

CLINICAL COMMUNITY DIVISIONAL POLICY

Policy for the Management of Controlled Drugs

Policy Number:	038
Scope of this Document:	All staff in Mersey Care
Recommending Committee:	Medicines Optimisation & Safety Group
Approving Committee:	Divisional Clinical Policies & Procedures
Date Ratified:	June 2019
Next Review Date (by):	June 2021
Version Number:	2019 – Version 12
Lead Executive Director:	Medical Director
Lead Author(s):	Medicines Safety Support Manager

CLINICAL COMMUNITY DIVISIONAL POLICY

2019 – Version 12

*Striving for Perfect Care and a
Just Culture*

CLINICAL COMMUNITY DIVISIONAL POLICY

Policy for the Management of Controlled Drugs

Further information about this document:

Document name	038 Policy for the Management of Controlled Drugs
Document summary	This policy to ensure the legal requirements of the Medicines Act 1968 and the Misuse of Drugs Act 1971 and Regulations in terms of prescribing and managing CDs are complied with while ensuring that patients who require them have access to controlled drugs in a timely fashion.
Author(s) Contact(s) for further information about this document	Debbie Bowden Medicines Safety Support Manager Telephone: 0151295 3525 Email: debbie.bowden@merseycare.nhs.uk
Published by Copies of this document are available from the Author(s) and via the trust's website	Mersey Care NHS Foundation Trust V7 Building Kings Business Park Prescot Merseyside L34 1PJ Your Space Extranet: http://www.portal.merseycare.nhs.uk Trust's Website www.merseycare.nhs.uk
To be read in conjunction with	Policy for the Management and Administration of Children's Own Medicines in Special Schools Clinical Policy for the Subcutaneous Administrations of Drugs via a Syringe Driver Medicines Overarching Policy End of Life Policy – Adults Procedure for Non-Medical Prescribers
This document can be made available in a range of alternative formats including various languages, large print and braille etc	
Copyright © Mersey Care NHS Trust, 2015. All Rights Reserved	

Version Control:

		Version History:
DRAFT Version 11.1	Circulated to David Fearnley, Lee Knowles and Sarah Rafferty and Kerrie Bermudez for comment	17/01/19

SUPPORTING STATEMENTS

This document should be read in conjunction with the following statements:

SAFEGUARDING IS EVERYBODY'S BUSINESS

All Mersey Care NHS Foundation Trust employees have a statutory duty to safeguard and promote the welfare of children and adults, including:

- being alert to the possibility of child / adult abuse and neglect through their observation of abuse, or by professional judgement made as a result of information gathered about the child / adult;
- knowing how to deal with a disclosure or allegation of child /adult abuse;
- undertaking training as appropriate for their role and keeping themselves updated;
- being aware of and following the local policies and procedures they need to follow if they have a child / adult concern;
- ensuring appropriate advice and support is accessed either from managers, *Safeguarding Ambassadors* or the trust's safeguarding team;
- participating in multi-agency working to safeguard the child or adult (if appropriate to your role);
- ensuring contemporaneous records are kept at all times and record keeping is in strict adherence to Mersey Care NHS Foundation Trust policy and procedures and professional guidelines. Roles, responsibilities and accountabilities, will differ depending on the post you hold within the organisation;
- ensuring that all staff and their managers discuss and record any safeguarding issues that arise at each supervision session

EQUALITY AND HUMAN RIGHTS

Mersey Care NHS Foundation Trust recognises that some sections of society experience prejudice and discrimination. The Equality Act 2010 specifically recognises the *protected characteristics* of age, disability, gender, race, religion or belief, sexual orientation and transgender. The Equality Act also requires regard to socio-economic factors including pregnancy /maternity and marriage/civil partnership.

The trust is committed to equality of opportunity and anti-discriminatory practice both in the provision of services and in our role as a major employer. The trust believes that all people have the right to be treated with dignity and respect and is committed to the elimination of unfair and unlawful discriminatory practices.

Mersey Care NHS Foundation Trust also is aware of its legal duties under the Human Rights Act 1998. Section 6 of the Human Rights Act requires all public authorities to uphold and promote Human Rights in everything they do. It is unlawful for a public authority to perform any act which contravenes the Human Rights Act.

Mersey Care NHS Foundation Trust is committed to carrying out its functions and service delivery in line the with a Human Rights based approach and the FREDA principles of **F**airness, **R**espect, **E**quality **D**ignity, and **A**utonomy

Contents

1. PURPOSE AND RATIONALE	5
2. OUTCOME FOCUSED AIMS AND OBJECTIVES	5
3. SCOPE	5
4. DEFINITIONS	6
5. DUTIES.....	7
6. PROCESS	8
6.1 Obtaining Controlled Drugs	8
6.2 Prescribing Controlled Drugs by Mersey Care Staff Working in Liverpool and South Sefton Community Division.....	10
6.3 Collection and Transport of Controlled Drugs to a Patient's Own Home	10
6.4 Storage of Controlled Drugs	11
6.5 Checking Stock Levels/Running Balance	12
6.6 Dealing with Discrepancies	14
6.7 Administration	16
6.8 Disposal	17
7. CONSULTATION.....	19
8. TRAINING AND SUPPORT	19
9. MONITORING.....	19
10. EQUALITY AND HUMAN RIGHTS ANALYSIS.....	20
Appendix 1 - Misuse of Drugs Regulations 2001 – Drug Schedules.....	23
Appendix 2 - Community Pharmacies Holding Palliative Care Medicines.....	24
Appendix 3 - Palliative Care Drugs List.....	28
Appendix 4 - Transporting Medication from Community Pharmacy to Patient Own Home Flow Chart.....	29
Appendix 5 - District Nurse Risk Assessment Pathway for Controlled Drugs in Patient Homes following completion of a syringe driver or administration of medication/injection care plan ...	30

1. PURPOSE AND RATIONALE

- 1.1 The Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001 govern the use of controlled drugs (CDs) in medicine. The Act imposes a total ban on possession, supply, import, export and production of Controlled Drugs (CDs) except as allowed by the regulations. Thus, only activities specified in the legislation are legal. Offences committed under the Act are criminal offences and carry penalties of fines, imprisonment or both.

The Regulations classify CDs into five schedules (appendix 1), each specifying the requirements governing activities such as possession, supply, prescribing and record keeping which apply to them. All drugs in schedules 2 to 4 are marked 'CD' in the British National Formulary (BNF).

- 1.2 The purpose of the policy is to:
- a) Outline the legal situation with regard to the prescribing, procurement, safe storage, distribution and disposal of CDs in line with The Misuse of Drugs Act 1971 and associated regulations, The Medicines Act 1968 and regulations of The Health Act 2006, The Human Medicines Regulations, 2012.
 - b) Promote best practice and to ensure CDs are handled in a correct, safe and secure manner by all staff employed by the trust who are in any way involved in the management of controlled drugs.
 - c) To act as a training tool for new and existing staff including agency staff .
 - d) To ensure trust staff are aware of the process for raising any serious concerns about individuals or organisations regarding CDs by contacting the trust's Controlled Drug Accountable Officer (CDAO).

2. OUTCOME FOCUSED AIMS AND OBJECTIVES

- 2.1 Mersey Care Liverpool & South Sefton Community Services Division (LSSCSD) has developed this policy to ensure the legal requirements of the Medicines Act 1968 and the Misuse of Drugs Act 1971 and Regulations in terms of prescribing and managing CDs are complied with while ensuring that patients who require them have access to controlled drugs in a timely fashion.

3. SCOPE

- 3.1 This policy is applicable to all staff that handle and administer CDs either on trust premises or in a patient's own home. This includes bank and agency staff.

4. DEFINITIONS

4.1

Policy	<p>A policy details the broad course or general plan of action to be adopted and emphasise rules to be adhered to and are stated in the form of directives e.g. "it is the responsibility of staff to..." or "each member of staff will..."</p> <p>A policy can be best described as a `must do` clinical guidance document.</p>
Guideline	<p>These provide staff with information on the advised course of action to be taken. They provide direction and act as guiding principles. Guidelines assist staff in making an informed decision regarding the appropriate action to be followed or advice/instruction to be given. Guidelines provide staff with guiding principles whereas policies state the rules to be adhered to. A guideline can be best described as a `should do` clinical guidance document.</p>
Protocol	<p>These provide step-by-step guidance and procedures for diagnosis, care following diagnosis, discharge and/or care following discharge. A protocol can be best describes as a `must do` clinical guidance document.</p>
Standard Operating Procedure (SOP)	<p>A standard operating procedure is a set of step-by-step instructions created to help workers carry out routine operations. Their purpose is to achieve efficiency, quality output and uniformity of performance, while reducing miscommunication and failure to comply with the organisation's regulations.</p>
Controlled Drug (CD)	<p>Controlled Drug. This is any drug included in schedules 1 to 5 of the Misuse of Drugs Regulations 2001 or in subsequent amendment regulations to the Misuse of Drugs Regulations 2001. Drugs are included in the schedules because they are considered sufficiently dangerous or otherwise harmful with the potential for diversion and misuse. The alternative categorisation of controlled drugs into Classes A, B and C derives from the Misuse of Drugs Act 1971 which is the enabling legislation upon which the current regulations are based.</p>
Controlled Drug Accountable Officer (CDAO)	<p>Controlled drugs accountable officers (CDAOs) are responsible for all aspects of controlled drugs management within their organisation</p>
Denature	<p>To take away or alter the natural qualities of a substance. Specifically in relation to a CD it is to</p>

	render drugs irretrievable prior to onward safe disposal.
Diversion	Drug diversion is a medical and legal concept involving the transfer of any legally prescribed controlled substance from the individual for whom it was prescribed to another person for any illicit use.
Local Intelligence Network (LIN)	Controlled Drugs Local Intelligence Network satisfies the requirements stipulated in regulation 14 (2) of The Controlled Drugs (Supervision of Management and Use) Regulations 2013. The priority of the Controlled Drugs Local Intelligence Network will be to share intelligence and ensure all reasonable steps are taken to improve patient and public safety with regards to the safe and secure handling, management and use of controlled drugs.

5. DUTIES

5.1 Controlled Drugs Accountable Officer

The Controlled Drugs Accountable Officer (CDAO) has responsibilities for the establishment and operational arrangements of:

- Securing the safe management and use of CDs
- Monitoring and auditing the management and use of such drugs
- Ensuring that relevant individuals receive appropriate training and that their training needs are regularly reviewed
- Monitoring and assessing the performance of such individuals in connection with the management or use of such drugs
- Making periodic inspections of premises used in connection with the management or use of such drugs
- Recording, assessing and investigating concerns expressed about incidents that may have involved improper management or use of such drugs
- Ensuring that appropriate action is taken for the purpose of protecting patients or members of the public in cases where such concerns appear to be well – founded
- Supporting and ensuring safe destruction of unused and out of date stock
- Where required by regulations, the sharing of information
- To inform the Local Intelligence Network (LIN) and CDAO for NHS England of any concerns or issues. A quarterly occurrence report of CD incidents is submitted by all organisations to the LIN

The Accountable Officer for Mersey Care NHS Foundation Trust is

Sarah Rafferty who can be contacted on

T: 01514727470

M: 07920365335

E: sarah.rafferty@merseycare.nhs.uk

5.2 Associate Directors/Clinical Leads

Directorate/Service Leads are responsible for the implementation of this policy within their localities. They are also responsible for the delivery of care and treatment in line with best practice.

5.3 The following general (statutory) duties apply

- a) It is the responsibility of all trust staff to act in accordance with legal requirements and local policy and procedure
- b) All GPs or healthcare professionals in legal possession of CDs are individually responsible for working within legislation and local policy regarding appropriate, safe and secure handling of controlled drugs
- c) All members of staff are responsible for bringing any serious concerns about individuals or organisations related to use of controlled drugs to the attention of the CDAO

6. PROCESS

6.1 Obtaining Controlled Drugs

It is important to differentiate between the different processes for obtaining CDs by different services within Liverpool and South Sefton Community Services Division

6.1.1 Obtaining Supplies of Controlled Drugs for Stock Intermediate Care Ward 35

- a) The ward should have a core stock list of CDs, this stock should be checked by two registered nurses at least once weekly to ensure there is a supply of these CDs on the ward at all times
- b) The order for CDs should be written in indelible ink and signed for by an authorised registered nurse. Requests should be made using the Ward CD requisition book (90-500).
- c) One drug per page
- d) The carbon paper should be placed between the top and the bottom page of the requisition
- e) The written requisitions should include:
 - Trust name
 - Ward
 - Drug name, form, strength, ampoule size (if more than one size available)
 - Total quantity required
 - Purpose for use
 - Signature and **printed name** of Registered Nurse/Doctor
 - Date of requisition
- f) The book is sent to LHCH pharmacy department inside the pharmacy green bag sealed with a tamper evident seal. Alternatively the requisition book can be given to a member of the pharmacy team on the ward.
- g) Only one CD requisition book should be in use at any one time. When not in use CD requisition books must be locked in the CD cupboard.
- h) Completed CD requisition books should be stored in the secure notes room on the ward. They will be retained on site for 2 years then archived for a further 5 years.

6.1.2 Obtaining Supplies of Midazolam Oromucosal Solution for Stock by Liverpool and South Sefton Division Community Dental Service

- a) In order to obtain a supply a mandatory requisition form FP10CDF must be completed and signed by an authorised signatory
- b) Upon receipt of requisition for Schedule 3 drugs (Midazolam) the FP10CDF CD Requisition Form must be processed immediately
- c) Community ATO will inform Medicines Distribution Service Manager (MDSM) of receipt of FP10CDF CD Requisition Form
- d) Staff will process FP10CDF CD Requisition Form using the link below and then raise an order on JAC
https://www.nhsbsa.nhs.uk/sites/default/files/2017-03/6-1387-Form_FP10CDF_v5_final.pdf
- e) Once order has been generated, staff will pick the order as per SOP
- f) When order is picked, it must be checked by band 5 and above Pharmacy Technician. This must be checked against original FP10CDF CD Requisition Form
- g) In the circumstance when orders are generated by Medicines Distribution in the event of expired stock, the following process must be adhered to:
 - Staff will complete parts A and B of the FP10CDF CD Requisition Form
 - This must be checked by Band 5 and above Pharmacy Technician before being sent
 - Once checked FP10CDF CD Requisition Form will be faxed to relevant service lead to sign
 - Upon receipt of signed FP10CDF CD Requisition Form steps 1 – 6 of the above process must be followed

6.1.3 Obtaining Supply of Controlled Drugs for Palliative Patients in Their Own Home

- a) To ensure that a supply of CD end of life medication is always available to administer stat doses or replenish a syringe driver it is good practice that the District Nurse is responsible for ordering further prescriptions from the patient's GP.
- b) A faxed request for further supplies should be made, where possible 48 hours' prior to being required. Be mindful of this around weekends and bank holidays.
- c) Prescriptions for schedule 2 and 3 controlled drugs (exception liquid methadone or installment FP10MDA prescriptions) can be sent electronically to community pharmacies for patients who use the Electronic Prescription Service (EPS). The GP practice must be contacted to ensure that the prescription has been sent electronically so as not to delay treatment. In some circumstances the prescription may need to be physically collected from the GP practice and taken to the community pharmacy.
- d) If a family member is to collect the prescription then they must be made aware of this.
- e) If the community pharmacy delivers medication to the patient the community pharmacy must be contacted to make them aware that a controlled drug prescription has been sent electronically or waiting to be collected from the GP practice. If being physically collected they can then instruct the driver to ask for the prescription.
- f) If a prescription for palliative medication is required out of normal business hours there are a number of community pharmacies across Liverpool and South Sefton who have agreed to keep a minimum stock level of drugs likely to be needed (appendix 2).

6.2 Prescribing Controlled Drugs by Mersey Care Staff Working in Liverpool and South Sefton Community Division

- a) Non-Medical Prescribers (NMPs) should refer to the Non-Medical Prescribing Policy for guidance on self-declaration and approval to prescribe, including CDs.
- b) Mersey Care prescribers should not prescribe CDs for themselves, family or friends.
- c) The quantity prescribed should be appropriate for the clinical need and situation of the patient.
- d) For oral CDs no more than **30 days'** supply to be prescribed.
- e) For injectable CDs no more than **7 days'** supply to be prescribed.
- f) It is unsafe to keep higher strengths of diamorphine speculatively and higher strengths e.g. 100mg should only be kept where there is active prescribing.
- g) Prescriptions for CDs may be computer generated but the signature must be in the prescribers own handwriting.
- h) Any changes to the prescription must be signed by the prescriber.
- i) Prescribing of CDs **MUST** be recorded on EMIS as this provides an audit trail.
- j) It is good practice that details of CD prescribing are also faxed to the patient's GP.
- k) Prescriptions for schedule 2 or 3 CDs must contain the following details written indelibly in black ink (by hand or computer generated):
 - Bear the name, address and age, if appropriate, of the patient
 - Specify the name, form and strength of the preparation
 - Specify the dosage. "As directed" is not acceptable
 - Specify the total quantity of the preparation, or the number of dose units (e.g. '10 (ten) tablets of 10mg') in both words and figures.
 - The prescription must be signed and dated by the prescriber with their usual signature. From June 2015 legislation changed to allow use of electronic signatures. It must also contain details that indicate the nature of the prescriber (doctor, dentist, nurse or pharmacist independent or supplementary prescriber etc.)
 - Contact details of the prescriber
- l) Any space on the prescription form below where then medication has been written must be blanked off e.g. by drawing a line through it to reduce the opportunity for fraud.
- m) Any concerns regarding the prescribing of CDs should be brought to the attention of the trusts CDAO.

6.2.1 Validity of Prescriptions

The validity period of NHS prescriptions for schedule 1, 2, 3 and 4 CDs is restricted to 28 days. The prescription will not be dispensed if more than 28 days have lapsed since it was signed and dated by the prescriber.

6.3 Collection and Transport of Controlled Drugs to a Patient's Own Home

- a) Registrants may transport medication to patients, where patients, their carers or representatives are unable to collect them, provided the registrant is conveying

- the medication to a patient for whom the medicine has been prescribed (for example, from a pharmacy to the patient's home).
- b) Before collecting medication from a community pharmacy to deliver to a patient in their own home the following must be checked:
 - Will the community pharmacy deliver?
 - Are there any family who can collect?
 - Are there any neighbours or friends who can collect?
 - c) When is the medication need? (how urgent) this may inform if chemist can deliver or if it can be collected by another person:
 - Today
 - Tomorrow
 - Next day
 - d) If after the check list has been completed and documented and all alternatives have been explored, if there is no alternative and Mersey Care staff need to collect medication then the following process must be followed
 - e) Two staff (e.g. 1 RN, 1 HCA) must collect medication
 - f) Before leaving the community pharmacy check prescription against the contents of the bag medication and that medication has been dispensed is as per prescription
 - g) Take medication immediately back to patients home
 - h) Transport medicines directly to the patient. They should be stored out of sight in the car, during the journey.
 - i) Record in the patient notes that item has been delivered to the patient (date, time and signature - see appendix 3)

6.4 Storage of Controlled Drugs

The Controlled Drugs (Supervision of Management and Use) Regulations 2006 specify that arrangements for storage of CDs should be covered by Standard Operating Procedures (SOPs)

6.4.1 Storage on Intermediate Care Ward 35

- a) The registered nurse must sign the pharmacy drivers log book on receipt of the pharmacy bag containing CDs. The registered nurse must check the bag is sealed and also check the serial numbers.
- b) The registered nurse must sign the CD requisition ward book / discharge prescription immediately.
- c) Immediately following the receipt of the CDs they must be checked against the prescription/requisition and entered into the correct CD register either the CD stock register or the patient's own CD register. The record should be made onto the correct page in the register completing all fields, this needs to be witnessed and signed by a second registered nurse in to the CD register
- d) The same Registered Nurse that signed the receipt should check the requisition/prescription corresponds with each CD received. Checks should include correct:
 - Drug
 - Strength
 - Formulation
 - Quantity
 - In date expiry
 - Correct patients name if supplied for a individually patient

- Correct directions if labeled for discharge
 - Discharge prescriptions for on-going inpatient usage should be checked against the current prescription chart
- e) **Any discrepancies should be reported to the pharmacy immediately and rectified**
 - f) The CD register should be stored safely out of sight close to the CD cupboard but not in it
 - g) The room where the CD cupboard is kept should be locked at all times and the number of people who have access to the cupboard kept to a minimum
 - h) Where practicable different strengths of the same drug should be segregated. The National Patient Safety Agency safer practice notice “Ensuring Safer Practice with High Dose Ampoules of Diamorphine and Morphine” – May 2006 also requires separate storage for low and high strength products
 - i) Containers of stock which has expired should be clearly marked “EXPIRED” and stored in such a way as to separate them from in-date stock. The drugs should be destroyed as soon as possible

6.4.2 Storage of Oromucosal Midazolam by Dental Service

- a) Midazolam oromucosal solution although a schedule 3 CD is exempt from safe custody requirements however any drugs liable to abuse which are held on Trust premises should be stored securely. As such midazolam kept by the dental service should be stored in a tamper evident box.
- b) When not in use this box must be stored in a locked cupboard which is fixed to a wall or floor.
- c) During clinic sessions the box may be placed on the side with the security seal in place ready for use if needed

6.4.3 Storage of Controlled Drugs in a Patient’s Own Home

- a) A risk assessment must be completed for patients prescribed CDs that are to be administered by District Nurses. The risk assessment needs to be completed to identify concerns relating to safe storage. The risk assessment is included in the following care plans:
 - Chronic pain
 - Acute pain
 - Administration of injections
 - Syringe driver
- b) Following completion of the risk assessment, the Risk Assessment Pathway for Controlled Drugs should be referred to for action to be taken (appendix 4)
- c) Safe storage of medicines should be discussed with the patient, carer or relative. The “Safe Storage and Disposal of Your Medicines” leaflet should be given to the patient, carer or relative

6.5 Checking Stock Levels/Running Balance

- a) All trust staff who supply or administer CDs should maintain a running balance of stock in their CD registers/stock control sheets. Regular stock checks must also be performed. The aim of the running balance and stock checks is to identify irregularities or discrepancies as quickly as possible.
- b) After each transaction the running balance of medication remaining should be calculated and recorded in the ward/care home’s CD Register and or the pink

stock control sheet this should be reconciled with the physical stock in the cupboard or patient's own home.

6.5.1 Intermediate Care Ward 35

- a) The maintenance of correct stock levels and regular checks of the ward.
- b) CDs are the responsibility of the registered practitioner in charge of the ward.
- c) A stock check of all CDs on the ward must be performed at each shift change over, by two registered nurses, one from each shift. This will be twice daily.
- d) Sealed, tamper-evident original manufacturers' packs of CDs should be opened to count the contents. Sometimes the seal can be peeled back and resealed without it being noticed. Also some patients are discharged with CDs they have been using on the ward and a part container may be issued on discharge.
- e) Oral liquid CD discrepancies. Due to limitations in measuring equipment checks should generally be made by visual inspection. When coming to the end of a bottle i.e. less than a quarter remaining the liquid should be measured. A small discrepancy may be discovered and adjustment of the stock balance must be made with a pharmacist as soon as possible after identification with the registered nurse being a witness. It is recommended that adjustment is made, each time a new bottle is required so any error does not accumulate. Discrepancies larger than 10% of the running balance must be reported on Datix and the Accountable Officer for CDs informed.
- f) The date, time, whether the stock level is correct or not, (yes/no) and the signature of two registered nurses completing the stock check should all be recorded in the CD register.
- g) The ward will check compliance with the CD checking regime through a regular audit program.
- h) Medicines Management will audit ward CD stock levels and other aspects of CD management every three months. This audit will be performed by a pharmacist or pharmacy technician. The audit must be conducted with a registered nurse from the ward.
- i) All discrepancies or concerns raised on the daily, monthly and three monthly checks and audits must be reported to the ward manager immediately. The Clinical Lead and Chief Pharmacist (or deputy) must be informed without delay. The procedure for CD discrepancies must be followed.

6.5.2 Patient's Own Home

- a) When CDs that are to be administered by trust staff, are received in to a patient's own home the stock levels should be recorded onto the pink stock control sheet by the first registered nurse from the trust who visits the patient's home following delivery. One sheet should be used for each drug /drug strength/drug formulation.
- b) Sealed, tamper-evident original manufacturers' packs of CDs should be opened to count the contents. Sometimes the seal can be peeled back and resealed without it being noticed. Also some patients are discharged with CDs they have been using on the ward and a part container may be issued on discharge.
- c) Oral liquid CD discrepancies. Due to limitations in measuring equipment checks should generally be made by visual inspection. When coming to the end of a bottle a small discrepancy may be discovered and adjustment of the stock balance must be made with another registered nurse as a witness as soon as possible after identification. It is recommended that adjustment is made, each time a new bottle is required so any error does not accumulate. Discrepancies

larger than 10% of the running balance must be reported on Datix and to the trust CDAO.

- d) Anticipatory medication stock levels must be checked weekly by a registered nurse and need assessed. This check should be witnessed by Health Care Assistant or Assistant Practitioner. If patient shows signs of improvement and no longer needs anticipatory medication then this should be denatured and disposed of according to policy (section 6.7).
- e) The date, time, whether the stock level is correct or not, (yes/no) and the signature of two registered nurses completing the stock check should all be recorded on the pink stock control sheet.

6.5.3 Care Homes

- a) If administering a CD to a patient in a care home then the quantity for the patient's own CDs must be checked and recorded onto the pink stock control sheet by the first registered nurse from the trust who visits the patient. One sheet should be used for each drug /drug strength/drug formulation.
- b) Sealed, tamper-evident original manufacturers' packs of CDs should be opened to count the contents. Sometimes the seal can be peeled back and resealed without it being noticed. Also some patients are discharged with CDs they have been using on the ward and a part container may be issued on discharge.
- c) Oral liquid CD discrepancies. Due to limitations in measuring equipment checks should generally be made by visual inspection. When coming to the end of a bottle a small discrepancy may be discovered and adjustment of the stock balance must be made with the care home manager/staff in charge on duty as a witness as soon as possible after identification. It is recommended that adjustment is made, each time a new bottle is required so any error does not accumulate. Discrepancies larger than 10% of the running balance must be reported on Datix.
- d) The stock levels recorded in the care home's own CD register must also be checked and recorded. This should be signed and witnessed by the manager/staff in charge on duty in the care home.
- e) Any discrepancies between the register, the pink stock control sheet and the physical stock must be reported to the manager/staff in charge on duty in the care home, District Nurse Team Leader/Case Load Holder and Datix completed.

6.6 Dealing with Discrepancies

6.6.1 Intermediate Care Ward 35

- a) If a discrepancy is spotted during a stock count, a recount should be performed immediately to verify this.
- b) The nurse in charge must be notified immediately
- c) A thorough check of the CD cupboard and the CD register must be conducted to check if the discrepancy has been caused by an incorrect entry or misplacement of stock.
- d) The ward manager must be informed immediately if the above checks fail to resolve the discrepancy
- e) Under the management of the ward manager, the immediate investigation must determine when the stocks were last correct. Have any doses been administered but not recorded? Use the prescription chart records to check

- against entries in the CD register. List all the staff on duty since the stock was last correct and question them about possible reasons.
- f) Report the discrepancy to the Chief Pharmacist, Medical Director (Trust CD Accountable Officer) and Deputy Director of Nursing. They will advise if there are any other routes of investigation worth pursuing.
 - g) The majority of stock discrepancies are caused by misplacement within the CD cupboard or incorrect entries in the CD register (eg. entry placed in wrong section of CD register for similar sounding drug). The majority of discrepancies are resolved within 24 hours.
 - h) If the discrepancy cannot be resolved, the CDAO and/or Chief Pharmacist and Deputy Director of Nursing will consider and advise if the incident needs to be reported to the Police. Cases where there is suspicion of theft or untoward practice will be reported to the police. The reporter to the Police must take details of the Police Incident Number to include in the Trust's electronic incident reporting system - Datix.
 - i) The incident must be recorded on Trust's electronic incident reporting system - Datix.
 - j) Correction of the CD balance in the CD register must be made by a pharmacist and witnessed by the nurse in charge.
 - k) Disciplinary action or staff development needs should be assessed in accordance with relevant policies and professional standards & guidance.

6.6.2 Patient's Own Home

- a) If a discrepancy is spotted during a stock count, a recount should be performed immediately to verify this.
- b) The Case Load Holder/Team Leader should be notified immediately
- c) A thorough check of the area around the patient and where the medication has been stored along with the pink stock control sheet and patient notes must be conducted to check if the discrepancy has been caused by an incorrect entry or misplacement of stock.
- d) The team leader must be informed immediately if the above checks fail to resolve the discrepancy
- e) Under the management of the team leader, the immediate investigation must determine when the stocks were last correct. Have any doses been administered but not recorded? Use the nursing notes to check against entries on the pink stock control sheet. List all the staff visiting the patient since the stock was last correct and question them about possible reasons.
- f) Report the discrepancy to the Chief Pharmacist AND the Medical Director (Trust CD Accountable Officer). They will advise if there are any other routes of investigation worth pursuing.
- g) The majority of stock discrepancies is caused by misplacement within the home or incorrect/lack of entries on the pink stock control sheet. The majority of discrepancies are resolved within 24 hours.
- h) If the discrepancy cannot be resolved, the CDAO and/or Chief Pharmacist and Deputy Director of Nursing will consider and advise if the incident needs to be reported to the Police. Cases where there is suspicion of theft or untoward practice will be reported to the police. The Chief Operating Officer for Community Division should be notified of this decision before proceeding. The reporter to the Police must take details of the Police Incident Number to include in the Trust's electronic incident reporting system - Datix.
- i) The incident must be recorded on Trust's electronic incident reporting system - Datix.

- j) Correction of the CD balance on the pink stock control sheet must be made by a registered nurse and witnessed by a Health Care Assistant or Assistant Practitioner.
- k) Disciplinary action or staff development needs should be assessed in accordance with relevant policies and professional standards & guidance.

6.6.3 Care Homes

- a) If a discrepancy is spotted during a stock count, a recount should be performed immediately to verify this.
- b) The care home manager/staff in charge on duty should be notified immediately
- c) A thorough check of the CD cupboard and the CD register must be conducted to check if the discrepancy has been caused by an incorrect entry or misplacement of stock.
- d) The care home manager must be informed immediately if the above checks fail to resolve the discrepancy
- e) The care home manager should be advised to:
 - Conduct an immediate investigation to determine when the stocks were last correct. Have any doses been administered but not recorded? Use the Medicines Administration Record (MAR) chart record to check against entries in the CD register and the pink stock control sheet.
 - List all the staff on duty since the stock was last correct and question them about possible reasons.
 - Report to the police where there is suspicion of theft or untoward practice
 - Report to local authority safeguarding team
- f) The majority of stock discrepancies are caused by misplacement within the CD cupboard or incorrect entries in the CD register (eg. entry placed in wrong section of CD register for similar sounding drug). The majority of discrepancies are resolved within 24 hours
- g) Mersey Care community division nursing staff must record the incident on Trust's electronic incident reporting system – Datix
- h) Correction of the CD balance on the pink stock control sheet and the care home CD register must be made by the care home manager/staff on duty in charge and witnessed by Mersey Care Community Division registered nurse present at the time

6.7 Administration

- a) Controlled Drugs may only be administered to patients in accordance with the directions of a qualified practitioner.
- b) It is good practice that in the community setting, wherever possible two nurses should be present at the administration of controlled drugs, however, where this is not possible, a Registered Nurse in the community may administer, without witness, a CD which has been obtained on prescription by the patient.
- c) There are situations when it is necessary for two nurses to undertake the procedure. These are listed below.
 - When a syringe driver is being commenced
 - More than one syringe driver is being used
 - Four or more drugs in any one syringe driver

- When the drugs prescribed for the syringe driver are outside the Merseyside and Cheshire Guidelines. Advice can be sought from the specialist palliative care team and www.palliativedrugs.com
- d) On a ward the administration of a controlled drug must be witnessed.
- e) A prescriber must complete an Authorisation to Administer form or on Ward 35 Patient Prescription Chart, authorising the nurse to administer a particular controlled drug. In the community a record of that administration must also be made on the pink stock control sheet, evaluation sheet and EMIS. On the ward administration must be recorded in the CD register and the Patient Prescription Chart.
- f) The following process must be followed:
- Check the identity of the patient. The patient's name and date of birth corresponds with the Authorisation to Administer form or Patient Prescription Chart and wherever possible is confirmed by the patient.
 - Check the patient is not allergic to the medicine prior to administration.
 - Ensure that the intended drug and dose for the patient is correct.
 - Know the therapeutic uses of the medicine to be administered, its normal dosage, side effects, precautions and contra-indications.
 - Check the Authorisation to Administer form/Patient Prescription Chart and the label on the medicine dispensed is clearly written and unambiguous.
 - Check the expiry date of the medicine.
 - Check the strength, dosage, weight, where appropriate method of administration, route and timing, frequency, start and finish dates.
 - Check previous administration record of controlled drug to ensure administration is due
 - Contact the prescriber without delay where contra-indications to the prescribed medicine are discovered, where the patient develops a reaction to the medicine, or where assessment of the patient indicates that the medicine is no longer suitable.
 - Where a nurse is administering a Controlled Drug that has already been prescribed and dispensed for that patient, obtaining a witness and second signature must be based on the local risk assessment.
 - A stock check of Controlled Drugs must be taken and recorded as part of the administration procedure

6.8 Disposal

The Home Office has advised that all Controlled Drugs in Schedules 2, 3 and 4 (part 1) should be denatured and, therefore, rendered irretrievable before being placed into pharmaceutical waste containers and sent for incineration.

6.8.1 Intermediate Care Ward 35

See SOP Record Keeping for Controlled Drugs on Bed Based Wards

6.8.2 Patient's Own Home

- a) CDs are the property of the patient and remain so even after death. Individuals are not legally allowed to possess CDs that have not been prescribed for them. The patient and the patient's relative should be advised of the legal status.
- b) When prescribed controlled drugs require disposal from a patient's home due to:
- The patient no longer needing the controlled drug
 - The expected death of the patient

- c) The patient or the patient's relatives must be advised in the first instance to return all controlled drugs to a community pharmacy for safe disposal
- d) Community Division staff **MUST NOT** take away/carry/transport any patient's controlled drugs that have not been denatured. However it is important to make a record of stocks remaining and advice given.
- e) CDs may be destroyed in a patient's home:
 - If the registered nurse has performed a documented risk assessment and has concluded that it is a risk to leave the patient or relatives to dispose of the CDs
 - When the patient or relative/carer are unable to return the CDs to a community pharmacy
 - Where the patient has died and the relative/carer are unable to return the CDs to a community pharmacy **and** the practitioner can determine that the CDs will not be required by the coroner because the death was expected.
- f) **Permission must be sought from the patient, relative or carer to destroy the CDs. Evidence of permission is required and the information must be documented in the patient's records**

6.8.3 Care Homes

- a) Community nursing staff administering CDs to patients in care homes are not responsible for their destruction. This is the responsibility of the Care Home staff

6.8.4 Residential Care Homes

- a) Residential Care Homes i.e. without nursing staff should return all medicines (including CDs) to the community pharmacy for safe disposal. Records should be kept in the home's usual record of returned medication and in the CD register if the medication is recorded there.

6.8.5 Nursing Homes

- a) Nursing Care Homes i.e. with nursing staff should denature the CDs using a recognised CD denaturing kit before consigning to a licensed waste company. This should be recorded in CD register.
- b) Destruction in either case should also be recorded on the pink stock control sheet. If this isn't at the same time as the care home's return/destroy then the CD register must be checked as evidence before recording on the stock control sheet. If there is no evidence of destruction then this needs to be reported and Datix completed

6.8.6 Destruction Process

- a) Community Nursing see SOP DN1: The Destruction of Controlled Drugs (CDs) in the community by Registered Community Nurses
- b) Intermediate Care Ward 35 see SOP Record Keeping for Controlled Drugs on Bed Based Wards

7. CONSULTATION

7.1 Individuals involved in developing the policy:

- Debbie Bowden, Medicines Safety Support Manager

7.2 This document was circulated for review to:

- David Fearnley, CDAO,
- Lee Knowles, Chief Pharmacist
- Sarah Rafferty, Medicines Safety Officer
- Kerrie Bermudez, Joint Head of Medicines Management Community Division
- Medicines Optimisation Group

8. TRAINING AND SUPPORT

8.1 Training

All staff involved in the handling of CDs must have completed the following training:

- Medicines Management - face to face training
- Controlled drugs and high risk medicines – eLearning
- Medicines calculations – eLearning
- Safe and effective use of medicines - eLearning

8.2 Support

Medicines Management service can be contacted for advice with this policy

8.3 Dissemination and Implementation

- a) This policy and any SOPs which underpin it will be disseminated by service leads.
- b) New staff will be informed of policies relevant to practice at the local induction.

9. MONITORING

- a) Controlled Drugs (Supervision of management and use) Regulations 2013 states that as part of their duties the CDAO should ensure monitoring and auditing of the management and use of CDs
- b) Audits will be completed as part of the organisation's audit schedule

10. EQUALITY AND HUMAN RIGHTS ANALYSIS

Title: Management of Controlled Drugs

Area covered: All staff involved in the handling of controlled drugs

What are the intended outcomes of this work?

To ensure the legal requirements of the Medicines Act 1968 and the Misuse of Drugs Act 1971 and Regulations in terms of prescribing and managing CDs are complied with while ensuring that patients who require them have access to controlled drugs in a timely fashion.

Who will be affected?

Mersey Care NHS Foundation Trust staff ordering, prescribing, administering and disposing of CDs.
Patient's being prescribed and administered CDs by staff employed by Mersey Care NHS Foundation Trust

Evidence

What evidence have you considered?

Controlled Drugs (Supervision of management and use) Regulations 2013
NICE guidance
Royal College of Nursing Standards for Medicines Management

Disability (including learning disability)

None

Sex

None identified

Race

Non identified

Age

Non identified

Gender reassignment (including transgender)

Non identified

Sexual orientation

Non identified

Religion or belief

Non identified

Pregnancy and maternity

Non identified

Carers

Non identified

Other identified groups

Non identified

Cross Cutting

Non identified

Human Rights	Is there an impact? How this right could be protected? Not applicable
Right to life (Article 2)	Use not engaged
Right of freedom from inhuman and degrading treatment (Article 3)	Not applicable
Right to liberty (Article 5)	Not applicable
Right to a fair trial (Article 6)	Not applicable
Right to private and family life (Article 8)	Not applicable
Right of freedom of religion or belief (Article 9)	Not applicable
Right to freedom of expression Note: this does not include insulting language such as racism (Article 10)	Not applicable
Right freedom from discrimination (Article 14)	Not applicable

Engagement and Involvement *detail any engagement and involvement that was completed inputting this together.*

None

Summary of Analysis *This highlights specific areas which indicate whether the whole of the document supports the trust to meet general duties of the Equality Act 2010*

Eliminate discrimination, harassment and victimisation
This policy does not discriminate within the target populations who require immunisation or medical therapy

Advance equality of opportunity
NA

Promote good relations between groups
NA

What is the overall impact?
NA

Addressing the impact on equalities
There needs to be greater consideration re health inequalities and the impact of each individual development /change in relation to the protected characteristics and vulnerable groups
NA

Action planning for improvement

Detail in the action plan below the challenges and opportunities you have identified. Include here any or all of the following, based on your assessment

- Plans already under way or in development to address the **challenges** and **priorities** identified.
- Arrangements for continued engagement of stakeholders.
- Arrangements for continued monitoring and evaluating the policy for its impact on different groups as the policy is implemented (or pilot activity progresses)
- Arrangements for embedding findings of the assessment within the wider system, OGDs, other agencies, local service providers and regulatory bodies
- Arrangements for publishing the assessment and ensuring relevant colleagues are informed of the results
- Arrangements for making information accessible to staff, patients, service users and the public
- An arrangement to make sure the assessment contributes to reviews of DH strategic equality objectives.

For the record

Name of persons who carried out this assessment:


Debbie Bowden

Date assessment completed:

17/01/19

Name of responsible Director:

Lynda Taylor



Date assessment was signed:

28 June 2019

Appendix 1 - Misuse of Drugs Regulations 2001 – Drug Schedules

Schedule 1

This includes drugs such as cannabis and lysergide (LSD) which are not used medicinally. Possession and supply are prohibited except in accordance with Home Office authority.

Schedule 2

This includes drugs such as diamorphine, morphine, pethidine, oxycodone, methadone, ketamine and cocaine. They are subject to the full controlled drug requirements relating to prescriptions, safe custody (except for secobarbital) and the need to keep registers etc. (unless exempted under schedule 5).

Schedule 3

This includes the barbiturates (except secobarbital), buprenorphine, diethylpropion, flunitrazepam, midazolam, mazindol, meprobamate, pentazocine, phentermine, temazepam and tramadol.

They are subject to special prescription requirements (except phenobarbital).

They are not subject to the safe custody requirements (except buprenorphine, diethylpropion, flunitrazepam and temazepam).

Registers do not need to be kept, but invoices must be retained for 2 years.

Schedule 4

Part I of the schedule includes 32 benzodiazepines (flunitrazepam, midazolam and temazepam are now in schedule 3), and pemoline, which are subject to minimal control.

Part II includes androgenic and anabolic steroids, clenbuterol, chorionic gonadotrophin (HCG), non-human chorionic gonadotrophin, somatotropin, somatrem and somatropin. CD prescription requirements do not apply and Schedule 4 CDs are not subject to safe custody requirements.

Schedule 5

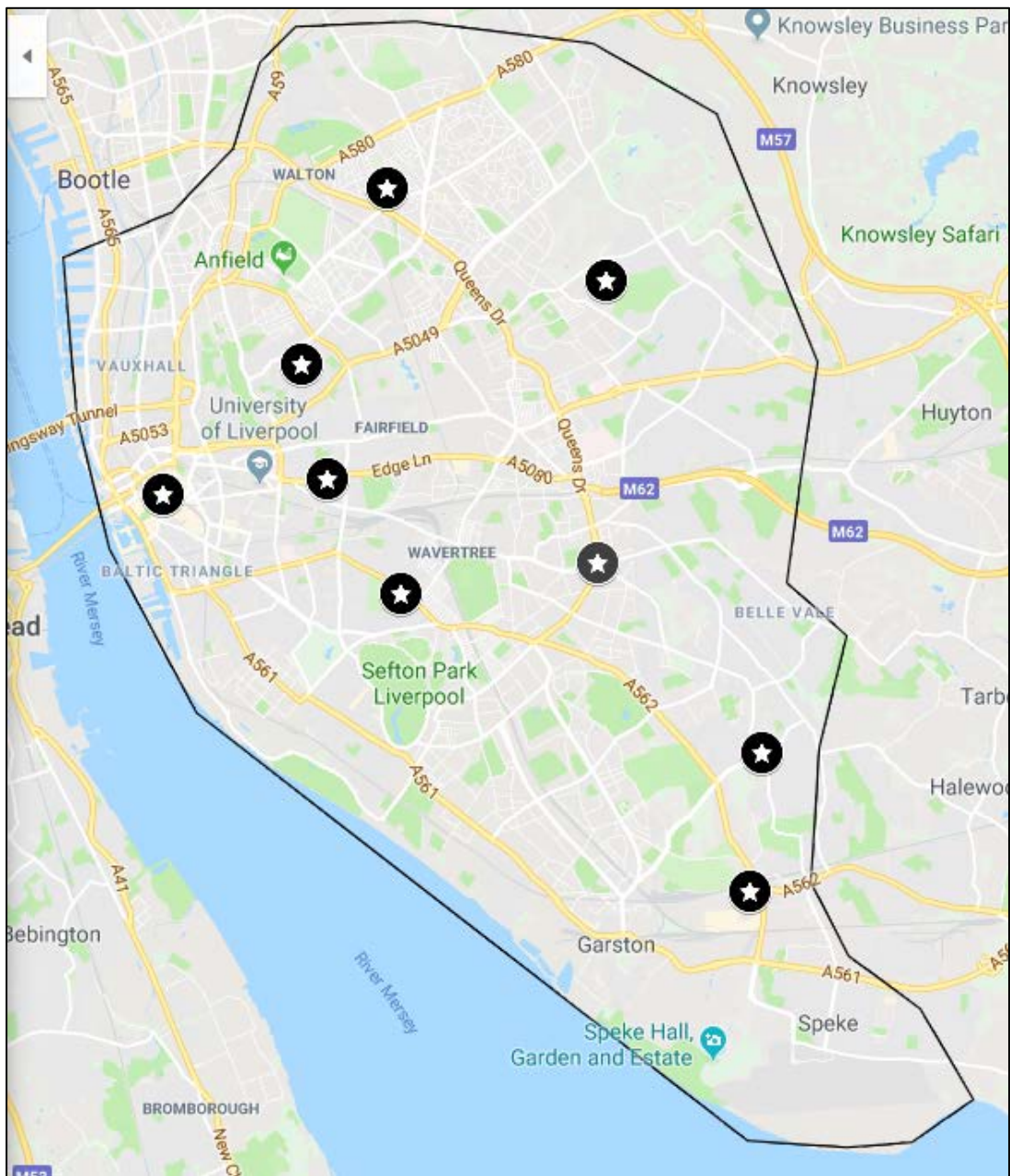
This includes those preparations which, because of their strength, are exempt from virtually all CD requirements other than retention of invoices for two years. This group includes Oramorph 10mg in 5ml Liquid, compound codeine preparations.

Appendix 2 - Community Pharmacies Holding Palliative Care Medicines

Liverpool

Area	Pharmacy	Address	Telephone No.	Opening Hours
Everton	Asda Pharmacy	Breck Road Everton L6 5DR	0151 264 6100	Mon: 8:00 - 23:00 Tues: 7:00 - 23:00 Wed: 7:00 - 23:00 Thur: 7:00 - 23:00 Fri: 7:00 - 23:00 Sat: 7:00 - 22:00 Sun: 10:30 - 16:30
Walton	Asda Pharmacy	Utting Avenue Liverpool L4 9XU	0151 256 7276	Mon: 8:00 - 23:00 Tues: 7:00 - 23:00 Wed: 7:00 - 23:00 Thur: 7:00 - 23:00 Fri: 7:00 - 23:00 Sat: 7:00 - 22:00 Sun: 10:30 - 16:30
West Derby	Deysbrook Pharmacy	1 Winterburn Cres Liverpool L12 8TQ	0151 228 9400	Mon: 7:00 - 18:45 Tues: 7:00 - 19:30 Wed: 7:00 - 18:45 Thur: 8:00 - 18:45 Fri: 8:00 - 18:45 Sat: 9:00 - 12:30 Sun: CLOSED
City Centre	Boots Pharmacy	9 -11 Church Street Liverpool L1 1DA	0151 709 3149	Mon: 8:30 - 20:00 Tues: 8:30 - 20:00 Wed: 8:30 - 20:00 Thur: 8:30 - 20:00 Fri: 8:30 - 20:00 Sat: 8:30 - 19:00 Sun: 11:00 - 17:00
Kensington	Kensington Health Centre Pharmacy	155 Edge Lane Edge Hill Liverpool L7 2PF	0151 263 1218	Mon: 7:30 - 22:00 Tues: 7:30 - 22:00 Wed: 7:30 - 22:00 Thur: 7:30 - 22:00 Fri: 7:30 - 22:00 Sat: 7:30 - 22:00 Sun: 9:00 - 22:00
Childwall	Cohens Chemist	Queens Drive Childwall Liverpool L15 6YG	0151 722 6267	Mon: 8:00 - 23:00 Tues: 8:00 - 23:00 Wed: 8:00 - 23:00 Thur: 8:00 - 23:00 Fri: 8:00 - 23:00 Sat: 9:00 - 22:00 Sun: 10:00 - 22:00

Wavertree	Asda Pharmacy	126 Smithdown Rd Liverpool L15 3JR	0151 734 6719	Mon: 8:00 - 22:00 Tues: 8:00 - 22:00 Wed: 8:00 - 22:00 Thur: 8:00 - 22:00 Fri: 8:00 - 22:00 Sat: 8:00 - 22:00 Sun: 10:30 - 16:30
Woolton	Lloyds Pharmacy	Sainsbury's 7 Woolton Street Liverpool L25 5QA	0151 428 1087	Mon: 8:00 - 20:00 Tues: 8:00 - 20:00 Wed: 8:00 - 20:00 Thur: 8:00 - 21:00 Fri: 8:00 - 21:00 Sat: 8:00 - 22:00 Sun: 10:00 - 16:00
Hunts Cross	Asda Pharmacy	Hunts Cross Shopping Centre Hunts Cross Liverpool L24 9WA	0151 728 4600	Mon: 8:00 - 20:00 Tues: 8:00 - 20:00 Wed: 8:00 - 20:00 Thur: 8:00 - 20:00 Fri: 8:00 - 20:00 Sat: 8:00 - 20:00 Sun: 10:00 - 16:00



Sefton

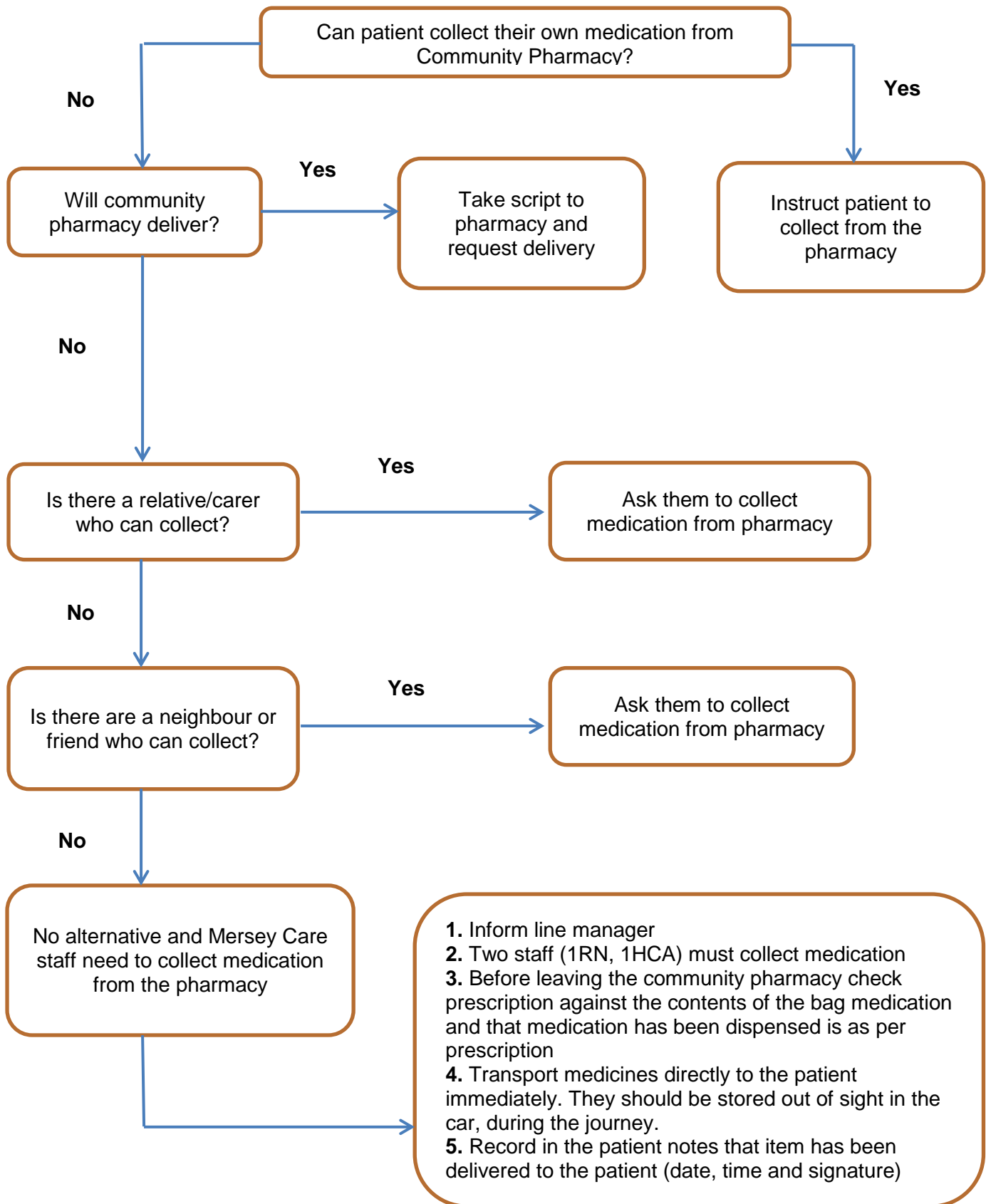
Area	Pharmacy	Address	Telephone No.	Opening Hours
Litherland	Bridge Road Pharmacy	54-56 Bridge Road Litherland Liverpool L21 6PH	0151 920 6361.	Mon: 7:00 - 23:15 Tues: 7:00 - 23:15 Wed: 7:00 - 23:15 Thur: 7:00 - 23:15 Fri: 7:00 - 23:15 Sat: 8:00 - 20:00 Sun: 8:15 – 15:00
Aintree	Asda Pharmacy	ASDA Store Ormskirk Road Aintree L10 3LN	0151 520 4410	Mon: 8:30 - 22:00 Tues: 8:30 - 22:00 Wed: 8:30 - 22:00 Thur: 8:30 - 22:00 Fri: 8:30 - 22:00 Sat: 8:30 - 22:00 Sun: 10:30 - 16:30
Churchtown	Cambridge Rd Pharmacy	137 Cambridge Road Churchtown PR9 7LT	01704 227065	Mon: 8:00 – 23:00 Tues: 8:00 – 23:00 Wed: 8:00 – 23:00 Thur: 8:00 – 23:00 Fri: 8:00 – 23:00 Sat: 8:00 – 23:00 Sun: 9:00 – 19:00
Southport	Tesco Kew Pharmacy	In-store Pharmacy Town Lane Kew Southport PR8 5JH	01704 862847	Mon: 8:00 - 22:00 Tues: 8:00 - 22:00 Wed: 8:00 - 22:00 Thur: 8:00 - 22:00 Fri: 8:00 - 22:00 Sat: 8:00 - 20:00 Sun: 10:00 - 16:00

Appendix 3 - Palliative Care Drugs List

Alfentanil 500microgram/ml injection 2ml ampoules
Cyclizine 50mg/ml injection 1ml ampoules
Clonazepam 1mg/ml injection 1ml amps
Dexamethasone injection 4mg/ml (2ml ampoules) (1ml amp)
Diamorphine 10mg injection
Diamorphine 30mg injection
Diamorphine 5mg injection
Glycopyrronium bromide 200mcg / ml injection 1ml ampoules
Haloperidol 5mg/ml injection 1ml ampoules
Hyoscine butylbromide 20mg/ml injection 1ml ampoules
Hyoscine hydrobromide 400 micrograms/ml injection 1ml ampoules
Hyoscine hydrobromide 600 micrograms/ml injection 1ml ampoules
Levomepromazine 25mg/ml injection 1ml ampoules
Metoclopramide 5mg/ml injection 2ml ampoules
Morphine sulphate 10mg /ml injection 1ml ampoules
Midazolam 5mg/ml injection 2ml ampoule (Hypnovel)
Octreotide 50mcg/1ml
Morphine / Oramorph 10mg/5ml Solution
OxyNorm (Oxycodone) immediate release 5mg capsules
OxyNorm (Oxycodone) immediate release 5mg/5ml liquid
OxyNorm (Oxycodone) 10mg/ml injection 1ml ampoules
Sevredol 10mg tablets
Sevredol 20mg tablets
Water for Injection 2ml ampoules
Water for Injection 10ml ampoules
Sodium Chloride 0.9% 2ml ampoules
Sodium Chloride 0.9% 10ml ampoules
Sodium Chloride 0.9% 1000ml intravenous infusion
Furosemide 250mg/25ml injection ampoules
Furosemide 50mg/5ml injection ampoules
Furosemide 20mg/2ml injection ampoules

The drug list may be altered, based on the needs of the local population and changes in prescribing trends within palliative care.

Appendix 4 - Transporting Medication from Community Pharmacy to Patient Own Home Flow Chart



Appendix 5 - District Nurse Risk Assessment Pathway for Controlled Drugs in Patient Homes following completion of a syringe driver or administration of medication/injection care plan

