POLICY FOR THE MANAGEMENT OF CONTROLLED DRUGS IN NON-HOSPITAL SETTINGS

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Version Number	1
Document effective from	1st April 2022
Next review due	1st April 2023

Intended audience	Manx Care settings (excluding Hospital settings)	
Superseded documents	None	
Stakeholders consulted prior to ratification	Primary and Community settings	
Ratified by	Integrated Medicines Optimisation Group (IMOG)	**Date** 25/3/22
Previous reviews	n/a	
Changes made during latest review	n/a	

Contents

1. INTRODUCTION

1.1 Purpose

This policy aims to identify robust systems for the obtaining, prescribing, storing, supplying, monitoring, administrating, returning and destroying of Controlled Drugs in accordance with current legislation and is intended for use across non-hospital settings.

1.2 Scope

This policy applies to all healthcare professionals working with, for, or under instruction of Manx Care in non-hospital settings, who deal in any way with Controlled Drugs. This includes the Ambulance Service, Adult Health and Social Care Homes, Prison, Community Nurses and Manx Emergency Doctors Service.

1.3 Definitions

1.3.1 Controlled Drug

- Any drug belonging to schedule 1, 2, 3, 4 or 5 of the Misuse of Drugs Regulations 2001. Hereafter referred to as Controlled Drugs in the policy.

1.3.2 Authorised Member of Staff

- This is either a Registered Healthcare Professional (e.g. Nurse, Paramedic, Doctor or Pharmacist) or a member of staff who has been signed off by their Manager (e.g. Member of care home staff).

1.3.3 Authorised Witness

- This is a person authorised to witness the destruction of Controlled Drugs on the island.

1.3.4 Intelligence

- Information relating to individuals where there is a suspicion of inappropriate or excessive prescribing or potentially illegal activity (which may be gathered or shared if appropriate as part of an investigation).

1.3.5 Patient Returned Controlled Drugs

- Controlled Drugs that have been prescribed for, and dispensed to, a named patient and then returned unused or part-used, by the patient or their representative.

1.3.6 Stock Controlled Drugs

- Controlled Drugs that have been held for the purposes of potential dispensing to patients, or supply of Controlled Drugs held for emergency use (either on the premises or in a Doctor's bag).

1.4 Roles and Responsibilities

1.4.1 Manx Care actively encourages all health and care professionals to seek advice/guidance from the Controlled Drugs Lead (Medical Director) and to share intelligence. The following types of issues regarding Controlled Drugs and their safe management must be reported:

- discrepancies in balances
- prescribing concerns (e.g. excessive quantities or unusual doses)
- suspected loss or theft of Controlled Drugs
- suspected loss or theft of a prescription for Controlled Drugs
- forged prescriptions for Controlled Drugs

1.4.2 Sometimes a small piece of information can fit into something wider. It is important to report issues or suspicions to the Lead Pharmacist for the area to assist in identification of potential trends. The information is not used to assign blame, only to ensure that there is safe and secure use of Controlled Drugs.

1.4.3 It is the responsibility of all healthcare professionals to ensure that they adhere to the legislation covering the safe management of Controlled Drugs and to report any relevant information to the Pharmaceutical Adviser and Head of Service, who would report to the CEO.

1.4.4 All healthcare professionals working with Controlled Drugs must ensure that there are SOPs in place for that activity and that the SOPs are adhered to.

2. RELATED POLICY/STRATEGY/LEGISLATION/GUIDANCE

2.1 Legislation

2.1.1 The management of Controlled Drugs is governed by Isle of Man legislation including the Misuse of Drugs Act 1976 and its associated Regulations. Please see the Appendix 2 for the further details of legislation.

2.1.2 Controlled Drugs are prone to misuse / abuse, and can cause significant harm whether obtained legally or illegally. Legislation stipulates how Controlled Drugs are procured, stored, transported, supplied, prescribed, administered, recorded, disposed of and possessed. A summary of the legal requirements pertaining to the main groups of Controlled Drugs can be found in Appendix 3. Schedule 1 drugs have been omitted from the table, as drugs in this group currently have no therapeutic uses outside of clinical trial and research.

2.1.3 When a Controlled Drug is specified as exempt from storage and/or recording requirements the manager in charge of the area may decide to override the

exemption, if for example, there is a security concern. In such instances a Standard Operating Procedure (SOP) must be written to ensure the relevant staff are aware.

2.2 Governance

2.2.1 All activity related to Controlled Drugs in all healthcare settings must be subject to standard operating procedures (SOPs). These must reflect the legal requirements and include all activities concerned with Controlled Drugs such as requisitioning, receipt, administration and investigation of discrepancies etc.

2.2.2 SOPs must be kept up-to-date, reflecting current legal and good practice requirements for Controlled Drugs.

2.2.3 SOPs must be developed by and approved by the Head of Service for each area. If advice is required then a member pharmacy team allocated to the service can be contacted for input. Please refer to Manx Care policy for the Development of Policies and SOP's (2021).

3. POLICY/PROCEDURE/GUIDELINES

3.1 Ordering and Supply of Controlled Drugs

Please refer to each individual service area below for details.

3.2 Transfer and Receipt of Controlled Drugs

Please refer to each individual service area below for details.

3.3 Storage of Controlled Drugs

3.3.1 Storage Regulations

3.3.1.1 The Misuse of Drugs (Safe Custody) Regulations 1973 (SI 1973 No 798) and the equivalent Manx legislation (Isle of Man Misuse of Drugs Act 1976) cover the safe custody of Controlled Drugs in certain specified premises. The Regulations also set out certain standards for safes and cabinets used to store Controlled Drugs.

3.3.1.2 Controlled Drug cupboards must conform to the British Standard reference BS2881 or be otherwise approved by the Pharmaceutical Advisor. This is a minimum security standard and may not be sufficient for areas where there are large amounts of drugs in stock at a given time, and/or there is not a 24-hour staff presence, or easy control of access. In this case a security cabinet that has

been evaluated against the SOLD SECURE standard SS304 (See www.soldsecure.com) must be used.

3.3.1.3 All Controlled Drugs must be stored in a locked cupboard that can only be opened by a person who can lawfully be in possession of Controlled Drugs, such as a person in charge, or a person working under their authority.

3.3.1.4 General measures for the storage of Controlled Drugs include the following:

- Cupboards must be kept locked when not in use
- The lock must not be common to any other lock in the area
- The Controlled Drug cupboard (Controlled Drugs) key must only be available to authorised members of staff and at any time the key-holder should be readily identifiable
- The area of the cupboard must be dedicated to the storage of Controlled Drugs
- No other items must be stored in the Controlled Drug cupboard (for example, patients valuables)
- No other drugs or medicines should routinely be stored in the Controlled Drug cupboard. Occasionally, in response to local circumstances an area may decide to allow other drugs (that are not Schedule 2 or Schedule 3 Controlled Drugs) to be stored in the Controlled Drug cupboard.
- Controlled Drugs must be locked away when not in use

3.3.1.5 There must be arrangements for keeping the Controlled Drug keys secure.

3.3.1.6 Patient's own Schedule 2 Controlled Drugs must be stored in the Controlled Drug cupboard and separated appropriately from any stock Controlled Drugs. Patient's own Schedule 3 Controlled Drugs however, can be stored appropriately in the patient's own room.

3.3.2 Controlled Drug Cupboard (Controlled Drugs) Keys

3.3.2.1 The manager or person in charge is responsible for the safekeeping of the Controlled Drug key. The holding of the key may be delegated to other suitably trained, Registered Healthcare Professionals or authorised member of staff, but the legal responsibility rests with the person in charge or manager.

3.3.2.2 Controlled Drug key:

- must be returned to the person in charge or manager immediately after use.
- must be kept on a separate bunch to other keys.
- may, for the purpose of stock checking, be handed to an authorised member of the Pharmacy staff.

3.3.2.3 If the Controlled Drug key cannot be found then urgent efforts must be made to retrieve it as speedily as possible e.g. by contacting any Nursing, Paramedic or staff members who have just gone off duty.

3.3.2.4 If the Controlled Drug key cannot be located then the manager must be informed as soon as possible. Each area has the responsibility to write an SOP for the process to be followed in the event of a lost key.

3.3.2.5 If the Controlled Drug key cannot be found then an entry onto the incident reporting system (currently Datix®) must be made and the relevant people must be informed as per area SOP.

3.3.3 Record Keeping

3.3.3.1 Schedule 2 Controlled Drug Record Books

3.3.3.2 Each area that holds stocks of Controlled Drugs must keep a record of their receipt and administration in a Controlled Drug register.

3.3.3.3 Controlled Drug registers are available from the dispensing pharmacy.

3.3.3.4 The person in charge is responsible for keeping the Controlled Drug register up to date and in good order.

3.3.3.5 The Controlled Drug registers are bound (not loose-leaf) with sequentially numbered pages. There must be separate pages completed for each drug, form and strength, so that a running balance can be kept easily. Entries must be made in chronological order and in black ink. For the Prison please refer to the Prison section.

3.3.3.6 All entries must be signed by an authorised member of staff and must be witnessed preferably by a second authorised member of staff.

3.3.3.7 If a mistake is made it must be bracketed in such a way that the original entry is still clearly legible. This must be signed, dated and witnessed by a second authorised person. A witness must also sign the correction. Incorrect entries must never be crossed out.

3.3.3.8 On reaching the end of a page in the Controlled Drug register, the balance must be transferred to another page. The new page number must be added to the bottom of the finished page and the index updated. As a matter of good practice this transfer should be witnessed.

3.3.3.9 On the commencement of a new register all balances must be transferred over to the new register (nil balances need not be added to the new register) and

countersigned by a witness. Annotate “transferred to register number x” after each final entry in the old register to provide an ongoing record.

3.3.3.10 On starting the new register the cover of the old register must be ‘crossed through’ or ‘labelled’ as old and the date of the planned destruction must be written on the front cover (2 years after the date of last entry).

3.3.3.11 The old register must be removed and stored securely in the care setting until the documented destruction date.

3.3.4 Record of Receipts

3.3.4.1 A record must be kept of all Schedule 2 Controlled Drugs that are received or administered.

3.3.4.2 Ensure that the correct page of the Controlled Drug register has been selected; check correct drug, strength and formulation.

3.3.4.3 For Controlled Drugs received, the following details must be recorded in the Controlled Drug register:

- Date of entry
- Serial number of requisition (if received from a requisition order) or where the controlled drug is received from (for example, the dispensing pharmacy)
- Quantity received
- Name/signature of authorised person making entry
- Name/signature of witness
- Balance in stock

3.3.4.4 It is best practice, when recording Controlled Drugs, to note for the number of units received to be recorded in words not figures (e.g. ten, rather than 10) to reduce the chance of entries being altered. A zero balance must always be recorded as a word (i.e. NIL or ZERO), not the number 0, to prevent alteration.

3.3.4.5 After every administration, the stock balance of an individual preparation must be confirmed to be correct and the balance recorded in the Controlled Drug record book. This entry must be signed and dated.

3.3.5 Archiving of Controlled Drug Records

3.3.5.1 All Controlled Drug registers and, where appropriate, Requisition books used in the organisation must be kept for a period of at least two years from the date the last entry was made.

3.3.5.2 Storage of completed Controlled Drug registers (and requisition books) are the responsibility of the area.

3.3.5.3 All local documents designed to track and/or monitor Controlled Drug usage must also be kept for two years after the last entry/date of use.

3.4 Controlled Drug Stock Checks

3.4.1 Schedule 2 Controlled Drug Stock Checks

3.4.1.1 It is recommended that the stock balance of all Controlled Drugs entered in the Controlled Drug register should be checked and reconciled with the amounts in the cupboard at least once in each 24 hour period when the area is open, to ensure that discrepancies can be identified in a timely way. Managers may choose to put local arrangements in place to carry out checks more or less frequently.

3.4.1.2 The person in charge is responsible for ensuring that the regular Controlled Drug stock check is carried out by staff in the area.

3.4.1.3 Two Registered Health Professionals or authorised members of staff must perform this check, with staff being rotated periodically.

3.4.1.4 The check must take account of the following points:

- The balance in the Controlled Drug register must be checked against the contents of the Controlled Drug cupboard, not the reverse, to ensure all balances are checked.
- It is not necessary to open packs with intact tamper-evident seals for stock checking purposes.
- Stock balances of liquid medicines should generally be checked by visual inspection but periodic volume checks using a measuring cylinder may be helpful. The balance must be confirmed to be correct on completion of a bottle. It may be appropriate to carry out volume checks at more regular intervals.
- A record indicating that this reconciliation check has been carried out, and confirming the stock is correct, is made in the appropriate section of the Controlled Drug register. This record must (as a minimum) state the date and time of the reconciliation check; and include wording such as, “check of stock level -correct”. This must be signed by the Registered Healthcare Professional or authorised member of staff and the witness

3.4.1.5 If a discrepancy is found, it should be investigated without delay and the person in charge of the area, and Pharmaceutical Advisor, must be informed. An incident report (such as a Datix® report form) must also be completed. It is

important to remember that a discrepancy may indicate an incorrect dose administered to a patient or misuse.

3.4.1.6 Stock checks are included as part of the rolling Controlled Drugs governance check, performed by Pharmacy staff or the dispensing pharmacy.

3.4.2 Management of Schedule 2 Controlled Drug Stock Discrepancies

3.4.2.1 The balances in the Controlled Drug register must always tally with the amounts of Controlled Drugs in the cupboard.

3.4.2.2 Discrepancies can arise with liquid Controlled Drugs as a result of manufacturer's overage, the measurement process, or spillage. A discrepancy of up to 10% can be acceptable (i.e. less than 10ml in each 100ml). Such overage or losses of liquid preparations must be reported to the person in charge of the area, recorded and the running balance adjusted. Any approved alterations in balances must be added as a new entry in the Controlled Drug register. For example 'date, time, volume of liquid as accurately measured, signature and signature of staff member in charge'.

3.4.2.3 On identification of a discrepancy of 10% or more for liquid Controlled Drugs (i.e. 10ml or more in each 100ml), or a discrepancy of any other Controlled Drug, the following must be carefully checked:

- All requisitions or prescriptions received have been entered into the correct page of the register.
- All Controlled Drugs administered, have been entered into the Controlled Drug register.
- Items have not been accidentally put into the wrong place in the cupboard.
- Arithmetic checked to ensure that balances have been calculated correctly.

3.4.2.4 If the error or omission is traced, the member of staff in charge must make an entry in the Controlled Drug register, clearly stating the reason for the entry and the corrected balance. This entry must be witnessed by a second authorised person and both individuals must sign the Controlled Drug register.

3.4.2.5 If no errors or omissions are detected then the discrepancy must be reported to the Head of Service (via the staff member in charge) and Pharmaceutical Advisor without delay. Adult Health and Social Care home staff must also inform the Registration and Inspection Unit.

3.4.2.6 When spillages or droppage occurs, every effort must be made to find another person who can verify that the spillage or droppage has occurred and this must be recorded and initialed by both the person who made the spillage or droppage and a second person.

3.5 Clinical Governance Stock Checks by Pharmacy Staff

3.5.1 Pharmacy staff will audit Controlled Drugs annually or more often if deemed necessary.

3.6 Prescribing

3.6.1 General Considerations when Prescribing Controlled Drugs

3.6.1.1 When making decisions about prescribing Controlled Drugs take into account:

- Benefits of treatment and risks of prescribing, including dependency, overdose and diversion.
- Any other prescribed and non-prescribed medicines the person is taking (particularly any centrally acting agents) and whether the person may be opioid-naïve.
- Evidence-based sources e.g. NICE, BNF.
- If you are in any doubt contact a more senior prescriber for advice.

3.6.1.2 When prescribing Controlled Drugs:

- Document clearly the indication and regimen in the patient's notes
- Check the patient's current clinical needs and, if appropriate, adjust the dose until a good balance is achieved between benefits and potential harms
- Discuss with the patient any arrangements for reviewing and monitoring treatment
- Be prepared to discuss the prescribing decision with other health professionals if further information is requested about the prescription

3.6.1.3 When prescribing 'when required' (PRN) Controlled Drugs:

- Document clear instructions for when and how to take/use the drug (for example state the number of tablets/capsules or amount of liquid) in the patients notes, prescription chart or care record
- Include dosage instructions and indication in the patients notes or care record, including maximum dose in 24 hours and frequency of doses
- Ask about and account for, any existing supplies the patient may have at home and/or at the community pharmacy

3.6.1.4 When prescribing, reviewing or changing Controlled Drug prescriptions, prescribers must follow approved local guidelines or national guidelines and take into account:

- Appropriate route

- Dose (including when dose conversions or dose equivalence is needed) – use a recognised opioid conversion chart and ensure the total opioid load is considered
- Formulation (to ensure appropriateness and availability)
- If guidance on prescribing is not followed, document the reasons why in the patient's care record
- Inform the patient's GP of all prescribing decisions

3.6.2 Prescribing of Controlled Drugs

3.6.2.1 Prescriptions for Controlled Drugs must meet the requirements of both the Isle of Man Medicines Act 2003 and the Isle of Man Misuse of Drugs Act 1976.

3.6.2.2 Prescribers must refer to the most recent BNF for advice on writing prescriptions for Controlled Drugs.

3.6.2.3 Schedule 2 and 3 Controlled Drug prescriptions must be written so as to be indelible ink (e.g. written by hand, typed or computer generated).

3.6.2.4 All prescriptions for Controlled Drugs must specify:

- The name and address of the patient and, where appropriate, age
- The name and form of the drug, even if only one form exists
- The strength of the preparation, where appropriate
- The dose to be taken
- The total quantity of the preparation, or the number of dose units, to be supplied in both words and figures
- The prescribers name and address (must be within the Isle of Man or UK as per reciprocal agreement)
- If the prescriber is a dentist, the words "for dental treatment only" must also be present

3.6.2.5 Additionally:

- The prescription must be signed by the prescriber with their usual signature (this must be handwritten) and dated by them (does not have to be hand written)
- Prescriptions for Schedule 4 and 5 Controlled Drugs are exempt from the specific prescription requirements; however they must still comply with the general prescription requirements
- It is illegal to issue a Controlled Drug prescription which does not meet all the Controlled Drug prescription requirements described above. It is also illegal for a Pharmacist to dispense such a prescription
- It is good practice to include patient's NHS number where possible.
- It is best practice that the duration of a Controlled Drug prescription should

not exceed 30 days unless there are exceptional circumstances

- Any part of the prescription that has not been written upon should be blanked off to reduce the opportunity for fraud
- It is inappropriate for a prescriber to prescribe or administer Controlled Drugs for personal use or for family members, other than in exceptional circumstances. If this occurs it must be reported via a Datix. Further information on this is available in the General Medical Council good practice guidance

3.6.2.6 Information should be given to the patient or carer and documented including:

- How long the patient is expected to use the drug
- How long it will take to work
- What it has been prescribed for
- How to use Controlled Drugs when sustained release (SR) and immediate release (IR) formulations are prescribed together and the difference between them
- How it may affect the person's ability to drive (see Appendix 4)
- That it is only to be used by the person it is prescribed for
- Provide advice and information about how to store Controlled Drugs
- Any side-effects and any interactions with other medications

3.6.3 Non-Medical Prescribers

3.6.3.1 Please refer to the Isle of Man Non-Medical Prescribing policy for details.

3.6.4 Pharmacist Amendments of Controlled Drug Prescriptions

3.6.4.1 Where there are minor technical errors to Schedule 2 & 3 Controlled Drugs but the clinician's intention is clear, a Pharmacist may amend the prescription and initial the amendment.

3.6.4.2 Minor errors include:

- Typographical errors
- Omission of the total quantity in either words or figures, but not both

3.6.4.3 A prescriber must be contacted to amend a Controlled Drug prescription other than for minor amendments as specified above.

3.7 Administration

3.7.1 General Notes

3.7.1.1 Registered Healthcare Professionals must follow their regulatory bodies standards and guidance. Authorised members of staff should follow their medication training guidance.

3.7.1.2 If you are in any doubt about the administration of a Controlled Drug seek advice or clarification from the prescriber, person in charge or dispensing pharmacy.

3.7.1.3 Registered Health Professionals (for example, Community Nurses) who use devices for continuous administration of Controlled Drugs must:

- Complete training in setting up the specific devices used and have their competence confirmed
- Seek specialist advice if needed

3.7.1.4 Administration of Controlled Drugs should involve two authorised members of staff. Both practitioners should be present during the whole of the administration procedure. They should both witness:

- The preparation of the Controlled Drugs to be administered
- The Controlled Drug being administered to the patient
- The destruction of any surplus drug (e.g. part of an ampoule or infusion not required)

3.7.1.5 A record must be made in the Controlled Drug Register when a Controlled Drug is removed from the cupboard. Ensure that the correct page is selected, confirming correct drug, strength and formulation.

3.7.1.6 For Controlled Drugs administered the following details must be recorded:

- Date and time when dose administered
- Name of patient and date of birth
- Amount administered
- Amount discarded (if applicable)
- Name/signature of authorised person who administered the dose
- Name/signature of witness
- Balance remaining in stock

3.7.1.7 If part of a vial is administered to the patient, the Registered Nurse or Registered Health Professional must record the amount given and the amount wasted e.g. if the patient is prescribed 2.5mg diamorphine and only a 5mg preparation is available, the record must show; "*2.5mg given and 2.5mg discarded*".

3.7.2 Breakages/Spillages

3.7.2.1 Any accidental, witnessed breakages or spillages must be recorded in the Controlled Drug register. The entry must contain the date and time the breakage/spillage occurred, what was broken/spilt/dropped (with approximate volume if appropriate) and the entry must be signed and witnessed. It is good practice to complete an incident report.

3.7.2.2 Any unwitnessed breakages must be reported to the person in charge and, where appropriate the pharmacy, and an incident report completed. Staff must not sign the Controlled Drug register as a witness if they did not witness the breakage/spillage.

3.8 Controlled Drug Disposal

3.8.1 Please refer to individual sections for specific instructions.

3.8.2 Schedule 2 Controlled Drugs must always be returned to the appropriate pharmacy.

3.8.3 The area and receiving Pharmacy must keep a record of drugs sent to the Pharmacy.

3.9 Ambulance Service

3.9.1 Ordering Controlled Drugs

3.9.1.1 The Ambulance Service orders Controlled Drugs through Nobles Pharmacy Department and the procedure is documented below.

3.9.1.2 **Requisitions for Schedule 2 & Schedule 3 Controlled Drugs**. The Head of the Ambulance Service is responsible for the requisitioning of Controlled Drugs for use in that area.

3.9.1.3 The Paramedic in charge can delegate the task of preparing a requisition to another Paramedic: however, legal responsibility remains with the Paramedic in charge.

3.9.1.4 Orders must be written in a Controlled Drug requisition book with duplicate pages and must be signed by an authorised signatory.

3.9.1.5 The cardboard divider must be placed under the duplicate order page when completing a Controlled Drug requisition to prevent writing from being transferred to other duplicate pages.

3.9.1.6 All stationery relating to Controlled Drugs must be stored securely and access restricted (locked cupboard or drawer – ideally in the Controlled Drugs cupboard).

3.9.1.7 There must be only one Controlled Drug requisition book in use at any time.

3.9.1.8 Controlled drug requisition books are obtained from Nobles Pharmacy and are generally supplied automatically as the previous book runs out. If required, a Controlled Drug requisition book can be ordered from Pharmacy using the ward stock requisition book. The old Controlled Drugs requisition book will be required as proof that the book is complete and all new books supplied will be issued through Nobles Pharmacy computer system and labelled for that area.

3.9.1.9 A copy of the signature for each authorised signatory should be available in Nobles Pharmacy department for validation. New members of staff must provide Pharmacy with their signature for identification, if authorised to order Controlled Drugs.

3.9.1.10 Each department must have an agreed stock list detailing Controlled Drugs required in that area and usual stock levels. This Controlled Drug stock list is produced by agreement between Nobles Pharmacy and the Paramedic in charge and should reflect the usual requirements of the area. The stock list must be reviewed every 6 months to ensure that it is still relevant.

3.9.1.11 Requisitions must contain the following information (on duplicate and original):

- Name of hospital
- Ward/Department
- Drug name, form, strength and for injections; ampoule / vial / bag size (if more than one is available)
- Total quantity required
- Signature and printed name of Registered Paramedic
- Date
- Signature of person issuing the item from the Pharmacy
- Signature of the person delivering or collecting the Controlled Drug from Pharmacy

3.9.1.12 There must only be one product ordered per page. If two strengths of a preparation are required to make the prescribed dose, they must be ordered as separate entries (see BNF for available preparations).

3.9.1.13 Controlled Drugs can only be ordered, collected and booked into the Controlled Drugs cabinet in the central medication store by Registered Paramedics.

3.9.1.14 When the drugs orders have been placed a note will be added to the service blog outlining what was ordered and when it needs to be collected.

3.9.2 Transfer of Controlled Drugs

3.9.2.1 When medicines have been collected from Nobles Pharmacy they must be checked against the order sheet to ensure that the medicines supplied are the correct medicines, concentrations and presentation. Any errors must be corrected immediately with Nobles Pharmacy.

3.9.2.2 Controlled Drugs must be transferred or conveyed in a secure, locked or sealed, tamper-evident container (e.g., Nobles Pharmacy transit bag with a numbered seal). The system used must be fully auditable and explicit as to who has custody of the Controlled Drugs at any point in time.

3.9.3 Receipt of Stock Controlled Drugs

3.9.3.1 The Registered Paramedic receiving the Controlled Drugs must check the Controlled Drugs against the requisition, including the quantity ordered and received. If this is correct then the duplicate sheet (pink) in the Controlled Drug requisition book must be signed and dated in the “received by” section in the presence of the Registered Paramedic who collected the Pharmacy bag.

3.9.3.2 Packaging and packaging seals must be checked as being intact when adding new stock to the Controlled Drug cabinet. There is no need to open sealed boxes to check quantities unless the packaging or seals are broken or damaged. If, when the tamper evident seal is broken, the contents do not match the expected amount stated on the pack, the Paramedic in charge must contact the Nobles Pharmacy Department. Appropriate records must be made in the Controlled Drugs Register and all necessary action taken to resolve the discrepancy.

3.9.3.3 As soon as possible after delivery the Paramedic in charge must:

- Place the Controlled Drugs in the appropriate Controlled Drug cupboard
- Enter the Schedule 2 Controlled Drugs into the Controlled Drug record book update the running balance and check that the balance tallies with quantity that is physically present (entries must be made in black ink)

3.9.3.4 Receipt of Controlled Drugs can be undertaken by one appropriate individual; however, entry of the Schedule 2 Controlled Drugs into the register must be witnessed by a second competent professional. Receipt, storage and updating the register must be done in a timely manner (normally immediately).

3.9.3.5 Expired Controlled Drugs stored in the Controlled Drug cabinet are included in the stock count but must be separated and marked clearly as expired to prevent inadvertent use. Contact Pharmacy to remove.

3.9.4 Storage of Controlled Drugs

3.9.4.1 Controlled Drugs must be stored securely at all times as per local Ambulance SOP.

3.9.5 Ambulance Stations Secure Room

3.9.5.1 The Ambulance station Controlled Drugs cupboard is located in the secure room. The secure room must be locked when it is unoccupied.

3.9.5.2 The key to the Controlled Drugs cupboard must be kept secure at all times as per local Ambulance SOP.

3.9.6 Checking Controlled Drugs

3.9.6.1 Please refer to local Ambulance SOP for more details.

3.9.6.2 Any expiring or expired Controlled Drugs must be identified and replaced as soon as possible. Controlled Drugs that are expiring must be replaced prior to their expiry date. This will ensure that Paramedics do not hold out of date stock when on duty.

3.9.6.3 Expired or expiring Controlled Drugs must be disposed of in accordance with section 3.9.13 of this policy.

3.9.7 Checking Ambulance Controlled Drugs within the Central Medication Store

3.9.7.1 Daily Controlled Drugs checks are required for all the drugs held within the Controlled Drugs cupboard in the central medication store.

3.9.7.2 The Controlled Drugs check must be carried out by the first ambulance crew at the Emergency Department that day (day shift crews). Two authorised members of staff must be present to carry out a Controlled Drugs check and one of those must be a Registered Paramedic.

3.9.7.3 Staff must count each drug contained within the Controlled Drugs cabinet and check this against the balance in the Drug Administration Registers held within the cupboard.

3.9.7.4 When checking full medicine boxes that contain ampoules or individually recorded medicines that come in external packaging, it is important to check that the packaging is not damaged and that the seals of the external packaging are intact. There is no need to open sealed boxes to check quantities unless the packaging is damaged or the seals are not intact.

3.9.7.5 Any packaging where the packaging or seals are not intact should be opened and a drug check completed to ensure the internal quantity correlates to the quantity indicated on the packaging. Both staff must witness the ampoule/drug quantities.

3.9.7.6 It is important that both staff witness that seals are intact on receipt of delivery from pharmacy. Any seals that are not intact should be opened and if discrepancies are found the drug must be immediately returned to pharmacy and reported on a Datix.

3.9.7.7 Do not combine opened boxes or overfill boxes of the same drug type. Although this may make sense in reducing the amount of boxes in the cupboard it does compromise batch numbers and expiry dates. Drugs must remain in their original box until signed out of the cabinet.

3.9.7.8 When opening a box of drugs mark the sides of the box with an "X". This identifies open boxes to staff obtaining drugs and prevents a situation whereby several boxes are open at once.

3.9.7.9 Any Controlled Drug found to be out of date must be placed in the "out of date" box contained within the Controlled Drugs cabinet.

3.9.7.10 The stock levels of drugs must reflect the overall stock within the cabinet, including out of date stock levels.

3.9.8 Drug Discrepancies

3.9.8.1 When making an entry into the Controlled Drugs Register it is imperative that details are recorded accurately and without error. If an error is made it must never be crossed out, altered or Tipp-ex over the error.

3.9.8.2 Any errors should be marked with a footnote carrying the initials of two authorized persons. No cancellation, obliteration or alteration may be made; any amendments must be made by annotation, i.e put brackets round the incorrect entry and annotate with explanatory note e.g 'entered in error' then record the correct entry. These amendments must be signed, dated and witnessed by a second authorized person.

3.9.8.3 When the Controlled Drugs stock is adjusted the Controlled Drugs administration register must be altered to reflect the adjustment. This must be signed and witnessed.

3.9.8.4 Any drug discrepancies must be reported as per section 3.4.1.4.

3.9.9 Lost or Stolen Drugs

3.9.9.1 Staff discovering a medication loss must immediately inform the Ambulance Service Duty Officer and complete a Datix report.

3.9.9.2 The Ambulance Service Duty Officer must start a log of events and co-ordinate a stock check for all Controlled Drugs. The Ambulance Service Duty Officer will decide on an appropriate course of action.

3.9.9.3 Procedure in the Event of a Controlled Drugs loss:

- The Paramedic responsible for the missing Controlled Drugs must inform the Ambulance Service Duty Officer immediately
- The Ambulance Service Duty Officer must start a log of events and co-ordinate a stock check for all Controlled Drugs
- If the drug is still not accounted for then the Ambulance Service Duty Officer must inform the Police on the same working day
- A Datix report must be completed immediately, by the Paramedic who was responsible for the drug check and identified the loss. Once completed the person completing the Datix report must inform the head of service that this has been completed
- The incident reporting procedure MUST be followed and the Patient Safety and Quality department notified as soon as possible

3.9.9.4 Procedure in the Event of any Controlled Drug being stolen all steps above must be followed with the addition of:

- The Ambulance Service Duty Officer must inform the Police and request their attendance as soon as possible
- All actions must be recorded and a Police incident number recorded
- The Ambulance Service Duty Officer will liaise with the Police and CQ and S team. A plan of action for the particular incident will be drawn up and instigated with those concerned

3.9.10 Administration of Medicines

3.9.10.1 Medicines will be administered in accordance with:

- Current Joint Royal Colleges Ambulance Liaison Committee (JRCALC) guidelines
- Patient Group Directions

3.9.10.2 It is best practice to have a two persons check when administering all drugs to check for correct drug, concentration/strength, expiry date and administration route.

3.9.10.3 Controlled Drugs, Intravenous (IV) drugs or drugs administered to children should have a two person check where possible.

3.9.10.4 Full accountability for the correct administration of drugs lies with the administering practitioner.

3.9.10.5 Anyone checking drugs is also accountable for their part in the process.

3.9.10.6 It is accepted that there are occasions when clinicians will need to administer Controlled Drugs whilst working alone. It is, however, the practitioner's responsibility to ensure the correct administration of medicines and that part-used medicines are destroyed in line with this policy.

3.9.11 Recording Medicine Administrations to Patients and Replenishing Stock

3.9.11.1 When a medicine is administered its administration must be recorded on the Isle of Man Ambulance Service Patient Care Record (PCR). Drug administrations must be completed fully including the time, drug name, dosage, route and the PCR ID of the staff member that gave the medicine:

- Drug names must be recorded in full and not abbreviated
- Drug codes must not be used
- The PCR must be signed by both staff members to indicate that drugs were administered and checked in accordance with JRCALC guidelines, PGD and the principles of the Manx Care and Isle of Man Ambulance Service medicines policies.

3.9.11.2 Please refer to the local Ambulance SOP for when medication is administered and needs replenishing.

3.9.12 Procedure for the Disposal of Part Used Drugs

3.9.12.1 With the exception of oral morphine, any part used Controlled Drugs must be disposed of as soon as possible and this must be witnessed by another clinician except when working alone.

3.9.12.2 Any Controlled Drugs prepared for patient administration and not used or part used must be destroyed of in a sharps container as per Manx Care Medicines Policy. This must be witnessed and documented in the appropriate drugs register.

3.9.12.3 Isle of Man Ambulance Service use 100ml bottles of Oral Morphine, with a local instruction to treat as "single use only":

- Part used bottles of oral morphine will be returned to the Controlled Drugs cabinet within the central medication store

- Part used bottles will have a label clearly marked with “part used” placed across the cap. The bottle will then be placed in the ‘out of date’ box or on the shelf containing out of date Controlled Drugs within the Controlled Drugs cabinet
- The balance in the drugs register will be adjusted to reflect the stock booked back in. Part used bottles will be included in the overall balance of the drug within the Controlled Drugs cabinet and counted as 1 unit/item
- When the level of part used oral morphine reaches 10 bottles then the duty officer should be informed by any Paramedic or Team Leader, (in working hours)
- The duty officer will, with a witness, denature them in crystals for this purpose, reduce the stock levels and dispose of the solid crystals as a clinical waste

3.9.13 Procedure for the Disposal of Out of Date Controlled Drugs

3.9.13.1 It is not permissible to transport out of date drugs in service vehicles for destruction at a later time.

3.9.13.2 Expired drugs must not be used for training purposes.

3.9.13.3 The following procedure must be used for the disposal of expired Controlled Drug:

- Out of date Controlled Drugs must be returned to the Controlled Drug cabinet within the central medication store
- The balance in the drugs register must be adjusted to reflect the stock that has been returned
- Diazepam and Midazolam must be disposed of in a sharps container
- Out of date Controlled Drug must be placed in the box marked ‘out of date’ and all of the packaging clearly marked to display the words “out of date”
- When the stock level of expired Controlled Drug is considered high (e.g. 100mg morphine sulphate or 10 part-used/expired of date bottles of oral morphine), then the duty officer must be informed by any Paramedic or Team Leader, (in working hours)
- The duty officer must contact the Pharmacy Department at Nobles Hospital directly and arrange a suitable time for both parties to meet at the central medication store and book the morphine sulphate out of the Controlled Drug stock with the Pharmacy representative
- At the same time the Pharmacy representative must perform a balance check with the Ambulance staff member and this will audit storage and record keeping
- Any alterations in stock levels must be recorded and witnessed in the drug registers

- Any drug discrepancies must be reported to the Duty Officer as per section 3.9.9.3

3.10. Adult Health and Social Care Homes

3.10.1 General Notes

3.10.1.1 For the purposes of all aspects of managing Controlled Drugs and to minimise the potential for errors, these procedures must be carried out by an authorised and trained member of staff and, as good practice dictates, be witnessed by another designated appropriately trained member of staff. This may not always be a practical reality however and a service user must not be deprived of prescribed medicine because there is only one member of staff on duty when they need it, this must be supported by an individual risk assessment.

3.10.1.2 In a domiciliary care setting no witness is required and any Controlled Drugs given by domiciliary care workers in a person's own home must be treated in the same way as for all other prescribed medicines, and must also be supported by an individual risk assessment. If there is a family member who is willing to check as a witness this would be good practice.

3.10.1.3 When Controlled Drugs are prescribed for a service user the receipt, administration and disposal of these medicines should be carried out and recorded. The additional steps below must also be carried out: Records of this type are not required in domiciliary settings.

3.10.2 Ordering/Collection

3.10.2.1 Service users or their representatives may need to supply evidence of their identity when collecting Controlled Drugs medication. If the medication is a Schedule 2 Controlled Drug and the person collecting the prescription is a health care professional acting in his/her professional capacity on behalf of the service user, the Pharmacist/dispenser will request their name and address and, unless they are acquainted with the person, request evidence of that person's identity. The Pharmacist/dispenser may supply the drug even if s/he is not satisfied as to the identity of that person.

3.10.3 Receipt

3.10.3.1 The receipt, administration and disposal of Controlled Drugs must be recorded in a Controlled drug register.

3.10.3.2 The 'register' must include the balance remaining for each product with a separate record page being maintained for each service user and each medication item. The balance of Controlled Drugs must be checked at each

administration and also on a weekly basis.

3.10.3.3 When an opened bottle of liquid medication is received into the service, an estimate of the amount remaining in the bottle must be recorded.

3.10.4 Storage

3.10.4.1 The secure storage of Controlled Drugs is specified in the Misuse of Drugs (Miscellaneous Enactments)(Application) Order 2013. In brief, the requirements for controlled drug storage are:

- Metal cupboard of specified gauge
- Specified locking mechanism
- Fixed to a solid wall or a wall that has a steel plate mounted behind it
- Fixed with either Rawl or Rag bolts

3.10.4.2 For those services where Controlled Drugs are not prescribed regularly, it is not necessary to comply with the above guidance, however a secure, double locked cupboard must be in use. No special cupboards are required in a domiciliary setting.

3.10.4.3 For safe practice the Controlled Drug cupboards must only be used for the storage of Controlled Drugs. Items of value such as jewelry or money should not be placed here. Only those with authorised access must hold keys to the Controlled Drug cupboard. Where the Controlled Drug is held in a monitored dosage system, the entire container must be stored according to Controlled Drug legislation, unless the person is totally self - medicating.

3.10.5 Disposal of Controlled Drugs

3.10.5.1 When Controlled Drugs have passed their expiry date or the need for the prescription has ceased the controlled drugs should be returned to the Community Pharmacist at the earliest opportunity for appropriate destruction. Following the death of a person all medication must be kept for a period of seven days before disposal, in case the Coroner's office or the Court requires them. Even when the medications are still in date, such drugs must not be reused for other service users.

3.10.5.2 Community Pharmacies can accept Controlled Drugs returned by people from their own homes and from care homes (personal care) for safe destruction and onward disposal, even if they did not originally dispense them.

3.10.5.3 Care homes must record the forms and quantities of Controlled Drugs they are returning, and the Pharmacist must sign for them on receipt. If Pharmacy staff collect the Controlled Drugs they must sign for them in the Controlled Drug

register at the time of collection. The authorised person must sign the register and must state that they are being returned to the Pharmacy. The returns book must have the name and signature of the driver who collected them for audit purposes.

3.10.5.4 Relevant details of any such transfer for disposal must be entered into the Controlled Drug register and signed by the authorised member of staff, returning the drug.

3.10.6 Audit of Controlled Drugs

3.10.6.1 Routine checks of all Controlled Drugs held, and the recorded running balances, must be carried out by two authorised members of staff, on a regular basis at least weekly. Each service should develop its own arrangements for this checking and a record must be kept of when checks are performed.

3.10.6.2 Where a discrepancy is found, it must be reported immediately to the Registered Manager who must investigate promptly.

3.10.6.3 If the discrepancy cannot be resolved, the Operational Manager for the area or on call Senior Manager must be informed immediately. A Datix report must be completed and the Registration and Inspection Unit must be informed on the next working day.

3.10.6.4 If the discrepancy is found to be an error of subtraction or addition in the calculation of stock balance, the following procedure should be followed:

- Do not change the balance column or use correction fluid. Under the last entry, details of the following should be made:
- the date
- the error in subtraction/addition (indicated with an asterisk)
- the correct balance
- the signature of the member of staff and the witnessing member of staff

3.10.6.5 If the above discrepancy cannot be identified, the Pharmacist who is providing a service to the home must be contacted to establish whether there were any unrecorded returns of Controlled Drugs. If confirmed by the Pharmacist, full details of such returns should be entered into the Controlled Drug register, together with the signature of the person who returned the drugs and that of the Pharmacist who received them. The correct date and the words ‘entered in retrospect’ must also be added.

3.10.6.6 If the reason for the discrepancy cannot be found, and the Controlled Drugs appear to have gone missing, then the procedure for medication errors must be followed (please refer to the Adult and Social Care medicines policy).

3.10.7 Self-Medicating Service Users

3.10.7.1 Service users can keep and take Controlled Drugs themselves. This must be following a medication risk assessment and only if it is indicated that the person is aware of the particular responsibilities of holding and managing Controlled Drugs.

3.10.7.2 Service users can hold Controlled Drugs in their own room within a lockable cupboard or drawer. A specific Controlled Drug cupboard is not required.

3.10.7.3 When the service user does not arrange the supply and collection of Controlled Drugs but relies on the care workers to do so, there must be clear records of receipt from the Pharmacist, supply to the service user and any subsequent disposal of unwanted Controlled Drugs. These records can be made on the Medicine Administration Record chart (MAR) however, for the purposes of good practice, entries should also be made in the Controlled Drug register.

3.10.7.4 Whilst it is not necessary to keep a record of the receipt, administration and disposal of Controlled Drugs within the Controlled Drug register when a service user is wholly independent, it is considered good practice to do so.

3.10.8 Non-Prescribed Controlled Drugs

3.10.8.1 Under section 8 of the Misuse of Drugs Act 1971, it is an offence for a manager/ employer to knowingly permit the use, production or supply of any non-prescribed Controlled Drugs taking place on their premises. This includes car parks, gardens and adjoining areas. It is also an offence to ignore such occurrences

3.10.8.2 The use of illicit or non-prescribed Controlled Drugs will not be tolerated within the care service. If anyone is known or believed to be in possession of a Controlled Drug, they will be informed that they are committing an offence under the Misuse of Drugs Act (1971) and will be advised of the legal risks that this carries.

3.10.8.3 Any member of staff who suspects that a service user has in their possession or is using illicit drugs must report their suspicions or findings to their Line Manager who will then inform the appropriate Senior Manager.

3.10.8.4 Any member of staff who visits a service user, whether in a care home or their own home, and the service user appears to be under the influence of illicit substances, has the right to leave the service user's home if they feel threatened. It is essential that they then inform their Line Manager immediately.

3.10.9 Domiciliary Care

3.10.9.1 There are no special requirements for Controlled Drugs schedule 2 or 3 in a domiciliary setting. They should be treated as any other medicine. However, this should be supported by an individual risk assessment.

3.10.10 Palliative/End of Life Care

3.10.10.1 The service may be responsible for the safe keeping of actual or anticipatory end of life medication (including 'Just In Case' boxes) and should record the receipt of these in the Controlled Drug register and store appropriately preferably in Controlled Drug cupboard or in a locked and secure drug cabinet/trolley with strictly Controlled access. This will also be in accordance with any guidelines provided by and jointly agreed with GP's and/or any specialist health professionals such as Palliative Care Nurses or Macmillan Nurses.

3.10.10.2 Following the death of a person all medication must be kept for a period of seven days before disposal, in case the Coroner's office or the Court requires them.

3.10.10.3 No staff within the service can dispose of medication themselves. It must be returned to the supplier, which in the majority of cases will be the Pharmacist who dispensed them. The Pharmacist is the only person who can and is responsible for the disposal of medication.

3.11. Prison

3.11.1 Administration of Controlled Drugs in Prison

3.11.1.1 These guidelines are intended to be used to assist Registered Health Practitioners, within the prison setting, to identify professional accountability and enhance the safe standards of practice when administering Controlled Drugs. All healthcare providers involved in the handling and management of Controlled drugs are required to have Standard Operating Procedures (SOP) for all principle activities.

3.11.1.2 The Misuse of Drugs Act (1971), Misuse of Drug Act Regulations (2001), and the Misuse of Drugs (safe custody) Regulations (1973), lay down the legal requirements in regards to prescribing, administration and safe storage of Controlled Drugs.

3.11.1.3 These regulations apply to all Controlled Drugs, all schedule 2 Controlled Drugs must be stored in a lockable cabinet, and certain schedule 3 medications also. The list of these medication can be located in the BNF or on their website: http://bnf.org. Please see the Prison SOP.

3.11.2 Ordering Controlled Drugs

3.11.2.1 Ordering of Controlled Drugs must be carried out, in the same way as ordering a normal repeat for the patient, by the Prison Healthcare staff. For the Controlled Drugs that are part of the stock items, these can be ordered when the medication is running low. Stock levels must be checked and ordered weekly.

3.11.2.2 All Controlled Drugs must arrive via the Pharmacy driver except on exceptional circumstances, if a member of staff needs to collect the medication due to urgency. When the medication arrives from the Pharmacy it must be clearly marked that a Controlled Drugs is in the delivery and this must be dealt with immediately following the storage of Controlled Drugs documented below (section 3.11.3).

3.11.3 Storage and Custody of Controlled Drugs

3.11.3.1 Schedule 2 Controlled Drugs and certain schedule 3 Controlled Drugs must be kept in a locked, secure cupboard located within a locked Pharmacy store (please see Prison SOP).

3.11.3.2 There must only be one key (with one spare) to the cupboard, with the practitioner in charge having overall responsibility for access. The key must be stored away from the Controlled Drug cupboard, and no identifier on the key to indicate what it is for. Only qualified healthcare personnel must have access to the Pharmacy store within which the Controlled Drug cupboard is located.

3.11.3.3 All Controlled Drugs, received into the prison, must be checked by two qualified members of staff who must record the following into the Controlled Drug register using black, indelible ink:

- Date of receipt
- Name and strength of the drug
- Supplier details
- Amount received
- Patient name (if applicable)

3.11.3.4 The amount must be added to the running balance and total recorded. Both Nurses/Practitioners should sign the register.

3.11.3.5 Any errors should be marked with a footnote carrying the initials of both Nurses. No cancellation, obliteration or alteration may be made; any amendments must be made by annotation, i.e put brackets round the incorrect entry and annotate with explanatory note e.g ‘entered in error’ then record the correct entry. These amendments must be signed, dated and witnessed by a second Nurse / healthcare practitioner.

3.11.3.6 Entries into the Controlled Drug Register must be made in chronological sequence.

3.11.3.7 Only government-approved Controlled Drug registers must be used. They must be securely bound with no loose pages (with the exception of methadone dispensed via the 'Methameasure' system which contains its own electronic log and is printed out daily). The name of the drug must be specified at the top of each page. Upon completion, they must be stored securely for a minimum of two years, following which must be shredded.

3.11.3.8 A stock check must be performed on a weekly basis. When carrying out the Controlled Drug balance check, it must be written within the Controlled Drugs book 'balance checked and verify' this then must be signed by the person carrying out the Controlled Drugs balance and countersigned. It is recommended to rotate the staff performing this stock check.

3.11.3.9 For liquids it is recognized that there may be small overage of the liquid due to manufacturer's overages, if this is found a stock adjustment may be required to reconcile the running balance. This must be completed at least weekly, and an entry into the Controlled Drug register made 'overage confirmed and verified.' This must then be signed by the person carrying out the Controlled drug balance.

3.11.3.10 Any discrepancies must be immediately reported to the healthcare team leader, and a Datix should be raised.

3.11.3.11 To document a spillage of liquid Controlled Drug – enter the date, time, a comment explaining the event (e.g. Spilled liquid) with the approximate volume of spillage, the two signatures of Nurse/healthcare practitioner, and the new balance.

3.11.4 Tramadol/Pregabalin/Gabapentin

3.11.4.1 Over the recent years these medication have become Schedule 3 Controlled Drugs, but exempt from safe custody requirement. Therefore, these medications if ordered for a specific patient can be stored as any other drug (i.e. it does not need to be entered into the Controlled Drug book). If however the medication is for stock this must be written into the Controlled Drug book and stored in the Controlled Drug cupboard as per protocol.

3.11.5 Prescribing and Administration of Controlled Drugs

3.11.5.1 Prescribing of Controlled Drugs must be by a Medical Practitioner or a Non-Medical Prescriber working within their field of competence. If hand written, the prescription must be clearly written on an appropriate prescription sheet, and

must be written signed and dated in indelible black ink. Guidelines on prescribing Controlled Drugs can be found in the BNF or on their website: http://bnf.org.

3.11.5.2 Prior to administration of a Controlled Drug, the practitioner must check the following:

- That the number/amount of drugs balance with amount stated within the register and recorded as correct
- The drugs match the instruction, including dose, route, frequency and time of administration
- The expiry date
- The identity of the patient

3.11.5.3 People must receive Controlled Drugs (schedules 2-4) under supervision except under exceptional circumstances agreed by the Manager of the Prison Healthcare. Methadone and Pregabalin should normally be administered from stock supply, to minimise selection errors if individually named supplies were used. For other Controlled Drugs named supplies must be provided (RPS 2017)

3.11.5.4 Following administration:

- Empty ampoules, needles and syringes must be placed in a sharps box immediately after use
- Details of the drug, dosage and expiry date/batch no (if applicable) must be entered on the medication administration record and in the controlled drug register (if applicable)
- The number/amount of drugs remaining must reflect what has been taken for the purpose of administration.

3.11.6 The Administration of Controlled Drugs in exceptional circumstances

3.11.6.1 In exceptional situations (e.g. due to acute staff sickness), designated non-medical personnel are able to act as a counter-signatory for the administration of Controlled Drugs using the same procedure as explained in section 3.3.2. The following prison personnel may assist the healthcare practitioner in performing this duty:

- The Prison Governor
- Deputy Governors
- Principle Officers

3.11.6.2 If none of the above are available, the Senior Officer in charge ('Oscar') may countersign for Controlled Drugs. The qualified practitioner will take ultimate responsibility for the administration of the medication and for the patient's

subsequent well-being.

3.11.7 Unused Controlled Drugs

3.11.7.1 Unused Controlled Drugs must be returned to the Pharmacy as soon as possible, for destruction, using the following procedure:

1. Two qualified practitioners must document the amount of medication being returned into the Controlled Drug book. This entry must contain:
   - The date
   - Where the drugs are being returned to
   - Signature of both practitioners
   - The final balance/stock

2. The returns book must also be completed and contain the same information and signatures

3. The returns book and Controlled Drugs must be sealed in a secure box and forwarded to the pharmacy as soon as possible.

3.12. Community Nurses

3.12.1 Obtaining Controlled Drugs

3.12.1.1 Community Registered Nurses may legally carry Controlled Drugs from the Pharmacy directly to the patient when the patient has no other means of collecting their drugs from Pharmacy.

3.12.1.2 The drugs should be kept in the locked boot of the car whilst in transit.

3.12.2 Just In Case (JIC) Drugs

3.12.2.1 Just in case medication can either be collected by the Nurse or the family members; if collected by the Nurse they should take a JIC box to the pharmacy where the Pharmacist will dispense directly to the box. If drugs are collected by family, the Nurse should take the JIC box to the patient's house and place the drugs into the box. In either case, the quantity of ampoules must be written on the prescribing and administration booklet and the drugs locked within the JIC box.

3.12.3 Hospice

3.12.3.1 When Controlled Drugs are required for a Hospice patient outside of normal working hours, staff may contact the Hospice for the number of the nearest Pharmacy in the Palliative Care Drugs Scheme. Community Nurses can contact the on-call community Pharmacist as per rota in the palliative care resource

folder. Alternatively, but only in exceptional circumstances, Hospice can transfer drugs to a patient from their Controlled Drug stock. The person collecting the medication from Hospice must be a Registered Nurse or Doctor, and they must have a valid prescription for the medication.

3.12.4 Storage

3.12.4.1 Controlled Drugs in the community are the patient's own property. Therefore, the Registered Nurse is not responsible for the stock level in the patient's home. However, it is good practice to be aware of stock held in a patient's home in order to ensure adequate stocks are available and also advise on disposal of Controlled Drugs no longer required.

3.12.4.2 Patients should be advised to store their Controlled Drugs out of sight and out of the reach of children. They should be advised to be discreet about the fact that they have Controlled Drugs on their premises.

3.12.4.3 Any unaccounted for discrepancy in stock level must be recorded in the patient's records and reported to the line manager and GP. An untoward incident form must also be completed.

3.12.4.4 Just In Case drugs must be stored within the JIC locked box until needed.

3.12.5 Checking

3.12.5.1 The NMC (2010) states that 2 Registered Nurses should carry the following checks of Controlled Drugs. If this is not possible then two individuals should carry out the checks, of which one must always be a Registered Nurse. The second individual may be another Registered Nurse/Professional, Senior Health Care Assistant or the carer/people with parental responsibility, provided the Registered Nurse feels they are competent to check the Controlled Drug.

3.12.5.2 In exceptional circumstances one Registered Nurse on their own may check and administer a Controlled Drug to an adult patient.

3.12.5.3 Hospice staff working in the community working with adult patients who feel competent may set up a syringe driver and administer controlled medications on their own.

3.12.5.4 In all cases the following checks must be made:

- Check that the prescription is written legibly, in indelible black ink and is dated and signed by the authorised prescriber
- The Controlled Drug must be labelled for the patient, and in date
- Confirm the identity of the patient

- Check stock level of Controlled Drugs in the patient's house and record on the prescribing and administration booklet
- All drugs to be administered by a Registered Nurse, including JIC drugs must be prescribed on the prescribing and administration booklet
- Ensure any unused Controlled Drug from an opened ampoule is disposed of in the sharps bin
- The administration, wasted and disposal of the Controlled Drug should be witnessed and recorded on the drug administration record sheet and in the patient's community/Hospice at Home notes by the Registered Nurse. The identity of the second checker should also be recorded in the patient records; (eg husband, mother). If the second checker is another Registered Nurse then he/she can countersign the drug administration record

3.12.6 Return of Unused Controlled Drugs

3.12.6.1 It is the responsibility of the patient/carer to return unused Controlled Drugs to the community pharmacy.

3.12.6.2 Unused Controlled Drugs may be returned to the pharmacy on the patient's behalf by the Registered Nurse. In this case the drugs should be transported safely to the pharmacy, ie kept out of sight and never left unattended. The Pharmacist should countersign the patient record that the drugs, and the amount, have been returned.

3.12.6.3 If the unused drugs are returned to Hospice, the in-patient unit Nurse in charge will check them into the Controlled Drug cupboard with the Community Registered Nurse and then arrange for their transportation to Noble's pharmacy at the earliest convenience.

3.12. Manx Emergency Doctors Service (MEDS)

3.12.1 Ordering

3.12.1.1 Controlled Drugs must be ordered manually using the Controlled Drug order book (pink) where possible this stock should be ordered on a Saturday morning first thing and collected from the Hospital Pharmacy before 12:30pm. N.B the sealed green pharmacy bag must be collected by a member of clinical staff the on duty Doctor/Nurse it cannot be obtained by the drivers/receptionist.

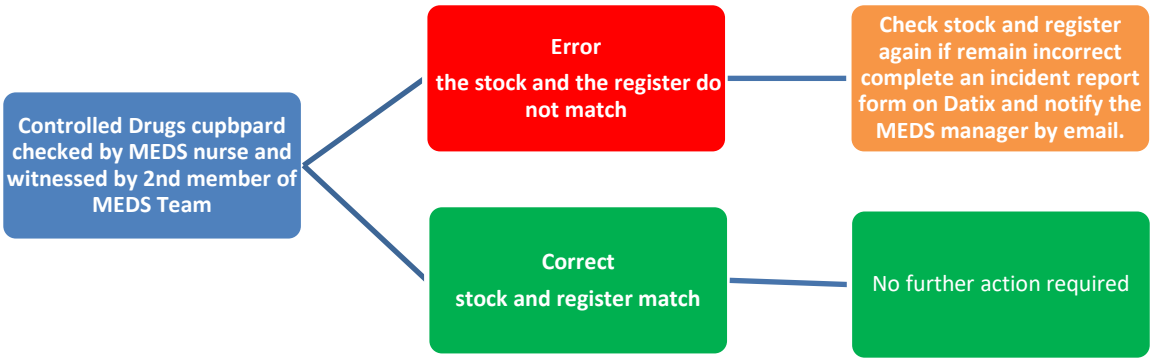
3.12.2 Issuing Controlled Drugs

3.12.2.1 When a GP/Nurse issues a Controlled Drug they must record it in the Controlled Drugs register and have this witnessed by a member of staff. This must include all of the patient's details.

3.12.3 Checking the Controlled Drugs

3.12.3.1 It is the responsibility of the MEDS on duty Nurse on a Saturday morning to check each of the stocked items in the Controlled Drugs Register. This must be witnessed and agreed by another member of staff who does not have to be clinical e.g. receptionist/driver.

3.12.3.2 If no Nurse is on duty it becomes the responsibility of the GP working the 8 – 14:00 Shift.



3.12.4 Audit

3.12.4.1 Monthly Audit of Controlled Drugs checking this against the patient EMIS record will be done by the MEDS Lead Nurse, reported to the MEDS Manager and discussed in quarterly team meetings with all clinical staff.

3.12.4.2 Any discrepancies will be raised on Datix for escalation to the senior MEDS management team.

4. REFERENCES AND/OR RESOURCES

[Adopt Harvard style referencing]

- *Noble's Hospital. Policy for the Management of Controlled Drugs 2021.*
- *Isle of Man Ambulance Service Medicines Policy 2019.*
- *Adult Social Care Services Medication Policy and Procedure, Isle of Man Government Department of Health and Social Care 2018.*
- *Manx Emergency Doctor Service Controlled Drug Protocol 2021.*
- *Community Nursing Standard Operating Procedure for the obtaining, checking, storage and return of Controlled Drugs and 'Just in case Medication', Isle of Man Government Department of Health and Social Care 2018.*
- *NICE. Controlled Drugs: safe use and management. 2016. [online] Available at: <https://www.nice.org.uk/guidance/ng46> [Accessed 9 February 2021].*
- *Isle of Man Misuse of Drugs Act 1976. [online] Available at: <http://www.legislation.gov.im/cms/images/LEGISLATION/PRINCIPAL/1976/1976-0021/MisuseofDrugsAct1976_1.pdf> [Accessed 16 March 2021]*
- *Isle of Man Medicines Act 2003. [online] Available at: <https://legislation.gov.im/cms/legislation/acts-of-tynwald-as-enacted/category/4-primary-2003.html?download=48:medicines-act-2003> [Accessed 16 March 2021].*
- *Isle of Man Government. Drug driving. 2021. [online] Available at: <https://www.gov.im/categories/health-and-wellbeing/health-advice/addiction/drugs-and-alcohol/drug-driving/> [Accessed 7 April 2021].*
- *Royal Pharmaceutical Society (RPS) (2017) Professional Standards for Optimising Medicines for people in secure environments.*
- *NHS (2018) Northampton Healthcare, MMPro27/HMP Controlled Drug Procedure for HMP Bedford.*

5. APPENDICES

5.1 Appendix 1

5.1.1 Definition of Schedules

5.1.1.1 Storage, Recording and Prescription Requirements of Controlled Drugs

- Under The Misuse of Drugs Regulations 2001 which was applied to the Island, subject to modifications, by Misuse of Drugs (Miscellaneous Enactments) (Application) Order 2013, Controlled Drugs are classified into five Schedules according to their therapeutic usefulness, need for legitimate access and potential for misuse. Schedule 1 Controlled Drugs have the highest level of restriction, Schedule 5 the lowest. A Pharmacist has the authority to supply Schedule 2, 3, 4 and 5 Controlled Drugs.

5.1.1.2 Schedule 1 Drugs (CD Lic)

- Schedule 1 includes hallucinogenic drugs and ecstasy which have virtually no therapeutic use.
- Production, possession and supply of these drugs are limited in the public interest and only practitioners with a licence from the home office may lawfully possess them

5.1.1.3 Schedule 2 Drugs (CD POM) and Schedule 3 Drugs (CD No Register POM)

- Schedule 2 includes diamorphine, morphine, pethidine, fentanyl, alfentanil, oxycodone, hydromorphone, cocaine, methadone, amphetamines and ketamine.
- Schedule 3 includes buprenorphine, phenobarbitone, temazepam, midazolam, tramadol, pregabalin, gabapentin and some minor stimulants.
- These drugs are subject to safe custody requirements and should be stored in a suitable locked cabinet secured to the fabric of the building at all times.
- Receipt and supply of Schedule 2 Controlled Drugs must be recorded in a Controlled Drugs Register.
- Written requisitions in the Controlled Drug requisition book (Schedule 2 & 3) must be made for ward stock supply.
- Discharge prescriptions for Schedule 2 and 3 Controlled Drugs must be written on official Isle of Man Hospital prescription stationery or electronically printed.
- There are special requirements for discharge and outpatient prescriptions. These prescriptions **must** include;
- The patient's name, address and hospital number. The patient's ID label should be used on hand-written prescriptions
- The name of the drug

- The form of the drug, e.g. tablets, capsules, mixture, injection
- The strength of the preparation
- The dose to be taken
- The frequency or direction
- Either the total number of dose units or the volume of a liquid in words and figures
- The prescription must be dated and signed by the prescriber. The prescriber should also clearly print his/her name and contact details/bleep number
- Discharge and outpatient prescriptions are valid for 28 days from the date the prescription was written.
- Repeat prescriptions are not permitted

5.1.1.4 Schedule 4 Drugs (CD Benz or CD Anab POM)

- Schedule 4 is split into two parts: part I includes benzodiazepines (such as diazepam) and non-benzodiazepine hypnotics (such as zopiclone); part II contains anabolic and androgenic steroids.
- Witnessed destruction requirements do not apply.
- Written prescriptions are valid for 28 days

5.1.1.5 Schedule 5 Drugs (CD Inv. P or CD Inv. POM)

- Schedule 5 includes preparations of certain Controlled Drugs, such as codeine.
- They are exempt from all Controlled Drug requirements (other than retention of invoice).

5.2 Appendix 2

5.2.1 Prescribing and Management of Controlled Drug Legislation:

Reference	UK Legislation links	Isle of Man Legislation
NICE guideline 46: Controlled drugs: safe use and Controlled drugs: safe use and management (April 2016)	www.nice.org.uk/guidance/ng46/resources/controlled-drugs-safe-use-and-management-pdf-1837456188613	
The Shipman Inquiry (15 July 2004) Fourth Report - The Regulation of Controlled Drugs in the Community	www.the-shipman-inquiry.org.uk/fourthreport.asp	
The Controlled Drugs (Supervision of Management and Use) Regulations 2013	www.legislation.gov.uk/uksi/2013/373/contents/made	n/a
The Health and Social Care Act 2012	www.legislation.gov.uk/ukpga/2012/7/contents	n/a
Misuse of Drugs Act (1971)	www.homeoffice.gov.uk/drugs/	Misuse of Drugs Act (1976) https://legislation.gov.im/cms/images/LEGISLATION/PRINCIPAL/1976/1976-0021/MisuseofDrugsAct1976_6.pdf
Medicines Act (1968)	www.legislation.gov.uk/ukpga/1968/67/contents	Medicines Act (2003) https://legislation.gov.im/cms/images/LEGISLATION/PRINCIPAL/2003/2003-0004/MedicinesAct2003_5.pdf
Misuse of Drugs Regulations (2001)	www.legislation.gov.uk/uksi/2001/3998/contents/made	Applied to the Island, subject to modifications, by Misuse of Drugs (Miscellaneous Enactments) (Application) Order 2013 https://legislation.gov.im/cms/images/LEGISLATION/PRINCIPAL/1976/1976-0021/MisuseofDrugsAct1976_6.pdf
The Misuse of Drugs (Amendment No. 2) (England, Wales and Scotland) Regulations 2013 (to include medicinal cannabis)	www.legislation.gov.uk/uksi/2013/625/contents/made	Applied to the Island via the above Order
The Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007	www.legislation.gov.uk/nisr/2007/348/contents/made	n/a
The Misuse of Drugs (Safe Custody) Regulations 1973	www.legislation.gov.uk/uksi/1973/798/contents/made	Applied to the Island, subject to modifications, by Misuse of Drugs (Miscellaneous Enactments) (Application) Order 2013
The Controlled Drugs (Supervision of Management and Use) Regulations 2013	www.england.nhs.uk/wp-content/uploads/2013/11/som-cont-drugs.pdf	n/a

The Controlled Drugs (Supervision of Management and Use) Regulations 2013. NHS England (**Single Operating Model)**	www.england.nhs.uk/wp-content/uploads/2013/11/som-cont-drugs.pdf	n/a
The Misuse of Drugs (Amendment No.2) (England, Wales and Scotland) Regulations 2012 (Amendment to Misuse of Drugs Act 2001 - extending the responsibilities of NMPs)	www.legislation.gov.uk/uksi/2012/973/contents/made	Applied via 2013 Order.
Good practice in prescribing and managing medicines and devices (2013) (GMC)	www.gmc-uk.org/-/media/documents/prescribing-guidance_pdf-59055247.pdf	
Department of Health, Safer management of Controlled Ddrugs: guidance on Standard Operating Procedures for Controlled Drugs (Jan 2007)	www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_064824	
Department of Health, Safer management of Controlled Drugs: private Controlled Drugs prescriptions and other changes to the prescribing and dispensing of Controlled Drugs (3 July 2006)	www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4131465	
National Patient Safety Agency (NPSA) incident decision tree	www.nrls.npsa.nhs.uk/resources/?EntryId45=59900	
Drug Misuse and dependence – UK guidelines on clinical management (Department of Health, September 2007)	www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_104819	
Home office circular November 2015	www.gov.uk/government/publications/circular-0272015-approved-mandatory-requisition-form-and-home-office-approved-wording/circular-0272015-approved-mandatory-requisition-form-and-home-office-approved-wording	

5.3 Appendix 3 – Summary of Controlled Drug Requirements

Legal requirements	Schedule 2 drugs	Schedule 3 drugs	Schedule 4 drugs (part 1)	Schedule 4 drugs (part 2)	Schedule 5 drugs
Prescription requirements	CD POM	CD no register POM	CD Benz POM	CD Anab POM	CD INV P or CD INV POM
Prescription validity	28 days	28 days	28 days	28 days	6 months
Repeat prescriptions permitted	No	No	Yes	Yes	Yes
Safe custody	Yes	Yes with exception of tramadol, gabapentin & pregabalin	No	No	NO
Record in Controlled Drug Register	Yes	*No	No	No	No

* Local decision may be made by practitioner in charge in conjunction with Pharmacy to record Schedule 3 drugs in Controlled Drugs register if necessary

See Definitions of Schedules

5.4 Appendix 4 – Isle of Man Government. Drug Driving. 2021

5.4.1 Drug Driving

5.4.1.1 Drug driving is not just confined to illegal drugs. Prescription and over-the-counter medicine may also pose a threat to safety.

5.4.1.2 Many drivers appear to be unaware of the dangers of driving under the influence of drugs and that the consequences can lead to serious and fatal injuries to the driver, passengers and other road users including pedestrians.

5.4.1.3 Did you know that driving whilst unfit through drugs, whether illegal, prescribed or over-the-counter medicines, is an offence that carries the same penalties as drink driving?

5.4.2 Drug Driving Penalties could result in a Fine, Disqualification or Imprisonment!

5.4.3 Over-The-Counter and Prescription Drugs

5.4.3.1 Many of the 'over-the-counter' treatments for colds, flu and hay fever that can be bought without a Doctor's prescription may cause drowsiness which could impair driving ability.

5.4.3.2 For many medications it is difficult to predict whether, how, when and for how long they will affect a person's ability to drive safely. A driver may not even notice that they have been impaired until it is too late.

5.4.3.3 The effects depend on how much, how often and how a medicine is used, plus the psychological and physical attributes of the person taking it.

5.4.3.4 Some medicines may cause:

- Drowsiness
- Dizziness or feeling light-headed
- Difficulty concentrating
- Feeling edgy, angry or aggressive
- Feeling nauseous or otherwise unwell
- Reduced coordination, including shaking
- Feeling unstable

5.4.3.5 Refer to the patient information leaflet enclosed with your medicine or check the external packaging to ensure that it does not cause drowsiness or recommend that you refrain from driving whilst taking the medication.

5.4.4 Illegal Drugs

5.4.4.1 Drugs can affect a driver's behaviour and body in a variety of ways (depending on the drug). These can include:

- Slower reactions
- Poor concentration and confused thinking
- Distorted perception
- Over confidence, resulting in taking unnecessary risks
- Poor co-ordination
- Erratic behaviour
- Aggression, panic attacks or paranoia
- Blurred vision
- Tremors, dizziness, cramps
- Severe fatigue the following day.

5.4.4.2 The effects of illegal drugs in more detail:

- **Cannabis:** Impaired concentration, resulting in slower driver reaction times. Impaired steering control and co-ordination. The drug can also induce feelings of paranoia, drowsiness and disorientation.
- **Cocaine:** This stimulant drug can result in drivers misjudging speed and stopping distances. The drug can give drivers a feeling of over-confidence, which can lead to aggressive driving and increased risk taking.
- **Ecstasy:** This stimulant drug has hallucinogenic properties and can distort the driver’s vision and affect concentration. Drivers under the influence of Ecstasy show a significant decrease in their awareness of road dangers followed by severe fatigue the following day.
- **LSD:** This hallucinogenic drug can strongly influence a driver's senses. Drivers may react to objects or sounds that aren’t there, placing themselves and other road users in danger.
- **Opiates such as heroin and methadone (and certain painkillers):** Opiates lead to slower reaction time, lethargy, sleepiness and impaired co-ordination.
- **Tranquillisers:** These drugs may impair driver reaction times and can cause drowsiness.