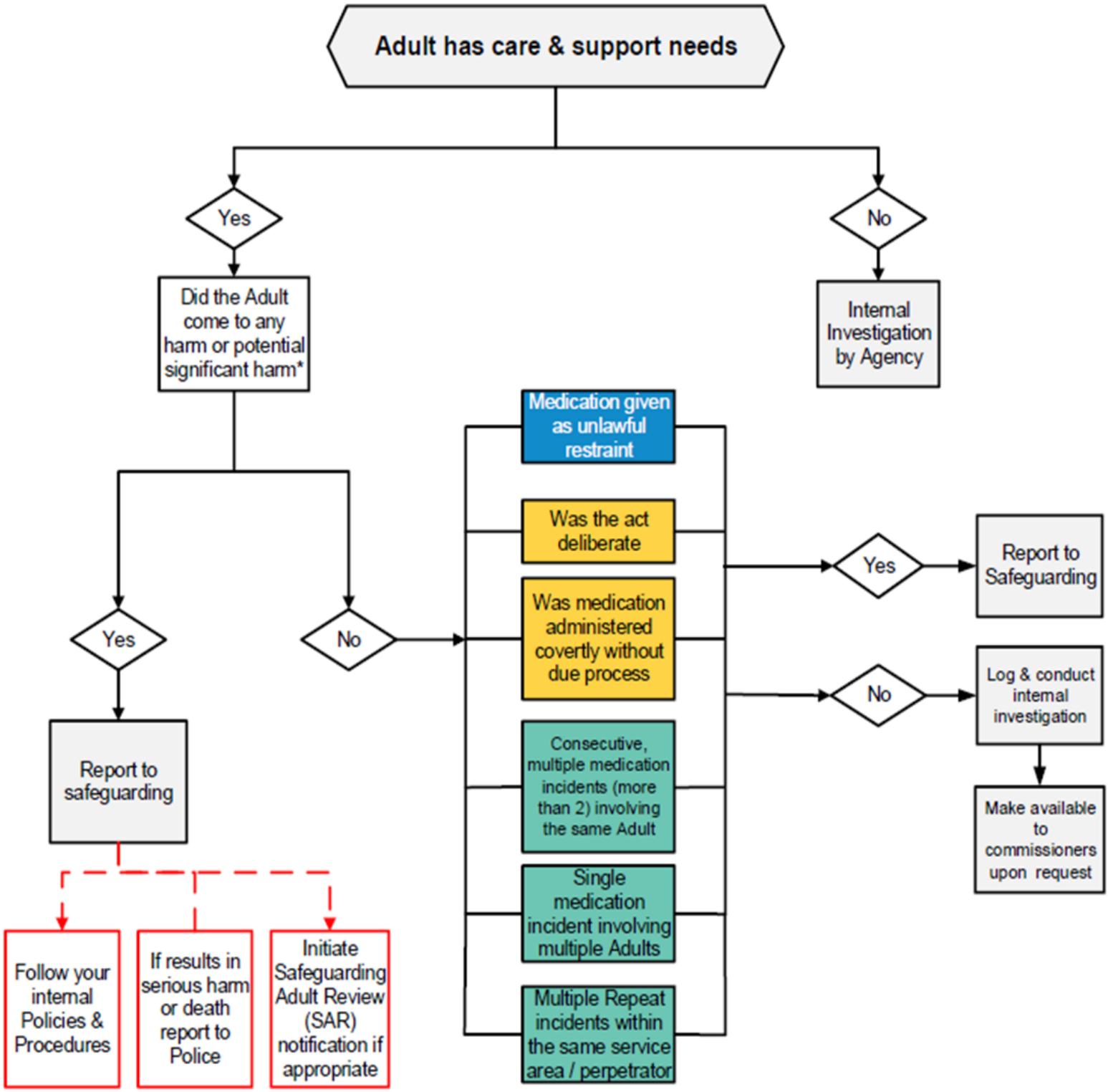
Safeguarding and Medicines Management: Guidance for Providers

Index

SOMERSET SAFEGUARDING ADULTS BOARD



Key - Types of abuse

- Physical
- Neglect & Acts of Omissions
- Organisational

* **Significant Harm:** Is defined as: Death or impairment to health which results in a permanent increase to a person's care and support needs.

1. Introduction

1.1 This guidance should be read in conjunction with the following:

Safeguarding adults in care homes (nice.org.uk)- references medication issues as a neglect factor 2021

Managing medicines for adults receiving social care in the community (nice.org.uk) 2017

Managing medicines in care homes (nice.org.uk) 2014

Reporting medicine related incidents - Care Quality Commission (cqc.org.uk)

1.2 Definition of medication error

The National Patient Safety Agency (NPSA) 2009 defines a medication error as 'an error in the process of prescribing, dispensing, preparing, administering, monitoring or providing medicine advice, regardless of whether any harm occurred'. Errors may result in an incident or an adverse event or where averted they can be classified as a 'near miss'.

2. Purpose

2.1 The Somerset Safeguarding Adults Board (SSAB) has developed this medication error practice guidance to assist with the appropriate reporting of medication issues as a safeguarding concern. This practice guidance is applicable to all settings where medication management is included as part of their service delivery and should be applied in conjunction with the services' policies and / or procedures / guidance. With the expectation that all adhere to best practice in this area with individuals involved in administration and management of medication are confident and competent who have undertaken relevant training and meet competency frameworks..

2.2 The SSAB recognises that maintaining high quality services is essential to identify, respond to and minimise medication errors. It is also recognised that for safeguarding to be relevant and effective it also needs to be proportionate to the incident and the level of risk.

2.3 This guidance will support staff in all sectors who are concerned that a medication related incident may have arisen as a result of poor practice, neglect or intention to cause harm and therefore have to decide whether to raise a safeguarding concern under multi-agency safeguarding policy and procedures.

• Assist providers to determine when they should raise a safeguarding concern with the Council's Adult Safeguarding Service; and,

• Ensure that providers are aware of when a safeguarding concern should be raised with the Council's Adult Safeguarding Service as well as the requirements for statutory notifications to the Care Quality Commission (CQC) for NHS and non-NHS Providers (in respect of providers registered under the Health and Social Care Act 2008); and,

• Identify examples of the actions to be taken in respect of medication incidents that do not require a statutory notification to CQC, and how these actions will be assessed by the Council.

2.4 Wherever possible the adult should be encouraged to discuss, with appropriate support, any medication issues they are experiencing with their prescriber or dispensing pharmacist.

2.5 Medication needs to be administered in accordance with the Mental Capacity Act (2005) and Mental Health Act (1983). Consideration needs to be given to whether or not someone has capacity to consent / refuse medication administration. If they do not have capacity, medication needs to be administered in accordance with the principles of the Mental Capacity Act. There are also occasions e.g. use of the MHA that can enable the administration of medication again the wishes of the individual. However, all of this must be reflected in the care plan and the care plan should be followed **and regularly reviewed** and as and when something changes. Information regarding covert administration of medication is included in appendix 1.

2.6 In the event of a medication error, advice should always be sought from the prescriber (i.e. GP) or dispensing pharmacist or out of hours the NHS 111 service or internal organisational procedures set out in the organisations Medicines Management policy. This document explains that this is important because some medicines can cause more harm than others when omitted or delayed.

2.7 All of the patient information leaflet, provided with the medication, should be read by the individual receiving the medication and the individual administering, before it is administered.

3. Scope

3.1 This guidance is relevant to all care providers of services to adults in Somerset to enable organisations to understand when a safeguarding referral to Somerset Council's Safeguarding Service is required.

3.2 If a crime has been committed in relation to any medication management issue causing serious harm or death, then this must be reported to the Police. Further guidance regarding referral routes and categories of safeguarding concerns can be found in the SSAB Risk Decision Making tool.

4. Examples of medication errors

4.1 Prescribing

- Duplicate medicine; a drug prescribed by the both brand and generic names or two medicines that have the same action
- Wrong dosage, strength or formulation
- Issuing of a discontinued medicine
- Medication requested from surgery, but no prescription supplied without reason
- A service user is prescribed a medicine that they are known to be allergic to
- A service user is prescribed a medicine that is contraindicated
- A service user is prescribed a medicine that is unnecessary for them
- A service user is prescribed a medicine that has an unwanted interaction with another medication that they are taking without the rationale for the risk having been documented.

4.2 Monitoring

- Monitoring not requested
- Monitoring requested but not carried out
- Monitoring performed but results not available
- Results not acted upon.

Examples of drugs requiring monitoring include: anticoagulants; cardiac glycosides; diuretics; antiarrhythmic; thyroid hormone; anti-manic agents; insulin and some anti-rheumatic drugs.

4.3 Dispensing

- Supply of duplicate medication
- Supply of the wrong dose / strength/ formulation / drug to that prescribed
- Supply of an out-of-date medication
- Omission in the supply of a prescribed medication
- Labelling error.

4.4 Administration

- Omission of a prescribed medication for a non-clinically indicated reason
- Administration of another person's medication which is not prescribed for them
- Administration of an extra dose(s) /wrong dose(s) / wrong medicine / wrong formulation
- Administration of a medication when a person has a known allergy to it.
- Administration of an out-of-date medication
- Administration of a medication at the wrong time
- Administration of a medication via the wrong route.
- Administration without consent and no legal framework in place to support this

4.5 Ordering and record keeping

- Stock not ordered
- Stock not booked in correctly
- Stock not carried forward correctly
- Booking in of discontinued /not prescribed medication
- Stock not stored in the appropriate location
- Controlled Drug (CD) records not completed correctly
- Medication Administration Record (MAR) form not signed
- MAR form signed inappropriately (e.g. as if medication was administered, when stock count/ Multiple Dose Systems (MDS) packs show the contrary
- Deliberate alteration or amendment of MAR chart.

See Appendix 5 for more information of Management if controlled Drugs in Care Homes and Community settings.

5. How to manage medication errors and near misses

5.1 In the event of a medication error:

If there is any doubt about the person's wellbeing, a 999 call for an ambulance must be made immediately. If the medication error results in serious harm or death report to the

Police and to the Care Quality Commission (CQC) if the incident has occurred in a regulated service.

5.2 Staff member's responsibilities

- Contact the resident's GP, on-call service or pharmacist for advice
- Monitor the resident in accordance with the instruction from the GP, on-call service or pharmacist
- Inform the Registered Manager
- Inform the resident and/or relative as appropriate
- Record full details of the incident, including time, medication given, action taken and full signature in the resident's care plan
- Complete Incident report form if applicable to service provision (in adherence to service policy)
- Complete a safeguarding referral if checklist at start of this document indicates this is required

5.3 Managers responsibilities

- Review each incident to decide whether further action or investigation is required
- Generate a safeguarding concern form if checklist at start of document indicates this is required and it has not already been generated
- Inform the Care Quality Commissioner (CQC) as per regulatory requirement.
- Share learning with entire team
- Ensure staff are supported following incident
- Encourage and open reporting culture
- A full report needs to be placed on the person's file along with a copy of the incident form.

5.4 Controlled Drugs

In the event of a discrepancy in the quantity of a controlled drug the Registered Manager must be contacted immediately / or if occurring in a community setting this would be reported back to the prescriber ie GP practice. The Registered Manager/ GP practice, with the person who has discovered the discrepancy should:

- Check the date of receipt of the controlled drug and the amount of tablets / liquid entered into the controlled drug book
- Check this amount against the subsequent entries for administration of this drug
- If the facts lead to a suspicion of theft, the Police, Somerset Council Safeguarding and the CQC must be informed.

6. What is the decision-making process for raising a Safeguarding concern?

6.1 Where a medication error triggers a notification to CQC and/or a report to the police (via 101/ 999 if a crime has been committed resulting in serious harm or death) a Safeguarding concern will always need to be raised with Somerset Council's Safeguarding Service. There are three ways to do this:

- Telephone: Adult Social Care on 0300 123 2224 (Monday to Friday 8.30am to 5.30pm, Saturday and Sunday closed)
- E-mail: adults@somerset.gov.uk
- By completing a secure electronic safeguarding referral form

6.2 Any referral made to the Local Authority Safeguarding service (see 6.3 below) should also result in a CQC notification when the cause or effect of a medication error results in:

- Death
- Injury
- Abuse or an allegation of abuse
- An incident reported to or investigated by the Police

Information on how to do this can be found here

6.3 In addition, a safeguarding referral must be raised where the person or persons in question came to harm.

In this context 'harm' is defined as any physical or mental change (psychological) experienced by an individual that is caused by, or consider likely to have been caused by, the error, which results in a permanent increase to a person's care and support needs and/or a high level of distress.

6.4 If any of the following occur, a Safeguarding concern MUST also be raised:

- Medication given as a form of unlawful restraint (e.g. a non-prescribed sedative is administered, or a prescribed medicine is administered at a higher dose or more frequently than prescribed).

- An indication that it may be a deliberate act to administer/neglect to administer medication contrary to the directions of the prescriber (e.g. deliberately increasing the dose of a medication or failing to administer it).

- A medication administered covertly (see Appendix 2 for more information about covert administration) where no specific approved covert medication protocol is in place (e.g. administering a tablet in yoghurt where a person with or without capacity has refused) **and** the person experiences harm.

- Consecutive/multiple medication incidents involving the same person (e.g. prescribed medication is not administered over more than one round because it has not been ordered or collected) **and** the person experiences harm.

- Single medication incident involving multiple people (e.g. a whole medication round missed or delayed) **and** there is a significant risk of a person or persons experiencing harm.

- Multiple/repeat incidents within the same service, or by the same person (e.g. medication is administered incorrectly by a specific member of staff on more than one occasion) where harm occurs.

- Where a controlled medicine is involved and there has been harm and/or a crime.

- Where a referral is required to a professional body

Appendix one
Additional guidance:

Over the counter (OTC) medicines and homely remedies - Care Quality Commission (cqc.org.uk)

Whilst the likely impact on patient care is small with **OTC** medication and **homely remedies**; it has the potential for errors in administration or the lack of use, allowing a gap in patient care. The provider's internal policies should be updated, and the allergy status should always be checked and updated.

Digital MAR - within Somerset, we have an increased number of homes using digital MARs - the responsibility for maintaining these sits entirely with the providers. Any issues with this process that leads to medication errors are reportable, and a SEA should be filled and actioned accordingly.

Covert Administration of Medication

Can we add this? Review dates from clinicians - are essential. Also, despite covert policies in situ, providers still have to attempt each time to administer medication, allowing choice for residents - time-specific and decision-specific. This can also lead to medication errors and potentially safeguarding issues.

Controlled Drugs

Best practice should be regular stock checks, always two senior staff and signed competencies for handling and administration of CD.
Controlled drugs in care homes - Care Quality Commission (cqc.org.uk)

Appendix 1: Covert Administration of Medication

Covert administration is when medicines are administered in a disguised format. The medicines could be hidden in food, drink or through a feeding tube without the knowledge or consent of the person receiving them. As a result, the person is unknowingly taking a medicine. Every person has the right to refuse their medicine, even if that refusal appears ill-judged to staff who are caring for them. Covert administration is only likely to be necessary or appropriate where:

• a person actively refuses their medicine

• that person is judged not to have the capacity to understand the consequences of their refusal. Such capacity is determined by the Mental Capacity Act 2005

• the medicine is deemed essential to the person's health and wellbeing

Covert administration of medicines should be a last resort. You must make reasonable efforts to give medicines in the normal manner. You should also consider alternative methods of administration. This could include, for example, liquid rather than solid dose forms

In circumstances where the medication is put into food to make it more palatable and the person is aware and has agreed then it is not being administered covertly. In these circumstances their agreement should be documented.

Always remember that administering medicines in food or drink can alter their therapeutic properties and effects. They could become unsuitable or ineffective. Always take advice from a healthcare professional to make sure medicines are safe and effective.

Further guidance on the covert administration of medicines is available from CQC: https://www.cqc.org.uk/guidance-providers/adult-social-care/covert-administration-medicines

Appendix 2

What action is required if a medication error does NOT trigger raising a Safeguarding concern?

If you have confirmed and documented that none of the circumstances in section 6 apply then, whether or not a medication error triggers raising a Safeguarding concern, ***any*** **identified poor practice in the administration of medication requires a management response by the service provider.**

This is because poor practice at any level which is not addressed can lead to medication errors which have a negative impact on the people that the service provides care and support to. Taking action in response to all medication errors mitigates against the risk of reoccurrence and improves practice.

Actions include:

• **Audit** – **Conducting a robust, regular audit of medication systems will assist in ensuring that errors and trends are quickly identified**. Look out especially for medications which sometimes have variable doses (e.g. Warfarin), those which are non-routine (e.g. antibiotics) and those stored other than in the medication cabinet (e.g. eyedrops and some topical creams) as errors often occur with these.

A good audit will check that each person's medication is administered in line with each person's needs, ordered in good time, that medication from the pharmacy is confirmed correct on receipt, that recording of administration, refusal and disposal is accurate, expiry dates are reviewed and that recording of administration is consistent with the remaining amounts of each person's medications that are held. The frequency of audit should be increased where new staff are deployed to administer medication, and in response to errors identified.

Training and guidance should be sought on best practice, and this should be regularly reviewed and updated. Consideration should also be given to arranging for an external organisation to support auditing processes.

• **Investigate** – **It is important to investigate the root cause of any medication error to determine whether written procedures need to be reviewed, individuals or teams of staff require additional training, or whether the risk of accidental error can be mitigated by implementing changes to practice**.
For more widespread concerns a thorough investigation report will include detail which might include: statements of involved staff, anonymised copies of MAR sheets, care delivery records, communication with relevant parties (e.g. prescriber, Safeguarding, CQC), a written factual account of the investigation conducted, conclusion and action taken.

• **Record** – **You should maintain a record of relevant medication errors for investigation, auditing and quality improvement process and to evidence the action you've taken to address the incident**. Organisations are required to put in place their own documentation to periodically audit medication errors to determine error trends which in turn may identify a specific training need or the requirement for a Safeguarding notification. The Somerset County Council Quality Assurance Team and any other relevant commissioners or the CQC may request information relating to medication errors to ensure that management processes are robust. Also refer to NICE guidance for best practice.

• **Share learning** – **Even if the medication error is relatively minor in nature it is good practice to share learning across the organisation**. Effectively communicating learning from investigation of medication errors is critical to creating a culture where it is acknowledged that errors can and do happen. Learning shared in a manner which promotes improved practice across the organisation rather than encourages staff to hide or disguise genuine errors for fear of punishment, is likely to result in more transparent disclosure of errors where they occur.

APPENDIX 3

Examples of poor practice which do *NOT* trigger a safeguarding notification
While the examples below may not trigger a safeguarding notification, they **MUST** trigger a management response through training, supervision or auditing and may still be notifiable. Remember to always record what action/s you have taken.

• **A gap in recording**. A single signature is missed on the MAR chart, but your investigation concludes that the medicine was correctly administered, **and** no harm has occurred, you have taken appropriate action with the member of staff concerned and recorded this.

• **Medication is not given on one occasion.** The person the adult does not receive prescribed medication (missed/wrong dose) on one occasion, advice has been sought from the prescriber, **and** no harm occurred. You have clearly recorded the incident, advice from the prescriber and action taken with the member of staff concerned.

• **Medication is not given on more than one occasion,** advice has been sought from the prescriber, and no harm has occurred (e.g. recurring missed medication or administration errors identified through observation or audit). You take swift action once identify through training, supervision. You monitor the situation closely until poor practice has been corrected. You have clearly recorded the incident, advice from the prescriber and action taken.

• **Medication was given late.** An unforeseen event meant that some people received their medication later than scheduled, you have checked to ensure that no medication was time-sensitive and where appropriate this has been confirmed this with the prescriber who has advised that no harm has occurred. You have clearly recorded the incident, advice from the prescriber and action taken.

• **A member of staff signs the MAR chart in incorrect coloured ink.** You have reminded the staff member of your policy and ensured a supply of black or blue pens is available and removed the incorrectly coloured pens.

• **The pharmacy has made a change and now delivers medication in patient packs instead of blister packs** You have checked that your medication procedure reflects the change in packaging, have familiarised staff with the procedure and have introduced a more frequent random ‘spot-check’ audit until you are content that the new system is working effectively. You have recorded your actions.

• **A member of staff has changed the initials and the sample signature sheet reflects their previous name**. You have ensured that the member of staff has signed the sample signature sheet again with their new initials and the date on which they started to sign MAR sheets with their new initials, the original entry remains on the sample signature sheet so that previous MAR entries can be traced to this person. You have recorded your actions.

APPENDIX 4

Examples which MAY trigger raising a safeguarding concern and where advice should be sought:

While, following consideration by Somerset County Council's Adult Safeguarding Service, the examples below may not result in an enquiry under section 42 of the Care Act (2014), they **MUST** trigger a management response through corrective action, the implementation of protective measures, training, supervision or auditing and may still be notifiable. Remember to always record what action/s you have taken.

• A one-off medication error involving more than one person with no harm caused **and** there is a significant risk of a person or persons experiencing harm

• Where previous concerns identified, and corrective action is not maintained

• Where insufficient prevention measures in place such as training, supervision and auditing

APPENDIX 5

Information relating to Management of Controlled Drugs for Care Homes and Community Care (taken from CQC website)

Care homes:
The Misuse of Drugs Act 1971 places controls on certain medicines. We call these 'controlled drugs'.

The Misuse of Drugs Regulations 2001 categorise controlled drugs into 5 schedules. The schedules correspond to the level of therapeutic usefulness and the potential for harm from misuse, with lower schedules having higher risk. The Home Office has produced a list of the most commonly prescribed controlled drugs.

Schedule 2 Drugs
These must be stored in a controlled drugs cupboard. Records of these drugs must be kept in your organisations controlled drugs register. Examples include:

- morphine
- diamorphine
- methadone
- fentanyl
- alfentanil
- oxycodone
- methylphenidate
- dexamphetamine
- ketamine
- tapentadol.

Some organisations may choose to store other schedule controlled drugs in the controlled drugs cupboard and record them in the controlled drugs register. Staff should always follow their organisations medicines policy.

Schedule 3 Drugs
These do not need to be recorded in the controlled drugs register. However, certain Schedule 3 drugs must be stored in the controlled drugs cupboard. This includes, for example, buprenorphine and temazepam.

Some other Schedule 3 drugs do not need to be stored in the controlled drugs cupboard. Examples include:

- midazolam
- pregabalin
- gabapentin
- tramadol
- barbiturates (phenobarbitone).

Other schedules
You do not need to store controlled drugs in Schedules 4 and 5 in the controlled drugs cupboard or record them in the controlled drugs register. However, they must be stored

securely. Accurate records of their receipt, administration and disposal must be kept to minimise the opportunity for diversion. Examples include:

- morphine sulfate solution (Oramorph®) 10mg/5mL
- zopiclone
- codeine
- benzodiazepines.

Care homes must have a policy or standard operating procedure that details how controlled drugs in that organisation. This should cover:

- ordering
- storing
- administering
- recording
- disposal.

It should include what to do if there's a discrepancy and the contact details of anyone who you need to inform. This should include the regional NHS controlled drugs accountable officer (CDAO) at NHS England or the police, depending on the circumstances. Check the contact details for:

- your local NHS England CDAO on our website: Controlled drug accountable officers
- your local police CD liaison officer: Your nearest CDLO
- you need to inform CQC if the incident meets the criteria of a statutory notification.

Community care:

Domiciliary care providers must have a policy or standard operating procedure which details how staff manage medicines. This must include controlled drugs.

Staff should assess what medicines support a person needs as part of their general assessment. This must include support with controlled drugs. Record the outcome of the assessment in their care plan.

Staff responsible for ordering and collecting medicines for a person must be documented in the individuals care plan.

Prescriptions for controlled drugs are valid for 28 days after the date on the prescription.

The Department of Health and Social Care strongly recommends that the maximum quantity of controlled drugs prescribed should not exceed 30 days.

Emergency supplies are not permitted, there must be a valid controlled drug prescription to get supplies from a pharmacy. Staff must make sure ordering processes are robust enough so that people do not run out of these medicines.

Staff collecting controlled drugs from a pharmacy may be asked to provide personal identification.

A risk assessment should be completed if staff are transporting controlled drugs. This should also consider what happens if staff are not going straight from the supplying pharmacy to the person's home. For example, if there are other support calls to make in between.

Storing controlled drugs

The controlled drugs belong to the person and are being stored in their own home. Unless the risk assessment highlights a need, there is no legal requirement for these medicines to be treated differently or stored separately from other medicines. The storage should be risk assessed in line with NICE guidance NG67. There is no requirement to keep a controlled drug cupboard or register in a person's own home.

Keeping records

Staff administering medicines including controlled drugs must be trained and assessed as competent to do so. There is no legal requirement for a second member of staff to witness and sign for the administration or support of controlled drugs in a person's own home.

Care providers should have policies and procedures that include information on record keeping for their staff to follow. Keep detailed records when administering topical controlled drugs, for example, patches. These should include the site of application and the frequency of rotation of the site.