

# Good Practice Guidance for Care Homes: Controlled Drugs (CDs) in care homes

## Introduction

The Misuse of Drugs Act 1971 places controls on certain medicines called 'controlled drugs' (CDs). The Misuse of Drugs Regulations 2001 split CDs into five schedules which correspond to their therapeutic usefulness and misuse potential.

Each schedule specifies the requirements for activities such as import, export, production, supply, possession, prescribing, and record keeping which apply to them.

The Home Office has produced a [list of the most commonly prescribed controlled drugs](#).

All CDs in care homes must be prescribed for individual patients by an appropriately qualified healthcare professional and dispensed by a pharmacy or dispensing practice.

Care homes with nursing may hold stocks of CDs for residents nearing the end of their lives.

Nursing homes may need a Home Office [controlled drugs license](#) to hold stock.

Residential homes **cannot** hold stocks of CDs. They may only hold CDs prescribed and dispensed for an individual person.

## Controlled drug policy

All care homes should have a policy which explains how CDs are managed within the care home. This should be included in the Medicines Policy. All processes relating to CDs should be covered:

- to ensure regulatory requirements are met, including ordering, storing, administering, recording and disposal of controlled drugs
- what to do if there is a discrepancy and contact details of anyone you need to inform, including details of the NHS Controlled Drugs Accountable Officer (CDAO) at NHS England
- procedures in place for identifying, reporting and reviewing incidents, errors and near misses involving CDs and sharing concerns about mishandling of CDs.

## Record keeping: Controlled Drugs Register (CDR)

CDs are subject to register requirements, dependent on their schedule (see appendix 3 for examples of these). The controlled drugs register (CDR) must only be written in and signed by suitably trained and authorised members of staff.

- The CDR must be a bound book, with numbered pages and used only for the purpose of recording the receipt, administration and destruction of CDs.
- All entries in the CDR must be made in ink or indelible ball point pen.
- Two authorised members of staff, suitably trained and competent with CDs should be involved and sign for CDs when making entries into the CDR and:
  - receiving
  - transferring
  - checking suitability
  - administering
  - disposing/ returning for destruction.
- A running balance should be kept and checked at every entry.

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References:

- Controlled drugs in care homes  
<https://www.cqc.org.uk/guidance-providers/adult-social-care/storing-controlled-drugs-care-homes>
- The Misuse of Drugs (Safe Custody) Regulations 1973  
[www.legislation.gov.uk/uksi/1973/798/made](http://www.legislation.gov.uk/uksi/1973/798/made)
- NICE guideline 46: Controlled drugs safe use and management  
[Recommendations | Controlled drugs: safe use and management | Guidance | NICE](#)
- RPS Professional guidance on the safe and secure handling of medicines  
[Professional guidance on the safe and secure handling of medicines \(rpharms.com\)](http://www.rpharms.com/professional-guidance-on-the-safe-and-secure-handling-of-medicines)

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# Appendix 1

## Controlled Drugs: Receipt, administration, and disposal in care homes

### Receiving Controlled Drugs

There must be a clear process for the safe handling of controlled drugs (CDs) when they are being delivered to the care home. CDs should be delivered separate to the main delivery of medicines and the package must be clearly marked that it contains a CD.

Care home staff must ensure that the CD delivery is:

- in a separate package on delivery and clearly marked
- checked, signed for and witnessed by two staff members who are trained and competent
- entered into the CD register immediately
- the correct balance confirmed every time
- discrepancies dealt with as per your Medicines Policy.

### Administration of Controlled Drugs

Administration of the CD should be documented on the medicines administration record (MAR) chart and recorded in the Controlled Drug Register (CDR).

When administering a controlled drug:

- the resident's MAR chart must be signed by the member of staff who administered the medication; it is good practice for this to be countersigned by the staff member who witnessed the resident being given the medication (both members of staff must be trained and competent in administering CDs)
- the care home staff responsible for administering the CD and an appropriately trained witness must sign the CDR
- if the medication has been administered by a visiting healthcare professional e.g. District Nurse, the care home staff must ensure that they get that visitor to sign the appropriate part of the CDR. The visiting healthcare professional will have their own record of administration but evidence of this should be noted on the MAR chart and/ or in the resident's care plan
- records must be completed after the CD has been administered and not before
- if administering transdermal (topical) CDs e.g. [patches](#), administration records should include the site of application and the frequency of rotation of the site.  
Body maps incorporating a record of the dates of application and removal of CD patches can help with their safe and effective management.

If the CD is transferred out of the care home, e.g. when the resident is away from the home for a short period of time or is transferred to another care home, a record should be made in the CD register and witnessed by a second trained member of staff.

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## Disposal of Controlled Drugs

Store unwanted or expired CDs awaiting disposal separate from those in use. Store them in line with your medicines policy.

### **Care homes without nursing**

- CDs should be promptly returned to the community pharmacy for destruction.
- CDs to be returned to the community pharmacy must be entered out of the CDR and signed by a trained and competent staff member returning the CD.
- A signing sheet or returns book should record the forms and quantities of the CDs being returned.
- The community pharmacy should sign for the CDs on receipt; this record should be retained by the care home.
- If pharmacy staff collects the CDs from the care home, they should sign for them in the CD register at the time of collection.

### **Care homes with nursing**

- CDs must be denatured before handing to the waste disposal company.
- The care home must have a valid T28 Exemption from the Environment Agency to allow denaturing to take place on the premises.  
[Register or renew waste exemptions \(England\) - GOV.UK \(www.gov.uk\)](https://www.gov.uk/register-or-renew-waste-exemptions)
- You can obtain a T28 Exemption:
  - Online: [www.wasteexemptions.service.gov.uk](https://www.wasteexemptions.service.gov.uk)
  - Email: [enquiries@environment-agency.gov.uk](mailto:enquiries@environment-agency.gov.uk)
  - Phone: 03708 506 506
- CDs should be denatured using a specially designed denaturing kit. CDs should be denatured by a registered nurse in the presence of an authorised witness for destruction before being handed to the waste disposal company. For more detailed information about denaturing refer to guidance within [B75. Care homes - Controlled drugs \(prescqipp.info\)](#)
- Details of the denaturing must be recorded in the CDR. The entry in the CDR should be signed and witnessed by both the registered nurse and the authorised witness undertaking the task.

### References:

- NICE SC1: Managing medicines in care homes  
[Overview | Managing medicines in care homes | Guidance | NICE](#)
- PrescQipp: Guidelines on the management of controlled drugs (CD) in care homes  
[B75. Care homes - Controlled drugs \(prescqipp.info\)](#)
- Controlled drugs in care homes  
<https://www.cqc.org.uk/guidance-providers/adult-social-care/storing-controlled-drugs-care-homes>
- The Misuse of Drugs (Safe Custody) Regulations 1973  
[www.legislation.gov.uk/ukxi/1973/798/made](http://www.legislation.gov.uk/ukxi/1973/798/made)
- NICE guideline 46: Controlled drugs safe use and management  
[Recommendations | Controlled drugs: safe use and management | Guidance | NICE](#)
- CQC: External medicines such as creams and patches  
[External medicines such as creams and patches | Care Quality Commission \(cqc.org.uk\)](https://www.cqc.org.uk/guidance-providers/adult-social-care/external-medicines)
- RPS Professional guidance on the safe and secure handling of medicines  
[Professional guidance on the safe and secure handling of medicines \(rpharms.com\)](https://www.rpharms.com/professional-guidance-on-the-safe-and-secure-handling-of-medicines)

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## Appendix 2

# Controlled Drugs: Storage in care homes

Care homes must comply with the Misuse of Drugs Act 1971 and associated regulations for storing controlled drugs (CDs). A dedicated cupboard in a suitable location should be used to store CDs.

### Controlled drug cupboards

The CD cupboard must 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. The walls of the room containing the controlled drugs cupboard should be of a suitable thickness and made of a suitable material, for example bricks.

The CD cupboard must be:

- securely fixed to a wall with bolts that are not accessible from outside the cupboard
- fitted with a robust lock
- made of metal with strong hinges.
- only used to store CDs, with the exception of 'Just in Case' (JIC) medications. If space allows, the box containing all of that resident's JIC medications may be kept in the CD cupboard.

The CD cupboard:

- must have access restricted according to need
- keys should be under the control of a designated person
- should have a list of the persons allowed to be in possession of the keys
- keys should have a clear audit trail of holders of the key
- must have spare keys stored securely
- can be fixed to an internal wall if it is secure
- does not need to be stored within another cupboard.

If you use a safe to store CDs, the CDs should be stored in a separate container within it. You must be able to show how the safe complies with the Safe Custody Regulations.

CDs requiring storage in a fridge can be stored in the locked medicines' fridge with other medications needing refrigeration.

There are no medicines' fridges available that meet the Misuse of Drugs Safe Custody Regulations. CDs must be stored separately within the fridge, such as in a separate lockable box.

If a resident has a monitored dosage system (MDS) containing a CD which requires safe custody, the MDS should be stored in a CD safe or cabinet.

If a resident self-administers their medication and a MDS is in use, this must be stored in a locked, non-portable cabinet or drawer in the resident's room.

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References:

- Controlled drugs in care homes  
<https://www.cqc.org.uk/guidance-providers/adult-social-care/storing-controlled-drugs-care-homes>
- CQC: Controlled drugs governance self-assessment tool for primary care organizations  
[Controlled drugs accountable officers | Care Quality Commission \(cqc.org.uk\)](#)
- The Misuse of Drugs (Safe Custody) Regulations 1973  
[www.legislation.gov.uk/ukxi/1973/798/made](http://www.legislation.gov.uk/ukxi/1973/798/made)
- NICE guideline 46: Controlled drugs safe use and management  
[Recommendations | Controlled drugs: safe use and management | Guidance | NICE](#)
- RPS Professional guidance on the safe and secure handling of medicines  
[Professional guidance on the safe and secure handling of medicines \(rpharms.com\)](#)

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## Appendix 3: Controlled Drugs Schedules



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### Schedule 2 Requirements

- You must store schedule 2 controlled drugs (CDs) in a CD cupboard.
- Keep records of these CDs in your controlled drugs register (CDR).
- Common examples include morphine, diamorphine, methadone, fentanyl, alfentanil, oxycodone, methylphenidate, dexamphetamine, ketamine and tapentadol.

Schedule 2 CDs		
Controlled drug	Brand names	Requirements
Alfentanil	Rapifen®	<p>Safe custody is required in a controlled drug cupboard.</p> <p>Records need to be made in the controlled drug register.</p>
Diamorphine	-	
Dexamphetamine	Amfexa®	
Fentanyl	Actiq® Durogesic DTrans® Fencino® Matrifen® Mezolar® Victanyl® Yemex®	
Methadone	Physeptone®	
Methylphenidate	Concerta® Delmosart® Equasym® Matoride® Medikinet® Ritalin® Xaggitin® Xenidate®	
Morphine	Morphgesic SR® MST Continus® MXL® Oramorph® concentrated solution 100mg/5ml Sevredol® Zomorph®	
Oxycodone	Longtec® Oxyact® Oxycontin® OxyNorm® Shortec®	
Pethidine	-	
Tapentadol	Palexia®	

The above list is not exhaustive.

If you receive anything not stated on this list and you are unsure what the legal requirements are then you should contact your community pharmacy or GP (list up to date as of July 2021).

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### Schedule 3 Requirements

- You do not need to record schedule 3 CDs in the CDR. Some care homes may choose to do so, which is good practice and is encouraged.
- You must store certain schedule 3 CDs** in the controlled drugs cupboard. This includes buprenorphine and temazepam.
- There are other schedule 3 CDs which you do not need to store in the controlled drugs cupboard. Refer to table below for requirements.

Schedule 3 CDs		
Controlled drug	Brand names	Requirements
Buprenorphine	<b>Tablets:</b> Subutex® Temgesic®	Safe custody is required in a controlled drug cupboard. There are some exceptions to this, usually exempt are: - Gabapentin - Midazolam - Phenobarbital - Pregabalin - Tramadol  Records do not need to be made in the controlled drug register. Care homes may choose to make records for Buprenorphine and Temazepam.
	<b>Patches:</b> Bupeaze® Butec® BuTrans® Reletrans® Transtec®	
Gabapentin	Neurontin®	
Pregabalin	Alzain® Axalid® Lyrica®	
Midazolam	<b>Injection:</b> Hypnovel®	
	<b>Oromucosal solution:</b> Buccolam®	
Phenobarbital	-	
Temazepam	-	
Tramadol	Marol® Maxitrom® Zamadol® Zydol®	

The above list is not exhaustive.

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## Other schedules

- You do not need to store certain schedule 4 and 5 medicines in the CD cupboard.
- You do not need to record them in the CDR. Some services may choose to do so. Oramorph® oral solution 10mg/5ml is not a schedule 2 CD. It is good practice to store it in a CD cabinet and complete CD records
- Although record keeping requirements are not required for schedule 4 part1 CDs, records **must** be kept for 2 years for cannabis-based medicines e.g. Sativex®

Schedule 4 CDs		
Controlled drug	Brand names	Requirements
Cannabis extract	Sativex®	Records need to be made in the controlled drug register.
Chlordiazepoxide	Librium®	Safe custody is not required.  Records do not need to be made in the controlled drug register.
Clobazam	Frisium®	
Clonazepam	-	
Diazepam	Stesolid® (rectal solution)	
Lorazepam	Ativan® (injection)	
Nitrazepam	Mogadon®	
Zopiclone	Zimovane LS® Zimovane®	
Zolpidem	Stilnoct®	

The above list is not exhaustive.

If you receive anything not stated on this list and you are unsure what the legal requirements are then you should contact your community pharmacy or GP (list up to date as of July 2021).

## References

- PrescQipp: Guidelines on the management of controlled drugs (CD) in care homes  
[B75. Care homes - Controlled drugs \(prescqipp.info\)](https://www.prescqipp.info/)
- Controlled drugs in care homes  
<https://www.cqc.org.uk/guidance-providers/adult-social-care/storing-controlled-drugs-care-homes>
- The Misuse of Drugs (Safe Custody) Regulations 1973  
[www.legislation.gov.uk/ukxi/1973/798/made](http://www.legislation.gov.uk/ukxi/1973/798/made)
- NICE guideline 46: Controlled drugs safe use and management  
[Recommendations | Controlled drugs: safe use and management | Guidance | NICE](https://www.nice.org.uk/guidance/ng46)
- Home Office Circular 006/2013: Scheduling of Sativex  
[Circular 006/2013: Scheduling of Sativex - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/262423/Circular_006_2013_Scheduling_of_Sativex.pdf)

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# Appendix 4

## Controlled Drugs: Discrepancies and incidents

### Introduction

All care homes must have a policy or standard operating procedure which details how controlled drugs (CDs) are managed within the care home.

This should include:

- what to do if there is a discrepancy, error, incident or near miss
- how discrepancies and incidents are reviewed
- learning arising from discrepancies, errors, incidents and near misses.

All incidents involving CDs (including balance discrepancies) must be reported in a timely manner to:

- the care home manager
- the Care Quality Commission (CQC) and
- the local NHS England Accountable Officer for Controlled Drugs at [NHS England CD reporting](#).

The name(s) and contact details of who you need to inform should be clearly stated in the policy. This includes the NHS Controlled Drugs Accountable Officer (CDAO) at NHS England. CQC holds a register of Controlled Drugs Accountable Officers.

Errors made in the controlled drug register (CDR) must **never** be crossed out.

If an error is made, complete the following actions:

- Incorrect entries should be put in brackets with:
  - a note made at the bottom of the page with the phrase '*entered in error*', or
  - '*entered in error*' can be written on a new line below the incorrect entry
- The incorrect entry should be signed, witnessed, and dated.
- The correct entry should be made using a new line.

### Discrepancies- Supply

If a discrepancy is identified between what is expected and the supply received then the following guidance is provided:

- Enter the stock received into the CDR; enter what was received, not what was requested.
- Store the incorrect CD stock received separately in the CD cabinet until the discrepancy can be resolved.
- Contact the supplier of the CD to resolve the discrepancy.
- Arrange for the supplier to collect the incorrect CD.
- When the incorrect CD supply is collected by the supplier:
  - obtain a signed receipt, and
  - make an entry in the CDR to record this.

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### Discrepancies – Unfit for use

If the CD received is deemed 'unfit for use' the following guidance is provided:

- Enter the stock received into the CDR.
- Store the 'unfit for use' CD separately in a bag marked 'damaged or unfit for use' in the CD cabinet until it can be removed.
- Contact the supplier of the 'unfit for use' CD to explain the issue.
- Arrange for the supplier to collect the 'unfit for use' CD.
- When the 'unfit for use' CD is collected by the supplier:
  - obtain a signed receipt, and
  - make an entry in the CDR to record this.

### Discrepancies –Running balance

If a discrepancy is identified between calculated stock figures (running balances) and actual stock the following guidance is provided:

- Check back through the entries in the CDR to ensure that there has not been an administrative error such as a missed or incorrect entry or a calculation error.
- Check MAR charts and records of disposed medicines.

**If the discrepancy can be identified** record the outcome; make any amendments to the CD register with a signed and dated entry at the bottom of the relevant page including reference to any supporting documentation that was used to resolve the discrepancy.

**DO NOT** cancel, cross out or through, obliterate and/ or alter any entry in the CD register.

**If the discrepancy cannot be explained** then the CQC, the Controlled Drugs Accountable Officer and the police should be informed.

### Medication errors, incidents and near misses involving CDs

Refer to Good Practice Guidance: Handling of medication errors, incidents and near misses in care homes

### References:

- PrescQIPP Guidelines on the management of controlled drugs (CD) in care homes  
[B75. Care homes - Controlled drugs \(prescqipp.info\)](https://www.prescqipp.info/B75_Care_homes_-_Controlled_drugs)
- CQC: Register of Controlled Drug Accountable Officers  
[Controlled drugs accountable officers | Care Quality Commission \(cqc.org.uk\)](https://www.cqc.org.uk/controlled-drugs-accountable-officers)
- Controlled Drug (CD) Reporting  
[Home of CD Reporting](https://www.cqc.org.uk/controlled-drugs-accountable-officers)

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