

MERSEY CARE NHS TRUST – HOW WE MANAGE MEDICINES

**MM 19 Procedure for the Safe and Effective Management of CONTROLLED DRUGS for the Specialist Learning Disabilities Division (Forensic and High Support Services)**

*Medicines Management Services aim to ensure that*

- (i) Service users receive their medicines at times that they need them and in a safe way.*
- (ii) Information on medicines is available to staff, service users and their carers*

**KEY ISSUES**

**This sets out the procedure for the safe and effective management of Controlled Drugs for the forensic and high support services that were formerly operated by Calderstones Partnership NHS FT.**

Medicines Management Procedure – MM19  
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## **SUMMARY OF AMENDMENTS**

### **11 TRANSFER OF CONTROLLED DRUGS BETWEEN MENTAL HEALTH WARDS**

- 11.1 Controlled Drugs must NOT be transferred between wards or services. A supply of the Controlled Drug should be obtained from the Emergency Drug Cupboard or pharmacy service.
- 11.2 Controlled Drugs must not be supplied for administration to a patient on another ward except in an emergency or out of hours and then only as a SINGLE DOSE for a named patient.
- 11.3 It is NOT permitted to transfer ward stock CDs from one Ward/ Department's CD cupboard, and Ward CD Record Book, to another. This would be seen as the nurse supplying a stock of a CD and would therefore be illegal.
- 11.4 There must be no transfer of stocks between sites

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**SUBJECT:   Controlled Drugs**  
**(Forensic and High Support Services)**

**1.     PURPOSE**

- 1.1    The purpose of this procedure is to outline the statutory requirements with regards to the management of controlled drugs and how this will be operational with the Trust.
- 1.2    NHS Trusts have responsibility to ensure that systems are in place for the safe and effective management of controlled drugs and that these are working effectively (*Safer Management of Controlled Drugs: Guidance of Strengthening Governance Arrangements – DOH January 2007*).
- 1.3    Controlled drugs (CDs) are an essential part of modern clinical care. They are medicines used to treat a variety of clinical conditions to help:-
- Acute pain
  - Chronic pain
  - Palliative care
  - Drug dependence
  - Mental disorders
- 1.4    Controlled drugs (CDs) are subject to special legislative controls because there is the potential for them to be abused or diverted causing possible harm. In response to the case of Dr. Harold Shipman the Government has introduced strengthened measures to make sure Controlled Drugs are managed safely. These requirements provide the framework for the Trust's Controlled Drugs Procedure.
- 1.5    NHS Trusts are also required to have arrangements in place for the monitoring and management of controlled drugs by all Healthcare Professionals they employ or with whom they contract.
- 1.6    In addition to which NHS Trusts are required to appoint an Accountable Officer to monitor the use of controlled drugs within their organisation and to take appropriate action where necessary.

The Accountable Officer will be responsible for ensuring the safe and effective use and management of controlled drugs within the local organisation subject to their oversight (*see Appendix C*).

1.7 This procedure will be implemented by all members of Trust staff involved in the:

- Procurement
- Dispensing
- Prescribing
- Transportation
- Storage
- Administration
- Destruction

of controlled drugs within the Specialist Learning Disabilities Division of the Trust.

There is a requirement for Trust staff involved with any of the above functions to be practice familiar with the requirements of this procedure appropriate to their role.

1.8 The Care Quality Commission and the Commission for Social Care Inspection will assess the management of control drugs as part of their regular inspection (*Standards for Better Health 4d*).

## **2. ACCOUNTABILITY AND RESPONSIBILITY**

2.1 The Registered Nurse in charge of the ward is responsible for the safe and appropriate management of controlled drugs in that area. In addition each Registered Nurse is personally responsible and accountable for their actions in the management and safe keeping of controlled drugs.

2.2 The Registered Nurse in charge of the ward can delegate control of access to the controlled drug cupboard to another Registered Nurse. However, the legal responsibility remains with the Registered Nurse in charge of the ward. Whilst the task can be delegated the responsibility cannot.

## **3. PRESCRIBING CONTROLLED DRUGS**

3.1 The prescribing of any controlled drugs within the Trust will be undertaken only by the following medically qualified personnel, i.e.

- General Practitioner
- Trust employed Medical Officer
- Trust employed Registered Dentist

3.2 All controlled drug prescribing will be handwritten on the Medicine Administration Record in accordance with the Control of Medicines Procedure 24.1.

## **4. REQUISITIONING OF CONTROLLED DRUGS**

4.1 There are no controlled drugs held on ward areas as stock items.

4.2 Controlled drugs will be ordered using the NHS Controlled Drug Requisitioning Book (*Appendix B*).

The book is carbon copied and serial numbered and is considered secure stationery, which requires that this documentation is kept in a locked drawer/cupboard on the ward. Add service user/patient name and NHS Number to requisition order.

- 4.3 Where a controlled drug has been prescribed the Nurse in Charge will ensure that the ward's Registered Nurse specimen signature sheet is copied and forwarded to the Pharmacy at time of initial controlled drug order – only 1 controlled drug can be ordered per sheet.
- 4.4 The book will be taken to the Porter's Lodge before 1.30pm and handed to one of the Porters who will place it in a yellow bag and record its transport with the ELHT driver.
- 4.5 The prescription should be scanned to Medication Inbox with scan sheet stating 'REQ BOOK IN TRANSIT'.

## 5. TRANSPORTING AND RECEIPTING OF CONTROLLED DRUGS

5.1 Upon receipt at Pharmacy of the Controlled Drug Requisition, i.e.

- Scan copy of Medicine Chart
- Controlled Drug Requisition Book
- Specimen Signature Sheet for Ward

The Pharmacist will activate and issue the Controlled Drug Register and dispense the controlled drug.

5.2 When the controlled drugs are delivered to the ward they are handed to the Registered Nurse in charge of the ward who will confirm receipt by signing the Porter's book and checking the sealed bag. The Registered Nurse will then sign the receipt in the order book. Two Registered Nurses will be required to enter the controlled drug into the Controlled Drug Register and both Registered Nurses sign to ensure that the stock received reconciles with the last entry on the register (*which will be a Pharmacy entry and locked away as soon as the check is completed in the approved controlled drug cupboard*).

## 6. STORAGE

6.1 Ward controlled drug cupboards must conform to BS2881 or be otherwise approved by the Trust Pharmacist. All controlled drugs must be stored within the ward controlled drug cabinet. This includes some schedule 3 drugs, i.e. Temazepam and Buprenorphine.

Phenobarbital and Midazolam do **not** need to be stored in the controlled drug cabinet.

6.2 The controlled drugs will be kept separate from all other medicines and only stored in the controlled drug cabinet.

6.3 The key to the controlled drug cupboard can only be held by "authorised persons" in Mersey Care NHS Foundation Trust. "Authorised persons" are only Registered Nurses. See trust-wide Policy SD12 Handling of Medicines

## 7. KEY HOLDING AND ACCESS TO CONTROLLED DRUGS

- 7.1 The Registered Nurse in charge of the ward is responsible for the controlled drug key.
- The controlled drug key will be returned to the Registered Nurse in charge immediately after use by another Registered Nurse.
- 7.2 The controlled drug key will be kept on the person of a Registered Nurse at all times, i.e. not stored in key cupboard.
- 7.3 The controlled drug key when in use will be identified by a red key tag labelled "Controlled Drug Keys".
- 7.4 The Registered Nurse in charge of the ward will sign the 24 Hour Report Book identifying themselves as the "Controlled Drug Keyholder".
- 7.5 Where a ward does not have a Registered Nurse in charge the Clinical Lead will hold the key and sign the 24 Hour Report Book accordingly.

## 8. RECORD KEEPING

- 8.1 It is the responsibility of the Registered Nurse in charge of the ward to ensure that the controlled drug stock is reconciled at the **beginning and end of each shift handover.**

**NB: It is not necessary to physically measure liquid medicines as these will only be dispensed in small quantities no more than 100mls in a bottle. However, there is a requirement that Registered Nurses make a visual check of the bottle to make a reasonable estimate if the amount looks correct.**

- 8.2 All administrations and reconciliations will be undertaken by a Registered Nurse and witnessed by a Registered Nurse with both nurses opening the Controlled Drugs Register.
- 8.3 All entries made by Registered Nurse in the Controlled Drug Ledger will be in black ink.
- 8.4 All entries will be in chronological order and made at the time the Registered Nurse undertakes the controlled drug task.
- 8.5 If a mistake is made there must be no correction made to the mistake, the mistake should be bracketed and annotated 'entered in error', initialled and dated.
- 8.6 On reaching the end of a page in the Controlled Drug Register the balance will be transferred to a new page – the new page number will be added to the bottom of the duplicated page and the index updated where more than 1 controlled drug is in use. This process will be undertaken by a Registered Nurse and witnessed by a Registered Nurse.

8.7 The Registered Nurse upon receiving a controlled drug must ensure that the following information is completed on receipt of the Controlled Drugs Register:-

- Date of entry
- Serial number of requisition
- Quantity received in numbers
  - Form (*name, formulation and strength*) in which controlled drug received.
- Name/signature of Registered Nurse making entry.
- Name/signature of Registered Nurse witnessing procedure.

Balance upon stock reconciliation.

8.8 After every administration from the controlled drug stock, the stock balance of an individual preparation must be confirmed to be correct and balance recorded in controlled drug reconciliation column.

## 9. ADMINISTRATION

9.1 The administration of a controlled drug will only be undertaken from a prescription written on the Medicine Administration Record which has been prescribed by a:-

- General Practitioner
- Trust employed Medical Officer
- Trust employed Dentist

Unless the controlled drug is administered by a Medical Officer or Dentist, 2 Registered Nurses employed by the Trust will administer controlled drug and are required to be present during the whole administration procedure. This includes:-

- The preparation of the controlled drugs to be administered.
  - The controlled drugs being administered to the service user/patient.
- The record keeping.
  - The destruction/disposal of any surplus controlled drugs (see *Section 10*).

9.2 The two Registered Nurses administering the controlled drug will ensure that a record is made of the controlled drug administration, details to be included are:-

- Completion of the MAR in accordance with Control of Medicines Procedure 24.1.
- Completion of the Controlled Drugs Register:-

- Time and date of dose administered.
- Name of service user/patient.
- Quantity administered.
- Name formulation and strength which is administered.
- Name/signature of Registered Nurse administering the controlled drug.
- Name/signature of Registered Nurse witnessing the administration of the controlled drug.

**NB: If part of an ampoule is administered to a service user/patient the Registered Nurses will record the amount administered and the amount wasted.**

e.g. If the service user/patient is prescribed 2.5mg of Diamorphine and only a 5mg ampoule is available the record will show:-

*"2.5mg administered"*

*"2.5mg wasted"*

These will be documented as separate entries on the Controlled Drug Ledger ensuring that compliance with Completion of the Controlled Drugs Register (see Section 8).

- 9.3 Individual doses of controlled drugs that have been prepared but not administered will be destroyed by the Registered Nurse in the presence of a witness and recorded in the Controlled Drugs Register (see Section 10 Disposal and Destruction).
- 9.4 A comprehensive record of the controlled drug administration will also be made in the clinical notes and 24 Hour Report.

## **10. DESTRUCTION/DISPOSAL**

- 10.1 Only small amounts of controlled drugs will be destroyed on the ward, e.g. the surplus when a dose smaller than the total quantity in the ampoule is drawn up then a dose is drawn up, or when a dose is drawn up and not used. The controlled drug should be rendered irretrievable by emptying into a sharps bin together with the emptied ampoule or vial. When the sharps bin is sent for destruction it should be labelled "contains mixed pharmaceutical waste and sharps – for incineration". All destruction must be documented in the appropriate section in the controlled drug register. The name of the service user/patient together with what is destroyed should be recorded. Destruction and entries in the register must be witnessed by a second Registered Nurse.
- 10.2 No controlled drug tablets will be placed in the sharps bin. If a tablet/capsule is refused quarantine tablet and inform Pharmacist.

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## **12. RETURNING CONTROLLED DRUGS TO PHARMACY**

- 12.1 Do not return any unused controlled drugs from wards to Pharmacy. (*Midazolam and Phenobarbital can be returned as they are not subject to safe custody requirements*).
- 12.2 Please contact the Pharmacist who will complete a risk assessment of all controlled drugs to ensure they are fit for reuse and return to Pharmacy if appropriate.
- 12.3 With regards to the disposal of smaller quantities this will be undertaken by the Pharmacist in the presence of nominated witnesses from the following roles within the Trust:-
  - Clinical Risk and Patient Safety Manager
  - Clinical Nurse Manager (Quality & Compliance)
  - Deputy Director of Nursing

## **13. ROLE OF ACCOUNTABLE OFFICER**

- 13.1 Under the Health Act 2006 and Regulations 3 and 4 of the Controlled Drugs Regulations 2006 NHS Trusts have a statutory duty to nominate a specific individual – an Accountable Officer to be responsible for a range of measures relating to the monitoring, safe use and management of controlled drugs in their organisation. This includes ensuring that safe systems are in place for the management and use of controlled drugs, monitoring and auditing the management systems and investigating of concerns and incidents related to controlled drugs.
- 13.2 The criteria for Accountable Officer with Controlled Drugs Regulations 2006 requires the Accountable Officer to be "*fit, proper and suitably experienced person, who does not routinely supply, administer or dispose of controlled drugs as part of his or her duties*."
- 13.3 The Accountable Officer is required to have sufficient seniority to take action regardless of how a concern is raised.
- 13.4 The Accountable Officer for Mersey Care NHS Foundation Trust has been designated by the Medical Director and the Trust Board. The role and responsibilities of the Accountable Officer are outlined in Appendix C.

## **14. INCIDENT MANAGEMENT**

- 14.1 All incidents and near misses involving controlled drugs will be reported through the Ulysses system as per Incident/Accident Reporting Procedure 27.5.
- 14.2 An incident or near miss involving controlled drugs will be reported to a manager.
- 9-5 - Monday to Friday respective Clinical Nurse Manager
- Out of Hours – Clinical Lead and On Call Clinical Nurse Manager
- Weekends – Clinical Lead and On Call Clinical Nurse Manager
- 14.3 The Manager will assess the seriousness of the incident with a view to informing/involving the Service Director or On Call Senior Manager especially when considering Police involvement.
- 14.4 In addition there is a requirement to notify the Trust's Accountable Officer of all incidents or near misses involving controlled drugs on the first working day following the incident either by e-mail (*high priority*) or telephone call.
- 14.5 In the absence of the Accountable Officer the Trust's Clinical Risk Manager will be informed.

## **15. TRAINING**

The training requirements of Registered Nurses involving the safe and secure management and use of controlled drugs will have their competencies assessed as part of the Medicine Assessment as outlined in Procedure M8.0 Medicine Management Continuous Professional Development

## **16. AUDIT AND MONITORING**

- 16.1 The Clinical Governance Support Unit will on an annual basis undertake on the standard operating procedures on the safe and secure management of controlled drugs.
- 16.2 Upon completion the audit findings will be reported through:-
- Clinical Audit Committee
  - Medicine Management Committee
  - Quality Committee

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## CONTROLLED DRUGS

### SCHEDULE INFORMATION

#### Schedule 1 Controlled Drugs (CD Lic)

The drugs listed in Schedule 1 have no recognised medicinal use. Examples of drugs listed in Schedule 1 include cannabis and cannabis resin, coca leaf, lysergamide, lysergide (LSD) and mescaline. Only certain persons have been licensed by the Home Office to possess them for research and other special purposes in the public interest and they are not available in general practice.

#### Schedule 2 Controlled Drugs (CD) POM

Examples of Schedule 2 controlled drugs include:-

Diamorphine  
Morphine  
Pethidine  
Methadone  
Oxycodone  
Dexamfetamine  
Cocaine  
Methylphenidate (Ritalin®)  
Concerta  
Equasym

Schedule 2 Controlled Drugs are subject, under the Misuse of Drugs (safe custody) Regulations 1973 (to safe custody requirements, except secobarbital).

#### Schedule 3 Controlled Drugs (CD No Reg) POM

Examples of Schedule 3 Controlled Drugs include:-

Barbiturates including Phenobarbital (*except Quinalbarbitone/Secobarbital*)  
Buprenorphine (Temgesic® and Subutex®)  
Diethylpropion  
Flunitrazepam (Rohypnol®)  
Meprobamate (Equanil®, Equagesic®)  
Pentazocine (Fortral®)  
Phentermine  
Temazepam  
Midazolam

Schedule 3 Controlled Drugs are exempt from safe custody requirements and can be stored on the open dispensary shelf (*Temazepam, Buprenorphine, Flunitrazepam and Diethylpropion are exceptions to this rule and must be stored in a complying receptacle*)

#### **Schedule 4 Controlled Drugs (CD Benz POM,CD Anab) POM**

This schedule is split into two parts, Part 1 (*CD Benzodiazepines*) and Part 2 (*CD Anabolic Steroids*). Schedule 4 Controlled Drugs are subject to lesser control. Controlled drugs prescription requirements do not apply and there is no requirement for storage in a locked receptacle. Invoices must be retained for 2 years.

#### **Schedule 5 Controlled Drugs (CD Inv)**

Schedule 5 Controlled Drugs are subject to minimal control.

For further information see:-

**The Misuse of Drugs Act 1971 and Misuse of Drugs Regulations 2001**

Please write clearly, in black ink, initial amendment and do not use tippex

**ORDER FOR CONTROLLED DRUGS**

**Serial Number** \_\_\_\_\_  
*(Repeat Prescriptions Only)*

**Name of Service User/Patient** \_\_\_\_\_ **NHS Number** \_\_\_\_\_

**Full Address** \_\_\_\_\_

To be presented at Pharmacy with Medicine Administration Record

<b>Name of Preparation</b>	<b>Strength</b>	<b>Quantity</b>

*(Enter each preparation to be ordered on a separate page)*

**Ordered by** \_\_\_\_\_ **Print Name** \_\_\_\_\_ **Date** \_\_\_\_\_  
*(Signature of Registered Nurse)*

**Supplied by** \_\_\_\_\_ **Print Name** \_\_\_\_\_ **Date** \_\_\_\_\_  
*(Pharmacist's Signature)*

**Accepted for Delivery** \_\_\_\_\_ **Print Name** \_\_\_\_\_ **Date** \_\_\_\_\_  
*(Signature of Person)*

**Received on the Ward by** \_\_\_\_\_ **Print Name** \_\_\_\_\_ **Date** \_\_\_\_\_

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### ROLE OF ACCOUNTABLE OFFICER

The Controlled Drugs (*Supervision of Management and Use*) Regulations 2006 outline the statutory responsibilities of the Accountable Officer role.

1. To have regard to best practice with regard to management and use of Controlled Drugs.
2. To secure the safe management and use of Controlled Drugs.
3. Ensure adequate destruction and disposal arrangements for Controlled Drugs.
4. Ensure adequate standard operating procedures for safe and secure management of Controlled Drugs are in situ within the organisation.
5. Ensure monitoring and auditing of management and the use of Controlled Drugs by the organisation and individual Practitioners.
6. To ensure relevant individuals receive appropriate training regarding the safe and secure management of Controlled Drugs.
7. To ensure investigation of any actual or alleged improper management or use of Controlled Drugs by any individual.
8. Take appropriate action where there are concerns.
9. To establish information sharing mechanism with other responsible bodies regarding management and use of Controlled Drugs.

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