

# Controlled drugs: safe use and management

NICE guideline

Published: 12 April 2016

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# Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should [assess and reduce the environmental impact of implementing NICE recommendations](#) wherever possible.

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# Overview

This guideline covers systems and processes for using and managing controlled drugs safely in all NHS settings except care homes. It aims to improve working practices to comply with legislation and have robust governance arrangements. It also aims to reduce the safety risks associated with controlled drugs.

## Who is it for?

- Health professionals providing care for people being treated with controlled drugs, for example, GPs, pharmacists and nurses
- Social care practitioners, for example, home care workers, personal assistants and social workers
- Commissioners of services using controlled drugs, 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
- People being treated with controlled drugs, their families or carers, and the public

# Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in [NICE's information on making decisions about your care](#).

[Making decisions using NICE guidelines](#) explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

These recommendations were developed using UK controlled drugs legislation and regulations, as amended and updated up to 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](#)).

## 1.1 Developing and establishing systems and processes for organisations

The recommendations in this section are for all organisations unless otherwise stated.

### Governance arrangements and accountability

- 1.1.1 Organisations should agree governance arrangements with clear lines of responsibility and accountability for controlled drugs in their contracts.
- 1.1.2 [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 Controlled Drugs \(Supervision of Management and Use\) Regulations 2013](#).
- 1.1.3 Consider appointing a [nominated person](#) in organisations that are not required by legislation to appoint a controlled drugs accountable officer, to:

- work in accordance with governance arrangements for the safe use and management of controlled drugs
- make sure processes are in place for safe use and management of controlled drugs, and the reporting and investigating of concerns
- liaise with the local [NHS England lead controlled drugs accountable officer](#) and [local intelligence network](#) members.

## Policies, processes and procedures

- 1.1.4 Develop a controlled drugs policy and [standard operating procedures](#) for storing, transporting, destroying and disposing of controlled drugs.
- 1.1.5 Establish processes for developing, reviewing, updating, sharing and complying with controlled drugs-related standard operating procedures, in line with legislation and national guidance. Consider using a risk assessment when establishing processes.
- 1.1.6 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, in line with [Regulation 11 of the Controlled Drugs \(Supervision of Management and Use\) Regulations 2013](#).
- 1.1.7 Ensure that national medicines safety guidance about controlled drugs, such as patient safety alerts, are incorporated into policy and acted on within a specified or locally agreed timeframe.
- 1.1.8 Consider developing standard operating procedures for risk assessing the use of controlled drugs in organisations providing inpatient care, 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.
- 1.1.9 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 the organisation's supervision.
- 1.1.10 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.

## Processes and procedures for storage, stock checks and audits

- 1.1.11 When developing standard operating procedures for storing controlled drugs, ensure that they are in line with the Misuse of Drugs (Safe Custody) Regulations 1973, meet the needs of the service and take into account:
- the setting for use and 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 (including unwanted or expired stock) and patients' own controlled drugs
  - any additional storage needs for controlled drugs of different strengths with similar or 'lookalike' packaging.
- 1.1.12 Ensure that a standard operating procedure is in place for 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
- visual inspection of liquid balances, periodic volume checks and checks to confirm the balance on completion of a bottle
- the frequency of stock checks, which should be based on the frequency of use and controlled drug-related incidents, and risk assessment; for most organisations stock checks should be at least once a week, but they may be carried out more or less often depending on the circumstances
- recording stock checks along with the date and signature of the health professional carrying out the check
- having 2 people present to carry out stock checks, if possible.

1.1.13 Develop 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.

## Processes and procedures for transportation

1.1.14 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.

1.1.15 Ensure that governance arrangements and processes are in place for the safe



transport of controlled drugs or prescriptions for controlled drugs if couriers, taxis or equivalent services are used.

## Processes and procedures for destruction and disposal

- 1.1.16 Arrangements for destroying and disposing of controlled drugs must be in place and in line with the [Misuse of Drugs Regulations 2001](#) and the [Controlled Waste \(England and Wales\) Regulations 2012](#), regardless of the source of supply.
- 1.1.17 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.
- 1.1.18 Consider developing standard operating procedures in primary care organisations based on local arrangements for destroying and disposing of controlled drugs that belonged to a person who has died.

## Policies and processes for prescribing

- 1.1.19 Ensure that prescribing policies support prescribers and do not create barriers that prevent health professionals who are competent to prescribe controlled drugs from prescribing.

# 1.2 Record keeping for organisations

## Controlled drugs registers

- 1.2.1 A separate controlled drugs register must be kept for each of the premises of an organisation where controlled drugs in Schedule 2 are stored, in line with

Regulation 20 of the Misuse of Drugs Regulations 2001.

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

## Requisitions, records of destruction and invoices

- 1.2.3 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 Misuse of Drugs Regulations 2001.
- 1.2.4 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.

## Using a locally determined standard requisition form

- 1.2.5 In organisations with an internal pharmacy, consider using a locally determined standard requisition form across the whole of an organisation when a mandatory form is not legally required for obtaining stock controlled drugs in Schedule 2 and 3. Include on the form:
- the signature and printed name of the person ordering the controlled drug
  - the name of the care setting
  - the ward, department or location
  - the controlled drug name, form, strength, and for ampoules, the size if more than 1 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.

## 1.3 Risk assessment for organisations

1.3.1 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 and quantities of controlled drugs used
- storage facilities available
- whether the security setting is low, medium or high risk
- checking for discrepancies in stock balances at shift handover
- frequency of staff turnover
- staff access to controlled drugs
- any data from relevant reported incidents.

1.3.2 Ensure that standard operating procedures for administering controlled drugs include sufficient safety measures to minimise the risk of administration errors. Safety measures may include:

- asking for advice from other health professionals (this could be by telephone or email)
- arranging for another health professional to carry out a second check of dose calculations and route for administration.

1.3.3 In organisations with an internal pharmacy or dispensing doctors, use a risk assessment (see Regulation 3 of the Management of Health and Safety at Work Regulations 1999) to determine locally the most appropriate place for destroying controlled drugs. This should take into account how close the place of destruction should be to where the drugs are used to help minimise risks of controlled drug-related incidents.

## 1.4 Processes for reporting controlled drug-related incidents

1.4.1 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.

1.4.2 Include in local processes for reporting controlled drug-related concerns or incidents:

- how to inform the controlled drugs accountable officer or nominated person
- reporting incidents in a timely way, ideally within 48 hours.

## 1.5 Prescribing controlled drugs

The recommendations in this section are for all health professionals prescribing controlled drugs unless otherwise stated.

### Making and recording prescribing decisions

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

- the benefits of controlled drug treatment
- the risks of prescribing, including dependency, overdose and diversion
- all prescribed and non-prescribed medicines the person is taking (particularly any centrally acting agents) and whether the person may be opioid naive
- evidence-based sources, such as NICE and the BNF, for prescribing

decisions when possible.

1.5.2 When prescribing controlled drugs:

- document clearly the indication and regimen for the controlled drug in the person's care record
- check the person's current clinical needs and, if appropriate, adjust the dose until a good balance is achieved between benefits and harms
- discuss with the person the arrangements for reviewing and monitoring treatment
- be prepared to discuss the prescribing decision with other health professionals if further information is requested about the prescription.

1.5.3 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 (with the maximum daily amount or frequency of doses) so that this can be included on the label when dispensed
- ask about and take into account any existing supplies the person has of 'when required' controlled drugs.

1.5.4 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.

- 1.5.5 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.
- 1.5.6 Use a recognised opioid dose conversion guide when prescribing, reviewing or changing opioid prescriptions to ensure that the total opioid load is considered.
- 1.5.7 When prescribing controlled drugs outside general practice (for example, in hospital or out of hours), inform the person's GP of all prescribing decisions and record this information in the person's care record so the GP has access to it. When sharing information, take into account the following 5 rules (from the Health and Social Care Information Centre's guide to confidentiality in health and social care, 2013):
- 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.
- 1.5.8 When prescribing controlled drugs for inpatients (for example, on a medicines or inpatient record) that are to be administered by different routes, prescribe each as a separate item and clearly state when each should be used to avoid administration errors.

## Providing information and advice to people taking or carers administering controlled drugs

- 1.5.9 Document and give information to the person taking the controlled drug or the carer administering it, 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 when sustained-release and immediate-release formulations are prescribed together
  - how it may affect the person's ability to drive (see the advice from the [Department for Transport on drug driving and medicine: advice for healthcare professionals](#))
  - that it is to be used only by the person it is prescribed for.
- 1.5.10 Inform people who are starting controlled drugs that they or their representative may need to show identification when they collect the controlled drugs.
- 1.5.11 When prescribing controlled drugs in primary care for use in the community, advise people how to safely dispose of:
- unwanted controlled drugs at a community pharmacy
  - used controlled drugs.

## Reviewing repeat prescriptions and anticipatory prescribing

- 1.5.12 When prescribing a [repeat prescription](#) of a controlled drug for treating a long-term condition in primary care, take into account the controlled drug and the person's individual circumstances to determine the frequency of review for further repeat prescriptions.
- 1.5.13 Follow locally agreed processes for reviewing anticipatory prescribing of

controlled drugs in primary care and palliative care services. Determine the type of review needed on a case-by-case basis, including the ongoing clinical need and, where practicable, the expiry dates of any controlled drugs already stored by the person.

## 1.6 Obtaining and supplying controlled drugs

The recommendations in this section are for all health professionals supplying controlled drugs unless otherwise stated.

### Standards and safety checks for supplying controlled drugs

- 1.6.1 When supplying prescribed controlled drugs:
- follow relevant standards set by the professional regulator
  - check with the prescriber about any safety concerns, such as whether the prescribed dose is safe for the person.
- 1.6.2 When supplying controlled drugs to a person or their representative, take reasonable steps to confirm their identity before providing the controlled drug.
- 1.6.3 If intending to supply dispensed controlled drugs to a person in police custody, first check whether the custody staff have adequate arrangements and handling facilities for controlled drugs.

### Providing information and advice to people receiving controlled drugs

- 1.6.4 When supplying more than 1 formulation (for example, immediate-release and sustained-release formulations) of a controlled drug, discuss the differences between the formulations 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.



- 1.6.5 When the total quantity of a controlled drug in Schedule 2, 3 or 4 cannot be supplied:
- inform the person receiving the drug that only part of their supply is available
  - tell them when the rest will be available
  - ask them to collect it within 28 days of the date stated on the prescription.
- 1.6.6 When supplying controlled drugs, advise people how to safely dispose of:
- unwanted controlled drugs at a community pharmacy
  - used controlled drugs.

## Recording supplies in the controlled drug register

- 1.6.7 When health professionals in primary care dispense controlled drugs in Schedule 2 in advance of collection, they should document the supply in the controlled drug register only after the drugs are collected by the person or their representative.
- 1.6.8 Pharmacists or dispensing doctors who are unable to supply the total quantity of a prescribed controlled drug in Schedule 2, must make an entry in the controlled drugs register for only the quantity of the controlled drug supplied, in line with [Regulation 19 of the Misuse of Drugs Regulations 2001](#). They must then make a further entry in the register when the balance is supplied.

## Using requisition forms to obtain stock controlled drugs

- 1.6.9 When obtaining controlled drugs for use in the community, health professionals in primary care must use the approved [mandatory form](#) for the requisitioning of controlled drugs in Schedule 2 and 3, in line with [Regulation 14 of the Misuse of Drugs Regulations 2001](#) and the [Misuse of Drugs \(Amendment\) \(No. 2\) \(England, Wales and Scotland\) Regulations 2015](#).
- 1.6.10 When obtaining stocks of controlled drugs in Schedule 2 and 3 from an

organisation's contracted external pharmacy, a requisition signed by a doctor or dentist employed or engaged in the organisation must be provided, in line with Regulation 14 of the Misuse of Drugs Regulations 2001.

## Part supplies of stock controlled drugs

1.6.11 Pharmacists in internal pharmacies (such as hospital and prison pharmacies) who are unable to supply the total quantity of a stock 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.

## 1.7 Administering controlled drugs

The recommendations in this section are for all health professionals administering controlled drugs unless otherwise stated.

### Standards and safety checks for administering controlled drugs

1.7.1 Follow the relevant standards set by the professional regulator when administering controlled drugs, and when necessary check with the prescriber about any safety concerns such as:

- 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.

## Providing information and advice to people having controlled

## drugs administered

- 1.7.2 Tell the person having the controlled drug the name and dose of the drug before it is administered, unless the circumstances prevent this.
- 1.7.3 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.

## Records of administration

- 1.7.4 Ensure records of administration for controlled drugs include the following:
- 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.
- 1.7.5 Ensure the record of administration of a controlled drug for inpatients and people in the community is readily accessible to:
- ensure continuity of care
  - prevent doses being missed or duplicated
  - avoid treatment being delayed.

## Using continuous administration for controlled drugs

- 1.7.6 When prescribing controlled drugs, involve the person's GP and any lead health professionals for other care teams involved in the person's care in decisions

about whether to use a device for continuous administration. Record the decision in the person's care record. If prescribing outside normal working hours, tell the GP about the decision the next working day.

1.7.7 Health professionals who use devices for continuous administration of controlled drugs should:

- complete training in setting up the specific devices used by their service and have their competence confirmed
- seek specialist advice if needed when setting up devices for continuous administration.

## Recording left over controlled drugs in the controlled drug register

1.7.8 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.

## 1.8 Handling controlled drugs

The recommendations in this section are for all health professionals handling controlled drugs unless otherwise stated.

### Records of handling controlled drugs

1.8.1 Keep records to provide an audit trail for the supply, administration and disposal of controlled drugs, and the movement of them from 1 location to another.

## Providing information and advice on storage to people prescribed controlled drugs

- 1.8.2 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 the controlled drugs will be accessible to people who should and should not have access to them
  - whether the storage method could increase the risk of controlled drug-related incidents, including patient safety incidents.

## Witnessing and recording the destruction and disposal of stock controlled drugs

- 1.8.3 Health professionals and service providers who are required by the [Misuse of Drugs Regulations 2001](#) to maintain a controlled drugs register must have an [authorised person](#) present to witness the destruction of [stock](#) controlled drugs in Schedule 2 in line with [Regulation 27 of the Misuse of Drugs Regulations 2001](#).
- 1.8.4 When destroying and disposing of stock controlled drugs in Schedule 2, health professionals:
- must record the following, in line with [Regulation 27 of the Misuse of Drugs Regulations 2001](#):
    - the name, strength and form of the controlled drug
    - the quantity
    - the date of destruction
    - the signature of the authorised person witnessing the destruction
  - should record the signature of the person destroying the controlled drugs.

- 1.8.5 If the legislation does not require a witness to be present when destroying stock controlled drugs in Schedule 3 and 4 (part I), consider having a witness present.
- 1.8.6 If the legislation does not require records to be kept of destruction and disposal of stock controlled drugs in Schedule 3 and 4 (part I), consider recording:
- 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 any witness to the destruction.

## **Witnessing and recording the destruction and disposal of returned controlled drugs**

- 1.8.7 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.
- 1.8.8 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 any witness.

## **Safely destroying and disposing of controlled drugs**

- 1.8.9 For stock controlled drugs, when disposing of bottles containing irretrievable amounts of liquid drugs:
- consider rinsing the bottle and disposing of the liquid into a pharmaceutical

waste bin

- remove or obliterate 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.

1.8.10 When a person has died in their home and controlled drugs need to be removed for destruction and disposal in primary care, 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, for safe disposal at the earliest opportunity.

## 1.9 Monitoring the use of controlled drugs

### Governance and safety in the use of controlled drugs

1.9.1 NHS England lead controlled drugs accountable officers should:

- work with local intelligence networks in other areas when needed
- identify and manage poor engagement
- consider including other relevant local organisations (such as substance misuse, palliative care and out-of-hours services, and secure environments)

in the wider network part of the local intelligence network.

1.9.2 NHS England lead controlled drugs accountable officers should:

- provide feedback (such as actions from controlled drugs related incidents and occurrence reports) to controlled drugs accountable officers
- share learning with their controlled drugs accountable officers, including trends or significant incidents.

## Systems for reporting concerns and incidents

1.9.3 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 systems for starting investigations) in line with Regulation 11 and Regulation 13 of the Controlled Drugs (Supervision of Management and Use) Regulations 2013. This should involve liaising with the following responsible bodies:

- a designated body
- the Care Quality Commission
- NHS Protect
- a police force
- a relevant regulated body.

## Identifying and reporting trends and barriers

1.9.4 NHS England lead controlled drugs accountable officers should consider identifying trends in incidents reported and barriers to reporting.



## Reviewing concerns and incidents and sharing information

1.9.5 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
- share information and learning throughout the organisation from controlled drug local intelligence networks.

## Terms used in this guideline

### Authorised person

Regulation 27 of the Misuse of Drugs Regulations 2001 requires that controlled drugs held as stock by health professionals or organisations must only be destroyed in the presence of an authorised person. 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.

### Care record

A record of the care provided to a person in a health or social care setting. Care records can be written or electronic. They may include notes of clinical decisions; medicines prescribed and administered, or discharge information. The type of care record may vary depending on the arrangements of the care setting. Care records enable health and social care practitioners to have access to essential information about a person's care to help provide safe treatment.

### Continuous administration devices

A 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 accountable officer

A person (defined as fit, proper and suitably experienced) 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.

See [Regulation 8 of the Controlled Drugs \(Supervision of Management and Use\) Regulations 2013](#) for more information.

## Designated body

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

See [Regulation 7 of the Controlled Drugs \(Supervision of Management and Use\) Regulations 2013](#) for more information.

## Diversion

Removal of controlled drugs for unauthorised use.

## External pharmacy

A pharmacy that is not owned by the organisation it supplies medicines to (a different legal entity), for example, a community pharmacy that supplies medicines to a hospital.

## Internal (or inpatient) pharmacy

An onsite pharmacy owned by the organisation it supplies medicines to (within the same legal entity), for example, a hospital or prison pharmacy that supplies medicines within the organisation.

## Local intelligence network

A local intelligence network is drawn from representatives of designated and responsible bodies. It is for the NHS England lead controlled drug accountable officer to determine the number and membership of local intelligence networks appropriate to their area. Local

intelligence network members have certain duties and functions set out in [Regulation 14](#), [Regulation 15](#) and [Regulation 16 of the Controlled Drugs \(Supervision of Management and Use\) Regulations 2013](#). These include a duty to cooperate with other local intelligence network members in identifying cases where action may be appropriate.

## **Mandatory form**

In the context of the [Misuse of Drugs \(Amendment\) \(No. 2\) \(England, Wales and Scotland\) Regulations 2015](#), this is the form approved by the Secretary of State, the Welsh Ministers or the Scottish Ministers, for requisitioning Schedule 2 and 3 controlled drugs.

## **Medicines or inpatient record**

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

## **NHS England lead controlled drugs accountable officer**

[Regulation 8 of the Controlled Drugs \(Supervision of Management and Use\) Regulations 2013](#), 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 for each of its local intelligence network areas. A lead controlled drugs accountable officer can be responsible for 1 or more local intelligence network 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.

## **Part supply**

An incomplete supply of a requested drug, for example, when a pharmacy does not have the full quantity of a medicine requested by prescription.

## 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 Controlled Drugs \(Supervision of Management and Use\) Regulations 2013](#) 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)

Controlled drugs that have not been issued or dispensed to a patient, but are kept by the healthcare provider or health professional for administration or supply.

## Total opioid load

The total dose of opioid (often converted to morphine equivalent daily dose 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.

## **Witness**

A person who witnesses controlled drugs-related activities such as administration or destruction. This can be a registered health professional, for example, a doctor, pharmacist, nurse or pharmacy technician, or another competent health or social care practitioner depending on the setting and local standard operating procedure.

# Putting this guideline into practice

NICE has produced [tools and resources](#) to help you put this guideline into practice.

Putting recommendations into practice can take time. How long may vary from guideline to guideline, and depends on how much change in practice or services is needed.

Implementing change is most effective when aligned with local priorities.

Changes recommended for clinical practice that can be done quickly – like changes in prescribing practice – should be shared quickly. This is because healthcare professionals should use guidelines to guide their work – as is required by professional regulating bodies such as the General Medical and Nursing and Midwifery Councils.

Changes should be implemented as soon as possible, unless there is a good reason for not doing so (for example, if it would be better value for money if a package of recommendations were all implemented at once).

Different organisations may need different approaches to implementation, depending on their size and function. Sometimes individual practitioners may be able to respond to recommendations to improve their practice more quickly than large organisations.

Here are some pointers to help organisations put NICE guidelines into practice:

1. **Raise awareness** through routine communication channels, such as email or newsletters, regular meetings, internal staff briefings and other communications with all relevant partner organisations. Identify things staff can include in their own practice straight away.
2. **Identify a lead** with an interest in the topic to champion the guideline and motivate others to support its use and make service changes, and to find out any significant issues locally.
3. **Carry out a baseline assessment** against the recommendations to find out whether there are gaps in current service provision.
4. **Think about what data you need to measure improvement** and plan how you will collect it. You may want to work with other health and social care organisations and specialist

groups to compare current practice with the recommendations. This may also help identify local issues that will slow or prevent implementation.

**5. Develop an action plan**, with the steps needed to put the guideline into practice, and make sure it is ready as soon as possible. Big, complex changes may take longer to implement, but some may be quick and easy to do. An action plan will help in both cases.

**6. For very big changes** include milestones and a business case, which will set out additional costs, savings and possible areas for disinvestment. A small project group could develop the action plan. The group might include the guideline champion, a senior organisational sponsor, staff involved in the associated services, finance and information professionals.

**7. Implement the action plan** with oversight from the lead and the project group. Big projects may also need project management support.

**8. Review and monitor** how well the guideline is being implemented through the project group. Share progress with those involved in making improvements, as well as relevant boards and local partners.

NICE provides a comprehensive programme of support and resources to maximise uptake and use of evidence and guidance. See our [into practice](#) pages for more information.

Also see Leng G, Moore V, Abraham S, editors (2014) *Achieving high quality care – practical experience from NICE*. Chichester: Wiley.

## 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. 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 have 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. This guideline provides further clarity and good practice recommendations for the safe use and management of controlled drugs across all NHS settings. It supports organisations and health and social care practitioners to minimise harms associated with controlled drugs by having robust systems and processes in place. The recommendations were developed with the aim of bringing together legislation, policy advice, good practice advice and published evidence.

Managing and using controlled drugs in care homes is not included because this is covered the [NICE guideline on managing medicines in care homes](#).

## Legislation for managing and using controlled drugs

This guideline looks at systems and processes for using and managing controlled drugs in Schedule 2, 3, 4 and 5 of the 2001 Misuse of Drugs Regulations. The recommendations



should be read alongside current legislation, in particular the legislation (and subsequent amendments) highlighted below:

- Misuse of Drugs Act 1971
- Misuse of Drugs (Safe Custody) Regulations 1973
- Misuse of Drugs (Supply to Addicts) Regulations 1997
- Misuse of Drugs Regulations 2001
- Human Medicines Regulations 2012
- Controlled Drugs (Supervision of Management and Use) Regulations 2013.

## Finding more information and committee details

To find NICE guidance on related topics, including guidance in development, see the [NICE topic page on medicines management](#).

For full details of the evidence and the guideline committee's discussions, see the [full guideline](#). You can also find information about [how the guideline was developed](#), including details of the [committee](#) (in appendix A).

NICE has produced [tools and resources to help you put this guideline into practice](#). For general help and advice on putting our guidelines into practice, see [resources to help you put NICE guidance into practice](#).

ISBN: 978-1-4731-1785-3

## Accreditation

