# MEDICINES MANAGEMENT GUIDE TO PRESCRIBING

## Section 10 – Controlled Drugs Management

## Contents





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## 10.1 CONTROLLED DRUGS (CD) governance arrangements

**Reproduced and adapted with acknowledgement to CQC's Nigel's surgery 28: Management of controlled drugs** http://www.cqc.org.uk/guidance-providers/gps/nigels-surgery-28-management-controlled-drugs

GP practices should have systems in place to ensure the safe management of controlled drugs. The following points will help practices identify and demonstrate that they have systems in place to minimise risk when managing CDs:

- each practice should have clear, written standard operating procedures (SOPs) covering all aspects of CD management that are known, understood and followed by all relevant staff.
- the SOPs should cover the ordering, storing, administering, recording, and destruction of CDs
- staff should be trained to ensure they have the relevant knowledge and skills to undertake the CD related tasks required of them
- staff should know what to do and who to contact if they have a concern about an incident or the performance or practice of other healthcare professionals / staff
- staff should know how to contact the Area Team Controlled Drugs Accountable Officer (CDAO).

**It is legal requirement for all CD related incidents to be reported to the Lead Controlled Drugs Accountable Officer (CDAO).**

**Julia McCann, Controlled Drug Accountable Officer**
**NHS England and NHS Improvement South** East
Controlled drugs emails to: england.southeastcdao@nhs.net
Mobile: 07900 715189

NHS England has now implemented a national online system for reporting controlled drugs incidents which can be accessed here:

www.cdreporting.co.uk

New users need to register initially as an organisation and can then report incidents.

## 10.2 ORDERING AND COLLECTION

### 10.2.1 Ordering controlled drugs

A GP can hold stocks of CDs in their practice or in their doctor's bag for dispensing to individual patients without the need for a Home Office Licence as GPs have authority to supply under the 2001 Regulations. However, stocks held for the purposes of wholesaling will require a Home Office licence. Details of how to apply can be found on the Home Office website.

It is recommended that practice stock levels of CDs are kept to a minimum, whilst ensuring that they are adequate to meet normal patient demand.

### 10.2.2 Obtaining controlled drug stock from a community pharmacy

If CDs from Schedule 2 or 3 are needed for practice stock or a doctor's bag, they must be ordered using the approved requisition form, FP10CDF. A community pharmacist will supply the controlled drugs in whole packs on receipt of a completed requisition form.

Legally, the requisition form must:

- be signed by the doctor
- state the prescriber's name, address and area of practice (e.g. GP)
- specify the total quantity of drug (the total quantity of drug does not have to be written in both words and figures)
- state the purpose of the requisition. (e.g. 'practice use')

It is recommended that the GP's / prescriber's professional registration number is included on the requisition so that the community pharmacist can confirm the validity of the requisition.

Requisitions and orders for controlled drugs must be preserved for two years.

Non-medical prescribers are also authorised to requisition CDs in their own right in the community under Regulation 14 of the Misuse of Drugs Regulations 2001, however, this authority is limited to stocks needed for their own use and within their competence.

- The Misuse of Drugs (Amendment) (No. 2) (England, Wal es and Scotland) Regulations 2015

### 10.2.3 Collecting controlled drugs

If someone from the practice goes to collect the CDs from the pharmacy, they must take a note with them which states that they have authority to be in possession of the CD.

The note must be signed by the doctor / prescriber who requisitioned the CDs.

### 10.2.4 Obtaining controlled drug stock from a wholesaler

CDs can also be ordered electronically from a wholesaler but the practice still has to provide the wholesaler with a signed requisition using the mandatory requisition form FP10CDF. Requisitions cannot be faxed because a fax has not been signed by the prescriber and therefore does not meet the legal requirements.

### 10.2.5 Receiving controlled drugs

When CDs are received into the practice, from a community pharmacy or wholesaler, the responsible person should check that the correct CDs have been delivered and then sign the delivery note (if one has been provided) – even if it has already been signed when collecting the CDs from the pharmacy.

## 10.3 REGISTERS AND RECORD KEEPING

### 10.3.1 Controlled drug registers

Any movement of a Schedule 2 CD into and out of the practice must be recorded in a CD register. This should be done as soon as possible but must be done within 24 hours. It is recommended that two people do this together and check stock levels at the same time. Also, practices are recommended to keep a running balance of the stock levels of each CD preparation as this makes

it much easier to spot and track discrepancies. Whilst the task of making the register entries can be delegated, the GP retains full responsibility.

The register must:

- be bound (this may be in the form of a separate bound booklet for each preparation)
- have separate sections for each class of CD and within this each formulation and strength should be recorded on a separate page
- have the name, form and strength of the drug specified at the top of each page.

The CD register should be kept on the premises to which it relates and be available for inspection at any time. The register should not be stored in the CD cupboard but should be stored safely close by. It should not be used for any other purpose and should be kept for a minimum of two years after the date of the last entry. A computerised CD register may also be used, subject to meeting the requirements of the Regulations (see paragraphs 9 and 10 of 'Safer Management of Controlled Drugs Gateway Reference: 6819')

In all CD Registers, entries must

- appear in chronological order
- be made on the day of the transaction, or within 24 hours
- be indelible (any errors should be left visible and the correction made should be signed and dated in the margin, or linked to a footnote at the bottom of the page. Tippex® or similar should not be used)
- show the strength and form of the preparation at the top of each page
- if it is a dispensing practice, then there should also be a record of who the controlled drug has been supplied to when the prescription is collected.

### 10.3.2 Running balances and dealing with discrepancies

It is recommended that practices keep a running balance of the stock levels of each CD preparation as this makes it much easier to spot and track discrepancies. A member of the practice should undertake a regular stock check of all CDs held on the premises and in doctors' bags. This is also a good opportunity to check for out of date CDs and identify those that will soon go out of date.

If a discrepancy arises between the actual and recorded stock level of a CD, that cannot be immediately resolved, an entry must be made in the CD register to that effect and the NHS England lead CDAO for the area informed. The CDAO may undertake an investigation and involve the relevant professional bodies, other inspectors or the police as appropriate.

## 10.4 STORAGE AND SECURITY

### 10.4.1 Storage

Schedule 2 CD stock medicines must be stored in a CD cupboard to which there is restricted access. The storage and access arrangements should be documented in an SOP.

The cupboard must be:

- secured to a wall and fixed with bolts that are not accessible from outside the cupboard,
- fitted with a robust multiple point lock (or be a digital code),
- made of metal with strong hinges and the walls of the room should be of a suitable thickness so that the cupboard is fixed securely

If a safe is used, there should be a separate receptacle within it to store the CDs. Other items, such as keys, money, valuables and paperwork, should not be stored in the CD cupboard.

Within the cupboard / safe, it is good practice to separate low strength preparations from high strength ones to minimise the risk of incorrect selection.

In the case of Schedule 3 CD stock medicines, some must be stored in a CD cupboard to which there is restricted access but others are exempt from the safe custody requirements.

### 10.4.2 Keys

A GP should normally be the person responsible for holding the keys to the CD cupboard within the practice, but they can authorise another person, such as the practice manager, to take on this task. However, the GP remains ultimately accountable for the management of the CDs within their premises. The keys to the CD cupboard or receptacle should always be stored separately from it.

If a safe with a digital code is used to store the controlled drugs instead of a cupboard, then the same would apply for the digital code.

### 10.4.3 Cold storage of controlled drugs

It is unlikely that the practice will need to hold CDs requiring cold storage. There are currently no medicine refrigerators on the market that comply with the Misuse of Drugs Safe Custody Regulations. CDs requiring cold storage are placed in a medicines fridge. They can be stored in the same medicines fridge as other medicines but should be stored separately i.e. in a separate lockable box. Access to the CDs should be restricted and the arrangements documented in an SOP.

### 10.4.4 Out-of-date / unwanted / patients' own controlled drugs and patient returned controlled drugs

All controlled drugs, including out-of-date / unwanted, patient dispensed and patient returned CDs awaiting destruction must be stored in the CD cupboard until they can be disposed of. They should be segregated from the in-date stock to minimise the risk of a patient receiving an out-of-date medicine.

### 10.4.5 Doctor's bags

A doctor's bag, if locked, is considered a suitable receptacle for storing CDs. However, a locked car is not. A doctor's bag should be a lockable bag, box or case and it should be kept locked at all times except when in immediate use. The person in lawful possession of this bag (i.e. the GP) should always retain the keys to it. A digital combination lock would provide an acceptable alternative and removes the problem of lost keys. It is not recommended to leave a bag containing CDs in a car overnight or for long periods of time. When the doctor's bag is in the practice, it should be stored in a safe place away from patient areas.

A separate record book should be maintained for the CDs held within the bag and the GP is responsible for the receipt and supply of CDs from their bag.

If a GP makes a domiciliary visit and either administers a CD from the bag or issues a handwritten prescription for a CD, they should make a note of this in the patient's record as soon as possible after the event. It is good practice to write a prescription for the item administered, endorse it with the word 'administered' and date it.

## 10.5 PRESCRIBING CONTROLLED DRUGS

### 10.5.1 Prescribing controlled drugs

Prescriptions for Schedules 2 and 3 CDs can be sent electronically via the Electronic Prescription Service (EPS) and signed with an Advanced Electronic Signature (AES) as well as handwritten. This follows changes to Home Office legislation and NHS and Human Medicines Regulations in July 2015.

Prescribers (both NHS and private) are strongly advised to limit the quantity of Schedule 2, 3 and 4 CDs prescribed to amounts that meet the patient's clinical need for up to 30 days supply. In exceptional circumstances, where the prescriber considers more than 30 days is clinically indicated and would not pose an unacceptable risk to patient safety, a record of the reasons for deviating from the guidance should be made in the patient's record and the prescriber should be able to justify the decision, if challenged.

It is not illegal for a pharmacist to dispense a prescription for CDs for more than 30 days' supply, but they must satisfy themselves as to the clinical appropriateness of the prescription before doing so. The pharmacist may contact the prescriber for clarification. It is inappropriate for a prescriber to prescribe a CD for themselves, a family member, or a friend unless in a clinical emergency.

- The Misuse of Drugs (Amendment) (No. 2) (England, Wales and Scotland) Regulations 2015
- The National Health Service (Amendments to Primary Care Terms of Service relating to the Electronic Prescription Service) Regulations 2015
- The Human Medicines (Amendment) (No. 2) Regulations 2015

### 10.5.2 Prescription stationery

Prescription stationery for CDs, including printer paper, must be stored securely to prevent theft and misuse to fraudulently obtain controlled drugs. There is guidance on the PAD regarding the safe and secure management of prescription stationery.

### 10.5.3 Private prescribing of CDs

Private prescriptions for all Schedule 2 and 3 CDs, to be dispensed in the community, must either be written on standard forms (FP10(PCD)) designed to be similar to, but distinguishable from, the NHS prescription form or prescribed electronically via the EPS system. Prescribers need to apply for a private prescriber identification number via their NHS England CDAO Team, before prescribing CDs privately.

## 10.6 DESTRUCTION OF CONTROLLED DRUGS

### 10.6.1 Controlled drug destruction

CDs must be denatured (e.g. tablets crushed, ampoules opened) before disposal. In order to do this, a practice must obtain a T28 exemption from the Environment Agency to negate the need to obtain a licence to carry out this process:

- Guidance Waste exemption: T28 sort and denature controlled drugs for disposal

The tables below set out the destruction requirements for both stock and patient returned CDs:

### 10.6.2 Denaturing and witness requirements

**For stock CDs**

| | **Is denaturing required?** | **Is an authorised witness required?** | **Record keeping** |
|---|---|---|---|
| Expired / obsolete / unwanted stock | Yes (for Schedule 2, 3 and 4(part1) | Yes if Sch 2<br><br>For Sch 3 – good practice to have another member of staff witness the destruction | For Sch 2 - an entry should be made in the CD Register<br><br>For Sch 3 - good practice to record the destruction |

**For patient returned CDs**

| | **Is denaturing required?** | **Is an authorised witness required?** | **Record keeping** |
|---|---|---|---|
| Patient returned CDs | Yes (for Schedule 2, 3 and 4(part1) | No<br><br>However, it is preferable for the denaturing process to be witnessed by another member of staff familiar with CDs | A record should not be made in the CD Register but a separate record made to maintain an audit trail.<br><br>For Sch 3 - good practice to do the same |

The NHS England CDAO team can provide a list of authorised witness contact details.

CDs in a doctor's bag that go out of date or are unwanted should be returned to practice stock for destruction. If the practice does not hold a stock of CDs, then the unwanted CDs in the doctor's bag need to be destroyed directly from the bag in the presence of an authorised witness.

### 10.6.3 CD Patient Group Directions (PGDs)

Only specific CDs in Schedules 2 and 3 can be included in a PGD and there are stipulations as to who can supply or administer them and under what circumstances:

- Who can supply or administer Controlled Drugs under the terms of a Patient Group Direction and under what circumstances?

All Schedule 4 CDs (except anabolic steroids and injectables for treating addiction) and all Schedule 5 CDs can be included in PGDs.

## 10.7 LEGISLATION AND GUIDANCE

The legitimate clinical use of controlled drugs is governed by the Misuse of Drugs Regulations 2001. These divide controlled drugs into five therapeutic 'schedules' according to the level of control they need with the higher the schedule indicating the need for the greatest control. You will be mainly concerned about those in schedule 2:

**Schedule 2** includes diamorphine (heroin), morphine and pethidine. All schedule 2 CDs are subject to the full controlled drug requirements relating to prescriptions and safe custody and the need to keep registers.

**Schedule 3** includes buprenorphine, diethylpropion, midazolam, pentazocine, phentermine, temazepam, and tramadol. They are subject to the special prescription requirements and some (temazepam and buprenorphine but not tramadol) are required to be stored in a CD cupboard. A register does not need to be kept.

The legislation that sets out the storage requirements:

- Misuse of Drugs Safe Custody Regulations 1973

However, as this legislation is now 40 plus years old, the Home Office has also recently published guidance:

- Security guidance for all existing or prospective Home Office Controlled Drug Licensees and/or Precursor Chemical Licensees or Registrants':

Measures to strengthen governance arrangements for controlled drugs were introduced as a result of recommendations made by the Shipman Inquiry in 2001. The Controlled Drugs (Supervision of Management and Use) Regulations 2006 were introduced following the Shipman Inquiry and came into force in England on 1 January 2007. They were superseded by the Controlled Drugs (Supervision of Management and Use) Regulations 2013, which came into force on 1 April 2013 to reflect the changes in the NHS:

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

There is also Information about the Regulations available from the Department of Health:

- Controlled Drugs (Supervision of management and use) Regulations 2013: Information about the Regulations