administered by healthcare staff from stock supplies requisitioned by the doctor. This is to ensure that any new prisoner can be treated without undue delay in obtaining supplies.

### Recording

Although it is not legally required to enter details of any Schedule 3 CDs in a register, it is strongly recommended that all prisons record details of any buprenorphine, or buprenorphine /naloxone medication, as for a Schedule 2 CD to ensure a robust audit trail.

Some prisons will have more than one area where CDs for substance misuse treatment are stored/administered. It is recommended that a CD Register is kept to record all deliveries into the prison, and that an audit of movement to other treatment rooms in the prison is by way of internal requisition, with a separate register (of the hospital-type which records the patient details, dose and time administered, and the signatures of the healthcare professional/witness) kept for each location where the CDs are stored and administered. The arrangements should be included in a SOP.

## Potential change in legislation

Legislation is before parliament to amend the requisition requirements, as they relate to prisons obtaining CDs from community pharmacies. The intention is that prisons will not have to use the FP10CDF requisition forms but can use the hospital-type requisition forms and will therefore not send these requisitions on to the NHSBSA. Requisitions would still be retained at the pharmacy for the minimum 2 years.



# Appendices





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

Schedule	Schedule 2 Includes opioids, (e.g. diamorphine, morphine, methadone), major stimulants (e.g. amphetamines), remifentanyl, secobarbital	Schedule 3 Includes minor stimulants, temazepam, diethylpropion, buprenorphine, midazolam, flunitrazepam, Barbiturates except secobarbital	Schedule 4 Part 1 Includes benzo-diazepines	Schedule 4 Part 2 Includes anabolic steroids, clenbuterol, growth hormones	Schedule 5 Includes low strength opioids
Designation	CD	CD No Reg	CD benz	CD anab	CD inv
Safe custody	Yes, except quinalbarbitone	No, except buprenorphine, diethylpropion and temazepam	No	No	No
Prescription requirements (including handwriting*) – apply to OP and discharge prescriptions	Yes	Yes, except temazepam	No	No	No
Requisitions necessary?	Yes	Yes	No	No	No
Records to be kept in CDR	Yes	No	No	No	No
Pharmacist must ascertain the identity of the person collecting CD	Yes	No	No	No	No
Emergency supplies allowed	No	No, except phenobarbitone for epilepsy	Yes	Yes	Yes
Validity of prescription	28 days	28 days	28 days	28 days	6 Months (if POM)
Maximum duration that may be prescribed	30 days as good practice	30 days as good practice	30 days as good practice	30 days as good practice	
Private prescription requirements	Yes	Yes	No	No	No

\* 'Prescriptions for schedule 2 and 3 CDs may be typed or computer generated but must be signed by the prescriber (SI 2005 No.28647).

## Appendix 2: Governance arrangements and settings

CD handling site	Governance arrangements
PCTs	<ul style="list-style-type: none"> <li>• AO with responsibility for all aspects of safe and secure handling of CDs</li> <li>• All CD activity defined in SOPs</li> <li>• Self-assessment and declaration to the CQC (formerly Healthcare Commission)</li> <li>• Develop and lead LIN</li> </ul>
NHS Hospital Trusts and Foundation Trusts	<ul style="list-style-type: none"> <li>• AO with responsibility for all aspects of safe and secure handling of CDs</li> <li>• All CD activity defined in SOPs</li> <li>• Self-assessment and declaration to the CQC</li> <li>• Member of the LIN</li> </ul>
Independent hospitals	<ul style="list-style-type: none"> <li>• AO with responsibility for all aspects of safe and secure handling of CDs</li> <li>• All CD activity defined in SOPs</li> <li>• Self-assessment and declaration to the CQC</li> <li>• Member of the LIN</li> </ul>
Non-statutory prescribing drug services in community and inpatient (including residential) settings	<ul style="list-style-type: none"> <li>• All CD activity defined in SOPs</li> <li>• Commissioner of service to specify assurance</li> </ul>
Non Controlled Drugs Designated Bodies e.g. private clinics and doctors	<ul style="list-style-type: none"> <li>• All CD activity defined in SOPs</li> <li>• Those registered with the CQC to complete self-assessment and declaration</li> <li>• For those not registered with the CQC, the AO of the PCT has the right of entry to investigate reported CD concerns</li> </ul>
Social care settings	<ul style="list-style-type: none"> <li>• Inspection by CQC Inspector</li> <li>• All CD activity defined in SOPs/policies and procedures</li> <li>• Self-assessment and declaration to CQC</li> <li>• CQC member of LIN</li> <li>• Individual duty to report concerns to the PCT AO/LIN</li> </ul>
GPs	<ul style="list-style-type: none"> <li>• Inspection by PCT AO</li> <li>• All CD activity defined in SOPs</li> <li>• Self-assessment and declaration to PCT</li> <li>• Individual duty to report concerns to the PCT AO/LIN</li> </ul>
Dentists with NHS contracts	<ul style="list-style-type: none"> <li>• Inspection by PCT AOs</li> <li>• All CD activity defined in SOPs</li> <li>• Self-assessment and declaration to PCT</li> <li>• Individual duty to report concerns to the PCT AO/LIN</li> </ul>
Prison service	<ul style="list-style-type: none"> <li>• All CD activity defined in SOPs</li> </ul>
Services commissioned by PCT	<ul style="list-style-type: none"> <li>• All CD activity defined in SOPs</li> <li>• Commissioner of service to specify assurance</li> </ul>
Community pharmacies	<ul style="list-style-type: none"> <li>• Inspection of all aspects of CD management by RPSGB</li> <li>• All CD activity defined in SOPs</li> <li>• Self-assessment and declaration to RPSGB</li> <li>• RPSGB member of LIN</li> <li>• Individual duty to report concerns to the PCT AO/LIN</li> </ul>

## Appendix 3: Monitoring prescribing

The Prescribing Support Unit (PSU) has published a detailed guide on how to monitor CD prescribing using the ePACT.net system.

### Technique to monitor Controlled Drug prescribing

Techniques to allow PCT advisers to monitor the prescribing of CDs have been devised and are available to all PCTs via the Information Centre website [www.ic.nhs.uk/services/prescribing-support-unit-psu/controlled-drugs](http://www.ic.nhs.uk/services/prescribing-support-unit-psu/controlled-drugs)

CD monitoring is also a core component of all NHS Prescribing Services (NHS RxS) ePACT.net training courses. It is recommended that AOs ensure that staff monitoring CD prescribing by using the ePACT.net system are competent users, are aware of the latest enhancements, and if necessary consider sending them for formal training. Details of NHS RxS training can be obtained from [www.nhsbsa.nhs.uk/prescriptionservices/815.aspx](http://www.nhsbsa.nhs.uk/prescriptionservices/815.aspx)

The techniques use 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. Techniques demonstrate how advisers can focus on prescribing patterns for these practices to determine the specific medicines and quantities prescribed, and produce trend graphs to see if the prescribing patterns are typical of palliative care.

Techniques have been revised and enhanced in 2009 to also allow advisers to monitor prescribing of excessive quantities of CDs on individual prescription forms, monitor prescribing for drug addicts on FP10(MDA) forms, identify where CD prescriptions were dispensed and monitor non-medical prescribing of CDs. The ePACT.net 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 ePACT data has no link to individual patients. The techniques simply identify prescribers with unusual prescribing patterns for CDs that may warrant further investigation.

It is becoming increasingly common for the main ePACT.net users in PCTs to come from a non-pharmaceutical background (data analysts etc). It is important that AOs ensure that ePACT.net reports obtained by these users are interpreted carefully by an experienced pharmaceutical adviser. Advisers can use the ePACT.net information, together with data from other sources and their local knowledge of practices, to decide if further investigation is warranted. 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 saved, in a suitable format, and archived securely, as this information may be required as evidence by other bodies.

The Prescribing Support Unit of the Health and Social Care Information Centre has produced educational resources relating to the analysis of Controlled Drug prescribing which cover the following areas:

- Overview of CD monitoring techniques and case history examples
- Monitoring CD injections
- Monitoring frequency of Schedule 2 & 3 CDs at practice level
- Monitoring the prescribing of unusual formulations or quantities
- Monitoring private CD prescribing
- Monitoring non-medical CD prescribing
- Advice on how to request prescription searches by the NHS RxS

## Appendix 4: Useful contacts

### **British Medical Association**

BMA House, Tavistock Square, London WC1H 9JP

Tel: 0207 979 2000

[www.bma.org.uk](http://www.bma.org.uk)

### **The Care Quality Commission (which replaced the Healthcare Commission, the mental Health Act Commission and the Commission for Social Care Inspection on 1 April 2009)**

Finsbury Tower, 103-105 Bunhill Row, London EC1Y 8TG

Tel: 03000 616161

[www.cqc.org.uk](http://www.cqc.org.uk)

### **Community Practitioners' and Health Visitors Association**

33-37 Moreland Street, London EC1V 8HA

Tel: 0207 389 8030

[www.amicustheunion.org/cphva/](http://www.amicustheunion.org/cphva/)

### **Council for Healthcare Regulatory Excellence**

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

Tel: 0207 210 4850

[www.chre.org.uk](http://www.chre.org.uk)

### **Department of Health**

Richmond House, 79 Whitehall, London SW1A 2NS

Tel: 01751 430835

[www.dh.gov.uk](http://www.dh.gov.uk)

### **Dispensing Doctors' Association**

Low Hagg Farm, Starfitts Lane, Kirbymoorside,

North Yorkshire YO62 7JF

Tel: 08708 506 506

[www.dispensingdoctor.org](http://www.dispensingdoctor.org)

### **Environment Agency**

Millbank Tower, 25th Floor, 21-24 Millbank, London SW1P 4XL

[www.environment-agency.gov.uk](http://www.environment-agency.gov.uk)

### **General Medical Council**

Regent's Place, 350 Euston Road, London NW1 3JN

Tel: 0207 448 9200

[www.gmc-uk.org](http://www.gmc-uk.org)

### **Home Office Drug Legislation Team, Drug Strategy Unit**

2 Marsham, Street London SW1P 4DF

Tel: 0207 035 4848

[www.homeoffice.gov.uk](http://www.homeoffice.gov.uk)

### **Home Office Drugs Licensing and Compliance Unit**

2 Marsham Street, London SW1P 4DF

Tel: 0207 084 2000 Fax: 0207 084 2353

[www.homeoffice.gov.uk](http://www.homeoffice.gov.uk)

### **Medicines and Healthcare products Regulatory Agency**

Market Towers, 1 Nine Elms Lane, London SW8 5NQ

Tel: 0845 357 3456

[www.mhra.gov.uk](http://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

[www.ncas.npsa.nhs.uk](http://www.ncas.npsa.nhs.uk)

### **National Patient Safety Agency**

4-8 Maple Street, London W1T 5HD

Tel: 0207 927 9500

[www.npsa.nhs.uk](http://www.npsa.nhs.uk)

### **National Pharmacy Association**

Mallinson House, 38-42 St Peter's Street, St Albans,

Hertfordshire AL1 3NP

Tel: 01727 832161

[www.npa.co.uk](http://www.npa.co.uk)

### **National Prescribing Centre**

Ground Floor, Building 2000, Vortex Court

Enterprise Way, Wavertree Technology Park, Liverpool L13 1FB

Tel: 0151 295 8671

[www.npc.co.uk](http://www.npc.co.uk) (Internet)

### **National Treatment Agency**

8th Floor, Hercules House, Hercules Road, London SE1 7DU

Tel: 020 7261 8801

[www.nta.nhs.uk](http://www.nta.nhs.uk)

**NHS Business Services Authority - Counter Fraud and Security Management**

Weston House, 246 High Holborn, London WC1V 7EX

Tel: 020 7895 4500

[www.nhsba.nhs.uk/fraud](http://www.nhsba.nhs.uk/fraud)

**NHS Business Services Authority - Prescription Services**

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

Tel: 0191 203 5050

[www.nhsba.nhs.uk/prescriptions](http://www.nhsba.nhs.uk/prescriptions)

**NHS Direct**

Headquarters, 207 Old Street, London EC1V 9PS

Tel: 0207 599 4200

[www.nhsdirect.nhs.uk](http://www.nhsdirect.nhs.uk)

**Nursing and Midwifery Council**

23 Portland Place, London W1B 1PZ

Tel: 020 7637 7181

[www.nmc-uk.org](http://www.nmc-uk.org)

**Pharmaceutical Services Negotiating Committee**

59 Buckingham Street, Aylesbury, Buckinghamshire HP20 2PJ

Tel: 01296 432 823

[www.psn.org.uk](http://www.psn.org.uk)

**Prescribing Support Unit**

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

Tel: 0113 254 7041

[www.ic.nhs.uk/services/prescribing-support-unit-psu](http://www.ic.nhs.uk/services/prescribing-support-unit-psu)

**Royal College of General Practitioners - RCGP Substance Misuse Unit**

14 Princes Gate, Hyde Park, London SW7 1PU

Tel: 0845 4564041 Ext. 217

[www.rcgp.org.uk/default.aspx?page=659](http://www.rcgp.org.uk/default.aspx?page=659)

**Royal College of Nursing - Head Office**

Cavendish Square, London W1G 0RN

Tel: 0207 409 3333 20

[www.rcn.org.uk](http://www.rcn.org.uk)

**Royal Pharmaceutical Society of Great Britain**

1 Lambeth High Street, London SE1 7JN

Tel: 0207 735 9141

[www.rpsgb.org](http://www.rpsgb.org)

**UK Home Care Association**

42b Banstead Road, Carshalton Beeches, Surrey SM5 3NW

Tel: 0208 288 1551

[www.ukhca.co.uk](http://www.ukhca.co.uk)

## Appendix 5: Glossary

### **ACMD**

Advisory Council on the Misuse of Drugs

### **BMA**

British Medical Association

### **British National Formulary (BNF)**

A reference providing UK healthcare 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 the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001

### **CDR**

Controlled Drugs 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

### **CQC**

Care Quality Commission

### **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

### **Domiciliary visit**

A visit made by a healthcare 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 Prescribing Analysis and Cost information system

### **Formal/home carer**

A carer who is paid for the purpose

### **FP10**

Prescription form used by healthcare professionals

### **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

### **NHS Prescription Services**

A service provided by the NHS Business Services Authority

**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

**PGDs**

Patient Group Directions

**PMR**

Patient medication record - computer record containing personal patient details and medicines supplied to them

**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 a prescriber

**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 healthcare 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)



## Appendix 6: NPSA Guidance

Guidance to protect patients from harm in respect of prescribing, dispensing and administering opioid and opiate (hereafter opioid) medicines has been issued by the National Patient Safety Agency (NPSA). These specify actions that are designed to reduce human-factor error.

In England organisations are required to notify the implementation status of NPSA guidance to the Department of Health Central Alerting System (CAS) by a specified date.

### Reducing dosing errors with opioid medicines. Rapid Response Report 05, July 2008

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

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

### Ensuring safer practice with high dose ampoules of diamorphine and morphine. Patient Safety Notice 12. May 2006

Recommended actions are to:

- risk assess and have procedures for safely prescribing, labelling, supplying, storing, preparing and administering diamorphine and morphine injections

- review therapeutic guidelines for the use of diamorphine and morphine injectable products for patients requiring acute care, including post-administration observation of patients who have not previously received doses of opiates
- update information concerning the safe use of diamorphine and morphine injectable products as part of an ongoing programme of training for healthcare staff on medication practice
- ensure that naloxone injection, an antidote to opiate-induced respiratory depression, is available in all clinical locations where diamorphine and morphine injections are stored or administered

Healthcare organisations should ensure local medicines and prescribing policies, including Standard Operating Procedures, are reviewed to reflect this guidance.

There is an expectation that organisations and practitioners will adhere to the NPSA's guidance; however, the responsibility, accountability and liability for failure to implement guidance is as yet untested in law. Therefore, the NPSA is unable to give definitive direction at this time. The following represents the best opinion of the NPSA legal advisors, and their assessment of the situation as it currently stands. We would strongly recommend that organisations obtain their own independent legal opinion.

Guidance could well be relevant in the context of a corporate manslaughter investigation where the acts or omissions of senior management are shown to have substantially contributed to a breach of duty that has caused a fatality. Evidence of ignoring specific relevant guidance from the NPSA, or even a generalised failure to act on such guidance, is likely to weigh in favour of a jury finding that there had been a 'gross' management failure, which is a necessary element for a successful conviction.

In order to rebut any suggestion of a gross management failure in such circumstances, an organisation would probably need to argue that it took different, but equally effective measures to minimise the risk in question, or of course try to show that the fatality would have been caused even if the relevant guidance from the NPSA had been implemented.

The nature of the corporate manslaughter offence means that, in terms of deaths arising out of the treatment of patients, those organisations such as General Medical (GP) Practices, Acute Trusts or Foundation Trusts, providing care directly to patients are most likely to be the subject of a prosecution. Such organisations are under a contractual obligation to have regard to all relevant guidance issued by the PCT, the relevant Strategic Health Authority or the Secretary of State, and to have an effective system of clinical governance. A failure to heed NPSA guidance is likely to place the organisation in breach of those requirements and a jury may view such a failure as particularly serious in such circumstances.

The PCT, as a commissioner of services, is potentially liable if it knew that guidance was not being followed and took no action to address the situation. Even then, a prosecution would find it difficult to establish that the PCT's failure to act caused death, rather than the actions or omissions of the organisation in question.

In addition to corporate manslaughter, there is scope for organisations providing direct care and/or PCTs to be prosecuted for other (lesser) health and safety offences. Similar considerations would be likely to apply; thus, failure to follow the guidance would be likely to be taken into account in determining liability.

Failure to act on NPSA guidance is likely to be addressed by bodies such as the Care Quality Commission or the Strategic Health Authority, rather than the NPSA itself.

## Appendix 7: Controlled Drugs prescribable by Nurse Independent Prescribers solely for the medical conditions indicated

Drug	Schedule <sup>1</sup>	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

<sup>1</sup>Schedule 1–5 of the Misuse of Drugs Regulations 2001

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

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*Policy Lead - Non-Medical Prescribing, Department of Health*

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*Head Pharmacist Commission for Social Care Inspection (former)*

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