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| **Review Sheet** | |
| Last Reviewed Last Amended Next Planned Review in 12 months, or  06 Jun '19 06 Jun '19 sooner as required. | |
| Business impact | Changes are important, but urgent implementation is not required, incorporate into your existing workflow.  **MEDIUM IMPACT** |
| Reason for this review | Scheduled review |
| Were changes made? | Yes |
| Summary: | Annual review with content updated. Please note that the reference on this policy has changed as it was previously CM09. |
| Relevant legislation: | * The Controlled Drugs (Supervision of Management and Use) Regulations 2013 * Medical Act 1983 * Medicines Act 1968 * The Human Medicines Regulations 2012 * 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: | * Author: NICE, (2014), *Guideline - Managing Medicines in Care Homes*. [Online] Available from: <https://www.nice.org.uk/guidance/sc1>[Accessed: 6/6/2019] * Author: CQC, (2018), *The safer management of controlled drugs.*. [Online] Available from: [https://www.cqc.org.uk/publications/major-report/safer-management-controlled- drugs](https://www.cqc.org.uk/publications/major-report/safer-management-controlled-drugs) [Accessed: 6/6/2019] * Author: Royal Pharmaceutical Society, (2018), *Safe and secure handling of medicines.*. [Online] Available from: [https://www.rpharms.com/recognition/setting-professional- standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe- and-secure-handling-of-medicinessegregated](https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicinessegregated) [Accessed: 6/6/2019] |
| Suggested action: | * Read the policy |



**1. Purpose**

* 1. To ensure the safe use and disposal of controlled drugs (CDs), and storage and record keeping according to specific legal requirements.
  2. To ensure compliance with the **Administration of Medicines Policy and Procedure**. This policy should be read alongside all associated medication policies and supports any local policies and procedures.
  3. To support Holbeach Hospital & Nursing Home in meeting the following Key Lines of Enquiry:

# Key Question Key Lines of Enquiry

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| CARING | C3: How are people's privacy, dignity and independence respected and promoted? |
| SAFE | S4: How does the provider ensure the proper and safe use of medicines? |
| WELL-LED | W3: How are the people who use the service, the public and staff engaged and involved? |
| WELL-LED | W4: How does the service continuously learn, improve, innovate and ensure sustainability? |

* 1. To meet the legal requirements of the regulated activities that Holbeach Hospital & Nursing Home is registered to provide:
     + The Controlled Drugs (Supervision of Management and Use) Regulations 2013
     + Medical Act 1983
     + Medicines Act 1968
     + The Human Medicines Regulations 2012
     + 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**

* 1. The following roles may be affected by this policy:
     + Registered Manager
     + Nurse
     + Care staff
  2. The following Service Users may be affected by this policy:
     + Service Users
  3. The following stakeholders may be affected by this policy:
     + Commissioners
     + External health professionals
     + Local Authority
     + NHS



**3. Objectives**

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



**4. Policy**

* 1. Holbeach Hospital & Nursing Home 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. Holbeach Hospital & Nursing Home 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 are 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 disposing of CDs safely



**5. Procedure**

# 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** and **Recording the Administration of Medication Policy and Procedure**, 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 Senior Care Assistant should only be asked to witness the administration of a controlled drug if there is no other Nurse available

# Recording of Named Service Users' Controlled Drugs

For medicines that are controlled drugs, and subject to CD recording requirements, Holbeach Hospital & Nursing Home must keep a separate CD Register, in addition to the record on the MAR.

* 1. An entry must be made in the home's Controlled Drugs Register, including:
     + The date and time of administration
     + The name of Service User
     + The dose administered
     + The signatures in full of the staff member who has administered the medicines and the witness
     + The remaining balance of stock should be checked on returning the stock to the cupboard

# 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
    - 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

# 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 Nurse and witness 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 Nurse administering the medication and the signature of the Nurse witnessing the administration. Update the running balance
    - **Disposal**: Record the date of disposal, the quantity disposed of, how the medication was disposed of, the reason for disposal, the signature of the Nurse arranging the disposal and the signature of the Nurse 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 Nurse arranging the transfer and the signature of the Nurse witnessing the transfer. Update the running balance
  1. **All Controlled drugs are to be kept in the CD cupboard and dispensed by trained staff.**

# Storage

* + - Holbeach Hospital & Nursing Home 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 the specified bolts
    - Suppliers of CD cabinets can confirm that a cupboard meets the legal requirements; Holbeach Hospital & Nursing Home 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
    - Schedule 3 CDs e.g. buprenorphine, gabapentin, pregabalin, temazepam, tramadol do not need to be stored or registered as a schedule 2 controlled drug is. Morphine Sulphate 10mg/5ml oral solution (e.g. Oramorph) is not a Schedule 2 controlled drug. However, Morphine Sulphate 20mg/5ml oral solution (e.g. Oramorph) should be treated as a schedule 2 CD and stored and recorded as such.

# Disposal of Named Service Users' 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 denatured using a recognised CD denaturing kit before consigning to a licensed waste company.
    - Even when still in date, such drugs should not be reused for other Service Users
    - The home must have a T28 exemption from the Environment Agency in place for the denaturing of CDs on site
    - The home must keep a copy of the Waste Transfer Note and make a record in its usual record of 'disposed of' medication
    - Documentation of details of any such transfer for disposal should be retained as per policy.
    - Appropriate records should also show:
      * The date
      * The controlled drug name and strength
      * The number or volume of tablets, liquid or patches
      * The signature of the authorised staff member
      * The signature of the witness

# Disposal of Transdermal Patches Containing Fentanyl or BuTrans

* + - Used patches still contain controlled drugs
    - Unused CD patches should be destroyed in-house, as above, by a registered nurse following the correct procedure
    - In all cases wash hands thoroughly

# Booking Out Named Service User 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 Holbeach Hospital & Nursing 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 and checked for quantity left against instructions on the label on the medicine's 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
    - Any discrepancies must be brought to the notice of the Registered Manager

# 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 week, and recorded in the controlled book.
    - Where a discrepancy is found, it should be reported immediately to the Registered Manager who must investigate immediately
    - 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, on a new line should be written in red ERROR the correct balance and the signature of two nurses.
    - 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. Where the police have been involved, a notification will be made to the CQC



**6. Definitions**

# CDs

* + - Controlled Drugs

# 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
    - Staff must ensure that any administration or receipt of controlled drugs is logged in the controlled drug record at Holbeach Hospital & Nursing Home
    - 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 specified fixings
* CD audits that check stock and expiry dates are necessary and are evidenced within the audit tool.



**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 multidisciplinary team to ensure that Service Users' needs and wishes are met
    - Providers support Service Users who wish to be self-managing 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



**Forms**

Currently there is no form accompanied to this policy.