

Good Practice Guidance C: Safe management of controlled drugs in Care Homes

Adapted from the CQC Guidance on the safe management of controlled drugs in care homes – QMP Document No 001-08 which has now been withdrawn.

Key Points

- The purpose of legislation is to impose control on controlled drug (CD) manufacture, prescribing, supply, possession and record keeping.
- The impact for care homes is that they require special arrangements for storage, administration, records and disposal of CDs.
- Specifications of cabinets and safes set out in the Safe Custody Regulations should be regarded as a minimum standard for the storage of CDs, in all care homes (with and without nursing), for all residents' CDs that are held in a central location within the care home.
- Safeguards are essential when any prescribed medicine is given to a resident by care home staff.
- Care homes should have a safe procedure for giving controlled drugs that will minimise the potential for a drug error.
- This should include a witness to the controlled drug administration who also signs the CD register when practicable. **However no one should be deprived of prescribed medicine because there is only one member of staff on duty when he or she needs it.**
- It is also important to ensure that the care home retains a record of all controlled drug administration, especially when the community nurse completes a record that is not left in the care home.
- The CD register should also include the balance of CDs remaining, which can be compared with the quantity in the CD cupboard.
- All discrepancies, incidents and errors should be reported immediately to the registered manager who should investigate promptly.
- If controlled drugs are missing, or there is a controlled drugs error, this is a serious incident and the care home must also notify the Oxfordshire CCG Accountable Officer.

Why are some medicines defined as ‘controlled drugs’?

Controlled drugs (CD) are prescribed medicines used to treat severe pain, induce anaesthesia or treat drug dependence. However some people abuse them by taking them when there is no clinical reason to do so or divert them for other purposes. For these reasons, there are legislative controls for some drugs and these are set out in the Misuse of Drugs Act 1971 and related regulations.

Different controlled drugs cause dependence or misuse in varying degrees. They are classed according to the extent of harm they may cause when misused and they are also listed in different schedules (1-5) according to the legal requirements concerning prescribing, storage and record keeping (refer to Appendix for further details).

The purpose of legislation is to impose control on CD manufacture, prescribing, supply, possession and record keeping. The impact on care homes is that they require special arrangements for storage, administration, records and disposal.

The Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007 include changes that will affect care homes. These include:

- Secure storage of controlled drugs in care homes
- Midazolam re-classified from schedule 4 to schedule 3
- Accountable Officers in primary care trusts will specify who can witness the destruction of stock supplies of controlled drugs (care homes with nursing only).

What do the regulations say?

[The Care Quality Commission document: Guidelines about compliance; essential standards of quality and safety](#) gives guidance on what providers should do to comply with regulations of the Health and Social Care Act 2008.

Regulation 13 states that the registered resident must protect service users against the risks associated with the unsafe use and management of medicines, by means of the making of appropriate arrangements for the obtaining, recording, handling, using, safe keeping, dispensing, safe administration and disposal of medicines used for the purposes of the regulated activity.

The guidance makes it clear that providers who comply with the regulations will:

- Handle medicines safely, securely and appropriately.
- Ensure that medicines are prescribed and given by people safely.
- Follow published guidance about how to use medicines safely.

This applies to all medicines, including controlled drugs.

The guidance also states that there should be clear procedures that are followed in practice, monitored and reviewed, for controlled drugs including:

- investigations about adverse events, incidents, errors and near misses
- sharing concerns about mishandling.

There should also be systems in place to ensure that providers comply with the requirements of the Medicines Act 1968 and the Misuse of Drugs Act 1971, and their associated regulations, the Safer Management of Controlled Drugs Regulations 2006, relevant health technical memoranda and professional guidance from the Royal Pharmaceutical Society and other relevant professional bodies and agencies.

How should controlled drugs in a care home be stored?

Specifications of cabinets and safes set out in the Safe Custody Regulations should be regarded as a minimum standard for the storage of CDs, in all care homes (with and without nursing), for all residents' CDs that are held in a central location within the care home. CD cupboards should meet British Standard BS2881:1989 security level 1.

The Safe Custody Regulations specify the quality, construction, method of fixing and lock and key for the cupboard. In brief, the requirements for CD storage are:

- CDs should be stored in a cabinet or safe, locked with a key or digital lock
- The cabinet or safe 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
- The walls of the room should be constructed to be suitable thickness using suitable materials

It is also important to ensure:

- The security of the location also needs careful consideration.
- For safe practice the CD cupboards should only be used for the storage of CDs. Items of value such as jewellery or money should not be placed here.
- Only those with authorised access should hold keys to the CD cupboard.

Suppliers of CD cabinets can confirm that a cupboard meets the legal requirements and it is recommended that care homes request formal confirmation when purchasing a CD cabinet.

It is a commonly held belief that a CD cupboard must be a 'cupboard within a cupboard' but this is not the case.

What safeguards must be in place when care home staff give controlled drugs to residents?

Safeguards are essential when any prescribed medicine is given by care home staff, including:

- Respecting the resident's choice and preference, particularly when these relate to ethnic or religious observance.
- Recognising the resident's right to refuse treatment.
- A robust system to make sure there is always an adequate supply of prescribed controlled drugs but that controlled drugs are not stockpiled.
- A safe procedure for giving controlled drugs that will minimise the potential for a drug error. This should include a witness to the controlled drug administration who also signs the CD register when practicable. **However no one should be deprived of prescribed medicine because there is only one member of staff on duty when he or she needs it.**
- Providing training for care home staff who are designated to give controlled drugs and also to those who will act as a 'witness'.
- Keeping full records of what has been given, when and by whom.

When administering controlled drugs to a resident;

- In care homes with nursing, administration should be by a registered nurse unless the resident self administers his or her medicines.
- In care homes without nursing, unless the resident is self administering, administration should be by care workers who have been trained and designated to do so.
- Administration should be witnessed by another trained and designated member of staff.
- Administration should be in full accordance with the prescriber's instructions.

The use of a witness is intended to reduce the possibility of an error occurring. To be effective, the witness must understand what the care home member of staff is doing and therefore needs the same level of training. The witness will confirm that:

- The care home staff member selects the correct controlled drug.
- The name on the label attached to the controlled drug is the same as the resident the care home staff member intends to give it to.
- The care home staff member has prepared the right dose, included on the label and in the MAR chart.
- The care home staff member gives it to the right resident – both the resident giving the controlled drug and the 'witness' should watch the resident taking their medication.
- The administration is recorded in the CD register as well as signed on the MAR chart.
- The remaining balance in the CD cupboard should be checked against the CD register balance and then initialled by both the nurse/ carer and the witness.

For the majority of care homes, the only controlled drugs that care home staff members will be responsible for will be prescribed for named people. They belong to the named resident, not the care home. It is therefore important for care home staff to treat controlled drugs as valuables that the resident owns.

In care homes (without nursing), any controlled drugs given by injection are the responsibility of community nurses. If a resident is likely to require an injected medicine it is important that the care home without nursing notifies the community nurses as soon as possible so a visit can be arranged, the care home should ensure the controlled drug is available for the community nurse to administer.

Can care homes keep a stock of controlled drugs?

Care homes without nursing cannot purchase and keep stocks of prescription only medicines, including controlled drugs.

The Medicines Act 1968 does permit a care home with nursing to purchase and use stocks of controlled drugs so long as they have a domestic licence issued by the Home Office or are mainly maintained by charitable funds. As care homes become involved in 'End of Life' care they may apply to the Home Office for a domestic licence. Details of how to make the application can be found on the [Home Office website](#). It is advised that any care home with nursing considering holding a stock of CDs discusses this with the local Medicines Management Team first.

The main difference for the care home with nursing that holds stock supplies is that the disposal of stock controlled drugs must be witnessed by an 'authorised resident'. The Accountable Officer at Oxfordshire CCG will advise who can do so locally.

Recording controlled drugs

It is also important to ensure that the care home retains a record of all controlled drug administration, especially when the community nurse completes a record that is not left in the care home. If the community nurse is not willing to make a duplicate record in the home's CD register, it will be important for the witness to complete this record.

It is important that care homes ensure:

- The Controlled Drugs Register (CDR) is a bound book with numbered pages.
- The CDR (see below) should have a column for recording running balances in order to maintain effective control and identify any discrepancies.
- The CD register should include the balance that remains and it is good practice to check stocks regularly e.g. weekly.

- The CDR should be used to record the receipt, administration and disposal of CDs held in the care home.
- Controlled drugs must be entered into the controlled drugs register as soon as they are received into the home.
- 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 resident as a witness. The correct balance should be verified each time.
- 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.
- A record must be made in the CD register of every dose administered to a care home resident. It is good practice for a second appropriately trained member of staff to witness the administration of controlled drugs and both staff should sign the CD register after the dose has been administered.
- 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 without nursing) or through a licensed waste management company (care homes with nursing)
- No alterations or crossings out may be made in the CD register. Any corrections must be made by marginal note or footnote and signed and dated.
- When stock is transferred to another setting, returned to the pharmacy or disposed of via a waste management company this must be recorded in the register and the balance recalculated correctly. Zero balances should be recorded. A record should be made of who returned them, the quantity and the date in **BOTH** the controlled drugs register and the returns book.

What are the issues when residents look after and take their own medicines?

Residents can keep and take controlled drugs themselves. For self-administration, the process of risk assessment is important; the care home staff should assess whether the resident understands:

- why they are taking the medicine
- how much and how often to take it
- what may happen if they miss a dose of the medicine

The resident should be re-assessed regularly to ensure they are able to continue to self administer. See 'Good Practice Guidance G: Self medication in Care Homes' for further details.

Precautions are important to make sure that controlled drugs are not stolen from the resident. Care homes do not need a CD cupboard in each bedroom but a lockable non-portable cupboard or drawer is essential. Through monitoring and review of the risk factors, the care home should regularly identify and document that controlled drugs are not left lying around where they could be taken by someone else.

If the resident does not arrange the supply and collection of their controlled drugs but relies on the care home staff to do so, there should be clear records including:

- receipt from the pharmacy,
- supply to the resident
- any subsequent disposal of unwanted controlled drugs.

These records should be made in the CD register.

The situation may arise when a resident chooses to use illicit drugs as distinct from prescribed controlled drugs. The care home is responsible for deciding how to deal with illicit use of drugs on the care home premises.

Discrepancies, Incidents and Errors

Controlled drugs are a target for theft and it is good practice to regularly check them. The CD register should include the balance of controlled drugs that remain, which can be compared with the quantity in the CD cupboard. All discrepancies, incidents and errors should be reported immediately to the registered manager who should investigate promptly.

If a discrepancy is noted, the care home should also have clear procedures for handling discrepancies including a process to investigate and establish what has happened, for example, has a care home staff member forgotten to complete the record.

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

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

If controlled drugs are missing, this is a serious incident and the care home must also notify the OCCG Accountable Officer, Geoff Payne on: geoffrey.payne@nhs.net or by phone on 01865 336 709. It may also be necessary to contact the police to discuss how to deal with the situation.

The care home should also have clear procedures for handling incidents and errors. If an error occurs when a controlled drug is given, this may have serious consequences for the resident involved. The care home staff should first of all contact the resident's doctor for advice.

Examples of drug errors include:

- wrong dose, too much or too little given
- given at the wrong time, e.g. a tablet that should be given every 12 hours is given every 4 hours.
- given to the wrong resident.

Care home staff are also required to notify the Accountable Officer (AO) on the above details of any controlled drug errors. The AO will want to know what happened, how the incident/error has been rectified and what is to be put in place to stop such an incident happening again. Documented information will be required by the AO for discrepancies, incidents and errors.

What are the statutory requirements around reporting medication errors?

From 1 October 2010, all adult social care must notify the Care Quality Commission (CQC) under the Health and Social Care Act 2008 about specific incidents. The law requires these notifications to be submitted within certain timescales – further guidance is available on what should be reported, how and in what timescales via the CQC guidance on [Statutory Notifications](#).

The notification must be made in writing and the CQC provide template forms to simplify the notification process. Further information and guidance is available on the ['Notifications'](#) section of CQC's website. Also refer to 'Good Practice Guidance H: The handling of medication errors, incidents and near misses in Care Homes' for further information.

Disposal of Controlled Drugs

It is important that controlled drugs are disposed of appropriately. When a *resident's own* controlled drugs are no longer required they should be disposed of safely and a record kept of who returned them, the quantity and date. A witness to this transaction is good practice. For care homes without

nursing they can be returned to the supplier. Care homes with nursing should use a company with a waste management licence.

For *stock* controlled drugs in nursing homes see 'Can care homes keep a stock of controlled drugs?' above.

Whilst *resident's own* controlled drugs remain the residents property, if a resident dies their controlled drugs should not be returned to their family but should be disposed of as above as the resident's family are legally not allowed to possess them.

What other information should be shared with the Oxfordshire CCG Accountable Officer?

Local areas have to have in place local intelligence networks (LIN) which look specifically at the management of controlled drugs. The LIN comprises representatives from health and social care, police and anti-fraud officers and regulators such as CQC and the Royal Pharmaceutical Society. Currently within Oxfordshire the LIN covers the Oxfordshire area.

As well as the above controlled drugs incidents care homes should notify the Accountable Officer of any other controlled drug concerns they are aware of. Examples include:

- Poor practice by healthcare professionals that the care home does not employ directly. This information may be essential to the NHS primary care organisation that contracts with the healthcare professional concerned.
- Poor clinical practice by a healthcare professional.
- A healthcare professional insists on removing unwanted controlled drugs from a care home.
- Concern about the practice of a registered nurse from a Nurses Agency who may additionally work in other care homes and/or NHS hospitals.

Further Information

- Further information on managing medicines in care homes is available in Outcome 9 of the [CQC Essential Standards of Quality and Safety](#)
- Further information on Notification of Other Incidents in care homes is available in Outcome 20 of the [CQC Essential Standards of Quality and Safety](#)
- Further information on [The handling of medicines in Social Care](#) can also be found on the Royal Pharmaceutical Society website: www.rpharms.com

- The Care Quality Commission have a section on controlled drugs which can be accessed via their website;
<http://www.cqc.org.uk/guidanceforallhealthcarestaff/managingrisk/controlleddrugs.cfm>
- National Prescribing Centre; [A guide to good practice in the management of controlled drugs in primary care \(England\)](#). Third Edition (December 2009)
- Other National Prescribing Centre via their website;
http://www.npc.nhs.uk/controlled_drugs/
- The Nursing and Midwifery Council (NMC) provides guidance and [advice on a number of topics](#) which is available on their website;
www.nmc-uk.org
- The Department of Health have a number of documents on controlled drugs such as;
 - [Safer Management of Controlled Drugs \(CDs\): Changes to Record Keeping Requirements Guidance \(For England only\)](#);
 - [Safer Management of Controlled Drugs:\(1\) Guidance On Strengthened Governance Arrangements](#)
 - [The Controlled Drugs \(Supervision of Management and Use\) Regulations 2006](#)
 - [Safer Management of Controlled Drugs: Guidance On Standard Operating Procedures For Controlled Drugs](#)Further information can be accessed via their website; www.dh.gov.uk
- The National Patient Safety Agency also contains safety alerts related to medicines; <http://npsa.nhs.uk/> including alerts on;
 - [Opioid medicines](#)
 - [Midazolam](#)
 - [Injectable medicines](#)
 - [Oral \(liquid\) medicines](#)
 - [Safer ambulatory syringe drivers](#)

The above links are made available solely to indicate their potential usefulness to users. The user must use their own judgment to determine the accuracy and relevance of the information they contain.

Oxfordshire CHUMS Working Group & Medicines Management Team

Appendix: Common Controlled Drugs and legal requirements for care homes.

Please note this list is not exhaustive and so advice should always be sought if care home staff are unsure of the schedule of a controlled drug

Schedule 2:

CD	Brand names	Legal Requirements
Morphine	Sevredol	<ul style="list-style-type: none"> • Store in a CD cupboard • Record in the CD register. <p>* Oramorph oral solution 10mg/5ml is not a controlled drug. However, CD storage and CD records are a good practice recommendation.</p>
	Oramorph Concentrated oral solution 100mg/5ml*	
	Morphgesic	
	Zomorph	
	MST	
Diamorphine		
Oxycodone	OxyContin, OxyNorm	
Fentanyl	Durogesic	
Pethidine		
Methylphenidate	Ritalin	
Dexamphetamine	Dexedrine	

Schedule 3:

CD	Brand names	Legal Requirements
Buprenorphine	Temgesic (tablets)	<ul style="list-style-type: none"> • Buprenorphine, and Temazepam must be stored in a CD cupboard. • Other listed schedule 3 controlled drugs do not need CD storage. • None of the controlled drugs in this schedule need to be recorded in the CD register but this is a good practice recommendation. <p>** Epistatus is not a licensed medicine.</p>
Temazepam		
Midazolam	Epistatus ** Hypnovel,	
Phenobarbitone		

Schedule 4:

CD	Brand names	Legal Requirements
Diazepam	Valium	<ul style="list-style-type: none">• No legal requirements for the care home
Zolpidem		