

Policy Document Control Page

Title

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- Section. Update of definitions
- 3.5 Clarification of role of Trust Accountable Office for CD
- 4.1 Inclusion of tramadol
- 5.1 Rewritten
- Addition of 6.3 and 6.4 to clarify prescribing rights of Independent NMP podiatrists.
- 10.1.3 Clarification around temperature checks
- 10.1.4 Clarification around storage
- 11.1.2/ 11.1.23 Additional information in accordance with NICE CG46
- 11.2.1/ 11.2.2 Additional information in accordance with NICE CG46
- 21.1.7 Clarification around removal of CD after the death of a patient
- 29.9 Additional reference NICE CG46 Controlled Drugs. Safe use and management

Originator

Originated by: Lesley Smith

Designation: Chief Pharmacist

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Responsibility of: Lesley Smith

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This policy is to be disseminated to all relevant staff

This policy must be posted on the Intranet

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POLICY FOR THE SAFE MANAGEMENT OF CONTROLLED DRUGS

1 INTRODUCTION

- 1.1 In accordance with the Government's response to the Shipman enquiry, NHS bodies and the private sector must put arrangements in place for the safe management of Controlled Drugs. This policy will include the management of controlled drugs in patient's homes, clinics and in-patient settings.
- 1.2 Additionally there is a statutory requirement for NHS bodies to appoint an Accountable Officer for Controlled Drugs within their organisation, responsible for the safe management of Controlled Drugs.
- 1.3 This policy is derived from guidance issued by the Department of Health and the General Pharmaceutical Council of Great Britain.

2 DEFINITIONS

Ward / Service Manager

A person appointed by Pennine Care NHS Foundation Trust to manage a ward or a service. This person need not necessarily be a Registered Nurse. In this instance, responsibility for medicines becomes that of the Senior Registered Nurse on duty.

Registered Nurse

A nurse currently registered with the Nursing and Midwifery Council (NMC)

Senior Registered Nurse

The Registered Nurse on duty, who has been rostered as being in charge for that shift.

Doctor

Medical Practitioner whose registration with the General Medical Council permits prescribing of medicines whilst employed by Pennine Care NHS Foundation Trust.

Dentist

A person who is trained and licensed to practice dentistry and is registered with the General Dental Council (GDC).

Non-medical Prescriber

A first level registered nurse, registered pharmacist, or allied health professional who has successfully completed a validated prescribing training programme and whose name is recorded on the appropriate professional register.

Allied Health Professional

A professional working in an occupation which is registered with the Health and Care Professions Council (HCPC) and is covered by the remit of the department of health chief allied health professions officer.

Pharmacist

A pharmaceutical chemist currently registered with the General Pharmaceutical Council (GPhC).

Pharmacy Technician

A qualified pharmacy technician currently registered with the General Pharmaceutical Council (GPhC)

Accountable Officer

A specific person nominated by a NHS Trust (CCG, Foundation Trust or independent hospital) to be responsible for a range of measures relating to the safe use and management of Controlled Drugs in their organisation.

Inpatient services

For the purpose of this policy inpatient services refers to a unit on which patients are admitted for the provision of healthcare and / or rehabilitation. Such units may be based in the hospital setting or within the community setting (for example, intermediate care).

Mental Health Services

Trust services providing healthcare to patients with mental illness.

Community Health Services

Community based services providing healthcare in a variety of settings and which joined the Trust under the Transforming Community Services (TCS) initiative from 1st April 2011.

Controlled Drugs Record Book

Department of Health registers with sequentially numbered pages for use on hospital wards, to record the receipt, stock balance, amount administered and who administered and witnessed the administration of a Controlled Drug.

Controlled Drugs Order Book

Department of Health order book with sequentially numbered and duplicated pages for use by hospital wards and departments to order and record the delivery and receipt of Controlled Drugs.

Controlled Drugs Record Sheet

A sheet for recording controlled drugs stock level and administration in patient's homes.

3 ACCOUNTABLE OFFICER

- 3.1 The Accountable Officer for Pennine Care NHS Foundation Trust is the Chief Pharmacist.
- 3.2 The responsibilities of the Accountable Officer are set out in the Controlled Drug Regulations (regulation 8 to 18).
- 3.3 For NHS Trusts the Accountable Officer must be an Executive Director or report directly to an Executive Director (regulation 5).
- 3.4 The Accountable Officer should not routinely supply, administer or dispose of Controlled Drugs as part of his or her duties (regulations 4 and 5).
- 3.5 The Accountable Officer should report concerns, take action on a case by case basis, share information and learning within the organisation and also with local intelligence networks

4 CONTROLLED DRUGS

- 4.1 “Controlled Drug” means a drug classified in one of the five schedules of the Misuse of Drugs Regulations 2001.

Schedule 1: Hallucinogenic drugs e.g. LSD and Cannabis, which may only be possessed or used by persons with a Home Office Licence for research or other special purposes.

Schedule 2: Includes opioids (e.g. diamorphine, morphine, methadone), major stimulants (e.g. amphetamine).

Schedule 3: Includes temazepam, the barbiturates, buprenorphine, midazolam, tramadol.

Schedule 4: Contains most of the benzodiazepines and anabolic and androgenic steroids.

Schedule 5: Contains certain preparations of Controlled Drugs which are exempt from full control when present in medicinal products of low strength, e.g. codeine in co-codamol.

- 4.2 This policy refers to the ordering, use and record keeping of Controlled Drugs in Schedules 2 and 3 of the Misuse of Drugs Regulations 2001.
- 4.3 In Mental Health Services (MHS) North Division (Bury, Oldham and Rochdale) certain solid dose medicines in Schedule 4 are designated Recorded Drugs. This is in line with the Recorded Drugs Policy of Pennine Acute Hospitals NHS Trust, the local Acute Trust SLA partner. The ordering and receipt of these

medicines in the Northern division will follow the Pennine Acute Hospitals NHS Trust Guidelines for the ordering, storage and administration of Recorded Drugs.

5 PRESCRIBING OF CONTROLLED DRUGS

5.1 Controlled Drugs must be prescribed in accordance with the British National Formulary (BNF), the Medicines Policy and the Misuse of Drugs Regulations 2001.

5.1.1 Prescribers of controlled drugs need to document clearly the indication and regimen for the controlled drug in the patient's medical record

5.1.2 When making decisions about prescribing controlled drugs take into account:

- Benefits of treatment
- Risks of prescribing, including dependency, overdose and diversion
- All prescribed and non-prescribed medication the patient is taking and whether the patient is opioid naïve

5.1.3 Use a recognised opioid dose conversion guide when prescribing, reviewing or changing opioid prescriptions.
NB: Prescribers must be aware of the limitations of opioid dose conversion charts and that many are aimed at palliative care and not, for example, chronic pain

5.1.4 Prescribe differing routes of administration separately. Clearly state when each should be used to avoid administration errors.

5.2 Subject to the exclusions of the schedules, prescriptions for Controlled Drugs must be indelible and state:-

- Name and address of patient
- The form and strength of the preparation
- The dosage instructions
- Total quantity or number of dose units in both words AND figures
- Signature of prescriber
- The date
- It is good practice to include a patient identifier (e.g. NHS number)

FP10 prescriptions must also include:-

- the address of the prescriber, which must be within the UK

- for dental prescriptions the words “for dental treatment only”.
- 5.3 Prescriptions for Controlled Drugs are valid for 28 days from the date of prescribing or from the “start date” specified by the prescriber.
 - 5.4 Prescribing should be limited to a maximum of 30 days supply. If a longer period is required, the reason for this must be recorded on the prescription
 - 5.5 Prescriptions with minor technical errors (for example if one of the requirements for words and figures has not been included) may be amended by the dispensing pharmacist, provided that such amendments are indelible and clearly attributable to the pharmacist.
 - 5.6 Prescribers must not prescribe or administer Controlled Drugs for themselves, close family or friends except in exceptional circumstances.

6 INDEPENDENT NON-MEDICAL PRESCRIBERS

- 6.1 Nurse independent prescribers (formerly extended formulary nurse prescribers) are able to prescribe, administer, and give directions for the administration of schedule 2, 3, 4, and 5 controlled drugs. This extends to:
 - Diamorphine , dipipanone or cocaine for treating organic disease or injury , but not for treating addiction
- 6.2 Pharmacist independent prescribers are able to prescribe, administer, and give directions for the administration of schedule 2, 3, 4, and 5 controlled drugs. This extends to:
 - Diamorphine , dipipanone or cocaine for treating organic disease or injury , but not for treating addiction
- 6.3 Podiatrist independent prescribers are able to prescribe for the treatment of organic disease or injury provided that the Controlled Drug is prescribed to be administered by the specified method:
 - Diazepam;
 - Dihydrocodeine;
 - Lorazepam; and
 - Temazepam

by oral administration.

6.4 Physiotherapist independent prescribers are able to prescribe for the treatment of organic disease or injury provided that the Controlled Drug is prescribed to be administered by the specified method:

- Diazepam, Dihydrocodeine, Lorazepam, Morphine, Oxycodone, Temazepam, by oral administration;
- Morphine for injectable administration; and
- Fentanyl for transdermal administration.

7 SUPPLEMENTARY NON-MEDICAL PRESCRIBERS

Supplementary prescribers can prescribe and administer any Controlled Drug as long as it is within the Clinical Management Plan specific to that patient and agreed between the independent prescriber, the supplementary prescriber and the patient and is within the scope of their practice and competency.

8 ORDERING OF CONTROLLED DRUGS

8.1 Ordering of Controlled Drugs in mental health services

8.1.1 Controlled Drugs must be ordered in accordance with the Trust Standard Operating Procedure 'The ordering, collection, receipt and storage of Controlled Drugs by wards and clinical areas' (SOP 0010)

8.1.1 Controlled Drugs must be ordered from the Acute Trust pharmacy department or dispensary of provider in the Controlled Drug Order Book.

8.1.2 The Controlled Drug Record Book and Controlled Drug Order Book must be kept in a locked cupboard when not in use.

8.1.3 Faxed copies of orders and telephone requests, for Controlled Drugs, are not permitted.

8.1.4 The order should be sent to the pharmacy department within normal working hours. Some departments operate an order 'cut off' time that must be taken into account when placing an order. Controlled Drugs must not be ordered on Saturday mornings except in exceptional circumstances.

8.1.5 Each item requested must be ordered on a separate page and the requisition must be signed by the Registered Nurse. The name of the Registered Nurse

must be printed in capital letters adjacent to the signature, for ease of identification.

8.1.6 A medical doctor must COUNTERSIGN the requisition in the Controlled Drug Order Book as an independent verification before it is sent to the pharmacy department. The medical doctor who countersigns the Controlled Drug Order Book is not responsible for the management and accountability of the Controlled Drugs within the ward or department. This responsibility falls within the remit of the Registered Nurse in charge. The doctor is just countersigning the order to verify that the Controlled Drugs will be being used on that particular ward or department.

8.1.7 Where a doctor is not available 'out of hours' or an emergency supply of a Controlled Drug is requested via the 'out of hours arrangements' a copy of the signed prescription will be provided as the countersignature of the medical doctor.

8.1.8 The Ward / Service Manager or Senior Registered Nurse must provide the pharmacy department or dispensary of provider with specimen signatures of Registered Nurses authorised to sign Controlled Drug orders. A specimen signature will be needed for each new Registered Nurse authorised to sign Controlled Drug orders.

Refer to:

- **Handover of Controlled Drug Cupboard Keys, Responsibilities, Access to Controlled Drugs and Authorised Signatures (SOP0013).**

8.1.9 The pharmacy department or dispensary of provider will hold specimen signatures for each Registered Nurse authorised to order Controlled Drugs.

8.1.10 The Medical Managers or pharmacy team must provide the pharmacy department or dispensary of provider with specimen signatures of medical staff authorised to countersign Controlled Drug Order Books.

8.1.11 The pharmacy department or dispensary of provider will hold specimen signatures for Medical Staff authorised to countersign the orders for Controlled Drugs.

8.1.12 In an emergency or out of hours a SINGLE DOSE of a Controlled Drug for a named patient may be supplied for a patient on another ward without completion or

countersignature of the Controlled Drug Order Book. For further details see section 16.

8.2 Ordering of Controlled Drugs in community health services

8.2.1 All Controlled drugs within community settings are ordered on FP10 prescriptions.

9 DELIVERY / COLLECTION, RECEIPT AND RECORDING

9.1 Delivery, receipt and recording in mental health services

9.1.1 Controlled Drugs will be delivered to the wards or departments in a tamper evident bag or locked box and must be in accordance with the Trust Standard Operating Procedure.

Refer to:

- **The ordering, collection, receipt and storage of Controlled Drugs by wards and clinical areas (SOP0010).**

9.1.2 Where Controlled Drugs for stock are collected by Trust staff these will be in a tamper-evident bag or locked box.

9.1.3 The porter or messenger accepting the delivery of the Controlled Drugs will sign to accept responsibility for carrying the tamper evident bag or locked box. The signature may be in the Controlled Drugs Order Book or appropriate paperwork of the pharmacy department or dispensary of provider.

9.1.4 The Registered Nurse receiving the tamper-evident bag or box on the ward or department locked or with seal intact will sign, in the presence of the porter or messenger to say it has been received in that condition. The signature may be in the Controlled Drugs Order Book or appropriate paperwork of the Acute Trust pharmacy department or dispensary of external pharmacy provider.

9.1.5 In the event of the seal not being intact the Registered Nurse must contact the pharmacy department whilst the porter or messenger is still present.

9.1.6 The Registered Nurse receiving the Controlled Drug order should then check in the presence of a second Registered Nurse the contents of the tamper evident bag or locked box against the order.

- 9.1.7 If the items supplied are correct the Registered Nurse must sign for receipt on the requisition/s in the Controlled Drugs Order Book.
- 9.1.8 Different forms or formulations of Controlled Drug entered in the Controlled Drug Record Book must be recorded on separate pages.
- 9.1.9 An entry must be made on the appropriate page of the ward or department Controlled Drugs Record Book certifying the amount of Controlled Drugs received and adding this to the total amount in stock.
- 9.1.10 Any discrepancy must be notified to a pharmacist employed by Pennine Care NHS Foundation Trust as soon as possible.
- 9.1.11 Where packs or boxes of Controlled Drugs are supplied with tamper evident seals, there is no requirement to open these packs for stock checking purposes.

9.2 Collection, transportation, receipt and recording of Controlled Drugs in community health services

- 9.2.1 Health care professionals involved in the delivery of patient care should not routinely transport a patient's own Controlled Drugs to and from the patient's home. Where this is essential, part of an organised service, or where pharmacies operate collection and delivery schemes to the housebound and other needy patients, it is good practice to keep Controlled Drugs out of view during transportation.
- 9.2.1 Controlled Drugs should not be routinely transported via taxi services or courier, except in exceptional circumstances and with managerial approval.
- 9.2.2 Registered Nurses should not routinely transport Controlled Drugs. This should only be undertaken in exceptional circumstances and in accordance with 9.2.1.
- 9.2.3 All supplies of Controlled Drugs to be administered by community based Registered Nurses must be recorded on the Borough Controlled Drug Record Sheet. The following must be recorded and signed by the Registered Nurse receiving the supply:
- entry date
 - name, form, strength of drug
 - quantity
 - batch number

- expiry date
- no lines should be left between entries
- a separate sheet must be used for each Controlled Drug and for different strengths for the same Controlled Drug
- A running balance must be maintained after each entry.

This must be done even if the drugs are not currently being administered to the patient.

9.2.4 When an episode of care is completed all the Controlled Drug Record Sheets should be filed in the patient's clinical record.

9.2.5 On receipt of Controlled Drugs all sealed boxes must be opened and checked.

9.2.6 Controlled Drugs may be checked, administered and recorded by one registered Nurse within the community, however, where possible a second person should be asked to provide an independent check. This can be another Registered Nurse or non- registered staff member who has previously been deemed competent to carry out the process.

9.3 Excess supply of Controlled Drugs

Any discrepancy including receiving more CDs than requested / ordered must be notified to a pharmacist or pharmacy technician employed by Pennine Care NHS Foundation Trust as soon as possible.

- The quantity received must be recorded in the CD Register by two Registered Nurses.
- The Nurse receiving the CD must contact the external provider who supplied the CD to inform them of the discrepancy
- Two registered Nurses must then sign the CDs out of the CD Register at the time when the excess CD is to be returned
- The person from the original supplier collecting the excess CDs must sign for them on receipt in order to maintain an audit trail.

10 STORAGE

10.1 Storage in inpatient services

10.1.1 Controlled Drugs must be stored in a locked cupboard that is permanently fixed to the wall. This may be separate from

or within another medicines cupboard used to store internal medicines.

10.1.2 Only Controlled Drugs or suspected illicit substances should be stored within the locked cupboard.

10.1.3 The temperature of the medicines cupboards should be recorded daily

10.1.4 Controlled drugs of different strengths with similar “lookalike” packaging should be separated in the cupboard.

10.1.5 The keys of the Controlled Drugs cupboard must be kept on the person of a Registered Nurse or in a locked key box. The Registered Nurse is responsible for controlling access to the Controlled Drugs cupboard.

Refer to:

- **Handover of Controlled Drug Cupboard keys, responsibilities, access to Controlled Drugs and authorised signatories (SOP0013)**

10.2 Storage of Controlled Drugs in community health services

10.2.1 Controlled Drugs prescribed for a patient are their property.

10.2.2 The patient, relative, carer should be supported and advised on the safe management of Controlled Drugs within the home. Consideration should be given to :

- Increasing awareness that packaging of different drugs and strengths can be very similar.
- Maintaining supplies of each drug and strength separately.
- Storage in a safe place with limited access only to those who have the responsibility for administration. A risk assessment may need to be carried out regarding the provision of lockable storage if a risk of theft is present.
- Maintaining appropriate quantities of Controlled Drugs without being excessive.

11 ADMINISTRATION AND RECORDING

11.1 Administration and recording within inpatient services

11.1.1 Two Registered Nurses must always be involved in the administration and recording of Controlled Drugs. One to

prepare and administer the dose(s) and the other to witness these actions.

11.1.2 The Registered Nurses must be certain the prescribed dose is safe for the patient at that time, in a suitable formulation and that past doses have been administered. Any concerns should be checked with the prescriber.

11.1.3 Where possible appropriate advice should be given to the patient about the controlled drug being administered.

11.1.4 The Registered Nurses involved with administering the Controlled Drug must ensure that the following information is recorded on the appropriate page of the Controlled Drugs Record Book:-

- Date and time of administration
- Name of patient
- Dose / volume of drug administered and if any wasted.
- The remaining stock balance (which must be checked, see point 12.1.5 for liquids)
- Signature of Registered Nurse who administered the Controlled Drug
- Signature of Registered Nurse who witnessed the administration of the Controlled Drug

11.1.5 An appropriate record of administration should also be made on the patient's in-patient prescription chart or medication record chart.

11.1.6 If all or part of a dose of a Controlled Drug is not used then both Registered Nurses involved in the procedure must witness its destruction and sign the Controlled Drugs Record Book indicating that the Controlled Drug has been destroyed.

11.1.7 Controlled Drugs must not be administered if the prescription is unclear, illegible or ambiguous or if there is any reason for doubt.

11.1.8 Controlled Drugs should be administered at the specified time and if not the reason should be documented.

11.2 Administration in community health services

Controlled Drugs may be administered and recorded by one registered Nurse within the community, however, where possible a second person should be asked to provide an independent check. This can be another Registered Nurse, Qualified Assistant Practitioner or a non-qualified health care worker, who

has previously been deemed competent to carry out the process. This could be the parent, carer or the patient themselves if nobody else is available.

11.2.1 The Registered Nurses must be certain the prescribed dose is safe for the patient at that time, in a suitable formulation and that past doses have been administered. Any concerns should be checked with the prescriber.

11.2.2 Where possible appropriate advice should be given to the patient about the controlled drug being administered.

11.1.3 The Registered Nurse involved with administering the Controlled Drug must ensure that the following information is recorded on the Controlled Drug record sheet :-

- date and time of administration
- name of patient
- dose / volume of drug administered and if any wasted
- the remaining stock balance
- signature of Registered Nurse who administered the Controlled Drug
- Second signature of witness if possible.

11.1.4 Where a calculation is required to work out the correct volume or quantity to be administered it is recommended that a second practitioner independently checks the calculation. The dose and volume (where appropriate) administered should be clearly recorded.

11.1.5 Registered Nurses involved in the administration and management of syringe drivers must

Refer to:

- **Guidelines for the use of the McKinley T34 syringe pump in palliative care (MMCH007)**

12 STOCK RECONCILIATION

12.1 Stock reconciliation in inpatient services

The stock balance of Controlled Drugs must be checked at least once every 24 hours. It is good practice to check the stock balance once per shift.

12.1.1 Two Registered Nurses must perform the check.

Refer to:

- **The Checking of Controlled Drugs Stocks by Registered Nurses on Wards / Clinical Areas(SOP0004)**

- 12.1.2 A record indicating that the check has been carried out must be made in the Controlled Drugs Record Book for each individual drug stocked, on the relevant page.
- 12.1.3 Stock balances of any preparations should be checked after each administration.
- 12.1.4 Providing a manufacturer's seal on a container is intact it is reasonable to consider the container is full.
- 12.1.5 Balances of liquid Controlled Drugs should be checked by visual inspection only. Periodic volume checks and confirmation of volumes must only be carried out with the Pharmacist or Pharmacy Technician present to countersign the balance amendment. The balance of liquid Controlled Drugs must only be confirmed by Registered Nurses on completion of a bottle and before the next new bottle is opened.
- 12.1.6 Any discrepancy must be reported immediately to the Ward Manager or Senior Registered Nurse who must inform a Pharmacist employed by Pennine Care NHS Foundation Trust and Senior Manager.
- 12.1.7 In the event of a discrepancy of a Controlled Drugs stock balance or the loss of Controlled Drugs, the matter should be investigated immediately. See section 13.
- 12.1.8 If it is clear during the initial investigation that Controlled Drugs are missing without explanation then the Ward Manager or Senior Registered Nurse should discuss with the locality pharmacist or Chief Pharmacist the option of reporting the matter to Greater Manchester Police and obtaining an Incident Number from the Greater Manchester Police operations room
- 12.1.9 A designated member of pharmacy staff will check the stock balances of all Controlled Drugs held in stock every 3 months. This will be carried out in accordance with Pennine Care NHS Foundation Trust Standard Operating Procedure or the agreed procedure of the Acute Trust pharmacy department or dispensary of external pharmacy provider.

Refer to:

- **Ward / Clinical Area Based Controlled Drug Check by Pharmacists and Pharmacy Technicians(SOP0003)**

12.1.10 An additional record of the 3 monthly ward based Controlled Drugs check will be made on the Controlled Drugs check record sheet (Appendix 1). This record will be submitted to the Chief Pharmacist.

12.2 Stock reconciliation in community health services

12.2.1 End of Life Care “Anticipatory Drugs” when prescribed should be recorded on receipt on the Controlled Drug Record and administration Sheet and reviewed at each visit.

In the event of a discrepancy of a Controlled Drugs stock balance or the loss of Controlled Drugs, the matter should be investigated immediately. See section 13.

13 CONTROLLED DRUG STOCK BALANCE, DISCREPANCY OR LOSS

- 13.1 In the event of a stock balance discrepancy or loss of a Controlled Drug the Ward / Service Manager or Registered Nurse must initially conduct a thorough search.
- 13.2 The investigation must include a stock check of all Controlled Drugs, the Record Book / Sheet and the Order Book (inpatient services) against all Controlled Drugs received and administered since the previous check found to be correct.
- 13.3 In the event of the discrepancy not being corrected or of the loss not being found the Ward / Service Manager or Registered Nurse must contact the Senior Manager or the relevant bleep holder.
- 13.4 A Pharmacist employed by Pennine Care NHS Foundation Trust must be informed of the incident at the earliest opportunity. If the incident occurs out of hours, this should be the next working day.
- 13.5 The Registered Nurse discovering the discrepancy must complete a Trust Incident Form.
- 13.6 Depending upon the nature and severity of the incident the Police may be asked to be involved at the discretion of the Senior Manager and/or the Chief Pharmacist.

- 13.7 In the event of a missing CD, refer to Appendix 1 – Algorithm for missing Controlled Drugs in the Community Health Services

14 DISPENSING OF CONTROLLED DRUGS

- 14.1 Pennine Care NHS Foundation Trust has no facilities for the dispensing of Controlled Drugs.
- 14.2 Controlled Drugs will be dispensed by:
- 14.1.1 Pharmacy Departments of the local Acute Trusts according to Standard Operating Procedures and under the terms of the service specifications of the Pharmacy SLAs.
 - 14.1.2 External private pharmacy providers (for example, Lloyds Pharmacy) under the terms of the contract.
 - 14.1.3 Community Pharmacists under the terms of the Community Pharmacy contract for patients of the Substance Misuse Services of the Trust on either FP10 (MDA) or FP10(HNC) prescriptions.
 - 14.1.4 Community Pharmacists for Community Health Services on FP10 prescriptions.

15 CONTROLLED STATIONERY FOR INPATIENT SERVICES AND DRUG AND ALCOHOL SERVICES

15.1 Controlled Drugs Record Books and Controlled Drugs Order Books

- 15.1.1 Controlled Drugs Record Books and Controlled Drugs Order Books are controlled stationery.
- 15.1.2 Controlled stationery should be obtained from the supplies department, NHS Supplies/Logistics on line
- Ward Controlled Drugs Record Book
Order code 90-501
- Ward Controlled Drugs Order Book
Order code 90-500
- 15.1.3 Orders and records must be made in indelible, photocopiable ink.

15.1.4 All controlled stationery books when full, must be retained at ward or service level for 2 years after the date of the last entry.

15.1.5 The Controlled Drugs Record Book and Controlled Drugs Order Book must be locked away when not in use.

15.2 FP10(HNC) prescription

15.2.1 FP10HNC prescription pads are controlled stationery.

15.2.2 The Standard Operating Procedure for the ordering, delivery, receipt and storage of FP10HNC prescription pads by Trust Units must be followed by units in all areas of the Trust.

Refer to:

- **Order, Delivery, Receipt and Storage of FP10HNC Prescriptions by Trust Units(SOP0008)**

15.2.3 The Standard Operating Procedure for the ordering, delivery, receipt and storage of FP10HNC prescription pads at Trust Headquarters must be followed at Trust Headquarters.

Refer to:

- **Order, Delivery, Receipt and Storage of FP10HNC Prescriptions at Pennine Care NHS Foundation Trust Headquarters.(SOP0007)**

16 TRANSFER OF CONTROLLED DRUGS BETWEEN MENTAL HEALTH WARDS

16.1 During the pharmacy department or dispensary of provider opening hours Controlled Drugs must NOT be transferred between wards or services. A supply of the Controlled Drug should be obtained from the pharmacy service.

16.2 Controlled Drugs must not be supplied for administration to a patient on another ward or department except in an emergency or out of hours and then only as a SINGLE DOSE for a named patient.

16.3 There must be no transfer of stock between wards or departments.

16.4 There must be no transfer of stocks between sites

- 16.5 A Registered Nurse must request the Controlled Drug from the Registered Nurse in charge of the supplying ward or department.
- 16.6 The Registered Nurse must take the in-patient prescription chart and present it to the Registered Nurse in charge of the supplying ward or department.
- 16.7 The Registered Nurses involved must take the medication and the Controlled Drug Record Book of the supplying ward or department to the ward or department where the medication is to be administered. After administration an entry must be made in the supplying ward or department's Controlled Drug Record Book and witnessed by the same two Registered Nurses. The entry should include the patient's name and ward or department.
- 16.8 The Controlled Drug Record Book must be returned immediately to the supplying ward or department.
- 16.9 Staff should also follow the procedures of the local Acute Trust pharmacy department or dispensary of provider in relation to the transfer of single doses of medicines between wards where these exist.

17 CLOSURE OF AN INPATIENT WARD OR SERVICES

Refer to:

- **Return of Controlled Drugs to Pharmacy Due to Discontinuation or Ward Closures(SOP0014)**

- 17.1 During short term ward closures arrangements must be made for the removal and temporary storage of Controlled Drugs by the pharmacy department or dispensary of provider and appropriate records made in the Controlled Drugs Record Book, if appropriate.
- 17.2 During long term ward closures arrangements must be made for the return of Controlled Drugs to the pharmacy department or dispensary of provider for re-use, if appropriate.
- 17.3 During short or long term ward closures appropriate records must be made in the Controlled Drugs Record Book and the Controlled Drugs Record Book and Order Book must be handed over to a Pharmacist by a Registered Nurse.
- 17.4 The Pharmacist will make arrangements for the secure storage of the Controlled Drugs Record Book and Order Book during the closure.

- 17.5 The Pharmacist will make arrangements for the return of stocks including reconciliation with the list of Controlled Drugs removed or the restocking of the ward when appropriate.

18 PATIENTS' OWN CONTROLLED DRUGS IN INPATIENT SERVICES

Refer to:

- **Storage of Patients Own Controlled Drugs on Inpatient Wards(SOP0012)**

- 18.1 As with other types of medicines, these remain the patients' own property and if not available as ward stock can be used until supplies are received from the pharmacy, providing that they are assessed as suitable for use.

18.1.1 Patients' own Controlled Drugs must be locked in the Controlled Drugs cupboard and an entry made on a separate page in the Controlled Drug Record Book for each drug indicating the patient's name and the name, strength, formulation and quantity of drug. This must be witnessed by a second Registered Nurse. Doses are then given and recorded in the usual way to the named patient, once prescribed.

- 18.2 On mental health wards, it is standard practice for patients' own Controlled Drugs to be recorded at the back of the Controlled Drugs Record Book. In other inpatient services where there are only patients' own controlled drugs, these must be recorded in the front of the controlled drugs record book.

- 18.3 The administration section on the prescription chart should be annotated to show that the patients' own Controlled Drug was used.

- 18.4 Patients' own Controlled Drugs must NOT be given or administered to another patient.

- 18.5 Patients' own Controlled Drugs must NOT be added to ward stock.

- 18.6 If the patients' own Controlled Drugs are not required for use on the ward they must be stored in the Controlled Drug cupboard for safe custody and recorded in the Controlled Drugs Record Book.

- 18.7 If the Controlled Drug is ultimately no longer required it should be disposed of in accordance with the procedure in Section 21.

18.8 If patients are found to be in the possession of a suspected illicit substance (which may be a Controlled Drug) then the Trust Policy on the Handling of a Suspected Illicit Substance in in-patient areas should be followed.

19 CONTROLLED DRUG DISCHARGE / LEAVE PRESCRIPTIONS FROM MENTAL HEALTH WARDS

- 19.1 A discharge prescription must be written in accordance with the procedures in Section 5.
- 19.2 The discharge prescription must be clinically checked by a Pharmacist employed by Pennine Care NHS Foundation Trust and then sent to the pharmacy department in accordance with the Standard Operating Procedure for the Acute Trust pharmacy department or dispensary of external pharmacy provider.
- 19.3 Once dispensed the Controlled Drug discharge prescription will be delivered to the ward in accordance with the procedures in Section 9.
- 19.4 The Controlled Drug discharge prescription should be received and records made in accordance with the procedures of the Acute Trust pharmacy department or dispensary of external pharmacy provider.
- 19.5 For Controlled Drugs discharge prescriptions the entries must be made in the patients' own drugs section of the Controlled Drug Record Book in accordance with the procedures of the Acute Trust pharmacy department or dispensary of external pharmacy provider until the patient is ready for discharge. These medicines should remain segregated from the ward Controlled Drugs stock.
- 19.6 When the patient is actually discharged a Registered Nurse must count and sign out the Controlled Drugs for discharge and this must be witnessed by a second Registered Nurse before handing the Controlled Drug discharge prescription to the patient or their representative.
- 19.7 It is considered good practice for the identity of the representative to be entered in the Controlled Drug Record Book.
- 19.8 Controlled Drug discharge prescriptions that are not actually supplied to the patient or their representative because, for example, the patient is not discharged, must be returned to the Acute Trust pharmacy department or dispensary of external

pharmacy provider partner by a Pharmacist, if appropriate (see Section 20).

- 19.9 A separate Trust Leave Prescription form must be used to prescribe Controlled Drug(s) where these are part of the leave prescription. This may result in two leave prescriptions being written for the same patient and reference should be made to this by the prescriber or pharmacist carrying out the clinical check. A Leave Prescription form for Controlled Drugs will not be returned to the ward to re-use for a subsequent leave as the pharmacy department are required to retain original prescriptions of Controlled Drugs for their records.
- 19.10 Controlled Drugs must not be dispensed from the ward. Prescriptions for Controlled Drugs must be sent to the pharmacy department for dispensing in plenty of time for the period of leave or time of discharge

20 RETURN OF CONTROLLED DRUGS FROM MENTAL HEALTH WARDS

- 20.1 When unexpired Controlled Drugs are no longer required on the ward or clinical area they must be returned to the pharmacy department or dispensary of provider ideally by a Pharmacist. This may not always be possible and in such cases a pharmacy technician may return them where they have been authorised to do so by the Accountable Officer for Controlled Drugs

Refer to:

- **Return of Controlled Drugs to Pharmacy Due to Discontinuation or Ward Closures(SOP0014)**
- 20.2 An entry must be made in the Controlled Drugs Record Book by the Pharmacist and be witnessed by a Registered Nurse that the removal has taken place.
- 20.3 The Pharmacist will make appropriate entries of the return in the Controlled Drugs Register of the pharmacy department.
- 20.4 Expired stocks of Controlled Drugs or Controlled Drugs which cannot be returned to the supplying pharmacy must be destroyed at ward level and witnessed by a Pharmacist (see Section 21).

21 DISPOSAL / DESTRUCTION

21.1 Disposal / destruction in inpatient services

21.1.1 Doses of Controlled Drugs that are prepared but not administered or only partly used must be destroyed immediately in the ward or department by the Registered Nurse and witnessed by a second Registered Nurse.

Refer to:

- **Destruction of Controlled Drugs on Wards/ Clinical Areas(SOP0015)**

21.1.2 A record of the destruction must be made on the relevant page in the Controlled Drugs Record Book.

21.1.3 The Registered Nurse responsible for destroying the Controlled Drug should ideally be the Registered Nurse who prepared it.

21.1.4 Controlled Drugs can be destroyed on a ward or department in the presence of a Registered Nurse and Pharmacist or pharmacy technician who has been authorised to do by the Accountable Officer for Controlled Drugs both of whom must sign the Controlled Drugs Record Book to witness the destruction.

21.1.5 Destruction will be carried out using a Controlled Drugs disposal kit that relates to drugs incapable of being retrieved

21.1.6 Controlled Drugs destruction kits for the use of pharmacists are available via the Chief Pharmacist's office.

21.1.7 Following the death of a patient, patient's own controlled drugs can be destroyed as described above, whilst taking coroner directions into account.

21.2 Disposal / destruction in community health services

21.2.1 Doses of Controlled Drugs that are prepared but not administered or only partly used must be destroyed immediately by the Registered Nurse.

21.2.2 All medication obtained for a patient via a prescription is the property of that patient and remains so even after

death. Under current legislation, when a patient dies, the relatives / carer are not entitled to possess the Controlled Drugs once there is no longer a clinical need. The relatives / carer must be advised to return the Controlled Drugs to the supplying pharmacy for safe destruction. If this is not possible or there is any doubt it may not occur, then Controlled Drugs may be destroyed in the patient's home (see 21.2.4)

21.2.3 If it is necessary for a Registered Nurse to destroy Controlled Drugs, this must be carried out as soon as practicable and in the presence of a witness. A record of the destruction must be made on the Controlled Drug Record Sheet of the name, strength and quantity destroyed.

21.2.4 If a Police Officer attends the patient's home following death and advises that they will be removing Controlled Drugs, the Registered Nurse (if present) should request that the Controlled Drug Record Sheet is completed detailing the name, strength and quantity being removed, the date of removal and signature and Identification Number of the Police Officer. This must be countersigned by the Registered Nurse. As soon as practicable the Registered Nurse must obtain an Incident Number from the Greater Manchester Police operations room and write this on the Controlled Drug Record Sheet. If the Registered Nurse is not present when the Controlled Drugs are removed by a Police Officer there is no requirement for them to pursue a Police Officer to sign the Record Sheet. However an Incident Number must be obtained from the Greater Manchester Police operations room and this should be written on the Controlled Drug Record Sheet.

Refer to:

- **Destruction of Controlled Drugs in Community Health Services (MMCH002)**
- **Procedure for Medicines Management Following the Death of a Patient (MM045)**

21.1.5 It is not recommended that Controlled Drugs are destroyed by General Practitioners.

22 SUSPECTED ILLICIT SUBSTANCES IN MENTAL HEALTH SERVICES

- 22.1 The term 'illicit substance' is used to describe an unidentified substance which may be a Controlled Drug that has not been prescribed.
- 22.2 In in-patient areas suspected illicit substances must be dealt with as per Trust policy.

Refer to:

- **The Management of Suspected Illicit Substances on Trust premises (CL40).**

- 22.3 In other areas of the Trust suspected illicit substances must be dealt with on a case by case basis in consultation with the Police and/or a Pharmacist until a policy on the handling of suspected illicit substances in these areas is developed.

23 DRUG AND ALCOHOL SERVICES

23.1 Supervised administration sessions

- 23.2 The Service Manager or Senior Registered Nurse of a Drug and Alcohol Service (DAS) which offers supervised administration sessions for Controlled Drugs (methadone or buprenorphine) must provide the Acute Trust pharmacy department with specimen signatures for each DAS Registered Nurse authorised to sign Controlled Drug orders.
- 23.3 The Acute Trust pharmacy departments will hold specimen signatures for each DAS Registered Nurse authorised to order Controlled Drugs.
- 23.4 DAS that offer supervised administration sessions for Controlled Drugs (methadone or buprenorphine) will order and collect Controlled Drugs in accordance with the Trust Standard Operating Procedure and in Section 8 and also the procedure for the ordering and collection of the Controlled Drugs agreed with the pharmacy department.

Refer to:

- **The Ordering, Collection, Receipt and Storage of Controlled Drugs by Wards and Clinical Areas (SOP0010)**

- 23.5 The DAS representatives must wear their Trust identification badges on all occasions where Controlled Drugs are being supplied or collected from or returned to the pharmacy department.

- 23.6 A Registered Nurse or designated member of staff must collect and transport Controlled Drugs from the pharmacy department.
- 23.7 Controlled Drugs for supervised consumption must be stored in accordance with the procedures in Section 10
- 23.8 Controlled Drugs for supervised consumption must be administered in accordance with the procedure in Section 11.
- 23.9 At the end of each supervised administration session the stock balance of Controlled Drugs must be reconciled in accordance with the procedures in Section 12.
- 23.10 10SS and FP10 MDA SS prescriptions
- 23.11 Each DAS of the Trust order FP10SS and FP10MDA SS prescriptions directly from the printers.
- 23.12 Each DAS of the Trust must follow the local SOP for the ordering, delivery, receipt and storage of FP10SS and FP10MDA SS prescriptions.
- 23.13 DAS practitioners must follow the Standard Operating Procedure for the safe issuing of prescriptions within DAS
- 23.14 The DAS Competency Assessment Framework (CAF) for the safe issuing of prescriptions must be undertaken by all new practitioners within DAS. Also by those practitioners involved in a prescription issuing error/ incident.

24 INCIDENT REPORTING

- 24.1 The Trust incident reporting system should be used to report any incident or near misses relating to Controlled Drugs or any aspect of Controlled Drugs management.
- 24.2 The Accountable Officer for Controlled Drugs (Chief Pharmacist) may be contacted directly if there are any concerns regarding the clinical use of safe or secure handling of Controlled Drugs.
- 24.3 The Trust, as a responsible body, has a duty of collaboration to share Controlled Drug related incidents with other responsible bodies. The Accountable Officer for Controlled Drugs of the Trust will liaise with the Accountable Officers of other NHS organisations as appropriate.

25 THE MANAGEMENT OF CONTROLLED DRUG INCIDENTS

- 25.1 The Accountable Officer for Controlled Drugs in conjunction with the Risk Department will maintain a database of Controlled Drugs incidents.
- 25.2 The Accountable Officer will provide details of Controlled Drug incidents to the NHS England (Greater Manchester) Local Intelligence Network (LIN) meeting via the Greater Manchester LIN website. This can be found at www.cdreporting.co.uk
- 25.3 The Accountable Officer will attend meetings of the NHS England (Greater Manchester) Local Intelligence Network (LIN)
- 25.4 The Accountable Officer will provide reports on Controlled Drugs to the Drugs and Therapeutics Committee and Risk and Clinical Governance Committee.
- 25.5 The Accountable Officer may be contacted directly by any member of Trust staff if there are any concerns regarding the clinical use or safe management of Controlled Drugs.

26 RELATED POLICIES AND PROCEDURES

This policy should be read in conjunction with:

- 26.1 Medicines Policy (CL15)
- 26.2 Policy on the Handling of Suspected Illicit Substances in in-patient areas (CL40).
- 26.3 Pharmacy Services Standard Operating Procedures relating to Controlled Drugs (SOP0003, SOP0004, SOP0010, SOP0011, SOP0012, SOP0013, SOP0014, SOP0015).
- 26.4 Guidelines for the ordering, storage and administration of Recorded Drugs (Pennine Acute Hospitals NHS Trust only) and Pennine Care NHS Trust Pharmacy Services Standard Operating Procedures relating to Recorded Drugs (SOP0005, SOP0006, SOP0033).
- 26.5 The transfer of medicines between wards when the pharmacy is closed (Pennine Acute Hospitals NHS Trust) in the North Division.
- 26.6 The Medicines Transfer Book and related procedure of Tameside Hospital NHS Foundation Trust (MHS Tameside).

27 TRAINING, MONITORING AND AUDIT

- 27.1 Any non-attendance of new starters on the Trust's induction training is reported to the individual's recruitment officer via e-

mail from the Organisational Learning and Development (OL&D) and a further date to attend arranged.

- 27.2 Training required for individual members of staff is identified through the Trust's IPDR process and arranged as appropriate. Any non-attendance is reported via e-mail from the OL&D Team to the individual's authorising manager.
- 27.3 Audit of practice in relation to this policy will be carried out as part of the Trust's annual clinical audit programme and reported to the Drugs and Therapeutics Committee.
- 27.4 A quarterly ward Controlled Drugs check will be carried out in wards and departments by pharmacists or pharmacy staff (see Section 12).
- 27.5 All prescribing on FP10(HNC) or FP10(MDA) prescriptions of the Trust will be monitored by the Trust pharmacy team via the ePACT.net system of the NHS Business Services Authority.
- 27.6 Prescribing of Controlled Drugs on FP10 (HNC) or FP10 (MDA) prescriptions of partner Clinical Commissioning Groups (CCG). DAS staff will be monitored by the partner CCG.

28 REVIEW

This policy will be reviewed every 3 years or sooner should the need arise

29 REFERENCES

- 1 Controlled Drugs (Supervision of management and use) Regulations 2013.
Information about regulation. Department of Health February 2013.
- 2 General Pharmaceutical Council – Controlled Drugs.
- 3 Safe and Secure Handling of Medicines – a Team approach
www.rpsgb.com accessed April 2011.
- 4 Guidance for pharmacists on the safe destruction of Controlled Drugs - England, Scotland and Wales www.rpsgb.com accessed April 2011.
- 5 Misuse of Drugs Act 1971.
- 6 Medicines Act 1968 and related Medicines Act Orders.

- 7 Medicines Ethics and Practice (34). A Guide for Pharmacists and Pharmacy Technicians. Royal Pharmaceutical Society of Great Britain. July 2010. Part 2 superseded in September 2010 by the General Pharmaceutical Council.
- 8 British National Formulary (71). British Medical Journal and Royal Pharmaceutical Society of Great Britain. March - September 2016.
- 9 Controlled Drugs: safe use and management. NICE guideline 46. Published 12 April 2016.

Appendix 1

Algorithm for missing Controlled Drug(s) in the Community Health Services

