The Management of Controlled Drugs Policy

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NHS Shetland Document Development Coversheet*

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Examples of reasons for presenting to the group	**Examples of outcomes following meeting**
• Professional input required re: content (PI)	• Significant changes to content required – refer to Executive Lead for guidance (SC)
• Professional opinion on content (PO)	• To amend content & re-submit to group (AC&R)
• General comments/suggestions (C/S)	• For minor revisions (e.g. format/layout) – no need to re-submit to group (MR)
• For information only (FIO)	• Recommend proceeding to next stage (PRO)
• For proofing/formatting (PF)	• For upload to Intranet (INT)
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***To be attached to the document under development/review and presented to the relevant group**

Please record details of any changes made to the document in the table below

Date	Record of changes made to document
16/5/24	Addition of stock check period for CD's in Primary Care on Page 10
16/5/24	Clarification, minor edits and spell check throughout document
9/7/24	Section 15. Minor alterations to reflect local practice
9/7/24	Section 11. Altered wording to include other recording documents for medicines as well as HEPMA
9/7/24	Section 13. Minor alterations to reflect local practice

Contents

1. Purpose of Policy

This document details the legal and good practice requirements for the management of Controlled Drugs (CDs) in Gilbert Bain Hospital, as well as in GP Practices and other unregulated dispensing premises in NHS Shetland. This policy is a new policy superseding earlier policy on controlled drugs as a result of significant changes to legislation and regulation in this area in recent years. The policy is underpinned by procedures providing detailed advice on implementation of the policy.

2. Introduction

This policy covers the ordering, storing, supply, prescribing, administering, recording and safe disposal of CDs while at the same time providing appropriate and convenient access for patients who require treatment with CDs.

It is relevant to all management and staff involved in the use and handling of CDs within NHS Shetland.

It applies to all categories of CDs in Schedule 2-5, although variation in handling according to Schedule will be highlighted.

3. Background

The following legislative documents are relevant to this policy

- The Medicines Act 1968, which applies to all Medicines in UK
- The Human Medicines Regulations 2012
- Misuse of Drugs Act 1971 and associated Regulations including Misuse of Drugs Regulations 2001
- Controlled Drugs (Supervision of Management and Use) Regulations 2013, which brought in the requirement for all NHS Boards to appoint a Controlled Drug Accountable Officer (CDAO) with specific responsibility for the safe management and use of CDs with their Health Board.
- Safer Management of Controlled Drugs – A Guide to Good Practice in Secondary Care (Scotland) CEL 7 (2008)(4)
- Safe and Secure Handling of Medicines, December 2018. The Royal Pharmaceutical Society.

4. General Principles

There are a number of overarching principles that are used to underpin the safe management of CDs. These include:

- Patients should have timely access to medicines prescribed for them, including CDs
- Organisations and individuals must comply with the current legal requirements and local guidelines for the management of CDs'
- CDs **must** be used and managed safely and securely
- There **must** be a clear audit trail for the movement and use of CDs

Staff must consider this policy relevant for any CDs requiring full storage, prescribing and recording requirements as well as those requiring a lesser level of regulation. See Appendix 1 for a summary of Handling Requirements for Commonly used CDs.

5. Roles and Responsibilities

Each Health Board is required to appoint an Accountable Officer for Controlled Drugs who is accountable for all aspects of the safe and secure management of CDs in his or her organisation.

The NHS Shetland Accountable Officer for Controlled Drugs is the Director of Pharmacy, Pharmacy and Prescribing Department, NHS Shetland, Upper Floor Montfield Hospital, Burgh Road, Lerwick ZE1 OLA and contactable through shet.dop@nhs.scot.

5.1. Responsibilities within acute wards or departments

The registered Nurse/Midwife/Operating Department Practitioner (ODP) in charge of the ward or department is responsible for ensuring –

- The safe custody of the keys of the controlled drug cupboard. Key-holding may be delegated to other suitably trained, registered healthcare professionals but the legal responsibility remains with the registered nurse/midwife/ODP in charge of the ward/department.
- Controlled Drug cupboard keys should be kept separate from other keys, and only be given to other approved staff when access to controlled drugs is required.
- Any duplicate key to the Controlled Drug cupboard must be kept secure at all times and access to this key restricted. Records of access to the duplicate key must be maintained. Pharmacy does not hold duplicate keys.
- Controlled Drugs cupboards must be kept locked when unattended.
- That all new stock is entered in the ward/department Controlled Drug Record Book (CDRB) immediately on receipt, and that the drugs match those ordered, and that the total in the book agrees with the physical stock balance and that this entry is confirmed by the signature of the member of staff making the entry.
- That the Controlled Drug stock check is carried out by staff in the ward/department and that this is recorded.
- That Standard Operating Procedures (SOPs) laid down for dealing with Controlled Drugs are complied with.

5.2. Responsibilities within Pharmacy departments

The Lead Clinical Pharmacist is responsible for the safe and appropriate management of CDs in the pharmacy department. The day to day management of CDs can be delegated to another pharmacist or pharmacy technician (Band 4 or above with a minimum of 6 months post registration experience and appropriate training).

- Entries made in the CDRB by pharmacy support workers must be countersigned by a registered pharmacy technician or pharmacist.

- The Pharmacy department must have SOPs covering dispensing, ordering, stock checks, management of CD stock holding and CD destruction.

5.3. Responsibilities within Health Centres and other Unregulated Dispensing situations

The doctor or registered nurse responsible for dispensing in that area is responsible for the management of controlled drugs. Where there is no permanent doctor with a practice for an extended period the responsibility sits with the Medical Director. Responsibility may be delegated to a locum doctor but the legal responsibility remains with the Medical Director. The practice staff are responsible to ensure that locum doctors are made aware of CD stocks and that they are given the opportunity to check what is in stock against the CDRB on assuming responsibility, that they check the stock again before leaving and that the keys for the CDRB remain within the practice.

The Doctor/registered nurse are responsible for ensuring that –

- Controlled Drug cupboard keys should be kept separate from other keys in a key safe to which only authorised members of staff have access when controlled drugs are required. Responsibility for the keys remains with the doctor responsible for dispensing or the registered nurse. Any duplicate key to the Controlled Drug cupboard must be kept secure at all times and access to this key restricted. Records of access to the duplicate key must be maintained by the doctor/ registered nurse or deputy appointed by the doctor responsible for dispensing.
- Controlled Drugs cupboards must be kept locked when unattended.
- All new stock is entered in the Controlled Drug Record Book (CDRB) immediately on receipt, and that the drugs match those ordered, and that the total in the book agrees with the physical stock balance and that this entry is confirmed by the signature of the member of staff making the entry as well as the doctor in charge of dispensing where appropriate.
- That the Controlled Drug stock check is carried out by staff in the practice a minimum of once per week and that this is recorded. Any discrepancies are immediately passed on to the doctor in charge of dispensing.
- Where the location is in a remote island with a nurse in charge a weekly check should be made and recorded by the nurse.
- That procedures laid down for dealing with Controlled Drugs are complied with.

6. Ordering of Controlled Drugs

6.1. Ordering of Controlled Drugs for wards & departments

- The registered nurse/midwife/ODP in charge of the ward or department is responsible for ordering of CDs for use in that area. Even if the ward or department is managed by someone other than a nurse/midwife, the most senior registered nurse/midwife/ODP present is responsible for the CDs.

- The task of ordering CDs can be delegated to authorised staff such as a registered nurse/midwife/ODP however the legal responsibility for the CDs remains with the registered nurse/midwife/ODP in charge.
- All registered nurses/midwives/ODPs who are authorised to order CDs must supply a specimen of their signature to pharmacy before attempting to order CDs for ward/department stock. This specimen signature must be authorised by the ward/department manager.
- Controlled drugs for ward stock must be ordered in a Controlled Drug Order Book (HMSO Code No. 90-500) which are obtained from pharmacy.
- Before an order is written, carbon paper must be correctly inserted between the top white copy and the pink copy, to ensure a carbon copy of the order is obtained.
- All orders must be written in ink or indelible ball point pen. Block capitals must be used when writing an order and the ward/department, drug name, form, strength, ampoule size if more than one available, and the quantity required must be stated.
- A separate page with carbon copy is used for each preparation ordered.
- The order must be signed in full by an authorised nurse/midwife/ODP. Initials are not acceptable.
- Any alterations made to an order must be initialled by the registered nurse/midwife/ODP signing the order, or registered member of staff amending the order.
- When the order is complete the whole order book should be sent to pharmacy without removing any pages.
- The pharmacy department will not make a supply against an incorrectly completed order and will provide advice on the correction required to the requesting staff.
- Any order which is to be cancelled before a supply is made must be crossed with two lines, marked “CANCELLED” and signed and dated by the person cancelling the order. Staff must ensure that carbon paper is in place before cancelling the order. The white copy of a cancelled order must remain in the order book and must not be removed by ward staff.

6.2. Ordering of Controlled drugs in Unregulated Dispensaries, including Dispensing Doctors, Out of Hours car, and Non-Doctor Islands with a resident nurse

- The doctor responsible for dispensing/registered nurse employed on the island is responsible for the ordering of CDs in that area. Even if the dispensing practice is managed by someone other than the doctor, the doctor remains responsible for the CDs.
- The task of ordering CDs can be delegated to authorised staff but the doctor/registered nurse is responsible for providing a signed order requesting the supply of the CDs.
- A signed order must be written in indelible ink and contain the following details –
    - Name of the doctor/registered nurse and registration number
    - Address of the practice/clinic where the CDs are to be supplied to
    - Drug name, form, strength, ampoule size if more than one available and quantity required.

- Total quantity required must be written in words and figures
- Signature of the Doctor/registered nurse. Initials are not acceptable.

- Any alterations made to a signed order must be initialled by the doctor/registered nurse signing the order or the registrant making the alteration.
- The signed order will be sent to the pharmaceutical wholesale dealer or in the case of Non-doctor Islands to the Pharmacy Department at Gilbert Bain Hospital.
- A supply cannot be made against an incorrectly completed signed order.
- Pharmaceutical Wholesale Dealers commonly allow electronic orders of CDs to be submitted and supply against these on the basis of receipt of a signed order on receipt of the goods.

7. Supply/Delivery of CDs

- Pharmacy will maintain a set of Standard Operating Procedures (SOPs) for processing requests for CDs.
- Pharmacy will maintain a CD collection log which will provide a full audit trail of all staff involved in the supply and collection of CDs from pharmacy.

7.1. Supply of CDs to a ward/department

- All CDs supplied to a ward/department within the hospital must be collected from pharmacy by an authorised member of staff. This member of staff is required to show their photographic identity badge.
- The member of staff collecting the CDs must check that each item supplied matches the description of the CD which has been ordered and is in the correct quantity. The member of staff collecting the CDs will then sign the “Accepted for delivery” section.

7.2. Supply of CDs to a Primary Care Location including Dispensing Doctors Practice, Non-doctor Island location and the Out of Hours car

- On receipt of a signed order the pharmacy department will supply CDs as requested to the Out of Hours (OOHs) car. The CDs are stored in a locked pouch inside the OOHs CD cupboard in the Emergency Department(ED) in Gilbert Bain Hospital.
- On receipt of a signed order the pharmacy department will supply up to 2 ampoules of Morphine Sulphate 10mg injection to a Non-Doctor island. These will be sent by registered post to the agreed address on the island. A receipt will be included with the medicine which should be signed on receipt of delivery and returned to GBH Pharmacy.
- CDs supplied by a pharmaceutical wholesale dealer will be supplied on receipt of an electronic order and followed up by the signed order.

7.3. Supply of CDs to a patient or their representative

Patients or their representatives should be asked to provide evidence of identity when collecting prescriptions for CDs recorded in the CD Record Book. The information regarding who collected the outpatient CD prescription must be recorded in the pharmacy CDRB. This must record –

- Whether the person who collected the CD was the patient, the patient's representative or a healthcare professional acting on behalf of the patient.
- If the person who collected the CD was a healthcare professional, acting on behalf of the patient, that person's name and work address, and also whether evidence of identity was requested/provided.

8. Receipt of CDs

8.1. Receipt of Ward/Department CDs

- Each ward/department must have its own Controlled Drug Record Book (CDRB). These are controlled stationery and are obtained from Pharmacy by submitting a written request.
- CDs must be received in the ward/department by a designated person who must check them against the details in the order book. The registered nurse/midwife/ODP receiving the CDs should be a different nurse/midwife/ODP from the person who ordered them.
- Any discrepancies must be reported to pharmacy immediately.
- If there are no discrepancies the registered nurse/midwife must sign the pink copy of the order in the Ward CD Order Book. The pink copy remains in the book.
- The CDs must be stored immediately in the CD cupboard on return to the ward/department.
- Details of the CDs received must be entered in the Ward/Department CDRB in red indelible ink. The right hand column must be completed detailing quantity in words, form, order number and date. The new balance must agree with the physical stock. Two registered staff are required for this checking procedure, one of the signatures must be that of the registered nurse/ODP who received the controlled drugs.
- Where a container of drugs with an intact manufacturer's seal is received, the box does not need to be opened to check the contents. Unopened containers of liquids do not need to be measured.

8.2. Receipt of CDs in Primary Care including Dispensing Doctors practice, Out of Hours Service and Non-Doctor Island location

- Each location must have its own CDRB.
- CDs must be received by a designated person who must check them against a copy of the signed order and if appropriate the delivery note/invoice received. In a dispensing doctor's practice, where possible, a different person should receive the CDs as the person who placed the order.
- Any discrepancies should be reported to the doctor/registered nurse responsible for the CDs and then reported to the supplier (Pharmaceutical Wholesale dealer or GBH Pharmacy) immediately.
- If there are no discrepancies, the member of staff must sign and date any paperwork (invoice/delivery note) received with the CDs to show that they have been received.
- The CDs must be stored immediately in the CD cupboard.

- Details of the CDs received must be entered in the CDRB in indelible ink. The right hand column must be completed detailing quantity, form, order number and date. The name and address of the supplier must also be recorded. The new balance must agree with the physical stock. The CDRB entry must be signed by the member of staff receiving the stock and also signed by the doctor responsible for the CDs. Where a registered nurse is lone working in a non-doctor island location it is acceptable to have only one signature in the register. In the OOHs car the stock is entered into the register by the pharmacy staff using two signatures. The stock is checked by the clinician at each shift change. A log of these checks is maintained.

9. Storage of CDs

- CDs must be kept in a locked cupboard conforming to or exceeding BS2881 and where an area is undergoing renovation the CD cupboard should be upgraded to meet the Sold Secure Standards (SS) 314- Specification for Security cabinets' standard – silver level. New CD cupboards should be approved by the CD Accountable Officer. CD cabinets within the hospital pharmacy must comply with the SS 314 standard.
- The CD cupboard must be used to store **only** CDs, and no other drugs or articles such as money or valuables. The only exception to this is strong potassium chloride in those designated areas that are authorised to keep this.
- The CD cupboard must be kept locked when not in use.
- The CD cupboard lock must not be common to any other lock in the hospital/ building.
- The CD cupboard must be of sufficient size to safely store CDs, patient's own CDs and out of date CDs. There should be enough room to allow adequate segregation of CDs, particularly where high strength CDs are in stock.
- All Schedule 2 CDs, temazepam and buprenorphine **must** be stored in the CD cupboards and recorded in the CDRB. Storage of other schedule 3 CDs (eg midazolam, tramadol, pregabalin, gabapentin and phenobarbital) in a CD cupboard is not legally required, however there may be areas that choose to store them in the CD cupboard for reasons of extra security or to manage the CD stock securely in the event of suspicion of diversion. If it is departmental/practice policy this should be documented in the departmental SOP and all staff must follow this process. See Appendix 1 – Summary of handling Requirements for commonly used CDs.
- If a ward/department is due to close and regular CD checks cannot be maintained pharmacy must be contacted for advice and to assist in temporary secure storage.
- Midazolam is a Schedule 3 controlled drug and as such is not subject to safe custody requirements for storage.

10. Prescribing of Controlled Drugs

10.1. Prescribing for inpatients

CDs must be prescribed on the Hospital Electronic Prescribing and Medicines Administration (HEPMA) system, on inpatient prescription sheets or on the anaesthetic record.

- CDs are prescribed in the same way as other medicines

- A CD can only be prescribed by a suitably qualified practitioner e.g. Doctor, dentist or Independent non-medical prescriber as per individual legislation and within their individual competency.
- For “as required” prescriptions, for example when prescribing for breakthrough pain a minimum time interval between doses should be stated e.g. every six hours. The maximum total quantity that can be administered in 24hours must also be specified.

10.2. Prescribing for discharge patients/outpatients

Prescriptions for patients who are leaving the hospital must be written in accordance with the requirements of the Misuse of Drugs Regulations for a CD prescription.

- Discharge prescriptions for Schedule 2 and 3 CDs must be completed via the HEPMA system which generates a discharge prescription which meets the legal requirements. The prescriber is required to sign the final copy in their own handwriting.
- Outpatient prescriptions must be written on HBP pads for dispensing in the hospital pharmacy or in community pharmacy. Pre-printed name and address labels should not be used on CD prescriptions.
- Hospital discharge prescriptions usually provide a minimum supply of 7 days medicines but no more than 30 days’ supply of CDs should be supplied via a discharge or outpatient prescription.
- A prescription for a Schedule 2 or 3 CD must contain the following details:
    - The patient’s full name, address and where appropriate age (Legally required if under 12 years of age)
    - The patient’s CHI number
    - The name and form of the drug, even if only one form exists.
    - The strength of the preparation.
    - The dose to be taken
    - The frequency of administration, in the case of “as required” a minimum dose interval should be stated.
    - The total quantity of the preparation or the number of dose units to be supplied in both words and figures.
    - The prescription must be signed and dated by the prescriber and if prepared by someone other than the prescriber this should be a registered healthcare professional.
- Where a dispensed prescription containing a CD is sent to the ward several hours/days before the patient leaves, the medicines must be stored securely in the CD cupboard. The CDs must be checked and entered as patient’s own in the CDRB. These medicines should be clearly marked and segregated from ward stock.

10.3. Prescribing of CDs in Primary Care settings

Where a clinician in primary care wants to prescribe a CD, the appropriate stationery should be selected according to their profession. The same information must be recorded as per the

Outpatient prescription. Most prescriptions are now prepared electronically containing all the correct information but the prescription must be signed in indelible ink by the prescriber.

11. Administration of Controlled Drugs

11.1. Administration of Controlled Drugs in hospital

Controlled drugs or preparations containing controlled drugs can only be administered to a patient in accordance with:-

- The written directions of a medical or dental prescriber.
- The written directions of an independent prescriber for any Schedule 2-5 controlled drug within their competence, except diamorphine, cocaine and dipipanone for the treatment of addiction.
- A Patient Group Direction (PGD) Schedule 2 only for diamorphine, permitted for cardiac pain in the hospital emergency department.

When controlled drugs are administered a **two person administration procedure** must be followed. This includes the preparation of the drug for administration, the administration and the destruction of any surplus. One of the persons must be a registered nurse/midwife/ODP, the second person may be another registered professional or student. The following should be checked before administration:

- The drug name must be checked against the prescription
- The dose that is requested must be checked in relation to safety for the patient and route of administration. Considering allergies, doses the patient previously received, increments of dose increase, concurrent medications. If there are any concerns these should be discussed with the prescriber before administration.
- The route of administration must be confirmed to ensure selection of the appropriate drug and formulation
- The most appropriate strength of the drug available, to make up the prescribed dose, should be selected to minimise wastage, e.g. when selecting the strengths of injectables to make up a syringe driver for a 60mg dose use 2x 30mg is available rather than 1x 100mg.
- The drug expiry must be checked
- If an injection or infusion is to be prepared the type and volume of infusion diluent must be confirmed along with the route and rate of administration. The information can be found on-line on MEDUSA.
- If a liquid is to be measured a suitable oral syringe and bung/measure should be used.
- The packaging must not be discarded until all the patient bedside checks are complete
- The total quantity of the item (e.g. tablet, ampoule) in stock of the strength and formulation to be used must be counted
- The amount of stock should be compared with the amount indicated in the last entry of the appropriate page of the Ward/Department CDRB

- The following details must be entered into the correct page of the ward/department CDRB checking the name, formulation and strength
    - Date
    - Name, and address of the patient. CHI should be added to distinguish patients with similar names.
    - Stock balance following preparation of the dose to be administered.
- **Both members of staff should take to the patient:**
    - The prepared drug
    - The CDRB
    - Access to the patient record on HEPMA or any alternative record approved for recording medicines, must be available at the bedside
- Patient identity and checks should be performed independently by both persons.

11.2. Administration of Controlled drugs in Primary Care

The same process should be followed as in hospital. There are situations in primary care however where the prescriber may be the same as the person administering the CD or where there is only one nurse available to carry out the administration as in a patient's home. It is best practice wherever possible to have two members of staff involved in the administration of CDs, but where that is not possible the lone practitioner must take particular care to check each aspect of the selection of drug, dose and administration as per the description above.

12. Recording the Administration of Controlled Drugs

- The administration of the CD must be entered in the CDRB in indelible ink.
- The administration of the CD must also be recorded in the patient's record in HEPMA. If the patient refuses the dose, or it is not given for any other reason, this must be clearly recorded in the CDRB and also on HEPMA.
- Entries made in error must not be obliterated or crossed out, brackets should be added around the error and the words "entered in error" should be written on the same or the next line. The entry must be signed and dated by the person who made the error.
- Where only part of an ampoule containing a CD is used, the amount used and the amount destroyed should be recorded in the CDRB. For example if only 20mg of morphine sulphate is used from a 30mg ampoule, the amount used and the amount destroyed should be recorded as shown below:-
    - 20mg administered to…(patient's name)…, 10mg destroyed
    - The nurse or doctor checking the procedure should also witness the destruction of the drug not used.

12.1. A nurse administering a CD must:

- Enter the date and time of the transaction in the CDRB
- Enter the patient's name and the dose supplied

- Reconcile the remaining stock balance
- Sign the record
- The nurse/doctor who witnessed the process must also sign the CDRB.

12.2. A doctor administering a CD must:

- Enter the details as described above and sign the record.
- The whole administration procedure must be witnessed and signed for by a registered nurse. The registered nurse shall check all aspects of the administration and must be present during the whole procedure. Both will be held accountable for their practice.

It is accepted that within the Primary Care Out of hours service and where a GP is carrying out emergency house a witness may not be available.

13. Supply/return of Controlled Drugs for Administration to Individual Patients in Operating Theatres

- The registered nurse/ODP in charge of the operating theatre may supply CDs to an anaesthetist for administration to a patient in theatre.
- It is recommended that single dose ampoules be used when parenteral drugs are used in theatre. The use of multidose ampoules is not regarded as good anaesthetic or aseptic practice.
- The registered nurse/ODP must
    - Enter the date and time of the transaction in the CDRB
    - Enter the patient's name and the dose supplied
    - See Appendix 2 for an example of the theatre CDRB
- The registered nurse/ODP and the anaesthetist both sign the entry. Where it is not immediately possible for the anaesthetist to sign for receipt of the controlled drugs, another registered professional should sign and the anaesthetist should countersign the entry at their earliest convenience but before leaving the theatre at the end of the list. In the theatre situation the signing in this instance is understood to be witnessing the dispensing of controlled drugs to the anaesthetist and not the actual administration of that drug to the patient.
- The registered nurse/ODP is responsible for ensuring that each entry in the CDRB is complete and that the balance is correct.
- The anaesthetist is then responsible for the control of the drugs obtained in the manner described above.
- The anaesthetist must ensure that each dose administered to a patient is entered in a permanent record relating to medicines. This record must be available to ward staff to reduce any risk of duplication of administration.
- The anaesthetist is responsible for destroying any unused portion of opened ampoules, or partly used vials of CDs. The amount destroyed must be recorded in the CDRB and on the anaesthetic record.

- A second suitably qualified person such as a registered nurse, medical practitioner or registered ODP or a Pharmacist must witness the entry indicating the quantity of CD destroyed.
- Un-opened issued ampoules/vials must be returned to stock. They are entered in the CDRB as being returned to stock by the registered nurse/ODP who signs and dates the entry. The name of the patient from whom the CD was returned is also entered. The anaesthetist also signs this entry.
- The key to the CD cupboard must be returned to the registered nurse/ODP in charge of the theatre immediately.
- The registered nurse/ODP in charge of the operating theatre must along with a second registered professional, before finishing the shift, check the stock, sign and date the register to confirm that the stock balance is correct.

14. Transfer of Patients to other clinical areas with Controlled Drugs attached (for example infusions, syringe drivers, patches etc)

- When a patient is transferred to another clinical area with CDs such as infusions, syringe drivers or patches attached to them, the current administration and monitoring chart must be transferred with the patient. It is understood that in some instances this will be an electronic entry in HEPMA.
- The registered nurse/ODP in the clinical area the patient leaves must check the administration system and volume/quantity remaining and sign, date/time the administration and monitoring chart to verify that the record is accurate when the patient is handed over, and that the quantity remaining is correct.
- The registered nurse in the clinical area to which the patient is transferred must check the administration system and volume, quantity remaining and sign, date and time of the administration and monitoring chart to confirm that the record is accurate.

15. Patient Controlled Analgesia (PCA)

- Controlled drugs for administration via a PCA device should be prescribed stating the drug concentration, bolus dose, lock out time and rate of background infusion, if appropriate.
- Two registered practitioners that have been trained and assessed as competent must be present during the set up and start of the device. One must prepare the CD to be administered and attach the device to the patient, the other must check each step. They must both verify the programme against the written prescription and must sign the administration record chart, as a record of this check. Both practitioners are equally accountable for the process.
- The following details should be recorded in the CDRB:
    - Date when the PCA was commenced
    - Name of the patient
    - Quantity in the syringe

- Name, formulation and strength administered
- Name/signature of practitioners who set up PCA (administered the CD)
- Balance in stock

- When the PCA is discontinued, the time, date and the residual amount of the drug in milligrams should be recorded on the PCA chart together with the signatures of the two practitioners involved. The residual CD must be disposed of in accordance with Pharmaceutical Waste guidance. Small residual amounts are disposed of in a clinical waste bin.

16. Controlled drug supplies for patients on pass, discharge or being supplied on prescription in primary care

- Individual patient supplies will be dispensed against a properly completed prescription. The prescriber should refer to the BNF for a full description of the legal requirements for CD prescriptions. These are summarised as follows:-
  - The prescription must be written in the prescribers own handwriting in indelible ink or a computer-generated paper prescription for all CDs including Schedule 2 and 3; all details except the signature can be computer generated.
  - The prescription must include the patient's name and address.
  - The prescription must be signed and dated by the prescriber
  - The prescription must include the following information
    - Drug – by generic name
    - Form – e.g. tablet, capsule, modified release tablet, liquid, suppository
    - Strength- e.g. 10mg, 20mg, 10mg/5ml
    - Dose and dosage instructions: - e.g. 20mg at 08:00 and 20:00
    - The **total amount of drug required must be stated in words and figures**. It is usual to request sufficient to cover a minimum 7 day supply.
  - Sustained release morphine sulphate tablets are available in various strengths. Any prescription for this drug must detail the amount of each strength of tablet to be supplied in order to make up the total required dose.
- It is illegal for a pharmacist to supply a CD against a prescription which does not fully comply with these requirements.
- An entry must be made in the CDRB as per Section 12

17. Key security

17.1. Key Security in wards and departments

- The registered nurse/midwife/ODP in charge is responsible for the CD keys and any duplicate keys.
- The keys for the CD cabinet must be kept separate to other keys.

- Key-holding may be delegated to other registered nurses/midwife/ODP but the legal responsibility remains with the registered nurse/midwife/ODP in charge.
- CD keys must be held by a registered nurse/midwife/ODP on their person or in an electronic key cabinet which restricts and tracks access (e.g. Abloy systems). When using an electronic key cabinet the responsibility for the keys remains with the registered nurse/midwife/ODP in charge, however the Abloy system can be used to delegate access.
- CD keys may be handed to an authorised member of pharmacy staff for the purpose of stock checking. The key must be returned immediately after the check to the key-holder.
- Duplicate keys to CD cabinets must be retained in a secure place with access restricted as for the in-use key. Records of access to duplicate keys must be maintained by the registered nurse/midwife/ODP in charge.

17.2. Key security in Primary Care

- The doctor in a dispensing practice/clinician in OOHs service/registered nurse in a non-doctor island location is responsible for the CD keys and any duplicate keys.
- The keys for the CD cabinet/bag must be kept separate to other keys.
- Key-holding may be delegated where appropriate to other members of staff such as the practice manager and arrangements for security of keys agreed, but legal responsibility for the keys remains with the doctor/registered nurse in that location.
- Where there is no permanent doctor in post in a dispensing doctor practice the Medical Director will assume responsibility for the CD keys and the security arrangements for the CDs.

17.3. Missing CD Keys/locks

- If a key for a CD cupboard goes missing it must be reported immediately to the registered nurse/midwife/ODP in charge or the doctor with responsibility for dispensing in a dispensing practice, who is responsible for ensuring that the following action is taken:-
    - Ask all staff on shift if they have the keys on their person
    - If the key is still missing, contact staff who have left the premises. If one of them has the key they must return it immediately.
    - If the key is still missing, conduct a thorough search of the premises.
    - If the key is still missing (either assumed lost or with a member of staff unable to return it) then a duplicate key may be issued for use.
    - Carry out a full inventory of stock.
- If the lock has to be replaced contact pharmacy for advice.
- Complete a DATIX form recording all relevant details and actions taken and submit to the relevant manager. Inform the Lead Pharmacist for the site, and complete a CD Incident form (see Appendix 3) within 3 days. The Accountable Officer will advise if there is any need to contact the police.

18. Controlled stationery

The lead registered nurse/midwife/ODP/Doctor in charge of dispensing in Primary Care must ensure that all controlled stationery is stored securely and that access is restricted to authorised staff.

The following are classified as controlled stationery:

- Controlled Drugs Record Book (CDRB)
- Controlled Drugs Order Book (where relevant)

The CDRB should be kept in a secure place. Where a CD order book is in use it should be stored in the CD cupboard. If either of these are missing it should be reported to the registered nurse/midwife/ODP in charge or the doctor with responsibility for dispensing, who is responsible for investigating the incident and reporting via DATIX. The Lead pharmacist for the area should be informed and a CD Incident form completed and sent to the CDAO within 3 days.

Completed CD Order books must be retained in the ward/department for two years after the date of the last entry. CDRBs must be retained in the ward or department for a period of 7 years from the last date of entry.

19. Stock Checks

19.1. Stock checks in the hospital

- At the point of administration of CDs the stock balance of that individual preparation should be confirmed as correct and the balance recorded in the Ward/Department CDRB.
- The balance of each CD stocked in a ward or department in the hospital at least once every 24hours. However the frequency of this check may be varied for local operational purposes by the ward/department manager in consultation with the Lead Nurse for Acute and the Lead Pharmacist.
- The registered nurse/midwife/ODP in charge is responsible for ensuring that these CD stock checks are carried out.
- Two registered nurses or midwives should perform this check (a student nurse or midwife may be the second checker provided they have the necessary knowledge to carry this out).
- The stock checks must be recorded: this may be in a register reserved for this purpose, or as part of the records kept for the individual controlled drugs in the CDRB.

  Each time the stock is reconciled the date, time and signatures of those carrying out the check will be recorded for each CD item.

  For example

  31.01.24 09:00 balance checked and correct. A registered nurse. B registered nurse.
- The stock check should take account of the following:
  - Checking the balance in the ward/department CDRB against the contents of the CD cabinet, not the reverse, to ensure all balances are checked.
  - It is not necessary to open intact packs with tamper evident seals for stock checking purposes.

- Stock balances of liquid medicines should generally be checked by visual inspection. The balance must be confirmed to be correct/amended if required on completion of a bottle. See Section 20
- Pharmacy staff will also carry out a 6 monthly CD check within the wards/departments which will be recorded in the CDRB against each preparation. This check will be carried out by a member of pharmacy staff and the nurse in charge of the ward.

19.2. Stock checks in primary care including dispensing doctors, OOH service and Non-doctor Island

- The balance of each CD stocked in a dispensing practice should be checked a minimum of once per week by a member of practice staff and the doctor responsible for dispensing. Where there is a change of locum the stock should be checked as one locum leaves and also when the new locum arrives. A log should be kept of these checks.
- The CD stock in the OOHs service will be checked once weekly by a member of pharmacy staff and will be checked by the clinician when they pick up the drugs at each change of shift. A record of these checks should be kept in a log for that purpose.

20. Stock Discrepancies

- Any discrepancy between the physical stock and the amount shown in the amount shown in the CDRB must be reported immediately to the person in charge of the ward/department/doctor responsible for CDs in the dispensing practice and investigated as follows:-
  - Check all the arithmetic since the last balance
  - Check all controlled drug stock held with a second person
  - Check other register sections for erroneous entries
  - Sense-check the record book e.g. check correct pack sizes have been entered, patterns of entry for potential missing entries, unusual quantities etc.
  - Check that orders have all been entered by checking ward order book, delivery notes etc.
  - Check staff roster and contact all members of staff during the relevant period to verify any supplies made that have not been entered.
  - Appendix 4 can be used to aid this process.
- If the discrepancy can be resolved a bracket should be placed around the wrong entry, initialled and dated by the nurse/midwife/ODP/Doctor in charge.
- Any discrepancy which cannot be resolved must be reported to the registered nurse/midwife/ODP/Doctor in charge, as well as the Lead pharmacist.
- A CD Incident form (Appendix 3) should be completed and sent to the CDAO within 3 days of the incident. A Datix should also be submitted.
- Difficulties with measuring quantities of liquid medicines accurately will lead to minor discrepancies. The CDRB volume may, in these circumstances, be adjusted as necessary and signed by two registered members of staff or in the primary care setting a

member of practice staff and the doctor responsible for dispensing. Adjustment should only be made when a bottle is finished and the discrepancy becomes apparent. Extra measuring episodes should not be undertaken as this is likely increase the discrepancy.

21. Breach of security involving Controlled Drugs

- A breach of security includes any deviation from the procedures that cause actual or potential loss or theft of medicines. Examples of such incidents include:-
  - Controlled drugs are found to be missing from pharmacy/ward/department/GP practice
  - Controlled stationery is found to be missing
  - A key for the controlled drugs cupboard is found to be missing
  - Patients own controlled drugs are found to be missing
  - An unauthorised person has access to controlled drugs or controlled drug stationary
- Theft of controlled drugs is a serious criminal offence under the Medicines Act 1968, the Misuse of Drugs Act 1971 and other legislation and will be dealt with accordingly.
- Any person who discovers a breach of security is responsible for reporting it immediately to the registered nurse/midwife/ODP/doctor in charge, who in turn will inform the Pharmacy at Gilbert Bain Hospital. All concerns will be treated in the strictest confidence regardless of whether the subsequent review substantiates these concerns. The registered nurse/midwife/ODP/doctor in charge must take reasonable steps to determine that CDs are in fact missing.
- All breaches of security that cause actual or potential loss or theft of CDs must be investigated and the appropriate corrective and preventative action taken. If medicines have been misappropriated police charges may be brought.
- If a staff member is unable to satisfy themselves that all medicines can be accounted for, they must report suspicions to the relevant manager immediately. Where a non-clinical manager has been informed of suspected or actual theft of medicines, they must inform relevant professional leads including the CDAO.
- Should the result of preliminary review identify any evidence of actual theft of CDs the senior nurse for the service or the doctor responsible for dispensing medicines will inform the CDAO and complete a CD Incident form (Appendix 3). Any evidence should be retained pending police investigation.

22. Disposal of Controlled Drugs

22.1. Disposal of Controlled Drugs at Ward Level (except expired stock)

Two members of staff must be involved in the disposal of CDs in a ward/department. One must be a registered nurse/midwife/ODP. The second may be from the same category or be a student nurse or midwife. In certain circumstances the second person may be a doctor, dentist, pharmacist or pharmacy technician.

A solidifying agent such as Vernagel must be added to pharmaceutical waste bins prior to adding any drugs.

CDs may be disposed of at ward/department level by nursing/midwife/ODP staff in the following circumstances:-

- **Disposal of Partly used Ampoules or Vials.** When the dose to be administered is less than the contents of the smallest available ampoule /vial, the required dose should be drawn up and the remaining drug should be denatured by emptying it into a blue lidded/yellow bodied pharmaceutical waste bin. The ampoule should also be disposed of in this bin. The amount discarded should be clearly recorded in the Ward/department CDRB.

  For example: if diamorphine 2.5mg was prescribed but only the 5mg ampoule is available, the record would show “2.5mg given and 2.5mg discarded”.

- **Disposal of part tablets**. Any remaining part tablet after administration should be crushed using a tablet crusher and then emptied into a blue lidded blue bodied pharmaceutical waste bin. The tablet crusher should be rinsed with the washing placed into the same bin. The amount administered/discarded should be recorded as follows :-

  For example: temazepam 5mg given, Temazepam 5mg discarded

- **Doses refused by patients.** Once removed from their original containers, drugs should be administered as soon as possible and must not be retained if refused.
  - If a dose of liquid CD is refused this can be denatured by discharging it into the blue lidded blue bodied bin.
  - If a solid dose form is refused this can be crushed as above and placed in the blue lidded blue bodied bin.
  - Capsules can be opened and the contents and shell placed in the blue lidded blue bodied bin
  - The entry in the CDRB should be marked “Patient refused and dose disposed of on ward”
  - Doses refused by patients must also be recorded on HEPMA.
- **Dropped tablets**. If a tablet or capsule is dropped it should be disposed of as above.
- **Spills and breakages**. Spillages should be cleaned up wearing gloves, with any paper towels and broken glass placed into a blue lidded yellow bodied bin. An entry in the CDRB and the balance corrected immediately.
- **Syringe pumps/epidurals/infusions**. If the contents are only partly used when removed from the patient the remaining contents must be denatured. This should be done by discharging this into the blue lidded blue bodied bin. Details regarding the volume disposed of should be recorded on the appropriate prescription recording chart and in the patient’s notes; this should be signed by both staff involved in the destruction process. Infusion lines should also be disposed of in the blue lidded blue bodied bin.
- **Patches** Used CD patches may still contain a small quantity of drug and therefore should be folded in half adhesive side together. The patches should then be disposed of in a blue lidded blue bodied bin. Where a patch has been removed from a patient, the removal should be recorded in the patient’s medical/nursing record and also on HEPMA.

22.2. Disposal of Drugs in Primary Care settings

The same provisions apply in primary care settings although it is understood that where administration has been undertaken in a patient's home and part used CDs will require transportation back to the nearest health centre for appropriate disposal.

23. Liquid Controlled Drugs

An oral syringe and bung should be used to measure liquid oral doses of CDs. Larger doses such as methadone, can be measured using a suitable glass conical measure.

The balance of liquids must be confirmed on reaching the end of a bottle. A suitable conical measure should be used to measure balances and overages where necessary. Discrepancies in liquid volumes may arise due to manufacturer overage or due to regular small losses when measuring frequent small volumes in addition to spillages.

- **Excess liquids (Overage)** when the end of a bottle is reached according to the CDRB, any excess liquid must be measured. The stock balance must be adjusted accordingly and this entry signed and witnessed by two members of registered nursing/midwifery/ODP staff. The excess must not be discarded. Misbalances of 10% or greater must be investigated and reported via Datix.
- **Shortage of liquids** when the end of a bottle is reached and there is a slight shortage i.e. less than 10%, two registered nurses/midwifes/ODPs must make an entry to correct the balance. If there is a larger misbalance (10% or greater), the ward/department clinical pharmacist must be notified to investigate the misbalance, notify the CDAO if required and adjust the CDRB balance. Misbalances of greater than 10% must be reported via Datix.

  When nursing/midwife/ODP staff are carrying out CD balance stock checks they need only visually estimate that the volume in the bottle is the same as the stock balance.

  When a pharmacist/pharmacy technician carried out a CD check, the balance should be measured and corrected as necessary.

The same provision apply in Primary Care settings.

24. Breakages

All breakages must be reported to the person in charge of the ward/department/dispensing practice. Breakages must be entered in the CDRB explaining the reason for the discrepancy between the physical stock and the amount shown in the CDRB. This should be signed by two registered practitioners or in the case of a dispensing practice a member of staff and the doctor responsible for dispensing.

For example:

31.01.24 1x 10mg ampoule morphine sulphate broken by A Nurse (Signature), Witnessed by B Nurse (Signature).

25. Expired Stock

25.1. Expired stock in the hospital setting

- When a ward/department/theatre controlled drugs reach their expiry date the Pharmacy should be informed. A member of pharmacy staff will visit the ward/department and destroy the CDs on the ward, witnessed by a member of ward staff.
- The member of pharmacy staff and the nurse in charge must both sign the CDRB and indicate the date on which the drugs were destroyed, the quantity and the reason for destroying them. Such entries should be made in red indelible ink.

  For example:

  31.01.24 destroyed by Pharmacy 4 x 10mg tablets expired. A Pharmacist/Technician (signature), A Registered nurse/midwife/ODP(Signature)

  The CD should be destroyed in such a way that the drug is denatured or rendered irretrievable so that it cannot be reconstituted or used. See Appendix 9.
- Expired stock should **not** be returned to pharmacy by a member of staff.

25.2. Expired stock in a Primary Care setting

- Where stock has expired in a GP Practice the CD Authorised Witness should be asked to attend to witness the destruction of the CDs. Contact details for the CD Authorised Witness can be obtained by contacting shet.pharmacyprimarycare@nhs.scot .
- Until the CD Authorised witness can attend the expired stock should be retained in the register but be identified in the balance as follows:-

  31.01.24 10 ampoules expired A.Nurse(Signature) B.Nurse (Signature) balance 30/10.

The balance of 30/10 shows that of the total 40 ampoules in stock 30 are in date and usable and 10 are expired. The stock can continue to be used with the balance of 30 reducing while the 10 remains static until it is destroyed when the balance will revert to being the total number of ampoules in date only.

- Where the 2 ampoules held as stock on a Non-Doctor island have expired the nurse should make an arrangement with the pharmacy at Gilbert Bain Hospital to return these for destruction and provide a signed order to replace these before the expiry date is reached. A copy/photograph of the CDRF page showing the removal of the expired stock should accompany the signed order. The pharmacy at Gilbert Bain will contact the Authorised Witness to arrange destruction of these ampoules.
- Where CDs in the OOHs stock expires the pharmacy staff at Gilbert Bain hospital will call the Authorised witness to destroy this.

26. Stock no longer required

When a ward/department has controlled drugs which they will not use before their expiry date they should contact the pharmacy department at Gilbert Bain Hospital for agreement from a registered pharmacist/pharmacy technician to return the stock to pharmacy. If it is agreed that the stock can be returned the stock should be brought to pharmacy along with the CDRB. The member of pharmacy staff and the registered nurse/midwife/ODP in charge must sign the

CDRB and indicate the date on which the drugs were removed and the quantity updated. Such entries should be made in red indelible ink.

For example:

31.01.24 Returned to Pharmacy 10x 50mg ampoules A. Pharmacist/Technician (Signature) A. Nurse (Signature)

Pharmacy staff must then record the return in the pharmacy CDRB.

27. Patient's Own Controlled Drugs

- Patient's own CDs must be stored in the controlled drug cupboard separate from ward stock.
- It is essential that patient's own CDs are identified and the name, form, strength and quantity is recorded. This can be in the ward CDRB or a separate CDRB can be kept for this purpose. If the record is in the ward CDRB the record must be on a separate page from ward stock records.
- The same page may be used for more than one patient's own controlled drugs. The balance of patients' own controlled drugs must be reconciled at least once every 24 hours.
- Subsequently the record should be completed, indicating whether the CDs are returned to the patient on discharge, to their relatives, or destroyed on the ward by a member of pharmacy staff, witnessed by a registered nurse/midwife.

28. Transfer of Controlled Drugs between wards

- When the pharmacy is open CDs must not be transferred between wards or departments.
- Sufficient stock should be held at ward level to avoid the need to obtain supplies from other wards/departments when they cannot be obtained from the pharmacy service.
- If a CD is required when pharmacy is closed the on-call pharmacist should be called via the switchboard for advice. If it is agreed that in the best interests of the patient a transfer between wards should take place the following process should be followed:-
    - A registered nurse/midwife from the requesting ward will contact the ward with stock and identify the patients' record on HEPMA to the ward staff.
    - The registered nurse/midwife/ODP from the ward requiring the CDs must write, sign and date a CD order for the drug detailing the strength, form and quantity to be supplied by the ward/department. The CD order must state "Supplied by (Ward/Department) in exceptional circumstances".
    - An entry must be made on the appropriate page of the CDRB of the supplying ward stating the date, time and amount of drug transferred and to which ward/department. Both members of staff must date and sign the entry.
    - It is recommended that a full or part box should be transferred; not individual ampoules or strips of tablets. These should remain in the original box with the batch number, expiry date and patient information leaflet. Alternatively the supplying ward can supply sufficient only for one dose.

- The registered nurse/midwife/ODP from the supplying ward must sign and date the “Supplied by” section of the CD order.
- The registered nurse/midwife/ODP from the receiving ward/department must sign the “Accepted for delivery” section on the order.
- The top (white) copy of the CD order must be retained securely by the ward/department supplying the drugs for a minimum of 2 years. It is recommended that this is stapled into the CDRB.
- On return to the original ward/department, two registered nurses/midwives/ODPs from that ward/department must check the CD order and the CDs received. The receipt must be documented in the ward CDRB, clearly stating the amount of drug received, from which ward/department and the CD order book/serial number. Both members of staff must date and sign this entry.

CDs that have been transferred between wards must not be replaced or returned. The receiving ward will now treat these as their stock.

28.1. Transfer of stock Controlled Drugs between theatres in exceptional circumstances

In exceptional circumstances it is acceptable to transfer CDs between theatres within the same department. The following process should be followed:-

- The registered nurse/ODP from the requesting theatre/area must take their theatre CDRB with them to the supplying area.
- The nurse/ODP responsible in the supplying area must make an entry in the supplying areas theatre CDRB stating clearly the amount of drug being transferred and to which area. This entry must be dated and signed by both nurses and the running balance altered accordingly.
- The balance of stock in the supplying area must be confirmed to be correct by checking the physical stock.
- In the receiving area CDRB the following should be recorded-
  - Date of transfer/receipt
  - Area the drug has been supplied from.
  - Amount received in words rather than numbers
  - Signatures of the nurse/ODP receiving the CDs
  - Signatures of the Nurse/ODP supplying the CDs
  - Balance in stock, confirmed by checking the physical stock.

29. Patients transferring Ward/Department

When a patient with their own CDs is transferred the following process should be followed. This should involve two registered nurses/midwives/ODPs or a registered nurse/midwife and student nurse/midwife in each ward area.

The **transferring** ward/department

- The patient's own CDs should be checked to confirm the drug, strength and current balance.
- The registered nurse/midwife/ODP should make an entry in the CDRB stating the date, time and quantity transferred with the patient. The ward the patient is being transferred to should also be recorded and the balance changed to zero. This should be signed by both members of staff.
- The registered nurse/midwife/ODP should contact the receiving ward and advise them the patient has their own supply of CDs and detailing the drugs and quantity being transferred.

The **receiving** ward/department

- The registered nurse/midwife/ODP should for each patient's own CD, make an entry in the ward patient's own CDRB stating the date, time and quantity transferred with the patient. The ward/department that the patient has come from should be recorded along with the details of the transfer in the CDRB. This should be signed by both members of staff.

Any discrepancies should be highlighted immediately to the transferring ward.

30. Admission and discharge of Patients Prescribed Opioid Replacement Therapy (ORT)

On admission of patients currently prescribed an Opioid replacement therapy (ORT) such as methadone or buprenorphine, their prescriber and community pharmacy must be contacted either by ward or pharmacy staff in order that:

- The current dose of the prescribed medication can be confirmed
- The date of dispensing of the last supervised instalment or date of receipt of last instalment, if unsupervised, can be confirmed
- The community pharmacy can be advised to temporarily suspend the patient's prescription until further notice, and so limit the possibility of the patient receiving a double dose or someone else trying to collect it on their behalf.
- The prescriber is aware of the patient's admission to enable continuity of care.

Where the patient's prescriber and/or community pharmacy cannot be contacted to confirm the dose and last dispensing/supervision of the prescription, the opioid substitute must not be prescribed. This is to minimise the risk of overdose. Instead, patients should be monitored for symptoms of withdrawal and managed accordingly. Prescribing for symptoms of withdrawal should be undertaken by clinicians with adequate experience in the prescribing for patients with opioid dependence.

Where a patient brings their own supply of ORT with them during an admission it may be used if deemed appropriate. The supply should be validated with the community pharmacy with consideration given to the risk of any contamination. It should be recorded as described in Section 27.

Discharge planning should be undertaken at the earliest opportunity to ensure continuity of treatment and minimise the risk of double dosing.

- The regular ORT prescriber and community pharmacy should be consulted to ensure that on-going prescribing and dispensing arrangements are in place. They should be informed of the date, time and quantity of the last dose that has been administered to the patients and the details of any supply provided by the hospital
- Any unused Patient Own supply should be returned to the patient and the prescriber and community pharmacy informed.

31. Cannabis based products

31.1. Cannabis based products for medicinal use (CBPM)

Currently the only licensed CBPM are Sativex®, Nabilone and Epidyolex®. Sativex® (Schedule 4) is licensed for moderate to severe spasticity due to multiple sclerosis. Nabilone (Schedule 2) is licensed for the control of nausea and vomiting, caused by chemotherapy in treatment of cancer. Epidyolex ® (Schedule 5) is licensed for treating seizures associated with Lennox Gastaut or Dravet syndrome.

The current regulations only allow individuals on the Specialist Register of the GMC to prescribe CBPM.

31.2. Hemp/Cannabis Oil

Products not meeting the definition of CBPM must not be prescribed, this includes unrefined plant materials or cannabis/hemp oils e.g. products which can be obtained from health food shops or on-line. These products do not meet the MHRA standards for good manufacturing practice and good distribution practice and are not for medicinal use. These products should not be recommended to patients as the strength, quality and contents cannot be guarantee. These products cannot be prescribed or administered to patients while in hospital.

32. Guidance on Standard Operating Procedure (SOP) Completion

- The SOP contains a number of headed sections which outline the activities to be carried out by ward/theatre/department staff to manage CDs safely
- The left hand column describes the area of the SOP being addressed
- The right hand column currently largely contains advice or an indication of the type of information (in bold) which should be entered in this section.
- In the majority of sections this right hand column should be updated with the relevant local information, describing the activity and its procedures applicable in that area.
- In some cases this may be as the example but in other cases this may require more detailed local information, i.e. where a cupboard is located, who has the key etc.
- Once updated with local information and processes the document can be saved as the SOP for that area with dates of completion.

33. Appendices

Appendix 1 – Summary of Handling Requirements for Commonly used CDs

Appendix 1
Summary of Handlin

Appendix 2 – Example of CDRB from theatre

Appendix 2 CDRB
from theatres.docx

Appendix 3 – Controlled Drug Incident form

Controlled Drug
Incident Reporting F

Appendix 4 – Stock Check sheet for a balance discrepancy

Appendix 4 CD
Balance discrepancy

Appendix 5 – SOP for areas of hospital

Appendix 5
Hospital SOP for CD

Appendix 6 – SOP for theatre

Appendix 6 Theatre
SOP for CDs.docx

Appendix 7 – SOP for Dispensing Practices

SOP FOR
DISPENSING PRACTI

Appendix 8 – SOP for Non Dispensing Practices

SOP FOR NON
DISPENSING PRACTI

Appendix 9 – Denaturing of CDs

National SOP describing methods

Appendix 10 – Rapid Impact Checklist

An equality and diversity impact assessment tool:

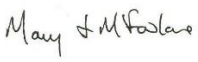
<table>
<tr><td colspan="2">Which groups of the population do you think will be affected by this proposal?*
All patients
Other groups:
• Minority ethnic people (incl. Gypsy/travellers, refugees & asylum seekers)
• Women and men
• People with mental health problems
• People in religious/faith groups
• Older people, children and young people
• People of low income
• Homeless people
• Disabled people
• People involved in criminal justice system
• Staff
• Lesbian, gay, bisexual and transgender

*the word proposal is used as shorthand for the policy, procedure, strategy or proposal that is being be assessed</td></tr>
<tr><td colspan="2">In the following sections, please consider what positive and negative impacts you think there may be and which specific groups will be affected by these impacts?</td></tr>
<tr><td>What impact will the proposal have on lifestyles?
For example, will the changes affect:
• Diet and nutrition
• Exercise and physical activity
• Substance use: tobacco, alcohol and drugs
• Risk taking behaviour
• Education and learning or skills</td><td>Nothing specific</td></tr>
<tr><td>Will the proposal have any impact on the social environment?
Things that might be affected include:
• Social status
• Employment (paid or unpaid)
• Social/Family support
• Stress
• Income</td><td>No</td></tr>
</table>

Will the proposal have any impact on the following? • Discrimination? • Equality of opportunity? • Relations between groups? • Fairer Scotland Duty	No
Will the proposal have an impact on the physical environment? For example, will there be impacts on: • Living conditions? • Working conditions? • Pollution or climate change? • Accidental injuries or public safety? • Transmission of infectious disease?	No
Will the proposal affect access to and experience of services? For example: • Health care • Transport • Social services • Housing services • Education	Healthcare – the policy will ensure that patients have appropriate and legal access to controlled drugs when they need them, and that controlled drugs are handled in accordance with the requirements of the law.

Summary sheet

Positive Impacts (note the groups affected)	**Negative Impacts (Note the groups affected)**
All patients will be able to access controlled drugs when they need them and can be assured that they do so safely and within the confines of the law.	Nil
Additional Information and Evidence Required	
Recommendations	
From the outcome of the RIC, have negative impacts been identified for race or other equality groups? Has a full EQIA process been recommended? If not, why not? No	

Signature(s) of Level One Impact Assessor(s): 

Date: 17/5/24

Signature(s) of Level Two Impact Assessor(s):

Date: