Controlled drugs: safe use and management

NICE guideline: short version

Draft for consultation, October 2015

This guideline covers the systems and processes needed for the safe use and management of controlled drugs used for treating people. The key areas include: prescribing, obtaining and supplying, administering, handling, recording and monitoring use. Recording information about controlled drugs will also be addressed in the guideline where relevant.

Who is it for?

This guideline is for:

- Health professionals providing care for people who need controlled drugs as part of their treatment (for example, GPs, pharmacists and nurses).
- Social care practitioners providing care for people receiving social care (for example, home care workers, personal assistants and social workers).
- Commissioners of services where controlled drugs are used (for example, local authorities and clinical commissioning groups).
- Providers of services where controlled drugs are used (for example, substance misuse services, ambulance services, home care providers, community pharmacies, community health providers, GPs and other independent prescribers, dispensing doctors, voluntary agencies and charities).

The guideline may also be relevant for:

- People using services and their families or carers and the public.
- Individual people and organisations delivering non-publicly funded services.
- Health and social care regulators.

- Secure environments.
- Police.
- Armed forces.
- Some voluntary services using controlled drugs.

It is anticipated that health and social care providers and commissioners of services will need to work together to ensure that people having treatment with controlled drugs benefit from the recommendations in this guideline.

This version of the guideline contains the recommendations, context and recommendations for research. The Guideline Committee's discussion and the evidence reviews are in the full guideline.

Other information about how the guideline was developed is on the project page. This includes the scope, and details of the Committee and any declarations of interest.

1

Contents

Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in Your care.

Making decisions using NICE guidelines explains how we use words to show the strength of our recommendations, and has information about safeguarding, consent and prescribing medicines (including 'off-label' use).

These recommendations were developed using UK controlled drugs legislation and regulations, as amended and updated up until the end of 2015. Organisations and health and social care practitioners should refer to the most recent legislation and regulations (see the government's legislation website). Throughout the guideline, the Misuse of Drugs Regulations 2001 will be referred to as "the 2001 Regulations", and the Controlled Drugs (Supervision of Management and Use) Regulations 2013 will be referred to as "the 2013 Regulations".

Prescribing controlled drugs

Recommendations for organisations

1.1.1 Develop processes that support prescribers who have been assessed as competent to prescribe controlled drugs. Processes should not place unnecessary barriers on prescribers.

Recommendations for prescribers

1.1.2 When making decisions about prescribing controlled drugs take into account:

- the benefits and risks of prescribing (for example, the risks of diversion in the person's home, overdose and access to the controlled drug by other people)
- any other medicines the person is taking (including any other centrally acting medicine prescribed) and whether the person may be opioid naive

- evidence-based sources for prescribing decisions when possible.

1.1.3 When prescribing controlled drugs:

- document clearly the indication for the controlled drug in the person's care record
- if appropriate, titrate the dose (up or down) until a good balance is achieved between clinical effect and side effects
- take into account the person's ongoing clinical needs and whether dose reduction may be needed
- discuss with the person the arrangements for reviewing and monitoring treatment for clinical and adverse effects.

1.1.4 Document and give clear instructions to the person taking or administering the drug, including:

- how long the person is expected to use the drug
- how long it will take to work
- what it has been prescribed for
- how to use controlled drugs prescribed in both sustained-release and immediate-release formulations.

1.1.5 When prescribing 'when required' controlled drugs:

- Document clear instructions for when and how to take or use the drug in the person's care record.
- Include dosage instructions on the prescription (including the maximum daily amount and how long the controlled drug should be used for) so that this can be included on the label when dispensed.
- Take into account any existing supplies the person has of 'when required' controlled drugs.

1.1.6 Prescribe enough of a controlled drug to meet the person's clinical needs for no more than 30 days. If, under exceptional circumstances, a larger quantity is prescribed, the reasons for this should be documented in the person's care record.

1.1.7 Inform people who are starting controlled drugs that they or their representative may need to show identification when they collect the controlled drugs.

1.1.8 When prescribing, reviewing or changing controlled drug prescriptions, prescribers should follow local (where available) or national guidelines and take into account the:

- appropriate route
- dose (including when dose conversions or dose equivalence is needed)
- formulation (including changes to formulations).

If guidance on prescribing is not followed, document the reasons why in the person's care record.

1.1.9 Use a locally agreed opioid dose conversion table when prescribing, reviewing or changing opioid prescriptions to ensure that the total opioid load is considered.

1.1.10 When prescribing a repeat prescription of a controlled drug for treating a long-term condition, take into account the controlled drug and the person's individual circumstances to determine the frequency of review for further repeat prescriptions.

1.1.11 When prescribing controlled drugs, advise people how to safely dispose of:

- unwanted controlled drugs at a community pharmacy
- used controlled drugs.

1.1.12 When prescribing controlled drugs outside of general practice, inform the person's GP of all prescribing decisions in line with the following 5 rules[1] :

- Confidential information about service users or patients should be treated confidentially and respectfully.
- Members of a care team should share confidential information when it is needed for the safe and effective care of an individual.
- Information that is shared for the benefit of the community should be anonymised.
- An individual's right to object to the sharing of confidential information about them should be respected.
- Organisations should put policies, procedures and systems in place to ensure the confidentiality rules are followed.

Record this information in the person's care record and use it to inform prescribing decisions.

1.1.13 Follow local processes for reviewing anticipatory prescribing of controlled drugs. Determine the type of review needed on a case-by-case basis, including the ongoing clinical need and the expiry dates of any controlled drugs already stored by the person.

1.1.14 When prescribing controlled drugs (for example, on a medicines or inpatient record) that are to be administered by different routes, prescribe each as a separate item.

Obtaining and supplying controlled drugs

Recommendations for organisations

1.1.15 When obtaining stocks of controlled drugs in Schedule 2 and 3 from an external pharmacy, a requisition signed by a doctor or dentist employed or engaged in that organisation should be provided.

[1] A guide to confidentiality in health and social care (2013) Health and Social Care Information Centre.

1.1.16 Requisitions of supplied controlled drugs should be kept by organisations for 2 years from the date on the requisition in line with Regulation 23 of the 2001 Regulations.

1.1.17 Controlled drugs registers must be kept for 2 years from the date of the last entry, in line with Regulation 23 of the 2001 Regulations.

1.1.18 Incorporate national medicines safety guidance about controlled drugs, such as patient safety alerts, into standard operating procedures for controlled drugs.

1.1.19 Consider using a locally determined standard requisition form across the whole of an organisation when a mandatory form is not legally required for obtaining controlled drugs in Schedule 2 and 3 for use as stock. Include on the form:

- the signature and printed name of the person ordering the controlled drug
- the name of the care setting
- the ward or department
- the controlled drug name, form, strength, and for ampoules, the size if more than one is available
- the total quantity of the controlled drug to be supplied
- the date of the request
- the signature of the person issuing the controlled drug from the pharmacy.

1.1.20 Hospital and prison pharmacies that are unable to supply the total quantity of a controlled drug requested by requisition should ensure that the recipient is aware that:

- a part supply has been made and no further supplies will be made for that requisition
- the quantity on the requisition has been amended to the amount actually supplied and is initialled or signed by the supplier.

1.1.21 Unless legislation specifies otherwise, consider keeping:

- records of the destruction of a patient's own controlled drugs for a minimum of 7 years
- invoices for controlled drugs for 6 years.

Recommendations for health professionals

1.1.22 When obtaining controlled drugs for use in the community, health professionals must use a mandatory form for the requisitioning of controlled drugs in Schedule 2 and 3, in line with Regulation 14 of the 2001 Regulations and the Misuse of Drugs (Amendment) (No. 2) (England, Wales and Scotland) Regulations 2015**.[Note this does not come into effect until 30th November 2015]**

1.1.23 Pharmacists or dispensing doctors who are unable to supply the total quantity, requested by prescription, of a controlled drug in Schedule 2 must make an entry in the controlled drugs register only for the quantity of the controlled drug supplied, in line with Regulation 19 of the 2001 Regulations. They must then make a further entry in the register when the balance is supplied.

1.1.24 When dispensing more than one formulation (for example immediate-release and sustained-release formulations) of a controlled drug, discuss the differences between the formulations of the controlled drug with the person, and their family members or carers if appropriate, and check that they understand what the different formulations are for and when to take them.

1.1.25 When dispensing controlled drugs in Schedule 2 in advance of collection, only document the supply in the controlled drug register once they are collected by the person or their representative.

1.1.26 When supplying controlled drugs, advise people how to safely dispose of:

- unwanted controlled drugs at a community pharmacy

- used controlled drugs.

1.1.27 When the total quantity of a controlled drug cannot be supplied, inform the person receiving the drug, tell them when the rest will be available and ask them to collect it within 28 days of the prescription date.

1.1.28 When supplying controlled drugs to a person or their representative, take reasonable steps to check their identity and use professional judgement to address any concerns about them.

Administering controlled drugs

Recommendations for organisations

1.1.29 Carry out a risk assessment to find out if standard operating procedures for administering controlled drugs should include additional safety measures, such as contacting other health professionals by telephone or email, or arranging for another health professional to carry out a second check for:

- dose calculations
- the dose and route to be administered
- assessing the skills and competence of health and social care practitioners administering controlled drugs.

Recommendations for health professionals

1.1.30 Follow the relevant standards set by the professional regulator when administering controlled drugs to a person, and when necessary check:

- with the prescriber if you are concerned about whether the prescribed dose is safe for the person
- whether other formulations have already been prescribed for the person
- whether the formulation is appropriate
- that any past doses prescribed have been taken.

1.1.31 Tell the person having the controlled drug the name and dose of the drug before it is administered, unless the circumstances prevent this.

1.1.32 Record the following in the person's care record after administering controlled drugs:

- name of the person having the dose administered
- date and time of the dose
- name, formulation and strength of the controlled drug administered
- dose of the controlled drug administered
- name and signature or initials of the person who administered the dose
- name and signature or initials of any witness to administration.

1.1.33 Record the administration of the controlled drug and ensure the record is kept with the person to ensure continuity of care and to prevent:

- doses being missed or duplicated
- treatment being delayed.

1.1.34 Provide advice on how different formulations of controlled drugs are administered and check that the person understands the advice. Ensure that appropriate equipment is available for the correct dose to be administered.

1.1.35 Complete relevant training and assessment to confirm competence in setting up devices for continuous administration of controlled drugs. Seek specialist advice if needed.

1.1.36 When prescribing controlled drugs, involve the person's GP and any lead health professionals for other care teams in decisions about whether to use a device for continuous administration and record the decision in the patient's notes. If prescribing outside of

normal working hours tell the GP about the decision the next working day.

Handling controlled drugs

Recommendations for organisations

1.1.37 Develop a controlled drugs policy and standard operating procedures for storing, transporting, destroying and disposing of controlled drugs.

1.1.38 Carry out a risk assessment to determine if controlled drugs in Schedule 3, 4 and 5 should be handled in the same way as controlled drugs in Schedule 2. The risk assessment may include:

- frequency of use
- storage facilities needed
- whether the security setting is low, medium or high risk
- quantities of controlled drugs expected to be used
- checking for discrepancies in stock balances at shift handover
- frequency of staff turnover
- accessibility for use by staff.

1.1.39 A separate controlled drugs register must be kept for each premise of an organisation where controlled drugs in Schedule 2 are stored, in line with Regulation 20 of the 2001 Regulations.

1.1.40 When developing standard operating procedures for storing controlled drugs, ensure that they meet the needs of their service and take into account:

- whether the security setting is low, medium or high risk
- staff access to controlled drugs
- the storage environment, including temperature and space in the controlled drugs cabinet
- storage of stock and patients' own controlled drugs

- any additional storage needs for controlled drugs with similar or 'lookalike' packaging and different strengths
- the setting for use.

1.1.41 Consider developing standard operating procedures for risk assessing the use of controlled drugs in organisations where patients' own controlled drugs may be used and handled. The risk assessment may include:

- self-administration or self-possession
- storage requirements
- record keeping
- disposal.

1.1.42 Consider developing a standard operating procedure for carrying out stock checks of all controlled drugs entered into the controlled drugs register. The procedure should include:

- checking the balance in the controlled drugs register against current stock
- measurements of liquid balances and checks of remaining liquid stock when finishing a bottle
- the frequency of stock checks, which should be determined using a risk assessment and should be at least once a week
- recording stock checks in the controlled drugs register along with the date and signature of the health professional carrying out the check.

1.1.43 When developing standard operating procedures for transporting controlled drugs, take into account:

- storage while in transit
- security (for example, use of locked doctor's bags and ambulances)
- record keeping, such as the movement of controlled drugs supplied for use at different locations

- the supply process.

1.1.44 Do not routinely use couriers, taxis or equivalent services to transport controlled drugs or prescriptions for controlled drugs. If there are exceptional circumstances of urgent clinical need, use a delivery service that needs a signature on delivery to ensure that there is an audit trail.

1.1.45 Arrangements for destroying and disposing of controlled drugs must be in place and in line with the 2001 Regulations and the Controlled Waste (England and Wales) Regulations 2012, regardless of the source of supply.

1.1.46 When developing standard operating procedures for disposing of controlled drugs, including unwanted or expired stock and drugs returned by people, take into account:

- the place of destruction
- local agreement and records of authorised people to witness the destruction of controlled drugs.

1.1.47 Arrangements for witnessing the disposal of stock controlled drugs in Schedule 2, 3 and 4 must be in place and in line with Regulation 27 of the 2001 Regulations.

1.1.48 In organisations with internal pharmacies, use a risk assessment (see the Management of Health and Safety at Work Regulations 1999) to determine locally the most appropriate place for destroying controlled drugs. This should consider how close the place of destruction should be to where the drugs are used to help minimise risks of controlled drug-related and patient safety incidents.

1.1.49 Consider developing standard operating procedures based on local arrangements for destroying and disposing of controlled drugs that belonged to a person who has died.

1.1.50 Non-healthcare settings, such as schools, should have systems and processes in place for storing, recording and transporting controlled drugs that belong to a person who is under their supervision.

Recommendations for organisations and health professionals

1.1.51 Consider keeping records to provide an audit trail for the supply, administration and disposal of controlled drugs and the movement of them from one location to another.

Recommendations for health professionals

1.1.52 When supplying dispensed controlled drugs to a person in police custody, check whether the custody staff have adequate arrangements and handling facilities for controlled drugs.

1.1.53 Provide advice and information to people who are prescribed controlled drugs about how to store controlled drugs safely. Discuss storage options taking into account:

- the person's preference for a lockable or non-lockable storage box
- whether they are accessible to people who should and should not have access to them.

1.1.54 Assess if a person's method of storing their controlled drugs in their home could lead to an increased risk of controlled drug-related incidents, including patient safety incidents.

1.1.55 For controlled drugs that are left over after administration, record in the controlled drugs register:

- the amount of controlled drug administered
- the amount of controlled drug to be disposed of after administration
- the signatures of the person disposing of the remaining controlled drug and any witness to the disposal.

1.1.56 When a person has died in their home and controlled drugs need to be removed for destruction and disposal, consider:

- discussing the removal of controlled drugs with a family member or carer
- recording the action taken and details of the controlled drugs listed in the person's medical record or notes
- having a witness to the removal
- any requirements of the coroner to keep medicines in the person's home for a period of time
- taking the drugs to a health professional such as a community pharmacist who is legally allowed to possess controlled drugs.

1.1.57 When destroying and disposing of stock controlled drugs in Schedule 2, 3 and 4 (part I), health professionals must record the following, in line with Regulation 27 of the 2001 Regulations:

- the name, strength and form of the controlled drug
- the quantity
- the date of destruction
- the signatures of the person destroying the controlled drugs and the authorised person witnessing the destruction.

1.1.58 Consider asking a second member of staff (preferably a registered health professional) to witness the destruction and disposal of a patient's returned controlled drugs.

1.1.59 Consider recording the destruction and disposal of controlled drugs that have been returned by people in a separate book for this purpose, and record:

- the date of receipt of the controlled drugs
- the date of destruction
- the signatures of the person destroying the controlled drugs and a witness.

1.1.60 When disposing of bottles of liquid controlled drugs containing irretrievable amounts:

- consider rinsing the bottle and disposing of the liquid into a pharmaceutical waste bin
- remove labels and other identifiers from the container
- dispose of the clean, empty container into the recycling waste.

Disposal of irretrievable amounts of controlled drugs does not need to be recorded.

Monitoring controlled drugs

Recommendations for organisations

1.1.61 Designated bodies must put in place the minimum standard operating procedures for processes relating to prescribing, supplying and administering controlled drugs, including clinical monitoring for people who have been prescribed controlled drugs, as specified in Regulation 11 of the 2013 Regulations.

1.1.62 Designated bodies must appoint a controlled drugs accountable officer, who will quality assure processes for managing controlled drugs in their organisation, in line with Regulation 8 of the 2013 Regulations.

1.1.63 Organisations that are not required by legislation to appoint a controlled drugs accountable officer should consider appointing a nominated person. The nominated person should:

- work in accordance with appropriate governance arrangements for the safe use and management of controlled drugs
- make sure processes are in place for safe management and use of controlled drugs and the reporting and investigating of concerns
- liaise with the local lead controlled drugs accountable officer and local intelligence network members.

1.1.64 Establish processes for developing, reviewing, updating, sharing and complying with controlled drugs-related standard operating procedures, in line with legislation and national guidance. A risk assessment may be used when establishing processes.

1.1.65 Commissioners of healthcare services should include governance arrangements with clear lines of responsibility and accountability for controlled drugs in their contracts with provider organisations.

1.1.66 When multiple systems are used for reporting controlled drug-related incidents (for example, local and national systems and occurrence reporting), consider developing a local process that coordinates these systems within the organisation. This may include:

- reviewing arrangements regularly to reflect local and national learning
- carrying out risk assessments of incidents
- sharing learning.

1.1.67 Consider including in local processes how to inform the controlled drugs accountable officer or nominated person of controlled drug-related concerns or incidents in a timely way, ideally within 48 hours.

1.1.68 Consider developing standard operating procedures for audits of controlled drugs registers and cabinets that include, but are not limited to:

- identifying the person responsible for auditing
- the frequency of audits
- reporting and managing discrepancies between stocks and records.

1.1.69 Consider putting processes in place to access prescribing data for all controlled drugs to identify:

- prescribing trends and potential risks of unintended use
- the reasons for very high, increasing or very low volume prescribing.

Recommendations for lead controlled drug accountable officers, controlled drugs accountable officers and nominated persons

1.1.70 Controlled drugs accountable officers must ensure that robust systems are in place for raising and reporting concerns or incidents about controlled drugs in a timely way (including those for starting investigations) in line with Regulations 11 and 13 of the 2013 Regulations.

1.1.71 Lead controlled drugs accountable officers with a responsibility for governance and safety in the use of controlled drugs should:

- include other relevant local organisations, such as substance misuse, palliative care and out-of-hours services, in local intelligence networks
- work with local intelligence networks in other areas when needed
- notify the Care Quality Commission of poor engagement by those legally required to attend local intelligence network meetings.

1.1.72 Lead controlled drugs accountable officers with a responsibility for governance and safety in the use of controlled drugs should consider:

- identifying barriers to reporting
- identifying trends in incidents reported
- providing feedback of actions from controlled drugs-related incidents, including patient safety incidents, and from occurrence reports to controlled drugs accountable officers

- sharing learning with their controlled drugs accountable officers, including trends or significant incidents, to support continuing professional development
- reporting organisations that submit occurrence reports infrequently or with insufficient detail to the Care Quality Commission.

1.1.73 An organisation's controlled drugs accountable officer or nominated person should review controlled drug-related concerns or incidents and take any action needed on a case-by-case basis.

Terms used in this guideline

Authorised person

Regulation 27 of the 2001 Regulations requires that controlled drugs that are held as stock by health professionals or organisations must only be destroyed in the presence of an authorised witness. The Act designates certain people as authorised witnesses. This includes any police constable and inspectors of the General Pharmaceutical Council.

The lead controlled drugs accountable officer of NHS England may also appoint people as authorised witnesses.

Continuous administration devices

Controlled automatic device for administering medicines, including controlled drugs, at a set rate of dose per time. An example of this is a syringe pump.

Controlled drugs

For the purpose of this guideline, the term 'controlled drugs' refers to controlled drugs in Schedule 2, 3, 4 and 5 of the 2001 Regulations.

Controlled drugs accountable officer

A 'fit, proper and suitably experienced person' who is appointed to ensure that systems for the safe management and use of controlled drugs are secure within their own organisation or in those they have a contract with.

Designated body

Designated bodies in England are NHS foundation trusts, NHS trusts, English independent hospitals, the NHS Commissioning Board[2] and the headquarters in England of regular or reserve forces.

See Regulation 7 of the 2013 Regulations for more information.

Diversion

Removal of controlled drugs for unauthorised use.

Doctor's bag

A lockable bag containing medicines and medical equipment, occasionally including controlled drugs that doctors use when outside, and sometimes inside, their surgeries.

External pharmacy

A pharmacy that is not part of the organisation that it supplies medicines to. For example a retail pharmacy supplying medicines to a hospital.

Health and social care practitioners

The term 'health and social care practitioners' is used to define the wider care team, including but not limited to, home care workers, personal assistants, case managers, care coordinators, social workers, GPs, pharmacists and nurses.

Internal (or inpatient) pharmacy

A pharmacy that is part of the organisation it supplies medicines to for example a hospital pharmacy or prison pharmacy that belongs to the organisation providing a service.

[2] The NHS Commissioning Board was established in legislation in the Health and Social Care Act 2012 but is now known as NHS England.

Irretrievable amounts

An immeasurable or residual amount of liquid remaining after use.

Medicines or inpatient record

A record of all the medicines the person is taking when in an inpatient setting. Each medicine has to be signed by a prescriber. The record forms the authority to administer the medicine.

Lead controlled drugs accountable officer

Regulation 8 of the 2013 Regulations, places a requirement on NHS England to nominate or appoint a fit, proper and suitably experienced person to be NHS England's lead controlled drugs accountable officer in respect of each of its local intelligent network (LIN) areas. A lead controlled drugs accountable officer can be responsible for one or more LIN areas.

Nominated person

A person who is not involved in the day-to-day handling of controlled drugs who has been appointed to oversee the management and governance of activities related to controlled drugs.

Opioid naive

When a person has a low tolerance to doses of opioid medicines.

Organisations

The term 'organisations' is used to include all commissioners and providers, unless specified otherwise in the text.

Part supplies of controlled drugs

An incomplete supply of a requested quantity of controlled drug. An example of a part supply would be when a pharmacy does not have the full quantity of the medicine to provide the quantity requested.

Repeat prescription

Prescription for a regular medicine on a repeat basis without the need for consultation with a prescriber.

Responsible body

Responsible bodies in England are regulatory bodies that include: designated bodies, clinical commissioning groups, NHS Protect, the Prescription Pricing Division of the NHS Business Services Authority, the Care Quality Commission, local authorities, and police forces.

See Regulation 6 of the 2013 Regulations for more information.

Standard operating procedure

A standard operating procedure specifies in writing what should be done, when, where and by whom in order to manage safely and accountably any set of processes. For example the management of controlled drugs.

Stock (controlled drug)

The term ‘stock’ refers to controlled drugs that have not been issued or dispensed to a patient but is for use by the healthcare provider for administration or supply.

Total opioid load

The total dose of opioid (often converted to morphine equivalent daily for comparison) that is taken in a 24-hour period.

When required

Medicines that are taken when they are needed to manage a symptom, for example a pain killer for short term pain.

Context

Controlled drugs are defined and governed by the Misuse of Drugs Act 1971 ("the Act") and associated regulations. Controlled drugs are managed and used in a variety of settings by health and social care practitioners and by people who are prescribed them to manage their condition(s). Controlled drugs are closely regulated because they are susceptible to being misused and can cause harm. To ensure that they are managed and used safely, legal frameworks for governing their use have been established.

Since the Shipman Inquiry's Fourth Report in 2004, the government has introduced significant legislative changes to the Act to strengthen the governance arrangements for controlled drugs. Arrangements have been established to encourage good practice in the management of controlled drugs, as well as helping to detect unusual or poor clinical practice, criminal activity or risk to patients. Organisations have variable systems and processes in place for obtaining, storing, supplying, recording, monitoring, disposing of and destroying controlled drugs. It is important that these systems and processes allow controlled drugs to be managed and used safely, while helping to ensure appropriate and convenient access for those people who need treatment with controlled drugs.

A lot of work has been done to help ensure that controlled drugs are managed and used safely at a local and national level. However, ongoing activity and vigilance is needed to sustain the positive developments that have been achieved since the change in the NHS structure. The guideline considers the following: changes to legislation and NHS structure; national polices; controlled drug-related patient safety incidents; and evidence for effective interventions, to provide further clarity and good practice recommendations for the safe use and management of controlled drugs across all NHS settings. The guideline supports organisations and health and social care practitioners to minimise harms associated with the use and management of controlled drugs by having robust systems and processes in place. The guideline aims to bring together legislation, policy advice, good practice advice and published evidence, along with committee experience and opinion in developing the recommendations.

The guideline is for all health and social care practitioners, organisations and commissioners (for example clinical commissioning groups or local authorities) providing or supporting the provision of NHS and other publicly funded services using controlled drugs. It is also relevant for adults, young people and children (including neonates) using or taking controlled drugs, and their families and carers. Managing and using controlled drugs in care homes

is not included in the guideline because this is covered the NICE guideline on managing medicines in care homes.

Systems and processes related to controlled drugs

The guideline looks at systems and processes that involve the use and management of controlled drugs in Schedule 2, 3, 4 and 5 of the 2001 Regulations in the following areas:

- prescribing
- administering
- obtaining and supplying
- handling
- monitoring.

Prescribing

When prescribing controlled drugs, there are many considerations that need to be taken into account, such as prescription writing requirements for controlled drugs in Schedule 2 and 3, clinical need and the person's values and preferences. Regulation 15 of the 2001 Regulations specifies requirements for writing prescriptions for controlled drugs. In addition to working within the legal framework, prescribers need to use their clinical and professional judgment when prescribing controlled drugs to people.

Obtaining and supplying

Regulation 14 of the 2001 Regulations sets out requirements for writing requisitions for controlled drugs in Schedule 2 and 3. Standard operating procedures need take into account the legal framework when obtaining and supplying controlled drugs.

Administration

Regulation 7 of the 2001 Regulations specifies who can administer controlled drugs in Schedule 2, 3, 4 and 5.

Handling

There are a number of regulations that apply to the handling of controlled drugs, including the Misuse of Drugs (Safe Custody) Regulations 1973, and the 2001 Regulations. Controlled drugs in Schedule 2 and 3 have additional restrictions placed on them and they are handled to allow their use to be monitored.

Monitoring

Monitoring of controlled drugs includes analysing, identifying and reporting incidents, recording harms, sharing information, sharing learning, addressing concerns and feedback. The aim of the 2013 Regulations is to strengthen the governance arrangements for the use and management of controlled drugs in different care settings.