

Good Practice Guidance:

The safe management of controlled drugs in care homes



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Purpose of this document

1. This document gives a guide to the special arrangements that should be made when controlled drugs are prescribed for people in care homes.
2. It covers:
 - why are some medicines defined as 'controlled drugs'
 - fundamental standards and CQC guidance
 - what is important when people look after and take their own controlled drugs
 - what safeguards must be in place when care workers give controlled drugs to people
 - what the requirements for controlled drug storage in care homes are
 - what are CD registers
 - what local intelligence networks (LIN) are

Why are some medicines defined as 'controlled drugs'?

3. Some prescription medicines are prone to being misused so they have stricter legal controls on their supply to prevent them being obtained illegally. They are controlled under the Misuse of Drugs Act 1971 and are known as 'controlled drugs' or CDs.
4. Controlled drugs are divided into five schedules* (1-5) depending on their potential for abuse if misused. The schedule a CD is in determines the requirements for safe custody and recording. Care homes need to be particularly aware of schedule 2 & 3 CDs. (See Appendix for some examples of controlled drugs and how these should be managed in a care home.)

Fundamental standards and CQC guidance

5. The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 detail the fundamental standards which service providers must meet.
6. The fundamental standard "Safe Care and Treatment" (Regulation 12) includes the requirement that providers must ensure '*the proper and safe management of medicines.*' However, all the standards must be applied to all aspects of care including the administration of medication.
7. CQC "Guidance for providers on meeting the regulations" states that '*policies and procedures must be in line with current legislation and guidance.*'
8. Further information on how to meet the fundamental standards can be found in the CQC document *Guidance for providers on meeting the regulations.*

*Schedule 1 controlled drugs have a high potential for abuse and are not used medically. Possession and supply is prohibited except under a Home Office license, for example, to carry out research. They are unlikely therefore to be legitimately present in a care home.

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

9. People can keep and take controlled drugs themselves. For self-administration the process of risk assessment is important, not the legal classification of the medicine.
10. Sensible precautions are important to make sure that controlled drugs are not stolen from the person. Care providers **do not** need a CD cupboard in each bedroom but a lockable cupboard or drawer is essential. The person must agree to keep the medication safe and locked away when not in use and not leave it lying around where it could be taken by someone else. The arrangements must be monitored and reviewed on a regular basis.
11. There is no need to keep a record in the CD register when the person is wholly independent. That is, he or she is responsible for requesting a prescription and collecting the controlled drugs personally from the pharmacy.
12. But if the person does not arrange the supply and collection of controlled drugs and relies on the care workers to do so, there should be clear records including:
 - receipt from the pharmacy,
 - supply to the person
 - any subsequent disposal of unwanted controlled drugs.These records should be made in the CD register.
13. The situation may arise when a resident chooses to use illicit drugs as distinct from prescribed controlled drugs. The care provider is responsible for deciding how to deal with illicit use of drugs on the care home premises.

What safeguards must be in place when care workers give controlled drugs to people?

14. Safeguards are essential when any prescribed medicine is given by care workers, including:
 - Respecting the person's choice and preference, and recognising the person's right to refuse treatment.
 - A robust system to make sure there is always an adequate supply of prescribed controlled drugs.
 - 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. But no one should be deprived of a prescribed medicine because there is only one member of staff on duty when he or she needs it.
 - Providing training for care workers 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.

15. 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 worker is doing and therefore needs the same level of training. The witness will confirm that:
- the care worker selects the correct controlled drug
 - the name on the label attached to the controlled drug is the same as the person the care worker intends to give it to
 - the care worker has prepared the right dose, included on the label and on the MAR chart
 - the care worker gives it to the right person

Both the member of staff administering the CD and the witness should sign the CD register. Only the member of staff administering the CD should sign the MAR chart.

16. In care homes (personal care), any controlled drugs given by injection are the responsibility of community nurses. When a community nurse is involved in the administration of controlled drugs in care homes they should be asked to complete both the CD register and the MAR chart and a trained and competent member of staff from the home should witness the administration and sign the CD register.
17. For the majority of care homes, the only controlled drugs that care workers will be responsible for will be prescribed for named people. They belong to the named person, not the care service. It is therefore important for care workers to treat controlled drugs as valuables that the person owns.
18. Controlled drugs are a target for theft and it is good practice to regularly check them. The CD register should include the balance that remains, which can be compared with the quantity in the CD cupboard. If a discrepancy is noted, the care provider should have a process to investigate and establish what has happened. For example, has a care worker forgotten to complete the record or have the controlled drugs been stolen. If controlled drugs are missing, this is a serious incident and it may be necessary to contact the police to discuss how to deal with the situation. If the police are involved this should be reported to CQC.
19. If an error occurs when a controlled drug is given, this may have serious consequences for the person involved. The care worker should first of all contact the person's doctor (or out of hours service, if necessary) 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 person

CQC should be notified as required by the Care Quality Commission (Registration) Regulations 2009 (as amended).

What are the requirements for controlled drug storage in care homes.

20. The Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007 included changes which mean that all care homes are now required to comply with the CD safe custody arrangements. All schedule 2 CDs and some schedule 3 CDs must be stored in a CD cabinet.

This guidance is based on documents that were previously issued by CQC (now withdrawn). Where necessary it has been updated in line with changes to the Regulations and the latest available guidance. Providers should use this advice in conjunction with NICE guidelines 'Managing medicines in care homes' 2014 and 'The Handling of Medicines in Social Care' (RPSGB 2007) and the latest CQC guidance.

21. The CD cabinet must comply with the requirements laid out in the Misuse of Drugs (Safe Custody) Regulations, including being fixed securely to a solid wall or floor with rawl or rag bolts.

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

22. Legal requirements for storage may appear to have little or no impact on the care given to people. What it does achieve is a greater deterrent against diversion and theft.
23. It is a commonly held belief that a CD cupboard must be a 'cupboard within a cupboard'. This is not the case. Stand-alone cupboards that comply with the legislation are available.

What are CD registers?

24. A CD register is separate record of the receipt, administration, transfer or disposal of controlled drugs. It is kept **in addition** to the MAR chart or other records at the home. A record should be kept in a CD register for all CDs in schedule 2. It is good practice to also keep a register for **any** CD stored in the CD cabinet. (See Appendix for further information.)
25. The register should either be a bound book with numbered pages or an electronic register which complies with the current guidance. Homes wishing to use an electronic CD register should seek further information before doing so.
26. The name, form and strength of each CD should be recorded at the top of the page along with the person's name. A separate page is required for each form and strength of each CD for each individual person.
27. The following details should be recorded on the correct page in the register
 - **Receipt:** On the day of receipt: record the date of receipt, where the medication was received from, the quantity received and the signature of the member of staff receiving the medication. Update the running balance.
 - **Administration:** Record the time and date of administration, the dose administered, the signature of the person administering the medication and the signature of the member of staff witnessing the administration. Update the running balance.
 - **Disposal:** Record the date of disposal, the quantity disposed of, how the medication was disposed of, reason for disposal, the signature of the member of staff arranging the disposal and the signature of a second member of staff witnessing the disposal. Update the running balance.
 - **Transfers:** Record the date of transfer, the quantity transferred, who (or where) the medication was transferred to, the signature of the member of staff arranging the transfer and the signature of a second member of staff witnessing the transfer. Update the running balance.

Disposal of CDs

28. Care homes without nursing should return all medicines (including CDs) to the pharmacy for safe disposal. Records should be kept in the home's usual record of returned medication **and** in the CD register if the medication is recorded there.

29. Care homes with nursing should denature the CDs using a recognised CD denaturing kit before consigning to a licensed waste company. (Some pharmacies are also willing to take back medication from nursing homes. The home must ensure that the pharmacy has appropriate arrangements in place.) The home must have a T28 exemption from the Environment Agency in place for this activity. The home must keep a copy of the waste transfer note, make a record in their usual record of disposed of medication **and** the CD register if the medication is recorded there.

What are local intelligence networks?

30. CQC is responsible for regulating the handling of controlled drugs in registered care homes. And when necessary they will use enforcement. CQC also collaborates at a local level with the NHS, police and other named authorities to share information when controlled drugs are not handled correctly. This is the local intelligence network (LIN).
31. The LIN comprises of representatives from regulators such as CQC and the General Pharmaceutical Council, police and anti-fraud officers, and other bodies as determined by the Controlled Drug Accountable Officer at the NHS England Local Area Team.
32. The LIN works to identify problems and support improvements in the management of CDs.
33. Where local arrangements are in place, the home should notify the Controlled Drug Accountable Officer at NHS England of incidents involving controlled drugs in care homes, including errors, concerns about a healthcare professional or receipt of an incorrect controlled drug or quantity from the pharmacy or dispensing GP.

What demonstrates good practice?

- Are there special arrangements for storage, administration, recording and disposal of controlled drugs?
- Do care workers know which prescribed medicines are controlled drugs?
- Are quantities of controlled drugs for individual people the same as the balance recorded in the register?
- Does the care provider investigate any discrepancies?

The advice in this document relates to controlled drugs which are dispensed and labelled for an individual. If a nursing home has stocks of controlled drugs, please contact the Medicines Management Social Care Support Team for further advice

Examples of controlled drugs and the requirements for storage and recording for care homes

Schedule 2:

CD	Examples of Brand names	Requirements
Morphine	MST Continus	<ul style="list-style-type: none"> • Store in a CD cupboard • Record in the CD register <p>* Morphine Sulphate 10mg/5ml oral solution (Oramorph) is not a schedule 2 controlled drug. However, CD storage and CD records are a good practice recommendation</p>
	Sevredol	
	Morphgesic SR	
	Oramorph Concentrated oral solution 100mg/5ml *	
	MXL	
	Zomorph	
Oxycodone	OxyNorm	
	OxyContin	
Diamorphine		
Methadone	Physeptone	
Methylphenidate	Ritalin	
	Concerta XL	
Fentanyl	Durogesic	

Schedule 3:

CD	Examples of Brand names	Requirements
Buprenorphine	Temgesic (tablets)	<p>Buprenorphine and temazepam must be stored in a CD cupboard. It is a good practice recommendation that buprenorphine and temazepam should be recorded in the CD register.</p> <p>There is no legal requirement to store these medicines in a CD cabinet or record them in the CD register.</p> <p>** Epistatus is not a licensed medicine.</p>
	BuTrans (patches)	
Temazepam		
Midazolam	Hypnovel, Buccolam Epistatus **	
Tramadol	Zydol, Zamadol	
Pentazocine	Fortral	
Phenobarbitone		

Schedule 4:

CD	Examples of Brand names	Requirements
Diazepam	Valium	<p>There are no requirements to store in the CD cabinet or to record these medicines in the CD register.</p>
Zolpidem	Stilnoct	
Zopiclone	Zimovane	
Lorazepam	Ativan	
Nitrazepam	Mogadon	

This list is not exhaustive. The advice of the pharmacist should be sought where necessary.