NHS
Kent and Medway
Clinical Commissioning Group

Kent and Medway CCG

Controlled Drug Management Best Practice Guidance

Best Practice Guidance

Approved by: KMMOC, Clinical Cabinet
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Legal Requirements

Care Quality Commission (CQC) Regulation 12: Safe Care and Treatment includes the requirement that providers must ensure 'the proper and safe management of medicines'. Care home providers should have systems in place that ensure compliance with current controlled drug legislation such as the requirements of the Misuse of Drugs Act 1971 and their associated regulations as well as current guidance.

What is a controlled drug?

A controlled drug is a prescription medication that is prone to being misused, which can lead to dependence and harm. Therefore extra safety measures are put in place ensure legal supply, use and storage.

Dependant on their level of potential abuse and misuse, controlled drugs are categorised into schedules. There are 5 schedules of controlled drugs, each schedule determines the requirements needed for supply, storage and record keeping. See appendix 1 for common controlled drugs and their legal requirements.

A risk assessment should be carried out to ascertain if schedule 3, 4 and 5 medications should be handled in the same way as schedule 2 CDs.

Key points

- There must be a controlled drug policy in place within the care home. This policy must cover in detail all processes related to controlled drugs.
- The supply, receipt, storage, administration and disposal of controlled drugs must meet regulatory standards.
- Procedures must be in place to identify, investigate and report incidents involving controlled drugs.

Receipt

- To allow for an audit trail, CDs should be signed for on receipt.
- The receipt of a CD should be recorded in the CD register. This should include the date, time, amount received and the running balance, which should be signed for by the member of staff receiving the medication as well as a witness signature.
- It is good practice for a member of the care home staff when collecting a CD (in person) from the pharmacy or dispensing doctor, to be asked to sign for the CD and for proof of identity.
- The pharmacy or dispensing doctor may provide paperwork which lists the contents of the delivery and thus allows for an audit trail.
- CDs must be checked on receipt against paperwork received. Where possible this check should be completed with a witness. The check should include:
    - Fit for purpose (e.g. ampoules not broken)
    - Drug name (Brand name and generic)

    - Formulation
    - Strength
    - Quantity
    - Expiry date
- There should be a written procedure in place to follow should there be any discrepancy between the product and the label, or what was ordered and the CD received.

Transfer of care

When a resident transfers into the care home, an appropriately trained and competent member of staff should complete an accurate list of the medications the resident is currently taking (see medicines reconciliation best practice guidance for further details).

If it is identified that the resident is on a controlled drug the same checks as listed above should be completed. As well as recording the name, formulation, strength, dose, frequency and timings, how the medication is taken, what the medication is for and the quantity received. The following should also be recorded:

- Date, time and amount taken of the last 'when required' dose taken
- If a patch is used – the number of patches being used (occasionally more than one patch is applied to meet the required dose), where the patch is, when it was applied and when it needs to be changed.

The controlled drugs should then be entered into the CD register, recording date, time and amount received. This entry should be signed by the member of staff carrying out the task and a witness.

If the resident is safe to administer their medications themselves including CDs (following a risk assessment) then these do not need to be entered into the CD register, instead they should be stored appropriately in the resident's room. See below for more information.

Storage

Providers of care homes must comply with the Misuse of Drugs Act 1971 and associated regulations when storing CDs.

- The CD safe or cabinet must comply with the requirements specified in the Safe Custody Regulations, see http://www.legislation.gov.uk/uksi/1973/798/made
- Assurance should be sought from the vendor or manufacturer that the storage unit specifications comply with the requirements
- If a CD is supplied in a monitored dosage system (MDS) the MDS should be stored in the CD cabinet.
- The CD cupboard should be used for the storage of CDs only. No other medications or belongings should be stored within the CD cupboard.
- The CD cupboard keys should be kept under the control of a designated person and there should be a clear audit trail of the holders of the keys.

- Keys should be on a separate bunch to the rest of the care homes keys.
- Spare CD key(s) should be stored in a secure place, with limit access and ideally it should be able to be evident if the CD keys have been accessed. (For example in a sealed envelope, with the seal signed and dated by the manager and a senior carer and the envelope kept in the safe).
- **Self-administering residents CDs:** Should be kept securely within the resident's room, either in a locked cupboard or draw. A CD cupboard within the resident's room is not required. It must be agreed with the resident that they are to ensure the CD(s) are locked away when not in use.

Administration

It is good practice that an appropriately trained and competent member of staff witnesses the full administration process. This aims to minimise the potential risks of a drug error. However no resident should be deprived of receiving a CD due to there being only one member of staff on duty when the medication is required.

- **Care home with nursing:** A registered nurse should administer CDs within the home and witnessed by an appropriately trained and competent.
- **Care home without nursing:** An appropriately trained and competent member of staff should administer CDs and witnessed by another appropriately trained and competent member of staff.
- **By a visiting healthcare professional** (e.g. district nurses giving CD injections in residential homes):
    - If the CD is stored by the care home, appropriate records should be made in the CD register if it is then given to a visiting healthcare professional to administer. A second appropriately trained member of staff should witness the transfer.
    - The care home staff should ask visiting healthcare professionals to make their record of administration available to the care home. The healthcare professional should also consider seeing the resident in the presence of care home staff responsible for administering medicines to the resident. Any administrations should be documented in patient notes and MAR as appropriate.
    - Care home staff should keep a record of medicines administered by visiting health
      professionals on the resident's MAR. This can be annotated
      with "Administered by district nurse".

Destruction/Disposal

Any CDs awaiting destruction or collection for destruction should be separated from stock being used. E.g. placed in a basket within the CD cupboard and clearly labelled for destruction away from stock being used currently.

Care home WITH nursing

- Agreements for collection of waste medication should be made with a Waste Management Regulations licensed waste disposal company.
- CDs must be denatured before being handed to the waste disposal company, e.g. in specially designed denaturing kits.
- A T28 exemption will be needed in order to comply with the legislation that is overseen by the Environment Agency.

Care home WITHOUT nursing

- CDs should be returned to the relevant pharmacist or dispensing doctor at the earliest opportunity for appropriate destruction.

See appendix 2 for further guidance on destruction of CDs.

Documentation

CD Register

- CD register must be bound with numbered pages
- Each individual CD for each resident should be recorded on its own page and titled including: Name of resident who the CD belongs to, Name drug, strength and formulation. Any additional stock of the same medication for the same resident can continue to be recorded on the original page. Following a record of receipt of the medication.
- CD records must be kept for a minimum of 2 years from the last entry. However it is good practice to retain for longer.
- All entries should be made as soon as possible and in chronological order
- The register should be securely stored when not in use
- The CD register should not be used for any other purpose
- Index page should be used and kept up to date
- When transferring a balance to a new page or new CD register the amount remaining should be identified with ‘carried forward from page x (plus register xx if a new register)’ written clearly as the first entry on the new page
- Entries should not be cancelled, altered or crossed out. Corrections must be made using marginal notes or footnotes which are signed and dated.
- A running balance should be kept for each drug and updated each time an entry is made. This should include an actual stock count of the drug being entered in or out. To ensure any discrepancies or irregularities are identified as soon as possible.

Receipt

A record of receipt should be made in the CD register as soon as possible after the receipt of the CD. The entry should include:

- Date and time received
- Where the medication was received from
- Quantity received
- Signature of member of staff who received stock

- Signature of witness

Administration

A record of administration should be made in both the CD register and the MAR chart, immediately after administration by the staff member responsible for administering the CD. The appropriately trained and competent witness should also sign the CD register. The following should be recorded in the CD registers entry:

- Name of resident receiving the dose
- Date and time of the dose
- Dose administered
- Signature of person administering the dose
- Signature of person witnessing the administration process

If there is any remaining CD after administration (e.g. only half an ampoule was required) then the following should also be documented in the CD register:

- Amount destroyed
- Signature of person disposing of CD
- Signature of witness of the destruction of the CD

Transfer of care

If CD(s) are being transferred to another care setting or home with a resident then this should be recorded in the CD register. The following should be recorded:

- Time and date of transfer of the CD(s)
- Amount being transferred
- Signature of person transferring the CD(s)
- Signature of the witness to the transfer

Destruction/disposal

Care home WITH nursing

- Date and time of destruction
- Quantity destroyed
- Signature of person destroying the CD
- Signature of witness of the destruction

Care home WITHOUT nursing

- Date and time of collection by pharmacy or dispensing doctor (or representative for either)
- Amount being returned for destruction
- Signature of person handing over CD
- Signature of the recipient of the CD or a witness of the handover
- A signing sheet or returns book should be prepared, including the name, form, strength and quantity being collected.

Self-administration
If the resident is solely responsible for their CD including the ordering and receipt of them then no records are required to be made in care homes CD register.

If the care home order and receive the CD on behalf of the resident a record of receipt, supply and disposal should be recorded in the CD register.

Checks and audits

Stock checks should be done at least once a week, however the frequency should be based upon the controlled drug related incidents, and frequency of use and risk assessments. Stock checks should involve counting the actual balance against the recorded balance. This should then be recorded and signed in the CD register 'stock balance checked and correct', ideally having a second person witness and sign the register.

Discrepancies

There should be a procedure for dealing with discrepancies, incidents and errors related to CDs. These should be reported immediately to the care home manager. Steps should be taken to establish what happened.

Supply
- Always enter the stock received in to the CD register.
- Segregate the stock received in the CD cabinet until the discrepancy can be resolved.
- Contact the supplier of the CD to resolve the discrepancy.
- If stock is deemed unfit for use and is picked up by the supplier obtain a signed receipt.

Record Keeping
- Check back over the CD register entries to ensure that there has not been a bookkeeping or numerical error.
- Check the MAR chart and records of medicine disposal.
- If the discrepancy can be identified the outcome should be recorded and the CD register should be corrected with a retrospective entry referencing how the discrepancy was resolved.

Incident reporting
If a discrepancy cannot be explained then the Care Quality Commission (CQC), the Area Team Controlled Drugs Accountable Officer and the police should be informed. There is a legal requirement for Care Homes to report all CD related incidents in a timely manner to the local NHS England Accountable Officer for Controlled Drugs.

Please complete an incident form following the link to inform the local CD accountable officer: https://www.cdreporting.co.uk/

The CD Accountable Officer Team for Kent can be reached at

england.southeastcdao@nhs.net for support or to inform them of a serious/urgent incident. The above form should still be completed in these circumstances.

Although immediate concern upon discovery of a CD incident is for patient safety, and this takes priority, incidents should be reported as soon as possible thereafter. There should be robust processes in place to identify, report and review incidents, errors and near misses.

If there is a medication administration error involving a CD this should be reported in accordance with the care home policy (which should include informing the resident's GP) and local commissioning arrangements. It should also be reported to the CQC if the medication error met the notification criteria; as outlined in regulations 16, 17, 18, and 20 of the CQC Guidance for providers on meeting the regulations, see link below: http://www.cqc.org.uk/sites/default/files/20150210_guidance_for_providers_on_meeting_the_regulations_final_01.pdf

Acknowledgements and references

https://www.nice.org.uk/guidance/ng46/chapter/recommendations

https://www.prescqipp.info/umbraco/surface/authorisedmediasurface/index?url=%2fmedia%2f1172%2fb75-care-homes-controlled-drugs-23.pdf

https://www.cqc.org.uk/guidance-providers/adult-social-care/controlled-drugs-care-homes

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Royal Pharmaceutical Society, Medicines, Ethics and Practice. The professional guide for Pharmacists. Edition 38, July 2014.

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Appendix 1: **Common controlled drug examples and legal requirements**

This list is not exhaustive; advice should be sought by the care home from the pharmacy or dispensing doctor if unsure of the legal requirements for safe custody and recording of a CD.

Schedule 2			
Controlled Drug (CD)	**Example Brands**		**Legal Requirements**
Morphine Sulphate	MST Continus®	Sevredol®	• Store in a CD cupboard • Record in the CD register • 2 staff (trained and competent) involved in transactions • Prescription valid for 28 days ** **Morphine oral solution** (Oramorph®) **10mg/5ml** is not a schedule 2 controlled drug. However, CD storage and CD records are a good practice recommendation.
	Zomorph®	MXL®	
	Cyclimorph®		
	Oramorph® **Concentrated** oral solution **100mg/5ml****		
Oxycodone	Shortec®	Longtec®	
	OxyContin®	OxyNorm®	
Fentanyl	Durogesic®	Mezolar®	
	Matrifen®	Fencino®	
	Actiq Lozenges®		
Methadone	Physeptone®		
Dexamphetamine	Dexedrine®		
Methylphenidate	Ritalin®	Concerta®	
	Equasym®	Medikinet®	
Diamorphine			
Pethidine			
Schedule 3			
Controlled Drug (CD)	**Brand names**		**Legal Requirements**
Buprenorphine	Temgesic®	BuTrans®	Buprenorphine and Temazepam are required to be stored in a CD cupboard and as good practice care homes should record them in the CD register (usually 2 staff involved in transactions as above)
	Subutex ®	Transtec ®	
Temazepam			
Gabapentin	Neurontin®		Other Schedule 3 controlled drugs do not require CD storage or recorded in the CD register
Pregabalin	Alzain®	Axalid® Lyrica®	
Midazolam			
Tramadol			
Phenobarbital			
Schedule 4			
Controlled Drug (CD)	**Brand names**		**Legal Requirements**
Diazepam	Valium®		Schedule 4 controlled drugs do not require CD storage or recorded in the CD register
Zopiclone	Zimovane®		
Zaleplon	Sonata®		
Zolpidem	Stilnoct®		

Appendix 2: **Destruction of controlled drugs in care homes WITH nursing**

The CDs should be denatured before they are disposed of using specially designed denaturing kits. Instructions for denaturing the different dosage forms may be provided by the manufacturer of the denaturing kit. If this has not been provided, the Royal Pharmaceutical Society guidance on the methods of destruction/denaturing CDs meets the requirements of the Misuse of Drugs Regulations 2001 and the health and safety needs of people undertaking the role.

Dosage form	Method
Solid dosage forms, e.g. capsules and tablets	• Remove from packaging • Crush or grind the solid dose. A small amount of water may be used to minimise dust particles being released into the air. • Add to denaturing kit. Ensuring no whole tablet/capsule is retrievable. It may also be necessary for the person involved in the grinding or crushing to wear a suitable face mask for protection, suitable gloves and ensure that the area is well ventilated.
Liquid dosage forms	• Pour liquid into denaturing kit. • Bottle can be rinsed, labels removed or obliterated of confidential information and bottle placed in recycling bin
Ampoules or vials	Ampoule/vial containing liquid • Open and pour contents into denaturing kit Ampoule containing powder Wearing suitable protective gloves • Open and add water to dissolve powder • Pour resulting mixture into denaturing kit Ampoules and vials to be disposed of in a pharmaceutical sharps waste bin.
Patches	• Remove from packaging • Remove backing of the patch • Fold the patch in half so it sticks to itself • Place in denaturing kit if available (preferred) or pharmaceutical waste disposal bin