CM09 - Controlled Drugs Policy and Procedure

Review Date: 24/03/17 Policy Last Amended: 28/04/17

Next planned review in 12 months, or sooner as required.

Note: The full policy change history is available in your online management system.

<table>
<thead>
<tr>
<th>Business Impact:</th>
<th>Low</th>
<th>Medium</th>
<th>High</th>
<th>Critical</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

Changes are important, but urgent implementation is not required, incorporate into your existing workflow.

- Reason for this review: New Policy
- Were changes made? Yes
- Summary: Annual review and updated content. This content was previously part of the CM02 Medications Policy and Procedure.
- Relevant Legislation:
  - The Controlled Drugs (Supervision of Management and Use) Regulations 2013
  - Medical Act 1983
  - Medicines Act 1968
  - Misuse of Drugs Act 1971
  - The Misuse of Drugs (Safe Custody) Regulations 1973
  - The Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007
- Underpinning Knowledge - What have we used to ensure that the policy is current:
  - RPSGB, (2007), The Handling Medicines in Social Care. RPSGB
  - NICE, (2014), Guidelines - Managing Medicines in Care Homes. NICE
- Suggested action:
  - Notify relevant staff of changes to policy
  - Share key facts with professionals involved in the service
  - Share key facts with people involved in the service
  - Discuss in team meetings
  - Discuss in supervision sessions
  - Confirm relevant staff understand the content of the policy
1. Purpose

1.1 To ensure the safe use and disposal of controlled drugs (CDs), and storage and record keeping according to specific legal requirements.

1.2 To ensure compliance with the Overarching Medication Policy and Procedure (CM02) and Administration of Medicines Policy and Procedure (CM11). This policy should be read alongside all associated Medication policies and supports any local policies and procedures.

1.3 To support in meeting the following Key Lines of Enquiry:

<table>
<thead>
<tr>
<th>Key Question</th>
<th>Key Line of Enquiry (KLOE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAFE</td>
<td>S4: How are peoples medicines managed so that they receive them safely?</td>
</tr>
<tr>
<td>CARING</td>
<td>C4: How people are supported at the end of their life to have a comfortable, dignified and pain free death?</td>
</tr>
<tr>
<td>WELL-LED</td>
<td>W2: How does the service demonstrate good management and leadership?</td>
</tr>
<tr>
<td>WELL-LED</td>
<td>W3: How does the service deliver high quality care?</td>
</tr>
<tr>
<td>WELL-LED</td>
<td>W4: How does the service work in partnership with other agencies?</td>
</tr>
</tbody>
</table>

1.4 To meet the legal requirements of the regulated activities that is registered to provide:

- The Controlled Drugs (Supervision of Management and Use) Regulations 2013
- Medical Act 1983
- Medicines Act 1968
- Misuse of Drugs Act 1971
- The Misuse of Drugs (Safe Custody) Regulations 1973
- The Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007

2. Scope

2.1 The following roles may be affected by this policy:

- Registered Manager
- Nurse
- Care staff

2.2 The following Service Users may be affected by this policy:

- All service users

2.3 The following stakeholders may be affected by this policy:

- External health professionals
- Local Authority
- NHS
- Commissioners
3. Objectives

3.1 To ensure the supply, receipt, storage, administration and disposal of CDs meets all regulatory requirements.

3.2 To ensure that there are procedures in place for identifying, reporting and reviewing incidents, errors and near misses involving CDs as well as sharing concerns about mishandling of CDs.

4. Policy

4.1 will ensure that all staff are aware of and follow the policy and associated procedures relating to the safe and secure handling and storage of controlled drugs in accordance with legal, regulatory and good practice guidance specified by the Department of Health, the Care Quality Commission and the Royal Pharmaceutical Society. will ensure through the use of this policy and procedure that:

- Staff are clear on the standards that are expected of them in relation to the handling and storage of controlled drugs
- Staff and visitors are not put at risk as a result of the incorrect handling of controlled drug medicines
- All legislation and guidance is adhered to with respect to controlled drugs
- Risks associated with the incorrect handling and storage of controlled drugs are reduced to a minimum
- There are robust systems for storing, supplying, transporting, administering, recording and disposal of CDs safely
5. Procedure

5.1 Administration of Controlled Drugs

In addition to the procedures relating to the administration and recording of other medicines outlined in the Administration of Medicines Policy and Procedure (CM11) and Recording the Administration of Medication Policy and Procedure (CM12), the following procedures must be carried out when administering controlled drugs:

- The administration of a Controlled Drug must be witnessed by a second member of staff
- A care worker should only be asked to witness the administration of a Controlled Drug if there is no other senior member of the team available

5.2 Recording

For medicines that are controlled drugs, and subject to CD recording requirements, must keep a separate CD register, in addition to the record on the MAR chart.

5.3 An entry must be made in the home's Controlled Drugs Register, including:

- Date and time of administration
- Name of Service User
- Dose administered
- Signatures in full of staff member who has administered the medicines and the witness
- Remaining balance of stock should be checked on returning the stock to the cupboard

5.4 The CD Register:

- The CD register must be a bound book with numbered pages
- There must be a separate page for each form and strength of each controlled drug for each person
- An electronic register which complies with the current guidance may be kept. will seek advice before using an electronic CD register
- The CD register must be used to record the receipt, administration, transfer or disposal of CDs
- The CD register should be kept for two years from the last entry
- Good practice would be to keep the CD register for longer as cases can take several years to come to light or before they go to court

5.5 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. A running balance should be kept and updated
- **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

5.6 Recording and Self Managing Service Users

People can keep and take controlled drugs themselves. For self-managing, the process of risk assessment is important, not the legal classification of the medicine. The Support Worker should assess whether the person understands:

- Why the medicine is prescribed
CM09 - Controlled Drugs Policy and Procedure

How much and how often to take it
What may happen if he or she does not take the medicine or takes too much

Sensible precautions are important to make sure that controlled drugs are not stolen from the person. The home does not need a CD cupboard in each bedroom; however, a lockable cupboard or drawer is essential.

The risk assessment process places responsibility on the person who keeps the controlled drug. Through monitoring and review of the risk factors, the home should identify that controlled drugs are not left lying around where they could be taken by someone else. 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.

If the person does not arrange the supply and collection of controlled drugs but relies on the home 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.

5.7 Storage

- is 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
- 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; will request formal confirmation when purchasing a CD cabinet
- For safe practice, the controlled drug cupboards should only be used for the storage of controlled drugs
- Items such as jewellery or money should not be placed in the cabinet
- Only those with authorised access should hold keys to the controlled drug cupboard
- If medication is provided in a monitored dosage system (MDS), the MDS should be stored in the CD cabinet
- Local policies will need to be adhered to in relation to the storage of Buprenorphine and Temazepam. It is a good practice recommendation that buprenorphine and temazepam should be recorded in the CD register. 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

5.8 Disposal of CDs

- When Controlled Drugs have passed their expiry date, the need for prescription has ceased, or the Service User has died, the Controlled Drugs should be referred to the relevant pharmacist or dispensing doctor at the earliest opportunity for appropriate destruction
- Even when still in date, such drugs should not be reused for other Service Users
- The home should record the forms and quantities of Controlled Drugs they are returning, and the pharmacist/dispensing doctor should sign for them on receipt
- If pharmacy staff collects the Controlled Drugs they should sign for the receipt of them in the ‘register’ at the time of collection
- Relevant details of any such transfer for disposal should be entered into the ‘register’ and signed by the authorised member of staff, returning the drug
- Appropriate records should also show:
  - Date
  - Controlled drug name and strength
  - Number or volume of tablets, liquid or patches
  - Signature of authorised staff member
  - Signature of witness

Disposal of Transdermal Patches - Containing Fentanyl or BuTrans

- Used patches still contain controlled drugs
Unused CD patches should be returned to the pharmacy for safe disposal or if a registered nursing home then destroyed in-house by registered nurse following correct procedure.

In all cases wash hands thoroughly.

5.9 Disposal of CDs for 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, but 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 disposal of medication and the CD register if the medication is recorded there.

5.10 Booking Out Controlled Drugs

Appropriate entries MUST BE RECORDED in the home’s controlled drugs register. Records should indicate the date of discharge of the Service User and the details of the medicines the individual has taken out of the home.

- There should always be two authorised persons booking out the medicines.
- The controlled drugs for booking out should be checked and counted against the Service User’s MAR sheet and checked for quantity left against instructions on label on the medicines original container.
- The balance of controlled drugs being booked out must be recorded in the controlled drugs register and signed and dated by each authorised person.
- Service Users or their representative should sign to say that they have taken the medicines out of the home.
- Medicines for self-administering Service Users do not have to be booked out; this includes controlled drugs.
- Any discrepancies must be brought to the notice of the Registered Manager.

5.11 Dealing with Discrepancies

- Routine checks of all Controlled Drugs held, and the recorded running balances, should be carried out by two authorised members of staff, each month, and a record kept.
- Where a discrepancy is found, it should be reported immediately to the registered manager who must investigate immediately.
- If the discrepancy cannot be resolved the advice of the local pharmacist must be sought, and CQC informed.
- If the discrepancy is found to be an error of subtraction or addition in the calculation of stock balance, the following procedure must be followed:
  - Do not change the balance column or use correction fluid. Under the last entry, details of the following should be made:
    - The date
    - The error in subtraction/addition (indicated with an asterisk)
    - The correct balance
    - The signature of the member of staff and the witnessing member of staff.
- Where a dose is given but the administering staff member fails to complete the register at the time of administration, the following procedure must be followed:
  - Under the last entry, details of the following must be made:
    - The current days’ date
    - ‘Dose administered but not recorded at the time’ followed by the Service User details
    - The signature of the administering member of staff and that of a witness
    - The correct balance if neither of the above discrepancies can be identified.
- The pharmacist who is providing a service to the home should be contacted to establish whether there were any unrecorded returns of Controlled Drugs.
- If confirmed by the pharmacist, full details of such returns should be entered into the Controlled ‘register’ together with the signature of the person who returned the drugs and that of the pharmacist who received them.
- The correct date and the words ‘entered in retrospect’ should be added.
- If the reason for discrepancy cannot be found, and the Controlled Drugs appear to have gone missing, then all relevant people, including the police, should be notified.
6. Definitions

6.1 CD’s

Controlled Drugs

6.2 Schedule 2 and Schedule 3 Controlled Drugs

The Misuse of Drugs Regulations 2001 (and subsequent amendments) define the classes of person who are authorised to supply and possess controlled drugs while acting in their professional capacities and lay down the conditions under which these activities may be carried out.

In the regulations, drugs are divided into five schedules (this includes Schedule 2 and 3) each specifying the requirements governing such activities as import, export, production, supply, possession, prescribing, and record keeping which apply to them.

Key Facts - Professionals

Professionals providing this service should be aware of the following:

- CDs prescribed by medical practitioners must comply with specific legal requirements
- CDs supplied by the dispensing pharmacy must comply with specific legal requirements
- Providers should have a CD cabinet that 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

Key Facts - People affected by the service

People affected by this service should be aware of the following:

- Service Users may self-administer controlled drugs

Further Reading

There is no further reading for this policy, but we recommend the 'underpinning knowledge' section of the review sheet to increase your knowledge and understanding.

Outstanding Practice

To be outstanding in this policy area you could provide evidence that:

- There is evidence of working with the multi-disciplinary team to ensure Service User's needs and wishes are met
- Providers support Service Users who wish to be self-caring with medication and robust procedures are in place to manage any risks
- There is a training programme in place and competency is assessed with staff given the opportunity to develop their skills and knowledge