# CONTROLLED DRUGS POLICY AND ASSOCIATED STANDARD OPERATING PROCEDURES

**POLICY**

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| **Approving Body** | Joint Drug and Therapeutics and Medicines Optimisation Committee | | |
| **Date Approved** | 9th February 2024 | | |
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| **Sponsor (Position)** | Chief Pharmacist and Controlled Drug Accountable Officer (CDAO) | | |
| **Author (Position & Name)** | Assistant Chief Pharmacist and Medication Safety Officer – Joanna Freeman | | |

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## CONTENTS

## 1.0 INTRODUCTION

This policy and associated Standard Operating Procedures (SOPs), which are available as appendices within this document, set standards for staff to ensure that good governance is applied at all stages of handling Controlled Drugs (CDs), including ordering, receiving, storing, dispensing, supplying, prescribing, administering, transporting and destroying CDs at Sherwood Forest Hospitals NHS Foundation Trust (SFH).

The management of CDs is governed by the Misuse of Drugs Act (1971) [1]and its associated regulations [2, 3, 4, 5, 6, 7, 15].

This policy describes the application of UK legislation pertaining to CDs at SFH.

The regulations require organisations to have SOPs in place for the management and use of CDs within the organisation.

The management of CDs in secondary care is also guided by the Department of Health publication entitled "Safer Management of Controlled Drugs" [8], and the National Institute of Heath and Care Excellence (NICE) guidelines. [9] This this policy incorporates the necessary guidance.

It is a statutory requirement for the Trust to have a Controlled Drugs Accountable Officer (CDAO) who is responsible for ensuring that safe and secure processes for controlled drugs are in place [6]. This is set out in the 'Controlled Drugs (Supervision of Management and Use) Regulations 2013'. At SFH, the CDAO is the Chief Pharmacist.

To ensure safe and secure handling of medicines, SFH may also apply similar restrictions to other high-risk medicines (as identified at a local and national level) even though not legally required to do so.

All areas where CDs are stocked or administered must also ensure that there is a stock of reversal agent. The clinical effects of medication is not covered in this policy but all staff involved in the administration and prescribing of CDs must also know how to escalate a suspected overdose and / or adverse effects which may be caused by this medication.

The management of CDs is subject to ongoing audit and review. There will be an annual report presented to the Joint Drug and Therapeutics and Medicine Optimisation Committee, the Patient Safety Committee and the Quality Committee in order to provide on going assurance within the Trust that CDs are being managed appropriately and safely. There will also be a quarterly report submitted to the regional CD Local Intelligence Network (CD LIN).

No deviation from the policy or SOPs is accepted without the specific authorisation of the SFH CDAO. In the absence of the CDAO, the Trust Medication Safety Officer (MSO) will deputise for the CDAO and must be consulted if a deviation from the Policy is felt necessary.

## 2.0 POLICY STATEMENT

It is a Trust requirement that all staff work within this policy and within the SOPs relevant to their role.

## 3.0 DEFINITIONS/ ABBREVIATIONS

### Controlled Drug (CD)

A Controlled Drug (CD) is a preparation that is subject to special legislative control because of the potential for abuse or diversion leading to harm [1, 2, 7].

These regulations refer to the ordering, receiving, storing, dispensing, supplying, prescribing, administering, transporting and destruction of CDs in five different 'schedules' and must be complied with under English law. Any infringement of this act may result in prosecution.

### Controlled Drug Schedules

The Misuse of Drugs Regulations 2001 [2] classifies CDs into five schedules according to the different level of control attributed to each. They are distinguished in the British National Formulary (BNF) [13] by the symbol **CD1** with the number indicating which schedule the medication belongs.

The five schedules are described briefly below.

Schedule 1 includes drugs not used medicinally such as hallucinogenic drugs. A Home Office licence is required for their possession, production and supply.

Schedule 2 includes opiates, major stimulants for example. This schedule is subject to full CD requirements relating to prescription, safe custody the need to keep a CD register. Possession, supply and procurement is authorised for pharmacists and other classes of people named in the 2001 regulations.

Schedule 3 includes barbiturates. These are subject to special prescription requirements. Safe custody requirements apply to some medication in this category. Register records are not legally required although invoices must be retained for 2 years.

Schedule 4 includes two parts, Part I, in which the medications are subject to minimal control and Part II. CD prescription requirement do not apply and registers do not ned to be kept with a few exceptions.

Schedule 5 includes medication which contain CDs at low strength.

To see which medication is grouped into which Schedule refer to the VCD regulation table hyperlinked in Appendix 7.

### Controlled Drugs Accountable Officer

The Controlled Drugs Accountable Officer (CDAO) is a statutory role [6], and is nominated by the Trust, in accordance with the Health Act and regulations 3 and 4 of the Controlled Drugs Regulations 2013. This is a fit, proper and suitable experienced person appointed or nominated by a designated body to ensure the safe, appropriate and effective management and use of CDs within the organisation. The name of this person must be notified to the Care Quality Commission (CQC).

**Authorised Witness for Controlled Drug Destruction**
A member of healthcare staff permitted by the Trust's Accountable Officer to witness the destruction of expired Controlled Drugs, or those deemed unsuitable for use for other reasons. This person will sign to confirm that the task has been performed accurately and correctly.

**Controlled Drugs requisition book**
A bound book with sequentially numbered, duplicate pages used by wards and departments for ordering of CDs for use within the Trust. A standardised book is used nationally.

**Controlled Drug Register**
A bound book with sequentially numbered pages used by wards and departments for recording all stocks of CDs and administration to patients. A standardised book is used nationally.

**Patient's Own Controlled Drugs (POD CDs): receipt, transfer and return book**
A bound book with sequentially numbered forms used for recording receipt, transfer to another ward, destruction and return to pharmacy for all POD CDs. The book should also be used for recording TTO CDs where applicable. The book was designed by and is printed for SFH.

**Local Intelligence Network (LIN)**
A regional network which the CDAO attends to share information between organisations and agencies regarding the handling and use of controlled drugs. Also known as Controlled Drugs Local Intelligence Network (CDLIN)

**Illicit or Illegal Drug**
This is defined in this context as one that the individual is not entitled to be in possession of under current legislation.

## 4.0 ROLES AND RESPONSIBILITIES

### 4.1 Medicines Safety Team (MST)

Medicines Safety Team consists of the Trust Medication Safety Officer (MSO), the Deputy MSO and two specialist Medicines Management Technicians (MMTs). The team is responsible for producing and maintaining this policy, review of audit results (from the regular CD audits), monitoring and reviewing incidents related to controlled drugs, and for reviewing relevant CD Local Intelligence Network quarterly communications.

### 4.2 Joint Drug and Therapeutics and Medicines Optimisation Committee (DTC/MOC)
This committee will be responsible for the final ratification of the Policy and will provide assurance to Patient Safety Committee (PSC) on all aspects of the Policy via regular reports on CD management.

### 4.3 Individuals

#### 4.3.1 All
All healthcare professionals responsible for prescribing, supplying, ordering, administering or disposing of CDs on a ward or clinical area must familiarise themselves with the relevant section of the BNF, the SFH Medicines Policy, CD SOPs relevant to their role, and any local procedures.

### 4.3.2 Prescribers

All prescribers, including doctors, and non-medical prescribers within their scope of practice, are responsible for adhering to the legal requirements for the prescribing of CDs. CDs may only be prescribed by legally authorised practitioners and in line with the SFH CD Policy.
All prescribers of CDs are accountable for, and have a professional duty to be knowledgeable of, the CD, dose, interval, associated risk of the medicine that they are prescribing and ensuring that the patient has been counselled in regard to the addiction potential of these medicines.

### 4.3.3 Pharmacists

Pharmacists must be confident that a prescriber is legally authorised to prescribe CDs, and that a prescription is legal prior to dispensing a prescription. The pharmacist may check the registration status on General Medical Council (GMC), Nursing and matron Council (NMC), General Pharmaceutical Council (GPhC) and Health and Care Professions Council (HCPC) websites. Pharmacists are responsible for their own safe and legal handling of CDs in accordance with this policy.

### 4.3.4 Chief Pharmacist or nominated deputy

Is responsible for overseeing the safe custody and handling of CDs within the Pharmacy Department including:

- Arranging for the CD stock and records in SFH Pharmacy to be checked and reconciled at least every six months;
- Receiving notification of all unresolved discrepancies and initiation of appropriate investigations within Pharmacy;
- Maintaining a record of all checks made by pharmacy staff, including the identities of the staff members carrying out those checks;
- Ensuring that the CD Policy and associated appendices are reviewed at least every three years and amended where necessary.

### 4.3.5 The Controlled Drugs Accountable Officer (CDAO) is responsible for:

- Ensuring the safe and effective use and management of CDs within their own organisation and by anybody or person providing services to their organisation;
- Ensuring that adequate and up-to-date Standard Operating Procedures (SOP) are in place in relation to the management and use of CDs;
- Producing quarterly reports of their CD occurrences to give to the CDAO leading the Local Intelligence Network (LIN) of which their organisation is a member. The occurrence report must describe details of any concerns that the organisation has regarding the management of CDs or confirmation that there have not been any concerns in the required timeframe.

The CDAO must also have regard to best practice in relation to the management of CDs:

- Ensuring there are appropriate processes in place for the ordering, receiving, storage, dispensing, supplying, prescribing, administration and transportation of CDs are in place.
- Ensuring adequate destruction and disposal arrangements for CDs
- Ensuring monitoring and auditing of the management and use of CDs
- Ensuring relevant individuals receive appropriate training
- Maintaining a record of concerns regarding relevant individuals

- Assessing and investigating concerns
- Taking action if these are well founded concerns
- Establishing arrangements for sharing information

**4.3.6 Ward or department leaders including theatres**

Are responsible for ensuring safe custody and handling of CDs in line with this Policy within their area. They are responsible for the security of the CD keys (section 6.2) and storage of CDs in line with this policy. They are responsible for the overarching security and safe keeping of CDs, including regular (at least once in 24hours) stock balance checks are completed and recorded. The exception to this will be if an area is closed or not in use, in which case a 24 hour check will not be required as long as the area is secure during this period and the CD keys appropriately stored, see section 6.2.

Only registered nurses, midwives, ODPs and pharmacists are permitted to fulfil certain functions regarding the ordering, supply and disposal of CDs. When the Appointed Practitioner in Charge is not from one of these professions (e.g. radiology) the responsibilities for CDs must lie with a designated practitioner. The Chief Pharmacist and Clinical Director for Medicines Optimisation, together with senior managers from the Division, must agree and authorise the named practitioner to be given these responsibilities.

**4.3.7 Registered Nurses, Midwives and ODPs**

Are responsible for the ordering, storage and availability of CD medications. The details of the responsibility is set out throughout this Policy with which all staff must be familiar.
In the theatre setting the ODP, nurse or midwife must act as a second checker to the anaesthetist where practical to verify the medicines being administered, the expiry date and the dose.

4.3.8 **Anaesthetists** are responsible for

- Clearly stipulating on the anaesthetic record which CD is required and the dose. Multiple doses and vials will not be supplied unless for immediate use.
- Checking the medicine to be administered, the dose and expiry with a second checker.
- Ensuring the safe custody of the CD if administration is delayed or the medication is to be titrated.
- Recording clearly the amount of medication administered in the patient's anaesthetic record.
- Returning unopened ampoules to the nurse, ODP or midwife and witnessing the return of this medication into the CD cupboard and countersigning the CD register.
- The safe disposal of any unused CD in the blue medicine waste bins. Any wasted medication must also be recorded accurately in the CD register and signed by the anaesthetist and a second witness (nurse, ODP or midwife)
- Label all syringes in accordance with the departmental practices.

## 5.0 APPROVAL

The Policy will be ratified by the Joint Drug and Therapeutics and Medicines Optimisation Committee.

## 6.0 DOCUMENT REQUIREMENTS – STANDARDS AND PROCEDURES FOR THE USE OF CONTROLLED DRUGS

### 6.1 Controlled Drugs Stationery

Transactions relating to Schedule 2 and 3 CDs must be entered in the appropriate CD stationery.

CD stationery includes:

- CD order books
- CD record books
- any local CD documents, such as CD returns advice notes, pharmacy distribution documents

A list of all commonly used CDs can be found on the government website at the following address: List of most commonly encountered drugs currently controlled under the misuse of drugs legislation - GOV.UK (www.gov.uk)

### 6.2 The Custody and Safekeeping of CD Keys

Keys for the CD cupboards are the responsibility of the shift co-ordinator which must be a registered nurse, ODP, midwife or radiographer and must be kept on their person. They must not be removed from the ward/department, unless for the purposes of storage during departmental closure.

CD keys must be kept separate to other ward keys.

The custody of the keys may be passed to another registered nurse/midwife/ODP working within the same ward/department if deemed necessary by the shift co-ordinator. The nurse, midwife, or ODP in charge may hand keys to a pharmacist or MMT for legitimate access to these areas. CDs keys must not be given to any individual who does not require access to the CD cupboard.

Pharmacists or MMTs should check CD stock levels as part of the CD audit, which occurs every six months, and this will be arranged between the ward and pharmacy department.

Refer to the Trusts Medicines Policy for advice on non-CD related keys.

There must only be one key in circulation for the CD cupboard. Copies and spares are not permitted. All additional keys must be irretrievably destroyed. Lost keys will mean a new lock and new key is required.

If a department closes temporarily e.g. at a weekend, then the keys must be safely stored in another department. If access will not be required out of hours, then keys may be stored in pharmacy. If access may be required out of hours, then keys may be stored in adjacent departments. In this scenario, the keys must be booked into the receiving departments CD register and kept in their CD cupboard. Two signatures are required in the register to book the CD keys in and out.

### 6.3 Ordering of Controlled Drugs

The responsibility for the ordering of CDs lies with the nurse in charge , ODP or midwife in charge. If they are not available then this responsibility may be devolved to a member of the team as set out in Appendix 1. On receipt of CDs from pharmacy, they will lawfully be in possession of them and are accountable for their custody.

Pharmacy must assure themselves of the validity of requests from these areas before dispensing.

For full procedure, see **APPENDIX 1 – PROCEDURE FOR ORDERING CDs BY WARDS AND DEPARTMENTS INCL THEATRES**

### 6.4 Transport and Receipt

#### 6.4.1 Transport or collection of CDs from pharmacy

All CD receipts must be documented in the appropriate CD registers in accordance with the SOP shown in Appendix 2.

#### 6.4.2 Persons authorised to transport CDs

The following may be authorised to transport CDs from Pharmacy to the clinical area named on the requisition

- Pharmacy staff who have received appropriate training.
- Any member of SFH staff (bearing Trust identification) who has been authorised by a nurse, midwife or ODP.
- Any porter who has received appropriate training.
- Healthcare Assistants may transport CDs in between wards due to patient transfer as long as they are immediately received by the receiving ward nurse.

For the full procedure covering collection and delivery of CDs see **APPENDIX 2 - PROCEDURE FOR COLLECTION OR DELIVERY OF CONTROLLED DRUGS DISPENSED BY PHARMACY**

For the full procedure for receipt of CDs delivered from pharmacy see **APPENDIX 3 - SECURE RECEIPT ON WARDS AND DEPARTMENTS OF CDS ORDERED FROM PHARMACY (TRANSFERRING CUSTODY)**

### 6.5 Transfer or Borrowing of CDs Between Wards

During the pharmacy department's opening hours, Monday – Friday 0900 – 1730 and Saturday, Sunday 0900-1300, the borrowing of medicines between wards/departments is not permitted, unless in an emergency or specifically authorised by pharmacy. Such uncontrolled borrowing creates further subsequent medicine availability problems. If CDs are required, then the CD requisition book must be sent to pharmacy in the usual way.

Stock orders will not be routinely processed out of hours or at weekends, the nurse in charge, ODP or midwife or nominated deputy is responsible for ensuring that all stocks of CDs are up to date. Emergency stock orders and items for temporary stock will be processed in the normal way and the record book must include identifiable details of the patient who requires the medication e.g. D number.

Outside normal Pharmacy Department's opening hours, all staff have access to an 'on-call' pharmacist if medicine supplies are urgently required. Exceptionally, out of hours, single doses of CDs, may be given to a patient on one ward from stock on another. The necessary CD records must be made in the CD register of the ward making the supply (to whom the stock belongs) by two registered nurses/midwives to book out only the dose required. The single does must then be taken back to the ward and immediately administered. Two nurses/midwives must complete this administration e.g. the nurse from the ward where the medication is borrowed from must attend the ward with the patient to witness the administration. Multiple doses may be administered in this way for a patient until the pharmacy department opens if required.

Refer to Medicines Policy for advice on borrowing non-CD medications.

### 6.6 Storage of Controlled Drugs

CDs on wards and departments must be locked in an approved CD cabinet compliant with CD regulations and be kept locked when not in use.

The CD cupboard is reserved solely for the storage of

- the CD order book;
- the CD register;
- schedule 2 CDs;
- schedule 3 CDs;
- patient's own CDs;
- confiscated unknown or potentially illicit substances;
- a CD key held for safe storage for another ward/department
- FP10 prescription pads if relevant to the department.

For areas with a double cupboard, the CD stationery may be stored in the outer CD cupboard.

Schedule 2 CDs and those schedule 3 CDs requiring safe custody e.g. *temazepam*, *buprenorphine* are legally required to be stored within the **inner** section of the CD cupboard. Other Schedule 3 CDs should be stored in the **outer** section of the CD cupboard this includes *midazolam, phenobarbital, tramadol, gabapentin and pregabalin.*

Access to the CD cupboard should be restricted and only for the purpose of accessing schedule 2 and 3 CDs or high strength potassium injections. For this reason, only CD items as listed above must be stored in the cupboard. The CD cupboard must not be used to store any other non-CD related items.

The CD cupboard must comply with the Misuse of Drugs (Safe Custody) Regulations 1973. It must be secured to the wall and be connected to a red light to identify when the outer door is open.

If a patient is self-administering under the Trust's Self-administration Policy they may store their own CDs within their patient's own drugs cabinet if this is their own CD from home or a specific TTO supply is made to them. In this instance the patient must be in possession of a POD locker key and be able to access the locker for the purposes of self-administration.

For further information on the management of Patients Own CDs please refer to **APPENDIX 4 – MANAGEMENT OF PATIENTS OWN CDs BROUGHT INTO SFH.**

### 6.7 Ward or Department Controlled Drug Requisition Books and Registers

Pharmacy staff will issue a new requisition book to a ward or department once the last page of the book has been used for ordering. Ward CD registers must be ordered in the requisition book by an authorised practitioner.

All records made in CD registers must be:

- Indelible
- Timely (i.e. made at the point of usage of the CD unless in exceptional circumstances. See separate theatres procedure)
- Any errors must not be crossed out, but bracketed, and an explanation specified, e.g., "error", at the top or bottom of the page, see Appendix 5
- All entries must be made by two practitioners.

See **APPENDIX 5 – WARD AND DEPARTMENT CD RECORD KEEPING** for information on the records which must be kept and the standards required for CD entries in the register.

CD registers and the CD requisition books must be locked in the CD cupboard when not in use. If the ward or department has an inner and outer CD cupboard then the CD stationery must be locked in the outer cupboard.

Wards and departments must only have one CD requisition book and register in use for CDs in that area at any one time. If an area has multiple locations e.g. theatres or ED, then there will be one book and register per theatre or CD cupboard location.

All ward areas will also be supplied with an additional register for recording the daily stock checks. Please see **APPENDIX 6 – WARD AND DEPARTMENT DAILY STOCK CHECKS OF CD BALANCES.**

### 6.8 Prescribing of Controlled Drugs

CDs in schedules 2 and 3 are subject by law to prescription requirements and it is unlawful for a pharmacist to dispense a CD unless all the information required is given on the prescription.

Refer to **APPENDIX 7 – CD REGULATIONS TABLE**, this table indicates which medicines have prescribing and storage restrictions for those products used within the Trust.

Refer to **APPENDIX 8 - CD PRESCRIBING STANDARDS** for more information on how to write a legal CD prescription.

CDs for patients to take out of the hospital must be prescribed on an FP10, TTO or white Trust outpatient prescription.

If a patient is in hospital but wishes to self-administer their own CD, then a supply must be made as if the patient were an outpatient e.g. prescribed on an outpatient prescription with full dosing instructions.

Prescribers should ensure that the appropriate clinical monitoring is in place for patients prescribed CDs. Onwards support and referral to ensure continuation of care and to ensure the effectiveness of prescribed medication is reviewed following, for example, transfers of care. More information on this may be found in NICE guidance 215 'Medicines associated with dependence or withdrawal symptoms: safe prescribing and withdrawal management for adults' published in April 2022

Pharmacists are legally permitted to make some amendments to a prescription without reference to a prescriber if it does not contain all the above details. Full details are available in the Medicine, Ethics and Practice publication.

Nationally, it is strongly recommended that a maximum of **thirty days** of CDs are prescribed for out patients. This is not a legal requirement and there may be clinical circumstances where a supply of more than thirty days is necessary. If these apply, the prescriber must be able to justify this on clinical grounds and it is good practice to clearly state this in the patient's medical notes. For discharge prescriptions, the minimum quantity must be supplied.

Outpatient prescriptions and FP10HP prescriptions are legally valid for 28 days from the date on the prescription (for CDs in schedules 2-4). Please ensure patients are aware of this as the pharmacy will be unable to supply after this date has elapsed. The 28 day includes the collection and supply of any owing medication. If the patient does not collect medication within the 28 days then the balance must be returned to stock and a new prescription will be required from the prescriber to supply the CD.

FP10HPs prescriptions for CDs will not be posted to individuals. If an FP10HP prescription is required then the patient must collect this in person from the prescribing clinician or clinic and take to their preferred chemist for dispensing. The dispensary at King's Mill Hospital does not currently hold a licence to dispense any FP10 prescription.

### 6.9 Administration Processes

Please see **APPENDIX 9 – ADMINISTRATION OF CDs ON WARDS AND DEPARTMENTS** for more information on the standards expected for the administration of CDs.

### 6.10 Returns and Destruction

Please see **APPENDIX 10 – RETURN OF CDs TO PHARMACY FROM WARDS AND DEPARTMENTS** for more information on how to remove unwanted CDs from the wards and departments within the Trust.

It is the responsibility of the ward / department team to check the expiry dates of the CDs when the daily balance checks occur. Please note that this will be not routinely checked by the pharmacy team due to access restrictions. Controlled Drugs which have expired or are no longer required (stock or patients' own) must not be returned to pharmacy but should be destroyed on the ward/clinic in the presence of a pharmacist or MMT.

All Controlled Drugs must be disposed of in a safe and effective manner as described in **APPENDIX 11 – SAFE DESTRUCTION OF CDs AT WARD / DEPARTMENT LEVEL**

### 6.11 Illicit Drugs

This policy prohibits the possession or use of illicit substances on Trust premises in line with legislation.

Doctors, nurses, midwives or pharmacists may be asked to deal with substances removed from, or given up by patients admitted to SFH or visitors. These may include Schedule 1 CDs.

A Home Office licence is required to possess Schedule 1 CDs, and the nurse, midwife, doctor or pharmacist cannot take possession of the substance other than in the following two situations where exemptions are granted:

1. Where a person takes possession of a CD for the purpose of destroying it.
2. Where a person takes possession of a CD for the purpose of handing it over to a police officer.

Under no circumstances can a Schedule 1 CD be returned to a patient or relative at any time, as the person doing so would be guilty of the offence of the unlawful supply of a CD.

Refer to **APPENDIX 12 – PROCEDURE FOR THE REMOVAL OF ACTUAL OR SUSPECTED ILLICIT DRUGS FROM A PATIENT OR VISITORS, INCLUDING PRESCRIPTION ONLY MEDICATIONS THAT THE PERSON IS NOT LEGALLY IN POSESSION OF**, for more information on how to handle the storage and subsequent disposal or onwards referral of illicit drugs in wards and department.

### 6.12 Reporting Losses or Discrepancies

Please refer to **APPENDIX 13 – INVESTIGATION OF LOSSES OR BALANCE DISCREPANCIES ON WARDS AND DEPARTMENTS, OR INVESTIGATION OF SUSPECTED FRAUD**, for further information.

### 6.13 Management of Closures

If a ward or department is to be permanently closed then the pharmacy department must be contacted to return or destroy all CDs. The CD cupboard keys will be stored in the pharmacy CD cupboard.

Email: sfh-tr.controlleddrugs@nhs.net

If a ward or department is to close temporarily e.g. for deep clean, then the CDs will be transferred to Pharmacy in a sealed bag. Email the address above to alert the team that action is needed. A member of the pharmacy team will attend the ward with an Envopak, ward label for the external window in the Envopak and a red numbered tamper evident seal. The CDs will be counted and sealed into the Envopak along with the register by the pharmacy team member and nurse, midwife or ODP. The count will be recorded in the blue CD count register and signed by both individuals. Two pharmacy personnel may perform this task if other HCPs are not available. The bag will then be sealed and stored in the Pharmacy CD cupboard.

The CD cupboard keys will also be sealed in this bag along with the medication and stored in pharmacy.

When the ward or department reopens, the bag will be returned to the ward by a member of pharmacy staff. The bag will be opened by a member of pharmacy staff in the presence of a nurse, ODP or midwife from the area and a stock check of the CD conducted and recorded in the CD count register. The CDs and the registers will then be returned to the CD cupboard and the cupboard locked.

If a ward is to transfer to a different location then a similar process will occur. A member of the pharmacy team will attend with an envopak and tamper evident seal. The pharmacy team member along side a nurse, midwife, ODP or second pharmacy team member will count all CDs and put them in the bag, recording the quantities in the blue count register. The bag will be sealed with the CDs and the register and transported by the pharmacy staff member to the new location. At the destination the team member along with a nurse, midwife or ODP will check the medication in the bag against the register and lock in the new CD cupboard.

### 6.14 Archiving of Records

All documentation relating to records of CD transactions must legally be retained for two years unless it contains information relating to POD CDs, in which case the record must be kept for seven years.
For record books containing more than one entry, the whole book must be retained from the date of last entry. Table 1 below shows a summary of retention periods for various CD related stationery.

Table 1: Retention periods for CD stationery.

| Documentation | Duration of storage | Location of storage |
|---|---|---|
| Ward CD requisition books and CD registers | 2 years from date of last entry (they may be destroyed as confidential waste after this period) | On ward |
| Ward stock Receipt, Removal and Disposal of Controlled Drugs book | 2 years from date of last entry | On ward/ Pharmacy CD dispensing area (if not issued to a ward) |
| Patient's own controlled drugs: receipt, transfer and return book | 7 years from date of last entry | On ward |
| Pharmacy CD registers | 2 years from date of last entry | Pharmacy CD dispensing area |
| Porters CD delivery sheets | 2 years | Pharmacy |
| Requisitions | 2 years | Pharmacy |
| External orders and delivery notes | 7 years | Pharmacy |
| Prescriptions (outpatients) | 2 years | Pharmacy |
| Prescriptions (discharge- TTO) | 2 years | Pharmacy |
| Forms to record destructions of stock CDs | 7 years | Pharmacy |
| White patient's own CD form to record destruction of patient's own CDs | 7 years | Pharmacy |

## 7.0 MONITORING COMPLIANCE AND EFFECTIVENESS

| Minimum Requirement to be Monitored<br>(WHAT – element of compliance or effectiveness within the document will be monitored) | Responsible Individual<br>(WHO – is going to monitor this element) | Process for Monitoring e.g. Audit<br>(HOW – will this element be monitored (method used)) | Frequency of Monitoring<br>(WHEN – will this element be monitored (frequency/ how often)) | Responsible Individual or Committee/ Group for Review of Results<br>(WHERE – Which individual/ committee or group will this be reported to, in what format (e.g. verbal, formal report etc) and by who) |
|---|---|---|---|---|
| Compliance with legal requirement of CD management at ward / department level | Specialist Medicines Management Technician – CDs with Ward / Department Leader as required | Audit | 6 monthly | Formal report to:<br>DTC/MOC<br>PSC<br>Nursing, Midwifery and AHP Group. |
| Review of CD Incidents | Medication Safety Officer | Incident review | Quarterly | CD LIN |

## 8.0 TRAINING AND IMPLEMENTATION

As this is a new Policy there will be a number of training opportunities for current staff.

- Communication Team to assist with socialisation of the new Policy.
- Training events throughout the year for qualified nurses to attend.
- Specific training to be delivered to ward leaders, Practice Development Team and supervisors to ensure a 'train the trainer' cascade to all staff.

On going training to new starters will be provided via the following mechanisms which are under development at the point of Policy publication.

- Competency package to be developed for the use with newly qualified nurses
- E-Learning packages to be developed for– administration, prescribing, safe storage and management of CDs.

## 9.0 IMPACT ASSESSMENTS

- This document has been subject to an Equality Impact Assessment, see completed form at Appendix 14.
- This document has been subject to an Environmental Impact Assessment, see completed form at Appendix 15.

## 10.0 EVIDENCE BASE (Relevant Legislation/ National Guidance) AND RELATED SFHFT DOCUMENTS

**Evidence Base:**

1. The Misuse of Drugs Act 1971
2. Misuse of Drugs Regulations 2001
3. Human Medicines Regulations 2012
4. Misuse of drugs (safe custody) Regulations 1973
5. Misuse of Drugs (supply to addicts) regulations 1997
6. Controlled Drugs (Supervision and management and use) Regulations 2013
7. The Health Act 2006
8. "Safer Management of Controlled Drugs, a guide to good practice in secondary care (England)" May 2007
9. NICE Controlled Drugs guidelines June 2016
10. Royal Pharmaceutical Society: Medicines, Ethics and Practice edition 45 July 2022
11. Reducing risk of overdose with midazolam injection in adults Dec 2008: NPSA/2008/RRR011
12. A guide to the good management of Controlled Drugs in Primary Care, England, 3rd edition 2009
13. British National Formulary, online
14. CQC 'The safer management of controlled drugs Annual update 2017', published July 18
15. Statutory Instrument: SI 2018/1383 The Misuse of Drugs and Misuse of drugs (Safe Custody) (Amendment) (England and Wales and Scotland) Regulations 2018- changes to gabapentin and pregabalin scheduling
16. Recommendations for the Retention of Pharmacy Records - prepared by the East of England NHS Senior Pharmacy Managers 2016

**Related SFH Documents:**

- Medicine Policy
- Self-administration of medicine by patients or carers procedure
- IV Policy – Intravenous (IV) medication and fluid therapy administration through a venous access device policy
- Hospitalised opioid misuser management guideline
- Intravenous opioid administration (morphine, oxycodone and fentanyl) by registered nurses and operating department practitioners policy

## 11.0 KEYWORDS

Opiate, Opioid, CD, Controlled, Drugs, Medication, Medicine Policy, Illicit, Diversion, Misuse

## 12.0 APPENDICES

- As listed in contents table

## Appendix 1 – PROCEDURE FOR ORDERING CDs BY WARDS AND DEPARTMENTS INCL THEATRES

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| Objective | This procedure describes how ward and department staff order CDs from Pharmacy, and who is permitted to do this. |
| Scope | All nursing, midwifery and ODP staff suitably trained in the handling of CDs and authorised via the signature register to order CDs.<br><br>All pharmacy staff validated to dispense and supply CDs.<br><br>All SFH staff responsible for collecting or delivering CDs.<br><br>This SOP applies to all CDs which must legally be ordered and received using a paper requisition. |
| Responsibilities | The CDAO is responsible to ensuring the overarching CD Policy is maintained and is up to date (by themselves or their nominated deputy).<br><br>Ward and department leaders including theatres are responsible for ensuring their staff adhere to this SOP and are appropriately trained.<br><br>Ward/department leaders, ODPs and midwives are responsible for ensuring all new staff register their signature with the pharmacy department by attending the department with the individual to sign a sheet.<br><br>Ward nurses, ODPs and midwives are responsible for checking the stock levels and ordering appropriately, this should occur during normal working hours for stock CDs.<br><br>Stock CDs will not routinely be supplied at weekends and all areas must ensure that stock levels are checked each week.<br><br>The exceptions to this include theatres, EAU, ED, ICCU, Ward 36, John Eastwood Hospice and Ward 11. Stock supply to these areas at weekend should not be routine and only in exceptional and unforeseen circumstances.<br><br>Pharmacy, medical staff and other healthcare professionals not mentioned above are not authorised to order CDs. |
| Related Policies and procedures | SFH Medicines Policy |
| Procedure | **1. Staff signature in CD requisition book**<br><br>The practitioner's name and signature must appear on the authorised signature sheet kept centrally within the pharmacy department.<br><br>This list is used to check the validity of the individual requesting CDs. |

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| | All signatures must be countersigned by the ward/department leader or their nominated deputy.<br><br>The deputy must be band 6 or above and be the operational deputy for the ward or department.<br><br>Exceptions to this will be made for the following areas where the authoriser may be the designated pharmacist for the area:<br>- Emergency department<br>- All Newark wards and departments<br>- All MCH wards<br>- John Eastwood Hospice.<br><br>If an individual starts work in an area where they will be expected to order CDs, they must present at the pharmacy department alongside the authoriser and sign the centrally held signature log (for above mentioned exceptions, this may be done locally with the designated pharmacist) Identification for both parties will be checked by the pharmacy team.<br><br>Each signature will be countersigned by the ward/department leader or pharmacist to verify authenticity of the signature.<br><br>The ward/department leader or their deputy, can have their signature countersigned by a Pharmacist or MMT. |
| | **2. Ordering CDs for use on wards and departments (stock use)**<br><br>CDs for use on wards and departments are only supplied by pharmacy against a correctly completed order written in a standard CD requisition book and signed by a registered nurse/midwife/ODP. See above for the requirement to be registered as an authorised individual with the pharmacy department.<br><br>Only one CD must be ordered per page of the CD requisition book. If multiple CDs are required then this will require multiple pages to be completed.<br><br>Please note that only registered nurses, midwives and ODPs are authorised to order Schedule 2 and 3 CDs using the CD requisition books.<br><br>Each page is sequentially numbered, seen in the top right hand corner, they must be used in sequence. |
| | **3. Stock lists for controlled drugs**<br><br>Each ward or department has an agreed list of CDs that may be held as stock. The list can be accessed via the ward stock section of the Trust intranet.<br><br>If the CD to be ordered is a ‘stock item’ then there is no restriction as to the quantity that can be supplied although this will usually be limited to a full box. |

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| | If a 'non-stock' CD is required a pharmacist must professionally screen the prescription on the ward and countersign the CD requisition, or the patient's D Number annotated onto the order sheet in the top right hand corner and the CD requisition book sent to Pharmacy. The D number will be used to check Nerve Centre and clinically screen the request. If the area does not use Nerve Centre for prescribing then a prescription must accompany the book to the dispensary.<br><br>In the case of non-stock CDs, a seven-day temporary stock supply will be made. The expectation is that when the patient requiring this medication has left the ward or department that this CD is then returned. Please see Appendix 10 for further information on returning a CD. |
| | **4. Sending completed requisitions to Pharmacy**<br><br>Completed CD requisitions must be sent for dispensing to the Pharmacy. This must be via the porter service, a member of the ward or pharmacy team as the books are classified as controlled stationery. The books must be under supervision at all times when not securely stored.<br><br>If a CD requisition book is to be sent to the pharmacy from an external location at weekends, then a Royal Voluntary Services (RVS) volunteer may be used. The availability of the RVS volunteer can be checked via the flow room on 6991. If a volunteer is not available then a taxi may be used. See the Transportation of Medication using a delivery service procedure for further information. The CD requisition book must be sealed into an envelope or bag. Please note that stock CDs will not be routinely supplied at weekends including Newark and MCH ward areas. |
| | **5. Storage of CD stationery**<br><br>CD order/requisition books must be stored in a locked cupboard or drawer when not in use for the purpose of ordering a CD. This will usually be in the outer CD cupboard. |

## APPENDIX 2 - PROCEDURE FOR COLLECTION OR DELIVERY OF CONTROLLED DRUGS DISPENSED BY PHARMACY

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| Objective | To ensure Controlled Drugs (CDs) are handled securely once they have left the Pharmacy department until custody is transferred to the receiving area. |
| Scope | All pharmacy staff suitably trained in handling CDs.<br><br>All SFH staff responsible for collecting or delivering CDs.<br><br>This SOP applies to all CDs for which safe custody and storage requirements apply |
| Responsibilities | The CDAO is responsible to ensuring the overarching CD Policy is maintained and is up to date (by themselves or their nominated deputy).<br><br>Ward and department managers are responsible for ensuring their staff adhere to the overarching CD Policy |
| Related Policies and procedures | SFH Medicines Policy |
| Background | All transfer of CDs must be documented on the appropriate CD delivery paperwork.<br><br>An audit trail must be traceable throughout the whole process including when the CD is in transit. During this time authorised custody transfers to the individual making the delivery. This temporary authority then transfers to the ward or department after delivery. Signatures are required at each stage in order to be able to trace the journey of the CD from ordering to delivery.<br><br>Only authorised persons can collect, transport or receive CDs onto wards and departments. Any member of staff can collect and deliver CDs from pharmacy if they have an ID badge. CDs will not be handed over to individuals without a valid Trust ID badge. |
| Procedure | **1. Records of delivery**<br><br>The dispensing process will follow the local pharmacy procedure for CDs within the pharmacy department (Procedure for the labelling and dispensing of Controlled Drugs). All documentation and registers will be completed within Pharmacy in line with the legal requirements and local SOPs. The accuracy checker in pharmacy will sign the CD order book and the top copy of the order retained in Pharmacy.<br><br>Pharmacy staff will place the dispensed CDs and the CD order book in a bag (Envopaks) sealed with a unique, tamper-evident numbered tag ready for delivery. |

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| | A carbon copied 'medication delivery documentation form' or transport slip, will then be completed by the accuracy checker including details of the destination ward/department and the tag number.<br><br>The sealed Envopak will be stored in the designated CD storage area in the pharmacy department until collected for delivery. |
| | **2. Delivery of CDs by porter staff**<br><br>CDs will be delivered to the on-site wards/departments by a porter at agreed time(s) of delivery runs.<br><br>CDs may be delivered to off-site units in a sealed bag by an authorised person (e.g. hospital transport)<br><br>The porter is to;<br><br>- Collect all sealed bags that are ready for delivery to wards.<br>- Ensure there is a completed transport slip<br>- Check the tag numbers match the numbers recorded on the transport slip<br>- If correct, sign the "delivered by" section on the delivery document.<br>- The top copy of the delivery document will be retained in pharmacy.<br>- The bottom copy will accompany the designated messenger completing the delivery.<br><br>Delivery and receipt document contains the following;<br>- Date<br>- Time of delivery<br>- Ward<br>- Requisition number (referenced in the CD order book) However, if the dispensed CD is for a specific patient's TTO, the patients initials will be logged instead.<br>- Tag number<br><br>The CDs in the sealed Envopak then become the responsibility of the porter for its security<br><br>The porter will then deliver the sealed Envopak to the designated areas and must obtain a signature from the registered nurse, ODP or midwife receiving the CD into that area.<br><br>Upon receipt of the CD delivery, the registered nurse/midwife/ODP will sign the delivery document after confirming the number on the tag is correct and matches the delivery document, in the presence of the porter or authorised messenger.<br><br>The CDs then become the responsibility of that individual.<br><br>The sealed bag will be opened by two registered nurses/midwives/ODPs or a registered nurse/midwife/ODP with a pharmacist or accredited MMT, and the supply checked against the CD order in the requisition book, which will be signed to confirm receipt. |

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| | The following must be checked for each item:<br>○ The medication name, strength and formulation matches that ordered<br>○ The correct quantity according to the order has been supplied, boxes containing vials or ampoules should be opened to ensure all items are intact.<br>○ The requisition number on the order sheet matches that on the dispensing label.<br><br>**Any discrepancies must be reported to pharmacy immediately.**<br><br>Two registered nurses/midwives/ODPs or a registered nurse/midwife/ODP with a pharmacist or accredited pharmacy= technician will record receipt in the ward/department CD register without delay and secure the supply in the CD cupboard immediately. The amount received and the running total must be recorded in the CD register.<br><br>The completed copy of the transport slip must be brought back to the pharmacy by the porter or authorised messenger at the next available opportunity. This should be completed within 24 hours if immediately is not possible.<br><br>**At no point should Envopaks be left unattended. If there is no-one available on the ward/department to accept the Envopak, it must be returned to the designated CD storage area in the pharmacy department.** |
| | **3. Collection of CDs by SFH staff**<br><br>Completed orders for CDs can be collected by ward/department staff who are employed by the Trust. This does not need to be a registered professional and can be a Healthcare Assistant or Receptionist if necessary.<br><br>Trust ID must be furnished for inspection by pharmacy staff when collecting CD orders for the ward/department.<br><br>Pharmacy staff should collect the appropriate sealed bag from the designated CD storage area, and ensure there is a completed transport slip<br><br>Pharmacy staff will ask the member of staff collecting the Envopak to check that the bag is sealed, that the tag number matches the transport slip, and is for the correct ward or department, and to sign the “delivered by” section on the transport slip, at the top. The CDs then become the responsibility of the person collecting.<br><br>The member of staff will then take the white copy of the transport slip to the ward / department. The pink copy is retained in pharmacy and later combined with the white slip from the ward to complete the audit trail for delivery. |

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| | On delivery, which must be made immediately to a registered nurse, midwife or ODP, the receiving member of staff will sign on the "received by" section of the transport slip to confirm they have received the CDs.<br><br>The bag and therefore CDs is now the responsibility of the receiving practitioner.<br><br>The white form must be returned to pharmacy immediately. If this is not possible then this must be returned within 24 hours for reconciliation and to complete the audit trail of the delivery process. The pharmacy team must reconcile the white and pink copies of the transport slips to ensure the deliveries have ben signed for and the audit trail complete. |
| | **4. Collection of CDs by Patients (out-patients)**<br>This process will follow the local Pharmacy SOP (Procedure for the labelling and dispensing of Controlled Drugs).<br><br>This is for outpatients only. Patients must not be sent from the ward to the pharmacy department to collect their discharge medication. |

## APPENDIX 3 - SECURE RECEIPT ON WARDS AND DEPARTMENTS OF CDS ORDERED FROM PHARMACY (TRANSFERRING CUSTODY)

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| Objective | This procedure describes how CDs ordered from Pharmacy may be accurately and securely received onto a ward or department. |
| Scope | All SFH staff responsible for collecting or delivering CDs, and ward or department managers responsible for the safe custody of CDs in their area.<br><br>This SOP applies to all CDs for which safe custody and storage requirements apply. |
| Responsibilities | The CDAO is responsible to ensuring the overarching CD Policy is maintained and is up to date (by themselves or their nominated deputy).<br><br>Ward and department managers are responsible for ensuring their staff adhere to the CD Policy. |
| Related Policies and procedures | SFH Medicines Policy |
| Background | All CD receipts must be documented in the appropriate CD register. Only authorised persons are to collect, transport or receive CDs onto wards and departments. |
| Procedure | **1. Receipt onto the ward or department for stock CDs**<br><br>The process for the receipt of CDs onto the ward will be the same for both Schedule 2 and Schedule 3 CDs. Please note however that balance checks and CD register entries only need to be made for Schedule 2 CDs. See below for details.<br><br>The receiving practitioner must be a registered nurse, midwife or ODP.<br><br>The receiver must check that the bag they are accepting is for their ward or department. There will be a visible label on the outside of the Envopak in a clear window which will show the intended destination of the bag. If this is not correct then do not sign for it and give back to the porter for delivery to the correct destination.<br><br>If the bag is in the correct location then the receiver must check the bag is sealed and that the tag number on the bag is the same as the number stated on the delivery sheet. If both match, the receiver must sign the ”received by” section of the transport slip.<br><br>If the number on the tag does not match the number on the delivery sheet then ring the pharmacy department immediately. If the bag is received out of hours then this will have to be the on call pharmacist. Do not sign the sheet until this conversation has occurred. The pharmacy team will advise on the course of action after checking local paperwork. The white transport slip must be returned to the Pharmacy immediately but certainly |

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| | within 24 hours. The white slip will be returned by the porter if this is the method of CD delivery |
| | **2. Entering <u>stock</u> Controlled Drugs into the Controlled Drug Register**<br><br>Please see section 3 below for the receipt of TTO CD orders.<br><br>The process below refers to Schedule 2 CDs only. Schedule 3 CDs do not require a balance check or entry into the register but the process of ensuring the correct item and quantity must be followed as above. The Schedule 3 stock medication must be locked within the outer or inner CD cupboard depending on the storage requirements as highlighted in documented linked within Appendix 7<br><br>Two healthcare professionals (HCPs), one of whom must be a registered nurse, midwife or ODP, must check the contents of the sealed bag against the order. The second healthcare practitioner or 'checker' must be a registered nurse, midwife, ODP, Pharmacist or MMT.<br><br>The HCPs must initially check that the requisition book is the correct book for the ward / department in question. The ward / department will be written at the top of each page. If this is not correct then there has been a delivery error, please immediately contact the pharmacy department, via the on call service if necessary to arrange collection.<br><br>The HCPs must check the following for every individual order (one per page):<br>○ The medication name, strength and formulation matches that ordered.<br>○ The correct quantity according to the order has been supplied, boxes of vials and ampoules must be opened to ensure all items are intact.<br>○ The requisition number on the order sheet matches that on the dispensing label.<br><br>The CDs must be entered immediately into the ward or department CD Register by the same two HCPs. The entry into the register must be complete and correct: they must complete all columns for received CDs and both sign their names in the register. It is best practice that entries showing medicines received from pharmacy should be in **red** ink<br><br>The new balance should be checked by both HCPs to ensure the balance in the register matches that in the cupboard. To do this the medication must be physically counted and confirmed. At this point if the CD register can be signed and the CDs placed into the cupboard.<br><br>When this process is complete the CD cupboard must be locked and the requisition book and register stored securely in the outer cupboard.<br><br>If it is necessary for pharmacy staff to alter the quantity ordered (e.g. to the ward stock level, or to that of the available stock in pharmacy, a whole pack or a whole blister strip), the quantity will be altered, signed |

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| | and dated on the white and pink copies of the requisition book by the pharmacist. |
| | **3. Receipt of Discharge (TTO) medication containing CDs**<br><br>Discharge medications (TTOs) containing CDs will be sent in a sealed bag with a numbered tag for delivery from pharmacy to the ward in the same way as stock CDs. Please follow the same process as described in section 1 in terms of checking the location is correct and the tag number.<br><br>When CD TTOs are received onto the ward a record must be made in the Patients Own CD register – blue cover. All areas must have a separate register for POD CDs.<br><br>The CDs must be stored in the ward / department CD cupboard until they are handed to the patient. Two nurses or midwives must complete the "patient's own CD" register and give the medicines to the patient when they are discharged, and CDs returned to the patient. See Appendix 4 for more information on this. |

## APPENDIX 4 - MANAGEMENT OF PATIENT'S OWN CDS BROUGHT INTO SFH

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| Objective | To ensure the secure storage of patient's own (POD) controlled drugs (CDs) and robust record keeping. |
| Scope | All SFH staff responsible for the handling of patient's own controlled drugs (POD CDs).<br><br>This SOP applies to all CDs for which safe custody and storage requirements and register entries are required- see Appendix 7 |
| Responsibilities | The CDAO is responsible for ensuring the overarching CD Policy is maintained and is up to date (by themselves or their nominated deputy).<br><br>Ward and department managers are responsible for ensuring their staff adhere to the CD Policy and for the safe custody of POD CDs in their area. |
| Related Policies and procedures | SFH Medicines Policy<br>Self-administration of medication by patients and carer policy |
| Background | This SOP details the action to be taken when a patient brings their own CDs into SFH from home and when these CDs are legally prescribed for and possessed by the patient. |
| Procedure | **1. Storage and custody of legally prescribed patients' own medicines**<br><br>When a patient is admitted to a SFH ward or department with their own CDs, Schedule 2 or 3, the CDs must be given to a registered nurse, midwife, pharmacist or MMT.<br><br>The authorised practitioner, in the presence of a second practitioner (nurse, midwife, pharmacist or MMT), must make a record of CDs brought into hospital by the patient by completing a form in the "Patient's Own Controlled Drugs book". It is good practice that this process is explained to the patient or their representative when the CDs are first handed over, and with their verbal consent.<br><br>The CDs must be stored in the ward or department CD cupboard.<br><br>If possible, patients' relatives could be asked to take the patient's CDs home following review by the pharmacy team. In this case, if the CDs are returned immediately to relatives to take home, then there is no need to make an entry in the POD CD register<br><br>Patients' own CDs must NOT be recorded in the ward CD register along with the stocks. |

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| | **2. Transfer of Patient's Own CDs to another ward**<br><br>If a patient moves from one ward to another, any of their own CDs must be transferred with them.<br><br>Two authorised practitioners from the original ward must complete the entry in the Patient's Own Controlled Drugs book.<br><br>The CDs must be sealed in an envelope for transport.<br><br>The CDs in the sealed envelope may be transported to the new ward by the staff transferring the patient e.g. a porter. The authorised practitioner from the original ward must inform the receiving ward that the patient is being transferred with CDs, this can be via telephone at the handover stage.<br><br>A new entry in the Patient's Own Controlled Drugs book must be completed for receipt of the CDs onto the receiving ward. A corresponding entry will be present in the transferring ward to book out the CDs for the transfer and closing this particular entry for the ward.<br><br>The CDs must be stored in the receiving ward's CD cupboard. |
| | **3. Return of POD CDs to the patient**<br><br>The POD CDs will be stored in the CD cupboard until they are either transferred to another area, used on the ward by the patient, given back to the patient, or destroyed on the ward.<br><br>When the patient is ready to be discharged, two authorised practitioners must sign the Patients Own CD register to confirm that the CDs have been returned to the patient. The patient or their representative then has responsibility for the CDs.<br><br>If the patient is no longer prescribed the CD(s) or is on a different dose, a new supply should be made. Permission should be sought from the patient or their representative to destroy the unwanted CDs.<br><br>Illicit CDs must never be returned to the patient.<br><br>POD CDs will not be returned to pharmacy and so if no longer required will be destroyed on the ward following the processes set out in Appendix 11.<br><br>Please note that CDs must not be delivered to patients via taxis in any circumstances. CDs must be directly handed over to the patient, carers or official hospital transport only. |
| | **4. Patient self-administration of CDs**<br><br>A patient who is independently self-administering their medicines may administer their own CDs according to the self-administration policy. |

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| | Please note that it is only possible to self-administer CDs under the current policy if they are brought in from home. Additional supplies cannot be made due to the legal requirements for prescriptions.<br><br>The CD must be locked in the POD locker at the patient's bedside. The CDs must also be recorded in the POD CD register with a note to say they are being stored at the patient's bedside, daily counts will still be required. |
| | **5. Stock balance checks of patient's own CDs whilst in hospital**<br><br>The following process should be used to undertake stock balance checks of patient's own CDs.<br><br>On patient admission the CDs should be entered into the 'Record of CDs brought into hospital by individual patients' book by two practitioners (one of which should be a nurse or midwife)<br><br>The CDs should be checked daily to ensure the balance is correct.<br><br>When completing daily stock checks the patient's own CDs must be checked as follows:<br>o For every patient's own CD item, ensure all items recorded are present in the CD cupboard<br>o If any discrepancies, investigate and complete incident form as appropriate.<br>o Following investigation, count and document as above. |

## APPENDIX 5 – WARD AND DEPARTMENT CD RECORD KEEPING

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| Objective | To ensure accurate, timely, and legal records of CD storage and administration are kept. |
| Scope | All practitioners responsible for handling CDs, including nurses, midwives, ODPs and anaesthetists.<br><br>This SOP applies to all CDs for which register entries are required, including those medicines which are not legally CDs, but are treated as such at SFH, see Appendix 7 |
| Responsibilities | The CDAO is responsible to ensuring the overarching CD Policy is maintained and is up to date (by themselves or their nominated deputy).<br><br>Ward and department managers are responsible for ensuring their staff adhere to the CD Policy. |
| Related Policies and procedures | SFH Medicines Policy |
| Procedure | **1. Making entries into the CD register**<br><br>All entries must be clear, unambiguous and in indelible ink.<br><br>All entries must be signed by two practitioners (one of whom must be a nurse/ midwife/ODP/Anaesthetist).<br><br>Only one type of dose and formulation of a CD may be entered per page of the CD register.<br><br>When one page in the register is full, another new page must be started for that CD. The new page number must be added to the bottom of the finished page and the index at the front of the register updated.<br><br>The previous page number must be added at the top of the new page.<br><br>The balance transfer to the next page must be countersigned by two practitioners.<br><br>Entries showing administration of a CD should be in **black** ink. It is best practice that entries showing medicines received from pharmacy should be in **red** ink. Pharmacy stock checks or returns to pharmacy should be in the pharmacist/MMT designated colour ink.<br><br>If part of a vial is given to the patient, then the register entry must state the amount given and the amount wasted: e.g. for morphine 10mg, “5mg given and 5mg wasted” must be recorded in the register if the patient is administered a 5mg dose. The remainder must be discarded as explained in Appendix 11 |

## 2. Transferring balances to new registers

When new registers are issued, two nurses, midwives or ODPs, must enter the details of the CD stock from the old register to the new register, checking the balance as they do so. The register must be signed by the two practitioners.

At the end of the section for each CD write 'transferred to new register page ….'

The old register needs to say which page the balance has been transferred to in the new register for each CD.

When transferring balances to new registers, any remaining empty pages, full and part, in the old register must be crossed through. This is to prevent old registers being used accidentally.

The new register needs to say which page in the old register the CD has been transferred from. At the top of the new page for each CD write 'transferred from old register page…..' This is to ensure continuous traceability. An example follows:

**Old Register**

Name, Form of Preparations and Strength ……Morphine 10mg/ml…… 2

| AMOUNT (S) OBTAINED | | | AMOUNT(S) ADMINISTERED | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Amount | Date Received | Serial No. of Requisition | Date | Time | Patient's Name | Amount Given | Given By (Signature) | Witnessed By (Signature) | STOCK BALANCE |
| Carried forward from page number……1…… | | | | | | | | | Balance on transfer |
| | | | 14/1/24 | 21:00 | Balance from previous page | | A Nurse | B Nurse | 12 |
| | | | 15/1/24 | 10:20 | Harry Potter | 10mg | A Nurse | B Nurse | 11 |
| | | | 16/1/24 | 16:44 | Luna Lovegood | 5mg given 5mg wasted | A Nurse | B Nurse | 10 |
| | | | | | | | | | |
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| | | | | | | | | | |

Carried over to page number…Balanced Transferred to New Register Page 1…..

**New Register**

Name, Form of Preparations and Strength ……Morphine 10mg/ml…… 1

| AMOUNT (S) OBTAINED | | | AMOUNT(S) ADMINISTERED | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Amount | Date Received | Serial No. of Requisition | Date | Time | Patient's Name | Amount Given | Given By (Signature) | Witnessed By (Signature) | STOCK BALANCE |
| Carried forward from page number……Balance transferred from previous register page 2…… | | | | | | | | | Balance on transfer |
| | | | 18/1/24 | 22:45 | Balance from previous register | | A Nurse | B Nurse | 10 |
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## 3 Errors & Entry Changes

When recording in the CD register, if an error is made, it must NOT be crossed out or obliterated, instead the incorrect entry should be bracketed and asterisked and the word 'error' recorded at the top or bottom of the page. The correct entry, as it should have appeared, should be made alongside. An example follows:

Name, Form of Preparations and Strength .....Morphine Sulphate Concentrated 100mg/5ml..... 2

| AMOUNT (S) OBTAINED | | | AMOUNT(S) ADMINISTERED | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Amount | Date Received | Serial No. of Requisition | Date | Time | Patient's Name | Amount Given | Given By (Signature) | Witnessed By (Signature) | STOCK BALANCE |
| Carried forward from page number.....1..... | | | | | | | | | Balance on transfer |
| | | | 14/1/24 | 21:00 | Balance from previous page | | A Nurse | B Nurse | 100ml |
| | | | 15/1/24 | 14:15 | Harry Potter | 10ml | A Nurse | B Nurse | 90ml |
| | | | 16/1/24 | 16:10 | Luna Lovegood | 5ml | A Nurse | B Nurse | 85ml |
| | | | 17/1/24 | 18:30 | Cho Chang | (5ml)* 10ml | A Nurse | B Nurse | (80ml)*75ml |
| | | | 17/1/24 | 18:45 | Harry Potter | 10ml | A Nurse | B Nurse | (70ml)*65ml |
| | | | | | | | | | |
| | | | | | | | | | |

*Error

Carried over to page number.....

In the example above 5ml was entered incorrectly on the third line but was not corrected until the next line. The incorrect entries are asterisked and bracketed, and the correct entries written alongside.In the event of a patient refusing a dose after it has been entered in the CD register, it must NOT be crossed out or obliterated, instead the whole entry should be bracketed and asterisked and the word 'dose not given' recorded at the top or bottom of the page. If the dose can be returned to stock the balance must be updated next to the original entry. An example follows:

Name, Form of Preparations and Strength .....Morphine Sulphate Concentrated 100mg/5ml.....

| AMOUNT (S) OBTAINED | | | AMOUNT(S) ADMINISTERED | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Amount | Date Received | Serial No. of Requisition | Date | Time | Patient's Name | Amount Given | Given By (Signature) | Witnessed By (Signature) | STOCK BALANCE |
| Carried forward from page number.....1..... | | | | | | | | | Balance on transfer |
| | | | 14/1/24 | 21:00 | Balance from previous page | | A Nurse | B Nurse | 100ml |
| | | | 15/1/24 | 14:15 | Harry Potter | 10ml | A Nurse | B Nurse | 90ml |
| | | | 16/1/24 | 16:10 | Luna Lovegood | 5ml | A Nurse | B Nurse | 85ml |
| | | | (17/1/24 | 18:30 | Cho Chang | 10ml | A Nurse | B Nurse | 75ml)* 85ml |
| | | | 17/1/24 | 18:45 | Harry Potter | 10ml | A Nurse | B Nurse | 65ml |
| | | | | | | | | | |
| | | | | | | | | | |

*Dose not given

Carried over to page number.....

If a dose is wasted due to a patient refusing, the entry must NOT be crossed out or obliterated, instead the whole entry NOT including the balance should be bracketed and asterisked and the word 'dose wasted, patient refused' recorded at the top or bottom of the page. The dose must then be disposed of following the process set out in Appendix 11. An example follows:

Name, Form of Preparations and Strength .....Morphine Sulphate Concentrated 100mg/5ml.....

| AMOUNT (S) OBTAINED | | | AMOUNT(S) ADMINISTERED | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Amount | Date Received | Serial No. of Requisition | Date | Time | Patient's Name | Amount Given | Given By (Signature) | Witnessed By (Signature) | STOCK BALANCE |
| Carried forward from page number.....1..... | | | | | | | | | Balance on transfe |
| | | | 14/1/24 | 21:00 | Balance from previous page | | A Nurse | B Nurse | 100ml |
| | | | 15/1/24 | 14:15 | Harry Potter | 10ml | A Nurse | B Nurse | 90ml |
| | | | 16/1/24 | 16:10 | Luna Lovegood | 5ml | A Nurse | B Nurse | 85ml |
| | | | (17/1/24 | 18:30 | Cho Chang | 10ml)* | A Nurse | B Nurse | 75ml |
| | | | 17/1/24 | 18:45 | Harry Potter | 10ml | A Nurse | B Nurse | 65ml |
| | | | | | | | | | |
| | | | | | | | | | |

*Dose wasted; patient refused

Carried over to page number.....

## APPENDIX 6 – WARD AND DEPARTMENT CHECKS OF STOCK CD BALANCES

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| Objective | This procedure describes the correct method for CD stock checks on wards and departments including theatres |
| Scope | All staff who have responsibility for the security of CDs in a ward or department |
| Responsibilities | The CDAO is responsible to ensuring the overarching CD Policy is maintained and is up to date (by themselves or their nominated deputy). The ward or department manager must ensure that these checks are carried out.<br><br>Ward pharmacist or nominated pharmacist/MMT will check CD stocks and registers every six months, including accurate liquid balance.<br><br>NB. Necessity for more frequent checks will be made at the discretion of Nurse/Midwifery manager in liaison with the Chief Pharmacist. |
| Related Policies and procedures | SFH Medicines Policy |
| Procedure | **1. Frequency of balance checks**<br>For all wards and non-theatre departments, the stock balance of all CDs entered in the register must be checked at least once every 24 hours (when the ward or department is open) against the actual stock held in the ward/ department.<br><br>In areas where a 24-hour service does not operate, two Registered Nurses/Midwives/ODPs must check stocks of CDs at the beginning and end of the working day.<br><br>In theatre, CD stock check will occur at the beginning and end of each theatre session, this may be multiple times in a 24-hour period. If a theatre is not in operation then a check does not need to be performed as long as the area is secure during this period of inactivity.<br><br>Balance checks should also be done when transferring entries from an old CD register to a new CD register.<br><br>The balance checks should be recorded in the CD checking book. If the department is closed then the word ‘closed’ must be written to make it clear that a check was not expected. This may be done in retrospect.<br><br>Checks must be countersigned by two authorised practitioners. Any discrepancies must be dealt with immediately and reported on the Datix system. |
| | **2. Checking of balances**<br>A record indicating the checks have been carried out and confirming the stock is correct must be kept in the CD checking book. |

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| | Checking of CDs involves checking of entries in the register against the contents of the CD cupboard, not the reverse, to ensure all entries are checked. It is good practice to remove all CDs from the cupboard during this process and returning them once checked. This way any items not recorded will be evident at the end of the process.<br>There is no requirement to open packs with intact tamper evident seals (except for boxes of vials or ampoules for stock checking purposes.<br><br>Two nurses/midwives/ODPs must perform the check.<br><br>The entry must be dated and signed by both people completing the check.<br>The staff performing the check must be satisfied that all the entries made in the register since the last check are correct.<br><br>Stock balances of individual preparations must be checked after every administration and recorded in the CD Register. For liquid CDs see section 3. Sealed packs must not be opened for counting purposes.<br><br>The expiry dates of each product must also be checked at this point, noting that some liquid preparations may have reduced expiry once opened. This check will not be carried out by the pharmacy team due to restricted access to these medicines.<br><br>If any discrepancies are noted, a review of the previous maths calculations must be done, and if errors are identified, the register balance should be corrected as below. It is strongly recommended a calculator should be available in the CD cupboard and is used for calculations. |
| | **3. Checking of liquid balances**<br>The amount of liquid CDs should be checked daily on the routine CD checks by physically looking at any bottles in the CD cupboard and by also visually estimating the amount in any opened bottles. Do not decant the liquid to measure it. Accurate measurements will be done during the 6-month audit.<br>Liquid medicine stock balances must be checked by visual inspection after each administration and the balance must be confirmed to be correct at the end of each bottle.<br><br>Bungs are available from pharmacy to assist in measurement of liquids and must be inserted into the neck of each bottle on opening. The bung will remain in place for the duration of use.<br><br>If any discrepancies are noted, a review of the previous maths calculations must be done, and if errors are identified, the register balance should be corrected as below. It is strongly recommended a calculator should be available in the CD cupboard and is used for calculations.<br><br>For all CD liquids with discrepancies of 10mL and over - report on Datix, inform nurse in charge and investigate. A pharmacist or designated technician must correct the register. |

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| | **4. Investigation of losses or discrepancies in balance checks**<br>See Appendix 13, Investigation of losses or balance discrepancies on wards and departments, or investigation of suspected fraud. |

## APPENDIX 7 – CD REGULATION TABLE

The CD regulation table will not be available as a hard copy within the policy and is available on line via the following link**.**

Controlled Drug Regulation Table

## APPENDIX 8 – PRESCRIBING STANDARDS

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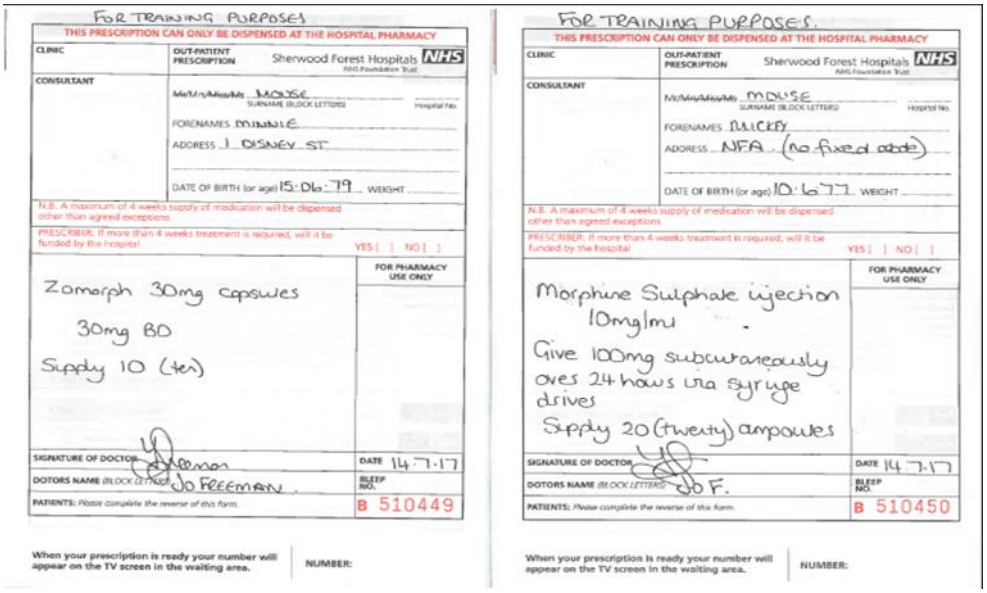
| Objective | This procedure describes the correct method for prescribing a CD in terms of legal requirements |
| Scope | All staff who have responsibility for the prescribing of CDs.<br><br>All staff who are responsible for screening or dispensing a CD prescription must also be familiar with the expected prescribing standards |
| Responsibilities | The CDAO is responsible to ensuring the overarching CD Policy is maintained and is up to date (by themselves or their nominated deputy).<br><br>The prescriber must ensure they are familiar with the content of this procedure. |
| Related Policies and procedures | SFH Medicines Policy: |
| Procedure | **1. Prescribing on EPMA (electronic prescription), for in patient administration**<br>As an inpatient, there are no additional prescribing requirements. A CD is prescribed in the same way as any other medication for inpatient administration. See section 2 for additional prescription requirements for outpatient prescriptions.<br><br>Due to the additional prescribing requirements on the TTO, described below, it may be that the prescriber has to select the correct strength of preparation in order to prescribe e.g. Zomorph 20mg twice daily would be prescribed as Zomorph 10mg capsules and the dose would be 20mg twice daily. This is because there is no 20mg preparation. Please ask a member of the pharmacy team for advice. |
| | **2. Prescribing a CD, general requirements.**<br><br>For schedule 2 and 3 CDs to be legally dispensed the prescription must contain the following:<br><br>• Prescriber signature<br>• Date<br>• Prescriber's address (i.e. ward or department for TTO. This will be pre-printed for FP10s and outpatient prescriptions)<br>• Medication name<br>• Dose and frequency<br>• Formulation (e.g. tablet, patch, syrup)<br>• Strength of preparation (if medicine available in more than one strength. If multiple strengths of one medicine required, prescribe these separately)<br>• Total quantity as the number of dose units to be supplied– in WORDS AND FIGURES. If multiple strengths are required prescribe these separately. |

- Name and address of the patient – if an addressograph sticker is used the prescriber must sign across the addressograph so that half the signature is on the prescription form and half on the addressograph.

An example out patient prescription can be seen below




### 3. Prescribing on a TTO.

For TTOs many of the legal requirements will be pre-printed e.g. Name address etc.

Please see the e-learning package on Sherwood E-Academy for more information on prescribing a TTO. This is available with appropriate log on details via this link:
Sherwood eacademy : Search results (sherwood-eacademy.co.uk)
Course number: ME382

When prescribing a CD onto an electronic TTO via Nerve Centre, the prescriber will be required to add a total quantity in word and figures, this may be done electronically. This can be total number of capsule / tablets e.g. 28 (twenty-eight) or a total amount e.g. if the capsules were 10mg each and 28 were required then 280mg (two hundred and eighty mg), would also be acceptable.
It is not acceptable to put 1 box or 1 bottle.

When completed, the EPMA TTO must be printed and each CD must be signed and dated by the prescriber. A 'wet' signature is required for each CD prescribed.

It is good practice for the prescriber who wrote the prescription to sign the CD copy.

Please note, the TTO cannot be released until a legal CD copy has been received in the dispensary.

## APPENDIX 9 – ADMINISTRATION OF CDS ON WARDS AND DEPARTMENTS

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| Objective | This procedure describes the correct method for administering CDs on wards and departments, to ensure safe administration and a legal and accurate record is made. |
| Scope | All SFH staff responsible for handling and administering controlled drugs.<br><br>This SOP applies to all CDs for which safe custody and storage requirements and register entries are required- see Appendix 7 |
| Responsibilities | The CDAO is responsible to ensuring the overarching CD Policy is maintained and is up to date (by themselves or their nominated deputy).<br><br>Ward and department managers are responsible for ensuring their staff adhere to the CD Policy and that accurate documentation is made in the CD register. |
| Related Policies and procedures | SFH Medicines Policy<br>Self-administration of medicines by patients or carers procedure |
| Background | When administering or checking CDs, the standard SFH procedures for the administration of medicines must be followed (see SFH Medicines Policy) |
| Procedure | **1. Administration of ward stock controlled drugs**<br><br>Two practitioners (one of whom must be a nurse/midwife/ODP) must both witness the preparation and administration of each dose of the CD.<br><br>The CDs must remain under the direct supervision of at least one of the two staff at all times.<br><br>An entry must be made in the ward or department CD register with details of:<br>○ date and time of administration;<br>○ name of patient;<br>○ dose administered;<br>○ full signature of both the administering practitioner and the witness<br>○ remaining stock balance<br><br>The remaining stock balance must be checked by both practitioners by physically counting the stock remaining, minus that administered.<br><br>Nursing associates are not permitted to handle CDs.<br><br>Students are not permitted to handle CDs. |

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| | Any medicine prepared and not used, or only partly used, must be destroyed in the presence of a second practitioner. An entry must be made in the CD register and signed by both practitioners. See Appendix 11 for more information on destroying CDs.<br><br>The two practitioners involved in the retrieval of the CD must both witness the process until the administration to the patient, this final check will occur at the patient's bedside and include positive patient identification. |
| | **2. Administration of liquid oral controlled drugs**<br><br>The volume of liquid CDs should be measured by using either an oral syringe and a bottle adaptor or quill for smaller doses. The bottle adaptor or 'bung' will be placed into the bottle neck and remain there for the duration of bottle use. A separate syringe must be used for each patient and must not re-enter the bottle neck after administration.<br><br>Do not decant the liquid in order to draw up the required volume as this leads to unnecessary loss of liquid and balance discrepancies. Syringes and bottle adaptors must be used for administration. For more information see Appendix 6, Section 3 on the measuring of liquid medications.<br><br>The process of recording will be the same as described in section 1 above.<br><br>It is not necessary to measure the volume of liquid remaining for the balance check; this will be checked at the 6 monthly audit by the pharmacy team. |
| | **3. Patient self-administration of CDs**<br><br>Patients who are admitted taking a stable dose of oral CDs can continue to self-administer these medicines.<br><br>These must be stored in the patient's own locker with the patient and staff nurse having key access.<br><br>These supplies also need to be documented in the CD Register and stock checked daily as per the CD Policy.<br><br>Patients' own CDs from home can be used for self-administration when suitable for use and if required further supplies should be brought in from home.<br><br>PLEASE NOTE: Supplies of CDs cannot be made for inpatient use due to legal requirements related to the prescription. Therefore only those patient who can bring in appropriate supplies from home will be able to self-administer under the current policy. |

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| | Any individual where the dose has changed, a CD has been newly initiated or if their dose has been changed in any way will not be able to self-administer whilst in hospital. |
| | **4. Disposal of prepared or partly administered CDs.**<br><br>Any dose of a CD that is prepared but not administered, including part-used vials, or unused PCA syringes must be destroyed on the ward in the presence of a second nurse, pharmacist, MMT, ODP or midwife<br><br>The entry in the CD register must state that the dose has been destroyed and both parties must sign the register. If the patient has been transferred with a CD infusion bag or PCA in situ e.g. from theatre to ward, then the amount waste must be documented on the patient analgesia prescription form or within the nursing notes.<br><br>If less than 10ml, the contents must be emptied into the ward / department blue bin designated for medication waste. The empty syringe should go in the sharps bin. The contents must NOT be put down the sink or sluice.<br><br>All part-used infusions containing a CD must be destroyed on the ward or department in the presence of either a second nurse, midwife, ODP, pharmacist or doctor. If there is a large volume of fluid to be destroyed (over 10ml) then these must first be decanted into a CD denaturing bottle. There are available with a 250ml or 2L capacity from pharmacy and can be ordered by calling the dispensary on 3166 or via the ward based teams. When the contents have hardened, this bottle may then be disposed of in the blue medicine disposal bin.<br><br>Where an oral sachet of CD has been drawn up with water and partly administered, the remainder of the dose must be emptied into the blue bin.<br><br>When a patch is removed from a patient then this should be folded over on itself, medicated side to the inside, and placed into the blue medicine disposal bin. |
| | **6. Broken ampoules**<br>Any ampoules which are found broken (and are therefore unusable), or which break during administration rendering them unusable should be recorded on Datix. It is good practice to record the Datix number, beginning DW, next to the entry in the CD register.<br><br>The broken vials should be booked out of the register with a note to state the number of vials broken and disposed of in the blue medicine disposal bin.<br><br>Information from the defective product should be relayed to the pharmacist so that it can be investigate (this will include manufacturer, drug, strength, batch number, expiry date), it is also good practice to record this on Datix. |

## APPENDIX 10 - RETURN OF CONTROLLED DRUGS TO PHARMACY FROM WARDS/ DEPARTMENTS

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| Objective | To ensure the secure and legal return of CDs from wards and departments to Pharmacy for re-use or destruction. |
| Scope | The procedure includes CDs previously issued from pharmacy as stock or temporary stock.<br><br>Patients own medication cannot be reused and so will be destroyed on the ward.<br><br>All pharmacy staff and other HCPs suitably trained in handling controlled drugs.<br><br>This SOP applies to all CDs for which safe custody and storage requirements and register entries are required- see Appendix 7 |
| Responsibilities | The CDAO is responsible to ensuring the overarching CD Policy is maintained and is up to date (by themselves or their nominated deputy).<br><br>Nursing, midwifery and ODP colleagues to support this process. |
| Related Policies and procedures | SFH Medicines Policy |
| Background | The Environment Protection Act 1990 and the Hazardous Waste Regulations 2005 determine the safe disposal of medicinal products.<br><br>To ensure Trust compliance with the regulations, supplies of CDs should be returned to pharmacy to allow the correct procedures to be followed. Small quantities may be destroyed on the ward or clinical area. |
| Procedure | **1. Return of CDs previously issued from Pharmacy**<br>Wards and departments should notify pharmacy when they have CDs that need returning. This should be communicated by using the email address: sfh-tr.controlleddrugs@nhs.net<br><br>The pharmacy team will endeavour to respond to all enquiries within 5 working days for routine return requests.<br><br>CDs that have been issued as temporary stock for specific patient must be highlighted for return within 48 hours of a patient being discharged unless this falls at a weekend.<br><br>Expired stock must be returned for destruction if in large quantities or can be destroyed on the ward. Please email the pharmacy using the address above. All returns and destructions at ward level must include a member of the pharmacy team, unless it is the destruction of a partially used dose as described above.<br><br>CDs of any schedule must never be placed into the pharmacy returns bin. |

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| | **2. Return of Patient's own CDs: Completion of Patient's own Controlled Drugs: receipt, transfer and return book**<br><br>On receipt of patient's own CDs, two authorised practitioners should complete a form in the Patient's Own Controlled Drugs book as described in Appendix 4.<br><br>On return, destruction or transfer of the POD CDs the corresponding entry may be completed by either:<br>• A nurse or authorised practitioner and a validated member of Pharmacy staff<br>• Two validated members of Pharmacy staff<br><br>If the register entry was not completed and the CDs need removing by Pharmacy, a nurse, midwife, pharmacist or MMT may retrospectively complete the form in the Patient's Own Controlled Drugs Receipt, Return and Transfer book with a validated member of Pharmacy staff. A nurse/authorised practitioner for the area must always countersign the form. |
| | **3. Return of all CDs to Pharmacy**<br>When returning stock CDs, a member of the pharmacy team along with a nurse, midwife or ODP will complete a white returns form. This will be provided by the pharmacy team when needed.<br><br>If a nurse, midwife or ODP is not available then this process may be carried out by two authorised pharmacy personnel.<br><br>For all CDs (unwanted stock/ non-stock CDs) returned to pharmacy, the following details should be entered onto the appropriate form :<br>○ Date, time and ward<br>○ Name of drug<br>○ Drug form<br>○ Quantity removed from ward (for liquids a visual inspection is adequate and must match the ward register)<br>○ Pharmacist/Technician signature<br>○ Nurse/authorised practitioner signature<br>○ Serial number of the Envopak tag which is being used to transport the drugs to Pharmacy<br><br>In addition, for ward stock/ non stock CDs the following must be entered in the ward/department CD register.<br>○ Date<br>○ Wording "Returned to pharmacy"<br>○ Quantity removed<br>○ Remaining stock level on the ward/department<br>○ Pharmacist/Technician signature<br>○ Nurse/authorised practitioner signature (or second pharmacy staff signature)<br><br>Check that the stock level in the register agrees with the stock level in the CD cupboard. If the stock level is zero, write NIL, do not write '0' |

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| | If any discrepancies are found at this point the senior nurse/midwife on the ward/department and the ward pharmacist must be informed immediately, a Datix report completed and an investigation carried out (see Appendix 13).<br><br>The member of pharmacy staff in the presence of the ward / department representative, should put the CDs for returning and the form into an Envopak and seal it. They should then be returned in a sealed Envopak to the dispensary. The Pharmacy staff now have custody of the CDs.<br><br>Pharmacy staff should take the CDs and the white form immediately to the pharmacy department.<br><br>In the department they will be handed over to the pharmacy assistant designated for CDs to return onto the system. If this is not possible immediately then they will be stored securely in the white CD cupboards and a note left on the outer door. |
| | **4. CDs returned directly by a patient to pharmacy**<br><br>Dispensary will not generally accept patient returns over the counter and patients should be signposted to their local pharmacy who will handle destruction of unwanted CDs.<br><br>Returns can be accepted on an individual case basis and will be at the discretion of the Dispensary Manager or nominate Deputy. |

## APPENDIX 11 – DESTRUCTION OF CDS AT WARD / DEPARTMENT LEVEL.

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| Objective | To ensure the appropriate destruction of CDs on the ward and in department.<br><br>The procedure includes CDs previously issued from pharmacy as stock or temporary stock and POD CDs. |
| Scope | All pharmacy staff and other HCPs suitably trained in handling controlled drugs.<br><br>This SOP applies to all CDs for which safe custody and storage requirements and register entries are required- see Appendix 7 |
| Responsibilities | The CDAO is responsible to ensuring the overarching CD Policy is maintained and is up to date (by themselves or their nominated deputy).<br><br>Nursing, midwifery and ODP colleagues to support this process. |
| Related Policies and procedures | SFH Medicines Policy |
| Background | The Environment Protection Act 1990 and the Hazardous Waste Regulations 2005 determine the safe disposal of medicinal products.<br><br>To ensure Trust compliance with the regulations, supplies of CDs should be returned to pharmacy to allow the correct procedures to be followed. Small quantities may be destroyed on the ward or clinical area. |
| Procedure | The destruction of CDs on the ward must be carried out in the presence of a member of the pharmacy team unless it is the disposal of a part used dose.<br><br>All Controlled Drugs in Schedule 2 and those in Schedule 3 subject to safe custody requirements must be rendered irretrievable prior to disposal.<br><br>Solid dose formulations should be removed from blister strips or bottles. Tablets do not need to be crushed but capsules should be opened before being put into a CD denaturing kit.<br><br>For parenteral formulations, ampoules should be opened and the liquid poured into a CD denaturing kit. Ampoules containing powder can have water added to dissolve the powder, and the resulting mixture can be poured into the CD denaturing kit. Empty ampoules should be disposed of in a sharps bin suitable for pharmaceutical waste.<br><br>Liquid dose formulations should be poured into a CD denaturing kit.<br><br>For transdermal patches (e.g. fentanyl patches), the backing should be removed and the patch folded over on itself before disposing of in a CD denaturing kit. |

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| | The denaturing kit must be disposed of in a suitable pharmaceutical waste bin (generally blue-lidded). |
| | **Destruction of partial doses during clinical practice e.g. theatre**<br><br>Small quantities (<10mL) of liquid CDs for internal use can be destroyed at ward level by nurses, midwives or ODPs by emptying them into the blue topped medicine disposal bins on the ward or department. These bins should include an absorbent pad on the base.<br><br>Staff must NOT empty liquids down the sluice or sink.<br><br>This destruction of partial doses must be witnessed by two nurses/midwives/ODPs and/or anaesthetists and both parties must enter the details into the CD register.<br><br>Larger volumes of liquids (10mL or greater) must be returned to the pharmacy for destruction as described above or destroyed at ward level in a CD destruction kit or 'DUP' bin of an appropriate volume. |

## APPENDIX 12 - PROCEDURE FOR THE REMOVAL OF ACTUAL OR SUSPECTED ILLICIT DRUGS FROM PATIENTS OR VISITORS, INCLUDING PRESCRIPTION ONLY MEDICINES THAT THE PATIENT IS NOT LEGALLY IN POSSESSION OF.

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| Objective | To provide clear guidance to staff on the process to be followed if a patient or visitor is suspected of being in possession of an actual or suspected illicit substance on Trust premises.<br><br>To ensure that illicit substances are dealt with according to legislation and Trust policy.<br><br>No deviation from this policy is accepted without the specific authorisation of the SFH CDAO. They will advise on the most appropriate course of action in the event of any special circumstances (i.e. patient harm or safeguarding issues). |
| Scope | All staff have a responsibility for the security of CDs in a ward or department. If this is not a direct responsibility then it may still be necessary to raise concerns to the ward or department leader if they arise. |
| Responsibilities | The CDAO is responsible to ensuring the overarching CD Policy is maintained and is up to date (by themselves or their nominated deputy).<br><br>All staff members are responsible for following the SOP if they suspect or find an illicit substance.<br><br>Pharmacists/ MMTs are responsible for the removal of the illicit substance from the ward CD cupboard at the earliest opportunity, for the purposes of return to the pharmacy CD room for collection and destruction by the police. |
| Related Policies and procedures | SFH Medicines Policy |
| Procedure | **1. Removal from the patient:**<br>Inform the nurse/midwifery manager.<br><br>If it is known or suspected that a patient is in unlawful possession of a CD, two staff members should approach the patient.<br><br>The patient should be advised that SFH policy prohibits use or possession of unidentifiable and / or illicit substances on Trust property.<br><br>The patient must be advised that continued use of an illicit or unidentifiable substance may compromise their clinical care and the safety of themselves and others.<br><br>The staff members should request that the drugs and any associated equipment are given into the possession of SFH staff for destruction.<br><br>Patient confidentiality will be maintained unless it is considered that the quantity is so large that it is unlikely that the substance is intended solely |

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| | for the patients' personal use. In such cases the situation should be discussed with a senior pharmacist to determine if the police need to be called.<br><br>The staff members should be aware of their safety and assistance should be sought from other staff members or security if necessary.<br><br>If the patient does not agree to hand over the substance, the patient should be advised it is not possible to guarantee patient confidentiality and the police may be informed.<br><br>An incident report form should be completed making note of all staff involved in the consultation.<br><br>Under no circumstance must the substance be returned to the patient as this constitutes an illegal supply and could be prosecutable. |
| | **2. Informing the clinical team**<br><br>The doctor in charge of the patient's care must be informed that the patient was in possession of illicit drugs to ensure that the appropriate monitoring and, if appropriate, substitute prescribing can take place.<br><br>It is important that the medical team are aware of any potential ingestion of illicit or unidentifiable substances as this may affect the subsequent management plan. |
| | **3. Prescription only medicines for which the patient does not have a prescription**<br><br>Any prescription only medicines, e.g. diazepam, brought onto Trust premises, where there is no indication that these have been prescribed by an authorised prescriber for that individual, should be managed in the same way as illicit substances.<br><br>Please note that some medicines may be prescribed by third parties e.g. substance misuse clinic and therefore not listed on GP records. Liaise with DALT as needed. |
| | **4. Non-patients/visitors and illicit substances**<br><br>If an individual who is not a patient is suspected of being in possession of an illicit or suspected illicit substance, a senior staff member should be informed who should then inform the senior manager or security if necessary.<br><br>The individual should be asked to leave Trust premises.<br><br>The individual should be advised that security and the police may be informed if there is a failure to comply. |

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| | **5. Reporting of illicit substances to the police**<br><br>The police have confirmed that they do not need to be contacted on occasions where quantities for personal use have been removed from patients. Quantities deemed for personal use will be subjective, the final decision on this will be made by the Trust CDAO or nominated Deputy.<br><br>Contact to the police will usually be made through the CDAO who can also provide a judgment on the quantity removed and if a call to the police would be appropriate. |
| | **6. Recording in the CD register:**<br><br>The substance must be securely packaged with a label describing the substance and name (if known), or label as "**substance unknown**".<br><br>The number of dose units should be recorded, or the amount estimated.<br><br>The label must be signed by the practitioner receiving the drug from the patient and a second practitioner.<br>An entry must be made in the POD CD register.<br><br>If the drug name is not known then a short description should be entered here e.g. unknown white powder.<br><br>The substance should then be held in the CD cupboard until it can be removed by the pharmacy team or the police.<br>Please inform the pharmacy team using the following email address or informing the ward-based team.<br><br>Email: sfh-tr.controlleddrugs@nhs.net<br><br>The item should be removed from the ward CD cupboard by the pharmacy team within 48 hours. |

## APPENDIX 13 – INVESTIGATION OF LOSSES OR BALANCE DISCREPANCIES ON WARDS AND DEPARTMENTS, OR INVESTIGATION OF SUSPECTED FRAUD

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| Objective | To ensure that all potential or actual CD losses or discrepancies are investigated in a thorough and consistent manner.<br><br>To ensure that the CDAO is made aware of relevant and significant unresolved losses and discrepancies.<br><br>To ensure that investigations of any other suspected fraud relating to medicines or suspected theft of medicines is reported and investigated appropriately. |
| Scope | CD balance discrepancies must be investigated for all CDs which require a CD register entry at SFH including patients own CDs.<br><br>Suspected theft of any other medicine (including CDs which do not usually require a CD register entry) or controlled stationery, including suspected fraud, must be investigated.<br><br>Serious or significant discrepancies or losses must be reported immediately to the ward pharmacist or on-call pharmacist for escalation to the Chief Pharmacist (who is also the CDAO). |
| Responsibilities | The CDAO is responsible to ensuring the overarching CD Policy is maintained and is up to date (by themselves or their nominated deputy).<br><br>Where there is any concern regarding the security of Controlled Drugs the Chief Pharmacist as the Trust Accountable Officer for Controlled Drugs must be informed. |
| Related Policies and procedures | SFH Medicines Policy |
| Procedure | **1. Investigation of CD ward stock discrepancies**<br>In the event of a discrepancy between the stock balance and register for CDs, the nurse, midwife or ODP in charge for that shift must immediately and thoroughly investigate the loss.<br><br>Any discrepancy not satisfactorily resolved during the initial investigation must be reported to the nurse/midwifery/theatre manager and a member of the senior pharmacy team.<br><br>A Datix may not be indicated at this point. As described below, if fraudulent activity is suspected, do not complete a Datix until asked to do so. The Datix may be more appropriate to complete once the investigation has been completed. This is because once a Datix report has been submitted, many people within the organisation are notified and this may compromise a confidential investigation.<br><br>If, during the course of the investigation, it is discovered an incorrect dose has been administered to a patient, the clinical team must be informed and a Datix incident form completed for that patient. |

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| | The Nurse/Midwifery/Theatre Manager and Pharmacist, as needed, will determine the appropriate course of action.<br><br>If fraud or theft is strongly suspected or confirmed, contact a pharmacist who should escalate it to the SFH CDAO who is also Chief Pharmacist (or their nominated deputy responsible for CDs) and a senior nurse such as a matron as soon as possible who will advise on the next appropriate course of action. They may advise not to complete a Datix form at that stage in order that the appropriate evidence can be collected. The decision for contacting the Local Security Management Service representative or police and/or NHS Protect lies with the CDAO. It is important to note that in this case, this could lead to a criminal investigation and so confidentiality is paramount.<br><br>In the event of ongoing CD discrepancies in a particular area contact a pharmacist to escalate to the SFH CDAO as above. |
| | **2. Out of hours (after 1730 weekdays and 1300 weekends)**<br>If discrepancies are found out of hours, the Duty Nurse Manager must be informed<br><br>The on-call pharmacist does not need to be called for **minor** CD losses.<br><br>The appropriate Nurse/Midwifery manager and senior pharmacy manager must be informed at earliest opportunity in working hours.<br><br>The CDAO must be alerted of any **significant** loss of CDs that may require the involvement of the police the next working day. |
| | **3. Investigation checklist for wrong balance of CDs on wards and departments**<br><br>When a balance discrepancy is noted, the appointed practitioner in charge or their nominated deputy must investigate the discrepancy straight away.<br><br>Follow the steps below:<br><br>1) What is the actual balance? What should the balance be?<br>2) Check calculations of recent entries.<br>3) Check CD order book to ensure all recent receipts have been recorded in the CD register, and for the correct amount received.<br>4) Review all pages of the CD register to see if an entry has been made in the wrong page (start with similar sounding names/strengths, and then review all pages if not found).<br>5) Check for loose tablets / ampoules in CD cupboard.<br>6) Undertake a thorough search around the CD cupboard/clinic area, bench and floor and check for loose tablets/ ampoules in the area.<br>7) Check sharps bin visually to see if has been put in there.<br>8) Identify all patients on ward who have been prescribed the missing CD in last 24/48 hours. Cross-check all treatment charts on the ward against the CD register entry to ensure all administration of CDs have |

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| | been recorded in the register, and correct doses of CDs have been administered. If administration box is blank contact staff responsible for that patient at that time to confirm administration. If in theatres, obtain notes for the preceding theatre list and cross check anaesthetic record and chart against the register entry.<br>9) Identify all patients who have received an infusion of the missing CD. Check with staff who prepared and checked the infusion regarding the calculation and method of preparation. Check if any ampoules /vials were wasted during the preparation and not recorded.<br>10) Check patient for signs of underdose/ overdose, to identify if incorrect dose administered.<br><br>For unresolved discrepancies also record on the Datix report where known:<br>• Details on the timing of the loss and when discrepancy was discovered<br>• Details of when the last physical checks were carried out<br>• Details of whether a pharmacist has been asked to second check any of the investigation<br>• Details of any procedural lapses (if known)<br>• It may be necessary in some case to ask for written statements from staff. These can be attached to the Datix report.<br>If the discrepancy is resolved following the above steps, follow the sections below and correct the balance in the register.<br><br>If not resolved, undertake a full stock check. This may be done with a pharmacist if available. Empty the CD cupboard and check quantity of each box carefully against the register.<br><br>**If it remains unresolved follow section 7 below.** |
| | **5 Correction of balances in the CD register**<br><br>Balance corrections in the CD register must be signed by two practitioners.<br><br>The on-call pharmacist should be notified for significant discrepancies.<br><br>The correction process is:<br>• Enter a new line into the register<br>• Complete date and time<br>• State “balance corrected due to error” and provide details of the discrepancy, e.g. mathematical error 5/11/19<br>• Record Datix number<br>• The new balance should be entered into the balance column<br>• Signature of both practitioners<br><br>Do not cross out any entries. Incorrect entries should be bracketed and details of the error documented. |

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| | This applies to all discrepancies, e.g. due to inaccurate record keeping which have been identified and resolved, missing items now resolved, or missing items which are still unaccounted for. |
| | **6 Action to take if the patient has received an under or overdose of Controlled Drug, or if the dose has been accidentally omitted**<br><br>Inform clinical team responsible for the patient and complete Datix form for the patient safety incident. |
| | **7 Reporting of unresolved CD discrepancies**<br><br>Discrepancies in the CD balances which cannot be resolved should be escalated to the matron and the ward or Divisional pharmacist, who may decide to escalate to the Divisional Director of Nursing and CDAO.<br><br>The CDAO (or nominated representative in their absence) will decide the lines of further investigation and escalation.<br><br>If out of hours, report significant discrepancies to the on-call pharmacist who will escalate to the CDAO if required. |
| | **8 Follow up of patient's own CD (requiring register entry) discrepancies**<br><br>1) Two practitioners should complete an investigation as below<br>2) Has patient been transferred from another ward? – if so check whether CD has been signed out of the transferring ward POD CD register<br>3) Check for loose tablets / ampoules in CD cupboard.<br>4) Check patient's own property, including POD locker and medicines bags, washbags<br>5) Undertake a thorough search around the CD cupboard/clinic area, bench and floor and check for loose tablets/ ampoules in the area. Check all patient areas to identify if they have been taken by other patients or visitors.<br>6) Check sharps bin to see if has been put in there – this check should be visual only.<br>7) Check the returns bin.<br>8) Report on Datix<br>9) Inform ward pharmacist at earliest opportunity<br>10) If possible, contact the patient at home to check if they received the medication on discharge home.<br><br>**Then follow section 4 of this SOP for correction of register**<br>11) If discrepancy is still unresolved follow section 7 of this SOP. |
| | **9. Follow up of Datix incidents**<br>All CD incidents relating to storage and security and balance discrepancies will be automatically sent to a senior pharmacist (Divisional Pharmacist Leads) to monitor trends. All investigations must be referred initially to the CDAO and Medication Safety Team. |

## APPENDIX 14 - EQUALITY IMPACT ASSESSMENT FORM (EQIA)

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| **Name of service/policy/procedure being reviewed: CD Policy** | | | |
| **New or existing service/policy/procedure: New** | | | |
| **Date of Assessment: 22.11.23** | | | |
| **For the service/policy/procedure and its implementation answer the questions a – c below against each characteristic (if relevant consider breaking the policy or implementation down into areas)** | | | |
| **Protected Characteristic** | **a) Using data and supporting information, what issues, needs or barriers could the protected characteristic groups' experience? For example, are there any known health inequality or access issues to consider?** | **b) What is already in place in the policy or its implementation to address any inequalities or barriers to access including under representation at clinics, screening?** | **c) Please state any barriers that still need to be addressed and any proposed actions to eliminate inequality** |
| **The area of policy or its implementation being assessed:** | | | |
| **Race and Ethnicity** | NA | NA | NA |
| **Gender** | NA | NA | NA |
| **Age** | NA | NA | NA |
| **Religion** | NA | NA | NA |
| **Disability** | NA | NA | NA |
| **Sexuality** | NA | NA | NA |
| **Pregnancy and Maternity** | NA | NA | NA |
| **Gender Reassignment** | NA | NA | NA |

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| **Marriage and Civil Partnership** | NA | NA | NA |
| **Socio-Economic Factors (i.e. living in a poorer neighbourhood / social deprivation)** | NA | NA | NA |

**What consultation with protected characteristic groups including patient groups have you carried out?**

- Not applicable as relates to process as opposed to patient care.

**What data or information did you use in support of this EqIA?**

- Not applicable

**As far as you are aware are there any Human Rights issues be taken into account such as arising from surveys, questionnaires, comments, concerns, complaints or compliments?**

- No

**Level of impact**

From the information provided above and following EQIA guidance document Guidance on how to complete an EIA (click here), please indicate the perceived level of impact:

Low Level of Impact

For high or medium levels of impact, please forward a copy of this form to the HR Secretaries for inclusion at the next Diversity and Inclusivity meeting.

**Name of Responsible Person undertaking this assessment:**
**Joanna Freeman**

**Signature:**

**Date: 22.11.23**

## APPENDIX 15 – ENVIRONMENTAL IMPACT ASSESSMENT

The purpose of an environmental impact assessment is to identify the environmental impact, assess the significance of the consequences and, if required, reduce and mitigate the effect by either, a) amend the policy b) implement mitigating actions.

| Area of impact | Environmental Risk/Impacts to consider | Yes/No | Action Taken (where necessary) |
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| **Waste and materials** | • Is the policy encouraging using more materials/supplies?<br>• Is the policy likely to increase the waste produced?<br>• Does the policy fail to utilise opportunities for introduction/replacement of materials that can be recycled? | Yes | The policy encourages the use of disposal bins for CDs, this is necessary for the safe disposal of controlled medication. |
| **Soil/Land** | • Is the policy likely to promote the use of substances dangerous to the land if released? (e.g. lubricants, liquid chemicals)<br>• Does the policy fail to consider the need to provide adequate containment for these substances? (For example bunded containers, etc.) | No | |
| **Water** | • Is the policy likely to result in an increase of water usage? (estimate quantities)<br>• Is the policy likely to result in water being polluted? (e.g. dangerous chemicals being introduced in the water)<br>• Does the policy fail to include a mitigating procedure? (e.g. modify procedure to prevent water from being polluted; polluted water containment for adequate disposal) | No | |
| **Air** | • Is the policy likely to result in the introduction of procedures and equipment with resulting emissions to air? (For example use of a furnaces; combustion of fuels, emission or particles to the atmosphere, etc.)<br>• Does the policy fail to include a procedure to mitigate the effects?<br>• Does the policy fail to require compliance with the limits of emission imposed by the relevant regulations? | No | |
| **Energy** | • Does the policy result in an increase in energy consumption levels in the Trust? (estimate quantities) | No | |
| **Nuisances** | • Would the policy result in the creation of nuisances such as noise or odour (for staff, patients, visitors, neighbours and other relevant stakeholders)? | No | |