GUIDELINES TO SUPPORT THE HEALTH BOARD POLICY FOR THE MANAGEMENT OF CONTROLLED DRUGS IN ACUTE SETTINGS

This document may be made available in alternative formats and other languages, on request, as is reasonably practicable to do so.

Policy Owner: Medicines Policy Group

Approved by: Medicines Management Group

Issue Date: November 2015

Review Date:

Next Review Due: November 2018

Policy ID:
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Guidelines to support the Health Board Policy for the management of Controlled Drugs in Acute Settings.

Controlled Drugs

1. Purpose
To provide a governance framework for controlled drugs (CDs) medicines management in the Health Board.
Where the term ‘controlled drug’ (CD) is used in this document this refers to Schedule 2 and 3 CDs (unless specified otherwise).

2. Governance
An ‘accountable officer’ is required to oversee all CD governance issues in the Health Board. This is the chief pharmacist. If you have concerns or queries with the management of controlled drugs not covered within the scope of the policy you may initially contact the Pharmacy Manager for advice:
Singleton – 01792 205666, Ext 36069
Morriston – 01792 703118
Princess of Wales – 01656 752752, Ext 52828
Neath Port Talbot – 01639 862025
Cefn Coed – 01792 561155, Ext 36584
If you wish to contact the accountable officer for ABM directly, the Chief Pharmacist can be contacted on 01792 704068.
The controlled drugs policy and procedures describe who can prescribe CDs and any constraints in place. This reflects Department of Health (DH) guidance.
The controlled drugs policy and procedure describes the processes to be followed when administering controlled drugs to patients within the Health Board. Administration of CDs to patients on the wards, theatres, or in a clinical area must be recorded in that area’s controlled drugs register (CD register) and on the drug chart.
A separate pharmacy standard operating procedure (SOP) describes the dispensing process and standards for management of CDs by the pharmacy department.

3. Responsibilities
The responsibilities of staff with regard to controlled drugs are defined within the controlled drugs policy.
4. Ordering, collection and receipt of controlled drugs

Controlled stationary is used to order and register CDs in the Health Board. This is available from the pharmacy department. All schedule 2 and 3 CDs must be ordered in a CD order book.

The responsibility for ordering, receipt and storage of CDs is that of the most senior/qualified nurse/midwife/operating department practitioner (ODP) in charge of the ward/clinical area. The senior nurse/midwife/ODP in charge may delegate the task of ordering to another nurse/midwife/ODP but the legal responsibility still lies with the senior nurse/midwife/ODP in charge of the clinical area.

5. Controlled Drugs stock list

All clinical areas are required to maintain an agreed controlled drug stock list. This stock list will be discussed with the ward pharmacist.

Certain controlled drugs carry additional formulary or patient safety restrictions (e.g. based on National Patient Safety Agency alerts and local restrictions). Controlled drug stock lists will reflect this. Controlled drugs with additional restrictions include:

- Midazolam high strength ampoules
- Morphine and Diamorphine high strength ampoules (30mg strength or greater)

6. Collection of Controlled Drugs from pharmacy

For schedule 2 and 3 stock CDs’ and discharge prescriptions the controlled drug may be either collected from pharmacy by a member of ward/clinic staff, or collected/delivered by a pharmacy porter.

7. Collection from pharmacy by a member of ward/clinic staff

The person collecting the CDs should be a member of ward staff. They must produce a valid identification badge. The person collecting should record in the CD order book when collecting CDs the following for each controlled drug collected:

- Signature
- Printed name
- Date

On arrival at the ward/clinical area the staff member delivering should ask a member of the ward clinical area nursing staff to record the following on the appropriate line (4th line on pink copy “received by”) in the CD order book:

- Signature
8. **Collection and delivery by pharmacy porter**

The person collecting should record in the CD order book when collecting CDs the following for each controlled drug collected:

- Signature
- Printed name
- Date

When delivering CDs that are part of the stock order, at ward level the porter must ask a nurse/midwife/ODP for that ward area to receive the CDs. The staff member receiving should record the following on the appropriate line (4th line on pink copy “received by”) in the CD order book:

- Signature
- Printed name
- Date

The delivery process is not complete until the above step has been followed. CDs will not be left without a signature and printed name being recorded on the slip for each controlled drug.

When delivering CDs that are part of a discharge prescription a record must be completed by pharmacy staff that includes the name, formulation, quantity of the controlled drug being delivered and for which patient and ward. This record is returned to be kept in pharmacy.

9. **Receiving Controlled Drugs onto the ward / department**

Stock CDs received within a clinical area must immediately be signed into the ward/clinical area CD register by two qualified members of ward/clinical area staff (nurse/midwife/ODP) and locked in the CD cupboard.

**Note:** Midazolam is exempt from CD storage requirements and may be stored in a locked drugs cupboard along with other medicines.

CDs included as part of discharge medication do not need to be entered into the CD register provided they are not to be used on the ward and that discharge is imminent.
10. **Collecting dispensed prescriptions for Controlled Drugs**
For patients or their representative collecting any schedule 2 or 3 controlled drugs the pharmacy staff should seek suitable identification details and record the name of the person collecting and the form of ID provided.

11. **Storage of controlled drugs**
All schedule 2 controlled drugs and ketamine must be stored in the CD cupboard reserved solely for the storage of CDs according to BS 2881:1989. All schedule 3 controlled drugs must be stored in the CD cupboard with the exception of midazolam which may be stored in another locked drugs cupboard.

The lock of the CD cupboard should not be common to any other lock in the hospital. The controlled drug cupboard must be kept locked at all times.

Access must be limited to suitably qualified nurses/midwives/ODPs and pharmacists with the exception of operating theatres/radiology where agreed alternative arrangements are in place.

The key to the CD cupboard must be kept on the person of a registered nurse/midwife/ODP. However, the legal responsibility rests with the nurse or midwife in charge of the ward. No duplicate key should exist for controlled drugs cupboards in any clinical area.

12. **Checking of controlled drug stock balances**
Two registered practitioners must check CD stock balances at least daily.
A record indicating that this check has been carried out must be kept on a separate page in the back of the CDs register confirming the stock is correct. The entry must be dated and signed by two registered practitioners. Where an area is staffed by only one registrant, refer to the main CD policy for further details.

Pharmacists are responsible for six monthly checks of controlled drugs use, storage and appropriate documentation in the necessary registers.

13. **Patients’ own drugs (POD’s) that are Controlled Drugs.**
Patient own CDs **should not** be routinely used during the inpatient stay.
CD medication brought in by a patient are the patient’s property. These drugs should not be destroyed or taken away from the patient without the patient’s consent.
All controlled drugs, which a patient has brought into hospital, are the legal property of that patient. Where the drugs belongs to a patient who is taking them for reasons other than
addiction e.g. analgesia, sedation, it is advisable to return the drugs to the patient’s home with a reliable relative/carer. If this is not possible the drugs should be stored in the ward controlled drugs cupboard and an entry made in a designated section of the ward register. However, they must be returned / destroyed as detailed in this section of the guidelines.

Where possible patients own drugs should be stored on a separate shelf to ward stock controlled drugs. The following details should be recorded:

- Patient’s name
- Drug name, form and strength
- Total quantity
- Date brought into hospital

Each separate drug for each patient must be recorded on a separate page of the CD register. Those areas handling large quantities of patients own drug may consider using a separate CD register for the recording of patients own drugs. Routine controlled drugs checks must also be applied to patients own drugs.

When the patient is discharged the controlled drug should be returned to the patient if clinically appropriate. The drug should be signed out of the register by a registered nurse/midwife and witnessed by another suitably registered person. If the drug is not returned to the patient it should be returned to the pharmacy for destruction with the ward pharmacist.

14. **Return of Controlled Drugs from Wards/Departments**

Ward stocks of controlled drugs for destruction (e.g. Date expired/unable to be returned to pharmacy stock for re-issue – such as opened liquids) may be signed out of the ward controlled drugs register, countersigned by a pharmacist and the registered practitioner in charge of the ward at the time, and entered into another register in the pharmacy department.

**NB.** Individual doses that are prepared and not administered/fully administered should be destroyed on the ward/department in the presence of a second person (who could be a pharmacist, registered practitioner or doctor). This includes the remains of partly used vials which in the case of small volumes should be disposed of in a sharps bin. An entry of the destruction is to be made in the register with both parties witnessing the destruction.
15. Prescribing of Controlled Drugs

Inpatient

- Controlled Drugs must be prescribed in accordance with the Health Board policy for the prescribing of medicines as described in the Medicines Policy – (Policy on Prescribing, Supply, Ordering, Storage, Security, Administration and Disposal of Medicines).
- Controlled drugs for inpatients can be written up and administered from the inpatient medication chart without the need for full prescription requirements expected for an outpatient/discharge prescription.

Outpatient

- Outpatient Prescriptions for Controlled Drugs are valid for 28 days from either the date of prescribing or a “valid from” date specified by the prescriber on the prescription.
- Outpatient Prescriptions must contain all the required information in accordance with the Misuse of Drugs Regulations (as specified in the current BNF). Prescriptions with minor technical errors may be amended and recorded by the pharmacist (e.g. if one of the requirements for words and figures has not been included).
- Prescriptions must be on official Health Board prescription stationery and in indelible ink – carbon copies/faxes for out-patient or discharge medication for schedule 2 and 3 controlled drugs are not acceptable for dispensing.

16. Administration of Controlled Drugs

- Only persons deemed competent may administer controlled drugs to patients-
- There must be two members of staff involved in the administration of a controlled drug, one of whom must be a registered nurse (RN), midwife, doctor or ODP.
- The second person i.e. the checker can be a RN, ODP, doctor, pharmacist or radiographer, senior 1.
- Where a ward, department or clinical area is staffed by one registered practitioner it is permissible for a HCSW and Radiographers’ senior 1 to check controlled drugs with the registered practitioner. This must be only in exceptional circumstances and agreed before hand with the relevant senior nurse and relevant professional lead. There must be a supporting statement signed by the senior nurse, professional lead and senior pharmacist for the managed unit.
• HCSW and radiographers’ senior 1 are providing a second check to confirm that, with reference to the inpatient medication chart the following details are correct:
  – Drug name, dose, expiry date and batch number
  – Patient’s demographic details.
However ultimate responsibility for the administration remains with the registered practitioner.
This process is only acceptable when there has been prior authorisation from the directorate head of nursing and is supported by a locally agreed policy. Student Nurses are not permitted to administer controlled drugs as their role must remain observational only.

• **Controlled Drugs must not be administered if the prescription is unclear, illegible or ambiguous or there is any other reason for doubt (e.g. patient condition / response to previous doses).**

• It is important that controlled drugs are administered at the specified time and if not the reason must be documented. The reason for any doses drawn up but not then given should be documented in the controlled drug register.

• The stock balance in the CD record book must be checked against the quantity in the CD cupboard. These must be identical. Discrepancies must be reported to the line manager, investigated immediately and other parties contacted when necessary/if not resolved. A similar line management approach should be used should the CD cupboard keys go missing. Incident forms must be completed where appropriate.

• The CD must be prepared by a Registered Nurse/Midwife, ODP or doctor and checked by a second person deemed competent (as above) before administration.

• The person administering the drug must complete the entry in the CD record book and sign it **after** the drug has been administered.

• The second person must sign the CD book to confirm that the administration and appropriate disposal of excess / waste has been correctly carried out and recorded.

• The administration record on the prescription sheet must be signed at the same time.

• Each different drug and preparation (i.e. form, strength etc) must have a separate page in the CD record book. Therefore if a dose requires the use of 2 strengths of a preparation both pages of the controlled drug register must be completed. All entries must be made in ink.
• Controlled drugs ordered for ward stock can only be administered to patients on that ward and cannot be transferred to patients on another ward except in an emergency and when authorised by the duty manager in consultation with the on-call pharmacist.

17. Associated documents

The following policies may also be referred to in support of this guidance document:

1. Policy on Prescribing, Supply, Ordering, Storage, Security, Administration and Disposal of Medicines. ABMU Health Board
2. Controlled Drugs Policy. ABMU Health Board
3. Intravenous Medicines Policy. ABMU Health Board.
4. Non Medical Prescribing Policy. ABMU health Board
Abertawe Bro-Morgannwg University Local Health Board

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<td>Equality Statement on all Policies:*</td>
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<tr>
<td>Published</td>
<td>November 2015</td>
</tr>
<tr>
<td>Keywords to assist with searching *</td>
<td>CD; CDs; Controlled Drugs;</td>
</tr>
<tr>
<td>Last Review:</td>
<td>N/A</td>
</tr>
<tr>
<td>Next Review / Guideline Expiry:</td>
<td>November 2018</td>
</tr>
<tr>
<td>Name of Group or Committee *</td>
<td>Medicines Management Board</td>
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| Name & Signature of Lead Pharmacist* | Roger Williams  
Head of Pharmacy Acute Services |

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