

## The Management of Controlled Drugs in Primary Care in Lincolnshire

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# The Prescribing, Supply, Storage and Disposal of Controlled Drugs in Primary Care

## Policy Statement

<b>Background</b>	The purpose of this policy is to provide guidance on all aspects of controlled drug management in primary care services within Lincolnshire Clinical Commissioning Groups. This version of the policy replaces all previous versions issued.
<b>Statement</b>	This policy incorporates all the legislative changes published by the Department of Health up to the end of April 2019. It also recommends areas of good practice to strengthen the governance arrangements for controlled drugs.
<b>Responsibilities</b>	Implementation and compliance with the policy will be the responsibility of all staff.
<b>Training</b>	This policy is a reference document and will be amended when further changes to legislation occur. All managers should ensure that staff work within the current legal and regulatory framework governing controlled drugs.
<b>Dissemination</b>	Lincolnshire Clinical Commissioning Groups Website: <a href="http://www.lincolnshire-pacef.nhs.uk">www.lincolnshire-pacef.nhs.uk</a>
<b>Resource implication</b>	The policy has been developed in line with Department of Health guidelines to enable the appropriate management of controlled drugs in primary care services within Lincolnshire Clinical Commissioning Groups. There are no additional resource implications.

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# The Prescribing, Supply, Storage and Disposal of Controlled Drugs in Primary Care

## 1. Background

1.1 This policy applies to all professionals and premises subject to inspection as part of the revised arrangements for the management and monitoring of Controlled Drugs (CDs). This includes all GP practices both dispensing and non-dispensing handling CDs within Lincolnshire.

1.2 The **Misuse of Drugs Act 1971** controls 'dangerous or otherwise harmful drugs' which are designated as Controlled Drugs. The primary purpose of this legislation is to prevent the misuse of this group of drugs. It does this by imposing a total prohibition on the possession, supply, manufacture, import or export of Controlled Drugs except as allowed by regulations or by license from the Secretary of State.

The medical use of Controlled Drugs is permitted through the **Misuse of Drugs Regulations 2001** and subsequent amendments. These Regulations classify CDs into five different schedules according to different levels of control with Schedule 1 being the most tightly controlled schedule and Schedule 5 the least tightly controlled. The five Schedules are summarised in tables at the end of this section.

1.3 In April 2016, NICE published their Guideline NG46: Controlled drugs: safe use and management.

1.4 On 1<sup>st</sup> April 2019 amendments to the Misuse of Drugs Regulations 2001 and the Safe Custody regulations 1973 came into force which reclassified pregabalin and gabapentin as Schedule 3 Controlled Drugs.

## The Prescribing, Supply, Storage and Disposal of Controlled Drugs in Primary Care

**Table 1: Ordering, Prescribing & Record Keeping Requirements**

	Schedule 2	Schedule 3		Schedule 4 (part 1)	Schedule 4 (part 2)	Schedule 5
Designation	CD POM	CD No Reg POM		CD Benz POM	CD Anab POM	CD Inv POM or CD Inv P
Common Examples	Morphine Diamorphine Oxycodone Ketamine Fentanyl Methylphenidate	Pregabalin Gabapentin Temazepam Buprenorphine Tramadol Midazolam		Diazepam Lorazepam Nitrazepam Zopiclone	Testosterone Clnbuterol	Co-codamol 8/500 (CD Inv P) Co-codamol 30/500 (CD Inv POM)
CD Prescription Requirements	✓	✓		N/A	N/A	N/A
Prescription validity from appropriate date	28 days	28 days		28 days	28 days	6 months
Recommended maximum number of days' treatment	30	30		30	30	
Requisition necessary to obtain supplies	✓	✓		✗	✗	✗
Requisition marked by the supplier	✓	✓		✗	✗	✗
Safe custody requirements with common examples	✓ <i>(except liquid secobarbital preparations)</i>	<b>Safe custody required:</b> Temazepam Buprenorphine Diethylpropion flunitrazepam	<b>Safe custody not required:</b> Pregabalin Gabapentin Tramadol Midazolam	✗	✗	✗
CD Register entries legally required	✓	✗		✗	✗ Except Sativex*	✗
Regular stock checks and records of running balances considered good practice	✓	<b>Good practice</b>		Not necessary		

\*Sativex<sup>®</sup> moved from Schedule 1 to Schedule 4 Part 1 in April 2013.

- Records should be kept for the receipt, supply and destruction of Sativex<sup>®</sup>, and the Home Office strongly recommends these are recorded in a CD register.
- These records should be kept for a minimum of two years.
- Sativex should be stored upright in a fridge with other prescription only medicines between 2-8°C. Once opened, it can be stored upright at room temperature for a maximum of 42 days.

## The Prescribing, Supply, Storage and Disposal of Controlled Drugs in Primary Care

**Table 2: Prescribers & Emergency Supplies**

	Schedule 2	Schedule 3	Schedule 4 (part 1)	Schedule 4 (part 2)	Schedule 5
<b>Designation</b>	<i>CD POM</i>	<i>CD No Reg POM</i>	<i>CD Benz POM</i>	<i>CD Anab POM</i>	<i>CD Inv POM or CD Inv P</i>
<b>Prescriber's address</b>	<i>Must be in the UK</i>	<i>Must be in the UK</i>	<i>Prescribers based in the EEA and Switzerland as well as those in the UK can prescribe these controlled Drugs</i>		
<b>Community pharmacists can provide an emergency supply to a patient</b>	✗	<i>Only phenobarbitone for a epilepsy if it has been prescribed by a UK registered prescriber</i>	✓	✓	✓

## Controlled Drugs (Schedules 2 and 3): Additional Prescription Requirements

### The prescription must:

- be signed by the prescriber issuing it with his/her usual signature (Advanced Electronic Signatures can be accepted for Schedule 2 and 3 CDs where EPS is being used).
- be dated
- be in ink or otherwise so as to be indelible
- if issued by a dentist, have written on it the words 'for dental treatment only'

#### Examples of unacceptable doses

- As directed
- When required
- As per chart
- Weekly

#### Examples of acceptable dosages

- One as directed
- Two when required
- Three ampoules to be given over 24 hours as directed

### And specify:

- the address of the prescriber (see Table 2 for further information)
- the full name and address of the patient for whom the treatment is issued
- the dose to be taken. This should be as specific as possible; the Home Office has stated that 'as directed' or 'when required' is insufficient, although 'one to be taken as directed/ when required' is acceptable
- the form (e.g. tablets, capsules, oral solution) even where the form is implicit in the proprietary name (e.g. MST Continus) or where only one form is available.
- the strength of the preparation where appropriate (e.g. if the medicine is available in more than one strength).
- either the total quantity of the preparation (in both words and figures) or the number of dosage units (in words and figures)
- in the case of a prescription for a total quantity intended to be dispensed in instalments, a direction specifying the amount of the instalments which may be dispensed and the intervals to be observed when dispensing.

*The name of the medicine is also necessary to identify which medicine is being requested.*

***Before dispensing any prescription, but particularly those for controlled drugs the signature should be checked and the prescription not dispensed if there are any concerns about whether it is genuine.***

### Prescribing a dose range for a CD in Palliative Care

If prescribing a dose range, the direction on the prescription and the Gold CD1 Form must always reflect the dose instructions on the medicines box. For example, the prescription should be written – "*Diamorphine 10mg ampoules: 10-20mg to be given as directed in association with a prescribed dose range written on the Gold Form (CD1)*". The Gold CD1 form would also state the dose range as 10-20mg.

### Prescription Requirements: Good Practice

Wherever possible the dosage and frequency of administration of the CD should be specified in full; this is particularly important when prescribing for syringe drivers, but is good practice with all CDs.

It is good practice for all prescriptions for Schedule 2 and 3 CDs, including private prescriptions, to include the patient's NHS number. This will enable the usage of CDs by individual patients to be audited.



## The Prescribing, Supply, Storage and Disposal of Controlled Drugs in Primary Care

**Table 3: Destruction and Disposal of Controlled Drugs**

	Schedule 2	Schedule 3	Schedule 4 (part 1)	Schedule 4 (part 2)	Schedule 5
Designation	CD POM	CD No Reg POM	CD Benz POM	CD Anab POM	CD Inv POM or CD Inv P
Common Examples	Morphine Diamorphine Oxycodone Ketamine Fentanyl	Pregabalin Gabapentin Temazepam Buprenorphine Tramadol Midazolam	Diazepam Zopiclone	Testosterone Clenbuterol	Co-codamol 8/500 (CD Inv P) Co-codamol 30/500 (CD Inv POM)
Denaturing is required prior to disposal	✓	✓	✓	✗	✗
Authorised witness is required for denaturing /destruction of expired/obsolete stock	✓	<i>Not legally required but is good practice to have a member of staff, preferably a registered healthcare professional familiar with CDs, for Schedule 3 and 4 (part 1)</i>			
Records of destruction of expired/obsolete drugs must to be kept	✓ <i>In the CD Register</i>	<i>Good practice to record the destruction in a designated book (not the CD Register)</i>			
Authorised witness required for denaturing/ destruction of patient-returned CDs	<i>Not legally required but is good practice to have a member of staff, preferably a registered healthcare professional, familiar with CDs, as a witness</i>				
Records of destruction of patient-returns required	✓ <i>Not in the CD register; in another designated record book</i>				

## **2. Prescribers**

### **2.1 Medical Prescribers**

Doctors, dentists and veterinary surgeons may legally prescribe all CDs in Schedules 2, 3, 4 and 5. However dentists may only issue NHS prescriptions for controlled drugs that are listed in the Dental Practitioners' Formulary.

Doctors are the only healthcare professionals that are able to prescribe diamorphine, dipipanone and cocaine to substance abusers for addiction and in order to do so they require approval by the Department of Health and need a special license issued by the Home Office. All doctors may prescribe these drugs for patients (including substance abusers) without a specific license if indicated for the relief of pain due to organic disease or injury.

Prescribers should not prescribe or administer CDs for themselves or for close family members except in an emergency. The General Medical Council advises that doctors should not prescribe a CD for themselves or someone close to them unless there is no other person with the legal right to prescribe available to assess the patient's clinical condition and to delay prescribing would put the patient's life or health at risk, or cause the patient unacceptable pain. The treatment should be immediately necessary either to save life or avoid significant deterioration in the patient's health or alleviate otherwise uncontrollable pain.

### **2.2 Non Medical Prescribers – Independent and Supplementary Prescribers**

Nurse and pharmacist independent prescribers may possess, prescribe, supply, administer, or direct another person to administer any schedule 2-5 controlled drug within their clinical competence the only exceptions to this are the prescribing of cocaine, diamorphine or dipipanone for the treatment of addiction. (See above).

Nurse and pharmacist independent prescribers should ensure that they only prescribe within their clinical competence and that they have up to date knowledge of the doses, side effects, interactions, cautions, and contraindications of the CDs they intend to prescribe.

Supplementary nurse and pharmacist prescribers may prescribe and administer any CD (except diamorphine, dipipanone and cocaine for substance misuse) as long as it is within the clinical management plan (CMP) specific to that patient and agreed between the independent prescriber (doctor or dentist), the supplementary prescriber and the patient.

Other supplementary prescribers e.g. chiropodists, podiatrists, physiotherapists, radiographers and optometrists, are also able to prescribe CDs, in partnership with a doctor and according to the patient's CMP.

Advanced Paramedics are also now able to train to become independent prescribers. However, they cannot prescribe controlled drugs until the relevant legislation is updated by the Home Office.

### **2.3 Midwives**

Midwives, who are not trained as nurse independent prescribers, may possess, supply and administer any medicine from the Midwives Exemption List, provided it is in the course of their professional midwifery practice. This list includes the following CDs for parenteral administration: diamorphine, morphine and pethidine.

### **2.4 Paramedics (non-prescribing)**

All registered Paramedics (acting in their capacity as such) may possess and supply diazepam and/or morphine sulphate injection (maximum 20mg) and/or oral morphine sulphate only for the purpose of administration for the immediate and necessary treatment of sick or injured persons.

## 2.5 Controlled Drugs and Patient Group Directions (PGDs)

The following CDs may be supplied or administered under Patient Group Directions (PGDs):

- Nurses and pharmacists can supply or administer morphine or diamorphine under a PGD for the immediate and necessary treatment of a sick and injured person in any setting.
- Ketamine.
- Midazolam is the only Schedule 3 CD that can be included in a PGD.
- All drugs listed in Schedule 4 of the Regulations except anabolic steroids and injectable formulations for the purpose of treating a person who is addicted to a drug.
- All drugs listed in Schedule 5 of the Regulations.

## 2.6 Private Prescriptions

### Private Prescriptions: FP10PCD

- Private prescriptions for controlled drugs must meet the legal requirements specified earlier.
- It is an additional statutory requirement for private prescriptions for Schedule 2 or 3 CDs (for humans) to be prescribed only on FP10PCD forms. Failure to comply with this may constitute a criminal offence.
- Community pharmacists and dispensing doctors cannot dispense a private prescription for a Schedule 2 or 3 CD unless it is prescribed on an FP10PCD form specifying the prescriber's private CD prescribing code. (CDs prescribed for NHS patients use standard FP10 prescription forms except in the case of instalment dispensing where the FP10MDA form is used).
- Private prescribers are allocated a unique 6-digit private CD prescriber code by the NHS Business Services Authority. In order to obtain this code the prescriber must contact the Controlled Drugs Accountable Officer by email ([England.centralmidlands-cd@nhs.net](mailto:England.centralmidlands-cd@nhs.net)) with a brief explanation why the code is required.
- The private CD code differs will start with a "6" and will be different to the prescriber's NHS code i.e. a prescriber who operates both within the NHS and privately will have two identifier codes.
- FP10PCD forms are ordered from the NHS England Controlled Drugs Accountable Officer's team: ([England.centralmidlands-cd@nhs.net](mailto:England.centralmidlands-cd@nhs.net)).
- Pharmacies and dispensing practices are required to send all original dispensed FP10PCDs to the NHS Business Services Authority on a monthly basis with the private CD prescription dispensing submission form (FP34PCD) which summarises the number of FP10PCD forms and private items dispensed.
- The NHS England Controlled Drugs Accountable Officer monitors the prescribing patterns of private prescribers using information from the NHS Business Services Authority and other local information as appropriate.

### 3. Requisitions for Controlled Drugs

Supplies of CDs for use as dispensary stock or stock for clinician's bags must only be acquired through the appropriate process; it is not permitted to use medicines dispensed against a prescription from a pharmacy/dispensary for a particular patient.

The standard requisition form, FP10 CDF for Schedule 2 and 3 CDs is available from the NHSBSA website:

<https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/prescribing-and-dispensing/safer-management> (accessed on 30/4/19)

It is a legal requirement to complete the FP10CDF and it can be completed electronically before printing or a blank copy can be printed and then be completed manually. In either situation a paper copy must be signed manually by the authoriser.

Sections B and C of the requisition form must be completed by the organization ordering the controlled drugs including the following:

- name, form, strength and quantity of the drug and the date on which it was ordered
- purpose for which the drug is required (there are options to tick)
- prescriber code (if applicable) and profession/occupation of the authoriser
- signed by the authoriser (must be handwritten)
- name address and practice code

Section A needs to be completed by the supplier of the stock controlled drugs this can either be by adding their name and address indelibly onto the requisition at the time the supply is made or by using a stamp. The supplier must submit all requisitions to the NHSBSA using form FP34PCD.

### 4. Prescription Stationery and Security

Prescription stationery for CDs, including blank prescription forms, must be stored securely to prevent theft and misuse to fraudulently obtain controlled drugs. Advice and information about the security of prescription forms is available on the CQC website [www.cqc.org.uk](http://www.cqc.org.uk) and also from the NHS Counter Fraud Authority's guide to the Management and Control of Prescription Forms. (Accessed 30/4/19)

[https://cfa.nhs.uk/resources/downloads/guidance/Management%20and%20control%20of%20prescription%20forms\\_v1.0%20March%202018.pdf](https://cfa.nhs.uk/resources/downloads/guidance/Management%20and%20control%20of%20prescription%20forms_v1.0%20March%202018.pdf)

### 5. Storage of Controlled Drugs

#### 5.1 Legal Requirements

All healthcare professionals in legal possession of a CD have a professional duty of care to take all reasonable steps to maintain safe custody of that CD at all times.

Some CDs are designated as subject to safe custody requirements under the Misuse of Drugs (Safe Custody) Regulations 1973. However, these Regulations only apply to the storage of such CDs in retail pharmacies, private hospitals and care homes. In such premises, the controlled drugs that must be kept under safe custody are:

- Schedule 1 drugs
- Schedule 2 drugs except some liquid preparations and quinalbarbitone (secobarbital). Details of exempted Schedule 2 Controlled Drugs are available from the Misuse of Drugs (Safe Custody) Regulations 1973 as amended
- Schedule 3 drugs unless exempted under the Misuse of Drugs (Safe Custody) Regulations 1973 as amended, where the full lists are available. Common exemptions include: phenobarbital, mazindol, meprobamate, midazolam, tramadol, pentazocine and phentermine.
- Common Schedule 3 Controlled Drugs which require safe custody include temazepam and buprenorphine.

A CD safe or cabinet should comply with the requirements stated in the Misuse of Drugs Regulations 1973. However, if for some reason it does not, the police can provide an exemption certificate certifying that the cabinet provides adequate security for holding CDs. Additional guidance is available from the Home Office. (Accessed 30/4/19)

Legally, a doctor's bag is regarded, once locked by either a key or a combination, as a suitable receptacle for the storage of CDs. A locked car is not regarded as a suitable receptacle.

## 5.2 Good Practice

Although many healthcare premises are not covered by the Misuse of Drugs (Safe Custody) Regulations 1973 e.g. GP practices, out-of-hours services, hospitals, hospices etc. these regulations are considered the minimum standards for safe custody and good practice recommendations should be followed.

CDs that are subject to the safe custody requirements should be stored in a locked secure cabinet that is not portable. Ideally this should be an appropriate CD cabinet or approved safe.

- The room containing the locked secure cabinet should be lockable.
- Access to the CD cabinet/safe should be restricted to authorised persons only.
- When not in use, the keys to the CD cabinet or approved safe should be stored separately from the cabinet or safe (e.g. in a locked key cupboard).
  - Access to CDs (including handling of keys to the CD cabinet/safe) should be documented in a Standard Operating Procedure (SOP). This should enable identification of who has had access to CDs and provide an audit trail for holders of the CD keys.
  - A key log could be used to keep an audit trail of who has had access to the keys, including overnight storage and the transfer of the keys from one member of staff to another during working hours.
- The CD cabinet should be used solely for the storage of CDs. There should be no reason why an unauthorised person without legitimate business relating to the supply or stock control of the CD stock should need to access the cupboard. Where CDs are kept in the practice safe, the CDs should be kept in a separate locked receptacle within the safe.
- It is recommended that all NHS premises where CDs are stored should be equipped with a lockable CD cabinet that is firmly fixed to the wall and complies with the safe custody requirements under the Misuse of Drugs (Safe Custody) Regulations 1973, or have arrangements in place where CD stocks are stored in the practice safe. The cabinet should not be visible to members of the general public passing by outside windows.
- All dispensed CDs should be stored in the CD cabinet or designated safe until they are collected.

## 5.3 Storage of CD stock in a clinician's bag:

Stock levels of CDs stored in a clinician's bag should be kept to an absolute minimum.

Oral preparations of CDs are not considered as essential components of a clinician's bag stock of CDs. Normally only one strength of each CD should be kept in the bag to minimise the risk of confusion, error or inappropriate administration.

A clinician's bag containing CDs should not be left in a vehicle overnight nor in a vehicle left unattended for a long period.

In the practice, the clinician's bag should be stored in a safe place away from patient areas.

## 6. Record Keeping Requirements and Controlled Drug Registers (CDR)

A CD register, compliant with the relevant regulations, must be kept to record all transactions involving Schedule 2 CDs.

The definition of a CDR in the 2001 Regulations has been amended to include a computerised system which complies with specified best practice guidance. If a CDR is held in computerised form, safeguards should be incorporated in the software to ensure that the author of each entry is identifiable, that entries cannot be altered at a later date and that a log of all data entered is kept and can be recalled for audit purposes.

### 6.1 Legal Requirements

#### Legally a CDR must:

- be bound if a hard copy is used (not loose leaved)
- contain individual sections for each class of drug
- use a separate page, within each section, for each strength and form of the drug
- have the name, strength and form of the drug specified at the top of each page
- have entries in chronological order and made on the day of the transaction or the next day
- have entries made in ink or otherwise indelible form, or be in a computerised form
- not have cancellations, obliterations or alterations; corrections must be made by a signed and dated entry in the margin or at the bottom of the page
- be kept at the premises to which it relates (or be accessible from those premises if computerised) and be available for inspection at any time. A separate register must be kept for each premises in which Schedule 2 CDs are stored (for example, not just in the main surgery)
- be kept for a minimum of two years after the date of the last entry once completed
- contain records kept in their original form or copied and kept in an approved computerised form
- not be used for any other purpose

Entries made into the CDR in respect of drugs obtained and drugs supplied may be made on the same page or on separate pages in the register.

### 6.2 Receipt of stock Controlled Drugs

When a Schedule 2 CD is received into stock the following details must be recorded in the CDR:

1. the date of receipt
2. the name and address of the supplier (e.g. wholesaler, pharmacy)
3. the quantity received

### 6.3 Supply of Controlled Drugs (dispensed or stock)

When a Schedule 2 CD is supplied to a patient (by prescription) or to a practitioner (by signed requisition or order) the following details must be recorded in the CDR:

1. the date on which the supply was made
2. the name and address of the patient or firm supplied
3. particulars of the license or authority of the person who prescribed or ordered the CD. (NB record details of the signatory and not the named prescriber if they are not the same)
4. quantity supplied
5. person collecting the CD (patient/ patient's representative/ healthcare professional) and if it is a healthcare professional, their name and (work) address
6. was proof of identity requested of patient/ patient's representative? (Yes/No)
7. was proof of identity of person collecting provided? (Yes/No)
8. in the case of a healthcare professional, proof of identity should be their professional registration number

Clinician's bag and each bag carrying stocks of Schedule 2 CDs should have a separate CDR relating to the bag.

Within a dispensing practice, the transfer of a Schedule 2 CD from the dispensary stock to the bag's stock should entail a record in the dispensary CDR detailing the supply and a record in the bag's CDR detailing the receipt.

*An entry recording the supply of a dispensed CD should not be made into the CDR until the supply has actually been made to the patient or their representative.*

#### 6.4 CD Register: Good Practice

- Wherever possible all transactions relating to CDs should be checked by two members of staff and both individuals should initial the entry in the CDR.
- It is recommended best practice that a running balance of current stock levels of all Schedule 2 CDs should be kept in the CDR. The running balance of drugs remaining should be calculated and recorded after each transaction and balances should be checked with the physical amount of stock at regular intervals. Registers with specific space for the recording of running balances are available. It is good practice to include quantities of out of date stock in the running balance.
- The CDR may also be used to record the prescriber identification number (e.g. the six digit private prescriber code) and/or professional registration number of the prescriber (where known) and the name and professional registration number of the pharmacist or dispensing doctor.
- Wherever CDs are being stored, it is good practice to carry out a regular stock check (e.g. weekly) in line with NICE guideline NG46 and any guidance from professional representative bodies etc. Frequency of CD stock reconciliation will vary according to local circumstances, volume and frequency of dispensing but should be included in the Standard Operating Procedures. Regular stock checks will allow any errors or discrepancies to be more easily identified. If discrepancies arise, more frequent reconciliation should be undertaken until the problem is resolved.
- The CDR should be stored safely outside the cabinet or safe, near to it but not easily visible or accessible.

#### 6.5 Discrepancies

*Where a discrepancy is identified, a thorough investigation should be instigated as soon as possible and the outcome recorded.*

*Any corrections to the CDR must be made by a signed and dated entry in the margin or at the bottom of the relevant page.*

*If the source of the discrepancy cannot be identified, the Controlled Drugs Accountable Officer (see Section 9) should be notified via the NHS England online reporting tool accessible at: [www.cdreporting.co.uk](http://www.cdreporting.co.uk). A formal internal investigation should be undertaken and if the situation is not resolved satisfactorily the police will need to be informed. All of these steps need to be covered in the written Standard Operating Procedure for the handling of CDs in use in the workplace.*

## 6.6 Collection of CD Dispensed Medicine or CD Prescription Form by a Patient or Patient's Representative

Any patient, or person collecting medicines on their behalf, who is collecting CDs against a Schedule 2 or Schedule 3 CD prescription (whether NHS or private) should be asked to sign for them. The FP10 forms contain a box on the reverse where a signature for a Schedule 2 or 3 CD can be inscribed.

Where the patient, or person collecting medicines on their behalf, is collecting **Schedule 2 CDs**, it is a legal requirement to ask for evidence of identity if this person is not known to the pharmacist/dispensing assistant. If no evidence of identity is available, the pharmacist/dispensing assistant is able to use discretion to decide whether to supply the CD or not. The pharmacist also has the discretion to not ask for evidence of identity if he/she feels that to do so might compromise patient confidentiality. Requests for evidence of identity and whether identity is confirmed must be recorded in the CD register. Where concerns exist and the identity of the person collecting the CD(s) is unknown and cannot be confirmed, supply should be refused until adequate evidence of identity can be provided. Proof of identity is not a requirement for the collection of Schedule 3 CDs.

It is good practice to keep a record of the name, address and role/relationship of the person collecting **Schedule 2 CDs**, particularly those people not previously known to pharmacy/dispensary staff. This information can be recorded in the CDR or in a separate CD collection book. The time at which the dispensed CD prescription was collected can also be recorded.

It is a legal requirement for pharmacists/GP dispensary staff to ascertain whether the person collecting a Schedule 2 CD is the patient, the patient's representative or a healthcare professional acting in their capacity as such.

Where the person collecting the prescription is a healthcare professional acting in his/her professional capacity on behalf of the patient, the dispenser must obtain the person's name and address (may use professional or work address) and must request evidence of that person's identity in the form of their professional registration number (unless already known). A supply of the drug may be made even if the dispenser is not satisfied as to the identity of that person. This enables the dispenser to use discretion in situations where the withholding of a CD from a patient could prevent the patient from having access to medicines that are needed and have been prescribed for them.

It is good practice for surgeries to follow similarly stringent policies in their issue of Schedule 2 CD prescription forms to patients or persons collecting prescription forms on their behalf who have not been previously known to surgery staff. Again, staff should ascertain whether the person is the patient, the patient's representative or a health care professional acting in their capacity as such (where this is not already known). Where the individual is not already known to the surgery staff, proof of identity should be requested and confirmed and a record kept of the name, address and role/relationship of the person collecting the Schedule 2 CD prescription form.

The Home Office has advised that Schedule 2, 3, and 4 Part 1 CDs should not be held at or collected from a central collection point, e.g. a Post Office.

Schedule 2, 3 and 4 Part 1 CDs must always be collected from the GP dispensary or community pharmacy or delivered direct from there to the patient's home.

## 6.7 Validity of Prescription

Schedule 2 and 3 CDs cannot be prescribed on repeat dispensing prescriptions. Repeat dispensing prescriptions for Schedule 4 CDs must be dispensed for the first time within 28 days of the appropriate date, after which the repeats are legally valid within the stated periods of validity of the repeatable prescription. Schedule 5 CDs must be dispensed for the first time within 6 months of the appropriate date, after which the repeats are legally valid within the stated periods of validity of the repeatable prescription.

Owing balances for Schedule 2, 3, or 4 CDs cannot be dispensed and supplied later than 28 days after the date on the prescription. Owing balances for Schedule 5 CDs cannot be dispensed and supplied later than 6 months after the date on the prescription.

For FP10MDA (instalment prescriptions) the first instalment will need to be dispensed within the 28 day validity period. The start date will either be the date of signing or the start date specified by the prescriber on the form. Patients will not be required to sign for each instalment.



## 6.8 Quantities to be supplied: Good Practice

Prescribers (both NHS and private) are strongly advised to restrict prescribed quantities of Schedule 2, 3, and 4 CDs to a maximum of 30 days' supply. In exceptional circumstances, where the prescriber believes that a supply in excess of 30 days is indicated and will not pose an unacceptable risk to the patient, a justification of the decision should be recorded in the patient's notes. It is not illegal for a pharmacist to dispense a prescription for CDs for more than 30 days supply, but they must satisfy themselves as to the clinical appropriateness of the prescription before doing so.

## 6.9 Preservation of Records

Registers, requisitions and orders for CDs must be preserved for a minimum of two years.

The 2001 Regulations have been amended to allow the information contained in these records to be preserved in the original paper form or in computerised form. Where records are preserved on computer, adequate safeguards should be in place to ensure that data cannot be altered at a later date, that all data can be recalled for audit purposes, that adequate backups are made and that systems are in place to minimise the risk of unauthorised access to the data.

It is mandatory to keep registers, requisitions, orders and invoices for CD stock for two years. In practice, it is advisable to keep invoices for much longer than this. Invoices should be stored for seven years to bring the system into line with value added tax (VAT) and tax storage requirements. Keeping records for this length of time will also help in the event of any subsequent police investigation as cases often come to court years after an event when paper records will ordinarily have been destroyed.

# 7. Schedule 3 - Controlled Drugs (CD No Register)

## 7.1 Storage

Schedule 3 CDs are subject to the same safe custody requirements as detailed in paragraphs 5.1. However, all drugs in the Schedule are exempted except temazepam, diethylpropion, buprenorphine and flunitrazepam. This means that all temazepam, diethylpropion, buprenorphine and flunitrazepam preparations must, by law, be stored in a locked receptacle, usually in an appropriate CD cabinet or approved safe, which can only be opened by the person in lawful possession of the CD or a person authorised by him/her.

## 7.2 Collection of CD Dispensed Supply or CD FP10 Prescription by a Patient or Patient's Representative

7.2.1 Any person collecting CDs against a Schedule 3 CD prescription (whether NHS or private) should be asked to sign the back of the prescription form in the declaration box (see Section 3.10 for more detail). There is no requirement for a person collecting a prescription or dispensed supply of Schedule 3 CDs to provide evidence of identity, although vigilance for suspicious circumstances is clearly best practice.

7.2.2 The Home Office has advised that Schedule 2, 3, and 4 Part 1 CDs should not be held at or collected from a central collection point, e.g. a Post Office.

7.2.3 Schedule 2, 3 and 4 Part 1 CDs must always be collected from the GP dispensary or community pharmacy or delivered direct from there to the patient's home.

## 7.3 Quantities to be supplied: Good Practice

7.3.1 Prescribers (both NHS and private) are strongly advised to restrict prescribed quantities of CDs to a maximum of 30 days supply. In exceptional circumstances, where the prescriber believes that a supply in excess of 30 days is indicated and will not pose an unacceptable risk to the patient, a justification of the decision should be recorded in the patient's notes.

## 8. Disposal of Controlled Drugs

### 8.1 Background

Controlled drugs must be disposed of efficiently, safely and with robust procedures in place to minimise environmental impact and risk to public safety. The safe disposal of all medicines is important, but is particularly acute with CDs as they are at risk of being diverted or misused if disposal is not managed efficiently and safely and is not properly witnessed and recorded.

The Home Office has advised that all Schedule 2, 3, and 4 Part 1 CDs must be destroyed/denatured before being placed into waste containers. All CD destruction should be undertaken using an appropriate CD denaturing kit and following the relevant local SOP. Such kits are available through most wholesalers and full instructions are provided with the kits.

Community pharmacies and GP practices do not need a license from The Environment Agency to denature CDs prior to disposal. However, a T28 exemption needs to be registered with The Environment Agency and is valid for three years. See the website for details. ([www.environment-agency.gov.uk](http://www.environment-agency.gov.uk))

### 8.2 Patient-Returned Controlled Drugs

'Patient-returned' CDs are those that have been prescribed and dispensed for named patients and then returned unused or part-used for disposal. All Schedule 2, 3 and 4 part 1 patient-returned CDs must be denatured before disposal.

The requirement for safe custody of certain CDs applies equally to patient returned CDs. They must be kept in the CD cabinet, segregated from stock CDs and clearly marked as returns until they can be destroyed.

***Under no circumstances should patient-returned CDs be re-entered into the CD register and taken back into stock for dispensing to another patient at a later time even during periods of shortage of supply or where a returned pack is unopened, in date and in good condition. Recycling of CDs in this way is potentially both fraudulent and illegal.***

These CDs can be denatured by staff working within a dispensing practice or community pharmacy without the supervision of an authorised witness. However, the destruction should be witnessed and recorded by an appropriate member of staff (e.g. dispenser, technician, practice manager etc).

All community pharmacies and dispensing practices should have complete records of patient returned Schedule 2 CDs received and destroyed. Records should clearly indicate which members of staff were involved in both disposing of and witnessing the disposal of each CD. Such a record would normally take the form of a small exercise book or equivalent. It is recommended that these records are retained for at least seven years. Preferably, all destruction of patient returned CDs should be witnessed by a registered healthcare professional.

### 8.3 'Expired Stock' Controlled Drugs

'Expired-stock' CDs can be defined as all Schedule 2, 3 and 4 part 1 CDs that have not been issued/dispensed to a patient. Schedule 2 CD stock can only be destroyed in the presence of a person authorised by the Controlled Drugs Accountable Officer to witness destruction.

When a GP practice or independent community pharmacy has Schedule 2 stock CDs that need to be destroyed, the Controlled Drugs Accountable Officer should be contacted using the online CD reporting tool: [www.cdreporting.co.uk](http://www.cdreporting.co.uk).

All community pharmacies and general practices holding stock CDs should have complete records of 'expired-stock' Schedule 2 CDs destroyed. Records should clearly indicate which member of staff was involved in the disposal of each CD. Details of the drug must be entered in the CDR including the drug name, form, strength and quantity, as well as the date of destruction, the words: 'Out of date stock destroyed' or similar, the signature of the authorised person who witnessed destruction and the person/professional destroying it (i.e. two signatures). It is good practice for the authorised witness to print their name and job title after their signature in the CDR.

8.3.1 'Expired-stock' CDs requiring safe custody must continue to be stored in the CD cabinet/safe segregated from other stock CDs and clearly marked until they can be destroyed. Quantities of expired

stock CDs should continue to be included in the running balance in the CDR, adding a note for clarification if necessary.

8.3.2 There is no legal requirement for CDs, other than those defined as Schedule 2, to be disposed of in the presence of an authorised witness.

8.3.3 An authorised person cannot witness the destruction of CDs that have been supplied to them or by them.

#### **8.4 Destruction of 'Expired Stock' Controlled Drugs: Authorised Witnesses**

An amendment to The Misuse of Drugs Regulations 2001 allows the Controlled Drugs Accountable Officer to authorise people to witness the destruction of CDs. The Controlled Drugs Accountable Officer cannot act as a witness themselves as they should be independent of the day-to-day management of CDs.

#### **8.5 Destruction of Controlled Drugs in the community following a Patient's Death**

On the death of a patient, all their medication technically forms part of their estate, and usually comes under the control of the patient's relatives. However, it is illegal to possess controlled drugs that have been prescribed for someone else. For this reason, and to minimise the risk that controlled drugs may be sold on to others, or accidentally ingested by children, it is recommended that controlled drugs are destroyed as soon as possible after a patient's death. There are three means of doing this:

- destruction in the patient's home by a healthcare professional
- transportation of the controlled drugs to a pharmacy or dispensing general practice by a healthcare professional
- transportation of the controlled drugs to a pharmacy or a dispensing general practice by a patient's relative

All three means are lawful. The preferred method is for community nursing staff (if they have been caring for the patient) to destroy the controlled drugs in the patient's own home using a CD destruction kit, normally during the first visit to the patient's home following death. When this is not possible, the patient's family or carer should be asked to return the CDs to a community pharmacy or the dispensing general practice that supplied the drugs.

### **9. Transportation of Controlled Drugs**

Nurses, midwives, doctors, pharmacists, pharmacy staff and other professionals plus formal carers and patients' representatives are legally allowed to transport CDs to the patient, provided the CD has been prescribed by an appropriate prescriber for that patient. However, healthcare professionals involved in the delivery of patient care should not routinely transport CDs to and from a patient's home.

Any nominated individual is allowed to return CDs from the patient to the pharmacy or practice for destruction.

9.1 CDs should be kept out of view when in transit.

9.2 CDs should not generally be transported via mail, taxi services or equivalent. Where urgent clinical need dictates and there is no other option, dispensed CDs can be sent to a patient via such routes. If the mail route is unavoidable, special delivery should be used to ensure that the pathway is auditable. If mail or taxi delivery is considered necessary on a regular basis, a standard operating procedure should be developed to cover all aspects of the process including a risk assessment.

9.3 Prescriptions for Schedule 2 CDs should not routinely be sent to the pharmacy or patient via the postal system but should be collected from the surgery by the patient, their representative, a health care professional or a member of their staff. If posting is unavoidable, a standard operating procedure should be developed to cover all aspects of the process including a risk assessment.

9.4 The Home Office has advised that prescriptions for Schedule 2, 3, or 4 Part 1 CDs should not be delivered to a central collection point e.g. Post Office for onward collection by the patient or patient's representative.

## 10. Standard Operating Procedures (SOPs)

See NICE guideline NG46 for further information about SOPs.

Standard Operating Procedures are required in all premises where CDs are handled e.g. general practice, community pharmacy, out of hours services, community hospitals and community nursing services.

The Controlled Drugs Regulations 2013 require commissioner and provider organisations to have in place up to date SOPs in relation to the management and use of CDs. The development and dissemination of SOPs are left to local determination and the discretion of Controlled Drugs Accountable Officers. However, SOPs must cover the prescribing, supply and administration of CDs and the clinical monitoring of patients who have been prescribed CDs.

It is recommended that SOPs cover all areas of CD management relevant to the service provided, for example

- ordering and receipt of CDs
- assigning responsibilities
- where CDs are stored
- who has access to CDs
- record keeping including checking stock levels against running balances
- administration
- incidents / concerns / dealing with discrepancies
- transport of CDs
- destruction of CDs

SOPs should cover all aspects of risk management and they should include audit trails for ordering, storing, prescribing, dispensing, recording, supplying, administering and destruction of CDs, appropriate to the setting and the team. SOPs should highlight the accountabilities and roles of all members of the relevant healthcare teams.

More details on SOPs are provided in the Department of Health Guidance on Standard Operating Procedures for Controlled Drugs and in the local Policy on the Development of SOPs.

## 11. Accountable Officer for Controlled Drugs

The Controlled Drugs Regulations 2013 have replaced the 2006 Regulations and designate those healthcare providers that are required to appoint a Controlled Drugs Accountable Officer (CDAO). The CDAO is required to oversee and monitor the prescribing, dispensing and destruction of controlled drugs, e.g. by healthcare professionals within their organisation or in those they contract from.

Organisations such as Clinical Commissioning Groups are not required to appoint a CDAO but are recommended to nominate an individual within their organisation to act as CD Lead to liaise and work with the NHS England Area Team CDAO.

The core duties and functions of the CDAO include: ensuring compliance with the Misuse of Drugs legislation, establishing systems for recording and reporting concerns or untoward incidents about CD use and ensuring that a range of up to date SOPs are available and regularly reviewed to support these governance arrangements.

The CDAO is responsible for the regular review and analysis of ePACT (electronic Prescribing Analysis and Costs) data on the prescribing of controlled drugs and will investigate further if there are any unusual prescribing patterns.

The CDAOs for NHS England Area Teams will require general practitioners to complete a periodic declaration and self-assessment of the use of controlled drugs within their premises.

Lead CDAOs for NHS England Area Teams are required to set up and run the Local Intelligence Network (LIN). The LIN should facilitate the co-operation of its members to identify and share information, incidents and concerns about the safe management and use of CDs and to agree actions to be taken in respect of these matters.

All incidents and concerns (including complaints) involving the safe use and management of CDs should be reported to the CDAO using the online CD reporting tool, available at [www.cdreporting.co.uk](http://www.cdreporting.co.uk).

The CDAO (at the time of publishing) for NHS England (Central Midlands) is Bhavisha Pattani. Bhavisha is the CDAO for all Lincolnshire CCG GP practices and Community Pharmacies and can be contacted on 0113 824 9614 or [England.centralmidlands-cd@nhs.net](mailto:England.centralmidlands-cd@nhs.net).

## 12. Care Quality Commission (CQC)

All providers of NHS general practice and other health and social care providers, for example out of hours services, hospitals and care homes, must be registered with the CQC. The CQC is responsible for inspecting these services, including the management of controlled drugs. The CQC will check, as part of these inspections that providers continue to meet the essential standards of quality and safety. For more information, see the CQC website [www.cqc.org.uk](http://www.cqc.org.uk)

## 13. Further Information

For advice and further information on all aspects of Controlled Drug prescribing and dispensing please contact the CDAO (details in section 11 above) or the Optum MMO team: [ohs.mmo.sharedservices@net.net](mailto:ohs.mmo.sharedservices@net.net)

## 14. References:

- a. NHS England, Central Midlands Area, Standard Operating Procedure for witnessing the destruction of Controlled Drugs, Lincolnshire Update January 2016
- b. NHS Lincolnshire, Policy on the Development of Standard Operating Procedures (SOPs) for the Safe and secure handling of Medicines, April 2017
- c. Department of Health, Controlled Drugs (Supervision of Management and Use) Regulations 2013, Information about the Regulations, February 2013
- d. Care Quality Commission, Management of Controlled Drugs, at [www.cqc.org.uk](http://www.cqc.org.uk)
- e. Home Office, Security guidance for all existing or prospective Home Office Controlled drug Licensees and/or Precursor Chemical Licensees or Registrants, 2014, accessed at: [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/271565/SecurityGuidanceBusinessesOrganisationsJan14.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/271565/SecurityGuidanceBusinessesOrganisationsJan14.pdf)
- f. <http://psnc.org.uk/dispensing-supply/dispensing-controlled-drugs/instalment-dispensing/> Prescribing of CDs by installment, accessed 3.4.18
- g. <https://www.england.nhs.uk/ahp/med-project/paramedics/> Non-medical prescribing by Advanced Paramedics, accessed 3.4.18
- h. <https://www.nice.org.uk/guidance/ng46> NICE guideline NG46: Controlled drugs: Safe use and management, April 2016, accessed 3.4.18