UT COMPLIANCE

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POLICY DOCUMENT

Controlled Drugs in Domiciliary Care

UT Compliance

BUNDLE PACKAGE | DOMICILIARY CARE

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CONFIDENTIAL DOCUMENT

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1. Scope

1.1 Purpose

This policy sets out the procedures and responsibilities that requires all staff to follow when handling controlled drugs in a domiciliary (home care) setting. It provides a clear framework for the safe receipt, storage, administration, recording, transportation, and disposal of controlled drugs within service users' own homes, ensuring compliance with UK legislation and regulatory standards.

1.2 Application

This policy applies to all employees, agency workers, bank staff, and volunteers engaged by who may come into contact with controlled drugs during the delivery of domiciliary care. This includes but is not limited to:

- Care workers and senior care workers who administer medication
- Team leaders and field supervisors who oversee medication practice
- The Registered Manager, Duty Manager, and all members of the management team
- Administrative staff involved in controlled drugs record-keeping
- Agency and temporary staff working under direction

1.3 Scope of Controlled Drugs Covered

This policy covers all drugs classified under Schedules 2 to 5 of the Misuse of Drugs Regulations 2001. The level of control and documentation required varies by schedule:

- Schedule 2 (e.g., morphine, oxycodone, fentanyl, methylphenidate): Subject to the full range of controlled drug requirements including safe custody, register entries, and witnessed destruction
- Schedule 3 (e.g., midazolam, tramadol, buprenorphine, temazepam): Require register entries and most safe custody requirements, though some exemptions apply depending on the specific drug
- Schedule 4 (e.g., diazepam, zopiclone, zolpidem): Require controlled drug prescriptions but are exempt from safe custody requirements in most cases
- Schedule 5 (e.g., codeine-based preparations in low strengths, co-codamol): Subject to record-keeping requirements but have reduced controls on supply and possession

1.4 Domiciliary Care Context

In domiciliary care, controlled drugs are typically stored in the service user's own home rather than in a centralised controlled drugs cupboard. This presents particular challenges around security, record-keeping, and accountability. This policy addresses these challenges by setting out clear expectations for how staff should manage controlled drugs in a home environment, including what to do when a second witness is not readily available, how to maintain accurate records without a central register, and how to ensure the security of medications within the home.

1.5 Interface with Other Policies

This policy should be read alongside the following related policies and procedures:

- Medication Management Policy
- Safeguarding Adults Policy
- Incident Reporting and Management Policy
- Whistleblowing Policy
- Record-Keeping and Data Protection Policy
- Health and Safety Policy
- Training and Development Policy

2. Legal and Regulatory Framework

The handling of controlled drugs in domiciliary care is governed by a wide body of UK legislation and regulatory guidance. is committed to full compliance with all relevant legislation. The table below summarises the key legal and regulatory requirements:

Legislation / Regulation	Requirements
Misuse of Drugs Act 1971	Primary legislation governing the classification and control of dangerous or harmful drugs. Creates the framework of offences related to production, supply, and possession of controlled substances. Establishes the five-schedule classification system.
Misuse of Drugs Regulations 2001 (as amended)	Sets out the detailed regulatory framework for lawful handling of controlled drugs, including requirements for prescriptions, safe custody, record-keeping, destruction, and supply. Defines the five schedules and their respective requirements.
Health Act 2006 (Part 3)	Introduced strengthened governance arrangements for controlled drugs following the Shipman Inquiry. Established the role of Accountable Officers within NHS organisations and required nominated bodies to share intelligence on controlled drug concerns.
Controlled Drugs (Supervision of Management and Use) Regulations 2013	Specifies the duties of Accountable Officers, reporting requirements for controlled drug incidents, and arrangements for inspection and monitoring. Requires cooperation with Local Intelligence Networks (LINs).
Health and Social Care Act 2008 (Regulated Activities) Regulations 2014	Regulation 12 requires the proper and safe management of medicines. CQC will assess compliance with controlled drug procedures as part of its inspection framework under the Safe key question.
Care Quality Commission (Registration) Regulations 2009	Sets out the registration requirements for providers of regulated activities. Providers must demonstrate competent medication management, including controlled drugs, as a condition of registration.
Care Act 2014	Establishes the legal framework for adult safeguarding. Relevant where controlled drug misuse, diversion, or negligent handling may constitute neglect or abuse of a vulnerable adult.

Human Medicines Regulations 2012	Governs the prescribing, dispensing, and administration of medicines for human use. Relevant to the lawful administration of controlled drugs by care workers operating under appropriate protocols.
Data Protection Act 2018 / UK GDPR	Controlled drug records contain sensitive personal data relating to health. All records must be processed lawfully, stored securely, and retained in accordance with data protection principles.
Health and Safety at Work etc. Act 1974	Places duties on employers to ensure the health, safety, and welfare of employees. Relevant to the safe handling, transportation, and storage of controlled drugs and sharps.
NICE Guideline SC1: Managing Medicines in Care Homes	Although directed at care homes, this guidance provides widely referenced best practice standards for controlled drug management that are equally applicable to domiciliary care with appropriate adaptations.
NICE Guideline NG67: Managing Medicines for Adults Receiving Social Care in the Community	Directly applicable to domiciliary care. Covers principles of safe medication management in community settings, including controlled drugs, and provides the evidence base for this policy.

3. Definitions of Key Terms

The following terms are used throughout this policy. All staff should be familiar with these definitions:

Term	Definition
Controlled Drug (CD)	Any substance listed in Schedules 1–5 of the Misuse of Drugs Regulations 2001. In domiciliary care, the most commonly encountered are Schedule 2–5 drugs prescribed for pain management, anxiety, epilepsy, or palliative care.
Controlled Drug Register (CDR)	A bound, paginated record maintained for each service user who is prescribed Schedule 2 or 3 controlled drugs. Records all receipts, administrations, returns, and running balances. In domiciliary care, this is typically maintained in the service user's home.
Accountable Officer (AO)	A senior person within the relevant Integrated Care Board (ICB) or NHS England region who is responsible for overseeing the safe management and use of controlled drugs in their area. All concerns or incidents relating to controlled drugs must be reported to the Accountable Officer.
Local Intelligence Network (LIN)	A multi-agency meeting convened by the Accountable Officer to share intelligence about controlled drug incidents, trends, and concerns. will cooperate fully with all LIN requests for information.
Witnessed Administration	The process by which a controlled drug is administered in the presence of a second competent person who observes the entire process from removal from the container to ingestion or application by the service user.
Dual Signature	A requirement for two competent persons to sign the controlled drug register or MAR chart at the time of administration, confirming the drug, dose, time, and amount administered.

MAR Chart	Medication Administration Record chart. A document used to record the administration of all prescribed medicines. For controlled drugs, additional fields may be required to capture witness details and running balance.
Safe Custody	The legal requirement under the Misuse of Drugs (Safe Custody) Regulations 1973 for certain controlled drugs to be stored in a locked receptacle that can only be opened by the person in lawful possession or a person authorised by them.
Patient-Specific Direction (PSD)	A written instruction from a prescriber for a medicine to be supplied or administered to a named individual. In domiciliary care, care workers typically administer controlled drugs under a PSD via the service user's prescription.
Diversion	The intentional redirection of a controlled drug from its lawful purpose. This may include theft, unauthorised removal, or the deliberate manipulation of records to conceal missing stock.
Discrepancy	Any difference between the expected balance of a controlled drug and the actual amount present. Discrepancies must be investigated immediately and escalated in accordance with this policy.
Destruction/Disposal	The process of rendering a controlled drug irretrievable. For Schedule 2 drugs, destruction must be witnessed by an authorised person. In domiciliary care, unused or expired controlled drugs are typically returned to the dispensing pharmacy.
Transdermal Patch	A controlled drug delivery system applied to the skin (e.g., fentanyl patches). Requires specific handling, application, and disposal procedures due to the residual drug content after removal.
Palliative Care	Care focused on providing relief from pain and other distressing symptoms for people with life-limiting conditions. Controlled drugs are commonly used in palliative care for pain and symptom management.
Covert Administration	The administration of a medicine hidden in food or drink without the knowledge of the service user. Covert administration of controlled drugs requires a specific best interests decision, GP authorisation, and pharmacist advice on suitability.

4. Policy Statement

4.1 Commitment

is committed to the safe, lawful, and effective management of controlled drugs in all domiciliary care settings. We recognise that controlled drugs are essential to the comfort and wellbeing of many of the people we support, particularly those living with chronic pain, palliative care needs, or mental health conditions. At the same time, we acknowledge the serious risks associated with the mishandling, loss, or diversion of these substances.

This policy sets out our commitment to maintaining the highest standards of controlled drug management, ensuring that every service user receives their prescribed medication safely and on time, while fully protecting both service users and staff from harm.

4.2 Core Principles

All controlled drug handling within is guided by the following principles:

- Safety first: The safety of service users, staff, and the public is the overriding consideration in every decision involving controlled drugs
- Legal compliance: All controlled drug handling complies with the Misuse of Drugs Act 1971, the Misuse of Drugs Regulations 2001, and all associated secondary legislation
- Accountability: Clear lines of accountability exist for every stage of the controlled drug journey, from receipt into the home through to disposal
- Transparency: Records are maintained accurately, contemporaneously, and in a manner that provides a clear audit trail
- Proportionality: Controls are proportionate to the risk presented by each schedule of controlled drug, in line with regulatory expectations
- Person-centred care: Controlled drug management supports, rather than hinders, the delivery of person-centred care within service users' own homes
- Continuous improvement: Practice is regularly audited, monitored, and improved based on learning from incidents, near misses, and best practice guidance

4.3 Zero Tolerance

operates a zero-tolerance approach to the theft, diversion, or deliberate mishandling of controlled drugs. Any member of staff found to have misappropriated controlled drugs, falsified records, or knowingly failed to report a discrepancy will face disciplinary action up to and including summary dismissal, and the matter will be referred to the police and relevant regulatory bodies.

4.4 Duty of Candour

Where a controlled drug incident results in, or has the potential to result in, harm to a service user, will comply fully with its duty of candour obligations. The service user (or their representative) will be informed promptly, given a truthful account of what happened, offered an apology, and kept updated on the investigation and any remedial actions taken.

5. Roles and Responsibilities

The safe management of controlled drugs is a shared responsibility. The table below sets out the specific responsibilities for each role within :

Role	Responsibilities
All Staff	Follow this policy and all associated procedures at all times when handling controlled drugsComplete all mandatory controlled drug training and maintain competencyReport any controlled drug discrepancy, incident, or concern immediately to the Duty Manager or Registered ManagerNever administer a controlled drug without verifying the prescription, checking the service user's identity, and confirming the dose against the MAR chartMaintain accurate, contemporaneous records for every controlled drug transactionReport any concerns about a colleague's handling of controlled drugs, including suspected diversion, in accordance with the Whistleblowing PolicyNever transport controlled drugs on behalf of a service user unless explicitly authorised and trained to do so

Registered Manager ()	Hold overall accountability for compliance with all controlled drug legislation and regulatory requirements across all domiciliary care servicesEnsure this policy is reviewed annually and updated in response to legislative or regulatory changeEstablish and maintain effective governance arrangements for controlled drug management, including audit schedules and quality monitoringAct as the primary point of contact with the CQC and the local Accountable Officer for controlled drug mattersEnsure all controlled drug incidents are reported, investigated, and notified to external bodies where requiredEnsure that sufficient trained and competent staff are available to safely manage controlled drugs at all timesReview controlled drug audit findings and implement improvement actions
Duty Manager	Provide day-to-day operational oversight of controlled drug management during their shiftAct as the first point of escalation for controlled drug discrepancies, incidents, or concerns raised by care staffConduct or coordinate immediate investigations into controlled drug discrepancies and report findings to the Registered ManagerEnsure that staffing rotas enable witnessed administration and dual signatures where requiredCarry out spot checks and observational audits of controlled drug practice in the fieldSupport and mentor staff in controlled drug competency and correct record-keepingCoordinate with pharmacies, GPs, and district nurses on controlled drug matters during operational hours
Safeguarding Lead ()	Assess whether any controlled drug incident constitutes, or may constitute, abuse or neglect of a vulnerable adultMake safeguarding referrals to the local authority where a controlled drug incident meets the threshold for adult safeguardingLiaise with the Registered Manager and Duty Manager on safeguarding aspects of controlled drug investigationsEnsure the voice and wishes of the service user are central to any safeguarding action arising from a controlled drug incident
Health and Safety Officer ()	Conduct risk assessments relating to the handling, transport, and storage of controlled drugs in domiciliary settingsAdvise on safe systems of work for controlled drug management, including sharps handling and transdermal patch disposalInvestigate any workplace health and safety incidents arising from controlled drug handlingEnsure that RIDDOR-reportable incidents involving controlled drugs are notified to the Health and Safety Executive
Data Protection Officer ()	Ensure that all controlled drug records are processed and stored in compliance with the Data Protection Act 2018 and UK GDPRAdvise on information governance aspects of controlled drug record-keeping, including retention periods and access controlsInvestigate any data breach involving controlled drug records and report to the ICO where requiredEnsure staff are trained on the confidential nature of controlled drug records and the consequences of unauthorised access or disclosure

6. Procedures

6.1 Receipt of Controlled Drugs

When a service user's controlled drugs are delivered by the pharmacy or brought into the home, the following procedure applies:

1. Verify the service user's name, address, and date of birth on the pharmacy label against the service user's care plan and MAR chart.
2. Check the drug name, strength, form, and quantity against the prescription and MAR chart.
3. Count the quantity of the controlled drug received. For liquids, check the bottle is sealed and note the volume on the label.
4. Record the receipt in the service user's Controlled Drug Register, noting the date, time, drug name, strength, form, quantity received, name of the person delivering, and the name and signature of the care worker receiving.
5. Ensure the controlled drug is stored immediately in the designated secure location within the service user's home (see Section 6.2).

6. Report any concerns about the condition, quantity, or labelling of the controlled drug to the Duty Manager before placing it in storage.

6.2 Storage in the Service User's Home

Controlled drugs subject to safe custody requirements (Schedules 2 and 3, unless exempt) must be stored securely in the service user's home. The following requirements apply:

- A lockable medication cabinet or box should be provided. While there is no legal requirement for a CD cabinet meeting British Standard specifications in a private dwelling, a robust lockable container fixed in a discreet location is strongly recommended.
- The key to the lockable container should be held by the service user, their nominated representative, or kept in a location agreed and documented in the care plan. Care workers should not routinely carry service users' medication keys.
- Controlled drugs should be stored separately from other medications where possible.
- Fridge-line items (e.g., certain liquid morphine preparations) must be stored in a lockable container within the fridge or in a dedicated fridge at the correct temperature, as specified by the pharmacist.
- The storage location, access arrangements, and any risk factors must be documented in the service user's care plan and reviewed at each care plan review.
- Where the service user has capacity and chooses to self-administer some or all of their controlled drugs, the storage arrangements and responsibilities must be clearly documented in the care plan following a risk assessment.

6.3 Administration of Controlled Drugs

The administration of controlled drugs must follow this step-by-step procedure:

1. Wash hands thoroughly and put on gloves if required.
2. Check the MAR chart to confirm the drug, dose, route, and time of administration. Check for any recent dose changes, GP instructions, or PRN protocols.
3. Retrieve the controlled drug from the secure storage location using the agreed access method.
4. Check the pharmacy label against the MAR chart: service user name, drug name, strength, form, dose, and expiry date.
5. Check the running balance in the Controlled Drug Register against the actual quantity present. If there is any discrepancy, do not administer. Stop, secure the drug, and contact the Duty Manager immediately.
6. Prepare the dose as prescribed. For liquids, use an oral syringe and measure at eye level. For tablets or capsules, tip the correct number into a medicine pot without touching them.
7. Administer the controlled drug to the service user, checking their identity and confirming consent. Observe the service user taking the medication (tablets swallowed, liquid consumed, patch applied).
8. Record the administration on the MAR chart and in the Controlled Drug Register. Record the date, time, drug, dose, quantity administered, new running balance, and sign.
9. Where a witness is present (see Section 6.4), the witness must observe steps 4–8 and countersign both the MAR chart and the CDR entry.
10. Return the remaining controlled drug to the secure storage and lock the container.
11. Document any observations about the service user's response to the medication in the care notes.

6.4 Witnessed Administration and Dual Signatures

Best practice requires that the administration of Schedule 2 controlled drugs is witnessed by a second competent person. In domiciliary care, this presents practical challenges as staff often work alone. adopts the following approach:

- Where two staff members are present at a visit (e.g., double-up calls), the second care worker must witness the administration and countersign the CDR and MAR chart.
- Where a single care worker is attending, a competent family member or informal carer who has been assessed and agreed upon may act as witness. This arrangement must be documented in the care plan.
- Where no witness is available, the care worker must record this fact on the CDR entry, note the reason, and carry out all other steps of the administration procedure meticulously. The Duty Manager must be notified at the earliest opportunity.
- For service users receiving Schedule 2 controlled drugs where no witness is routinely available, a risk assessment must be completed and reviewed monthly. The risk assessment must consider whether additional safeguards such as more frequent audits, phone verification, or adjusted rotas are needed.
- The Registered Manager will ensure that rotas are planned to maximise opportunities for witnessed administration, particularly for high-risk controlled drugs or where previous concerns have been identified.

6.5 PRN (As Required) Controlled Drugs

Some controlled drugs are prescribed on a PRN (pro re nata) basis, meaning they are given only when needed rather than at fixed times. The following additional requirements apply:

- A clear PRN protocol must be in place in the service user's care plan, specifying the indication (reason for use), maximum dose in 24 hours, minimum interval between doses, and any specific instructions from the prescriber.
- Before administering a PRN controlled drug, the care worker must check when the last dose was given to ensure the minimum interval has elapsed and the maximum daily dose has not been reached.
- The reason for administering the PRN dose must be recorded on the MAR chart and in the care notes.
- If the service user is requesting PRN controlled drugs more frequently than anticipated, or if the PRN protocol appears insufficient to manage their symptoms, the care worker must report this to the Duty Manager, who will arrange a review with the prescriber.

6.6 Transdermal Patches (e.g., Fentanyl)

Transdermal controlled drug patches require specific handling:

- Apply patches to a clean, dry, non-hairy, non-irritated area of skin as directed by the prescriber. Rotate the application site with each new patch.
- Record the site of application on the MAR chart and body map.
- When removing a used patch, fold it in half with the adhesive sides together, place it in the sharps bin or designated pharmaceutical waste container, and record the removal in the CDR.
- Never cut transdermal patches unless the prescriber and pharmacist have confirmed this is appropriate for the specific product.
- Check at every visit that the patch is still in place. If a patch is missing or has fallen off, record this as a discrepancy, secure the area, and notify the Duty Manager immediately.

- Used fentanyl patches retain significant quantities of active drug. They must never be placed in domestic waste.

6.7 Disposal and Return of Controlled Drugs

Controlled drugs that are no longer required, have expired, or belong to a deceased service user must be disposed of safely:

1. Unused or expired controlled drugs should be returned to the dispensing community pharmacy. Care workers must record in the CDR the date, drug name, strength, form, quantity returned, and the name of the pharmacist receiving.
2. Where a service user has died, the controlled drugs should remain secure in the home until they can be collected by the community pharmacy or destroyed in accordance with local arrangements. The Duty Manager must be notified promptly.
3. Care workers must never dispose of controlled drugs by flushing them down a toilet, placing them in domestic waste, or giving them to family members.
4. For Schedule 2 drugs, destruction should ideally be witnessed. The pharmacy will typically manage the formal witnessed destruction process in accordance with their own Standard Operating Procedures.
5. A record of all disposals and returns must be maintained in the CDR and a copy kept by for audit purposes.

6.8 Transportation of Controlled Drugs

In certain circumstances, care staff may need to transport controlled drugs (e.g., collecting a prescription from a pharmacy on behalf of a service user). The following rules apply:

- Staff must only transport controlled drugs when authorised by the Duty Manager or Registered Manager and only where this has been risk-assessed and documented.
- Controlled drugs must be transported in a sealed, tamper-evident bag, kept on the person at all times, and delivered directly to the service user's home without any stops.
- The time of collection, quantity collected, and time of delivery must be recorded in the CDR.
- Staff must never store controlled drugs in their own home, in a vehicle overnight, or in any unsecured location during transit.
- Where possible, a second person should be present during the collection and handover of transported controlled drugs.

6.9 Incident Management and Discrepancies

Any incident, error, or discrepancy involving a controlled drug must be managed in accordance with the following procedure:

1. If a discrepancy is identified (e.g., the actual count does not match the CDR balance), the care worker must stop, not administer, secure the drug, and contact the Duty Manager immediately.
2. The Duty Manager will conduct an initial investigation, which may include re-counting, checking all CDR entries, reviewing the MAR chart, and speaking to all staff who have recently administered the drug.
3. If the discrepancy cannot be resolved within two hours, the Registered Manager must be informed. A decision will be made on whether to notify the police, the Accountable Officer at the ICB, and the CQC.
4. All controlled drug incidents must be recorded on 's incident reporting system, categorised by severity, and investigated to root cause.
5. The service user (or their representative) must be informed in accordance with the Duty of Candour where there is any

possibility that the incident has caused, or could cause, harm.

6. Lessons learned from all controlled drug incidents must be shared with the wider team through team meetings, supervision sessions, and updated guidance where necessary.

6.10 Covert Administration of Controlled Drugs

Covert administration of controlled drugs (i.e., hidden in food or drink without the service user's knowledge) must only occur in the following circumstances:

- The service user has been assessed as lacking capacity to consent to taking their medication, and this assessment is documented in accordance with the Mental Capacity Act 2005.
- A best interests meeting has been held involving the prescribing GP, the pharmacist, the service user's representative, and relevant professionals. The outcome is documented and kept in the care plan.
- The prescribing GP has provided a written direction authorising the covert administration.
- The pharmacist has confirmed that the specific controlled drug is suitable for covert administration (i.e., it can safely be crushed, dissolved, or mixed with food or drink without affecting its efficacy or safety).
- The method and vehicle of covert administration (e.g., mixed with yoghurt, dissolved in juice) are documented in the care plan and reviewed at each care plan review.

7. Training and Development

7.1 Mandatory Training

All staff involved in controlled drug handling must complete the following training:

- Induction training: All new staff receive controlled drugs awareness training as part of their induction, covering the legal framework, schedules, record-keeping requirements, and the key procedures in this policy. Staff must not handle controlled drugs until this training is complete.
- Annual refresher training: All staff complete annual refresher training on controlled drug management, incorporating any changes to legislation, guidance, or internal procedures.
- Specialist training: Staff who administer controlled drugs in palliative care settings, or who handle syringe drivers or other specialist delivery systems, must complete additional training provided or approved by a relevant clinical professional.

7.2 Competency Assessment

Completion of training alone is not sufficient. All staff must demonstrate practical competency through:

- Observed practice: Each care worker must be observed administering a controlled drug by a competent assessor (senior care worker, team leader, or manager) before being signed off as competent. This observation must be repeated annually.
- Knowledge assessment: Staff must pass a written or verbal knowledge assessment covering the key elements of this policy, including the legal framework, administration procedure, record-keeping, and incident reporting.
- Ongoing monitoring: Competency is monitored through routine audits, spot checks, supervision, and feedback from service

users and families.

7.3 Supervision and Support

Controlled drug practice must be regularly discussed within staff supervision sessions. Supervisors should explore any concerns, near misses, or challenges the care worker is experiencing and offer guidance. Where a care worker's competency is in question, additional supervised practice and reassessment will be arranged before they are permitted to handle controlled drugs independently.

8. Monitoring and Review

8.1 Audit Programme

maintains a structured audit programme for controlled drugs:

- Monthly CDR audits: The Duty Manager or designated senior staff member will audit each service user's Controlled Drug Register at least monthly, checking running balances against physical stock, completeness of entries, and accuracy of records.
- Quarterly management review: The Registered Manager will review aggregated audit findings, incident data, and compliance trends on a quarterly basis and present findings to the governance meeting.
- Annual policy review: This policy will be reviewed annually or sooner if there is a change in legislation, regulatory guidance, or following a significant controlled drug incident.
- Spot checks: Unannounced spot checks of controlled drug practice will be carried out in the field on a random and risk-based schedule.

8.2 Quality Indicators

The following indicators will be monitored to assess the effectiveness of controlled drug management:

- Number and nature of controlled drug discrepancies
- Percentage of CDR entries completed fully and accurately
- Percentage of controlled drug administrations that were witnessed
- Number of controlled drug incidents reported and outcome of investigations
- Timeliness of incident reporting and notification to external bodies
- Staff training compliance rates for controlled drug training
- Outcomes of CQC inspections or ICB reviews relating to controlled drugs

8.3 Continuous Improvement

is committed to learning from every controlled drug incident, near miss, audit finding, and piece of external guidance. Improvement actions arising from these sources will be tracked through an action plan, assigned to a named individual, and

reviewed for completion at governance meetings. Trends will be analysed to identify systemic issues that require a broader response.

9. Reporting Concerns

9.1 Duty to Report

All staff have a professional and legal duty to report any concern relating to controlled drugs. This includes, but is not limited to:

- Discrepancies in controlled drug counts or register entries
- Suspected theft, diversion, or misappropriation of controlled drugs
- Concerns about a colleague's handling of controlled drugs, including potential impairment
- Errors in controlled drug administration (including wrong drug, wrong dose, wrong route, wrong time, or missed dose)
- Inadequate storage or security arrangements in a service user's home
- Any attempt by a service user, family member, or other person to pressurise staff into deviating from this policy

9.2 Reporting Channels

Concerns should be reported through the following channels:

1. Immediate concerns: Contact the Duty Manager on shift by phone. If the Duty Manager is unavailable, contact the Registered Manager directly.
2. Incident reporting: Complete 's incident report form as soon as possible after the event, and no later than the end of the shift.
3. Safeguarding concerns: If the concern involves potential abuse or neglect of a service user, report to the Safeguarding Lead () and follow the Safeguarding Adults Policy.
4. External reporting: The Registered Manager is responsible for notifying the CQC, the ICB Accountable Officer, and the police where required.

9.3 Whistleblower Protection

is fully committed to protecting any member of staff who raises a genuine concern about controlled drug practice. Staff who report concerns in good faith will not be subjected to any form of detriment, victimisation, or disciplinary action. Reports can also be made externally to the CQC, the police, or Public Concern at Work (now Protect) if the staff member feels unable to raise the concern internally.

9.4 External Notifications

The following external bodies must be notified of controlled drug incidents as required:

- Care Quality Commission (CQC): Notification of any significant controlled drug incident in accordance with the CQC notification requirements.

- Accountable Officer (ICB): Notification of any controlled drug discrepancy, theft, or significant incident via the appropriate Occurrence Reporting form.
- Police: Notification where theft, diversion, or criminal activity is suspected.
- Local Safeguarding Adults Board: Referral where the incident constitutes or may constitute abuse or neglect of a vulnerable adult.
- Health and Safety Executive (HSE): RIDDOR notification where a controlled drug incident results in a reportable workplace injury or ill health.

10. Risk Assessment

10.1 Individual Risk Assessment

A controlled drug risk assessment must be completed for every service user who is prescribed a controlled drug. This assessment must be reviewed:

- At every care plan review
- Following any change to the service user's controlled drug prescription
- Following any controlled drug incident or discrepancy
- At least every three months

The risk assessment must consider:

- The schedule and nature of the controlled drug prescribed
- The service user's capacity and ability to self-administer
- The security and suitability of the storage arrangements in the home
- Whether other people in the household may present a risk of diversion (e.g., known substance misuse)
- The availability of a witness for administration
- Any history of controlled drug discrepancies or incidents for this service user

10.2 Organisational Risk Assessment

The Registered Manager will maintain an organisational risk assessment for controlled drug management, reviewed quarterly, covering workforce capacity and competency, geographical challenges affecting witnessed administration, quality of relationships with local pharmacies, trends in incidents and discrepancies, and any emerging risks identified through the LIN or CQC communications.

11. Related Policies

This policy should be read and applied in conjunction with the following policies and procedures:

- Medication Management Policy

- Safeguarding Adults Policy
- Mental Capacity Act and Deprivation of Liberty Safeguards Policy
- Incident Reporting and Management Policy
- Whistleblowing (Raising Concerns) Policy
- Record-Keeping and Documentation Policy
- Data Protection and Confidentiality Policy
- Health and Safety Policy
- Training and Development Policy
- Complaints Policy
- Duty of Candour Policy
- End of Life and Palliative Care Policy

Policy Approval & Review

APPROVED BY	SIGNATURE
Not Specified	*No signature on file*
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1 January 1970	**12 April 2027**