

**MEDICINES STANDARD A7:  
PRESCRIBING AND MANAGEMENT OF CONTROLLED DRUGS  
(INCORPORATING DESTRUCTION OF CONTROLLED DRUGS)**

This guidance aims to identify robust systems for obtaining, prescribing, storing, supplying, monitoring and destruction of controlled drugs in primary care in accordance with the current regulatory framework as required by legislation.

**REGULATORY BACKGROUND**

The Misuse of Drugs Act 1971 (MDA):

Schedule 2 of the MDA lists those drugs which are controlled, and divides them into 3 classes – A, B & C. The class depends on the degree of danger the drugs present when misused. The class determines the maximum penalty available on conviction for an offence under the Act. For example, offences involving heroin (class A) attract a higher maximum prison sentence or fine than those involving either amphetamine (class B), or nitrazepam (class C).

Misuse of Drugs Regulations 2001 (MDR):

The MDR divides CDs into 5 schedules according to the degree of control required. A summary of these schedules and the handling and record keeping requirements for each schedule can be found in appendix C.

As a consequence of passing the Health and Social Care Act 2012, the 2006 regulations have been revised to reflect the new architecture in the NHS in England. The Controlled Drugs (Supervision of Management and Use) Regulations 2013 came into force in England on 1st April 2013.

**DEFINITIONS**

**Controlled drug** – any drug belonging to schedule 1, 2, 3, 4 or 5 of the Misuse of Drugs Regulations 2001. Hereafter referred to as CDs in the policy.

**Controlled Drug Accountable Officer (CDAO)** – the controlled drug accountable officer is appointed by each NHS England Area Team as a suitably experienced and qualified person to act as the lead CDAO.

**CCG Controlled Drug Lead** - a suitably experienced and qualified person within the CCG that monitors CD related activities and reports to the Area Team CDAO as necessary. For the CCG, this is the Chief Pharmacist.

**Authorised witness** – this is a person authorised by the NHS England Wessex Local Area Team Controlled Drug Accountable Officer (CDAO) to witness the destruction of controlled drugs in the CCG area.

**Information** – Information related to known inappropriate or excessive prescribing of controlled drugs, misuse or illegal activity (must be reported to the NHS England LAT Accountable Officer and may be shared by the CDAO under the information sharing requirements of the Controlled Drugs (Supervision of Management and Use) Regulations 2013.

**Intelligence** – Information relating to individuals where there is a suspicion of inappropriate or excessive prescribing or potentially illegal activity (which may be gathered or shared if appropriate as part of an investigation as required by the Controlled Drugs (Supervision of Management and Use) Regulations 2013.

**Patient returned controlled drugs** – CDs that have been prescribed for, and dispensed to, a named patient and then returned unused or part-used, by the patient or their representative.

**Stock controlled drugs** – CDs that have been held for the purposes of potential dispensing to patients, or supply of CDs held for emergency use (either on the premises or in a doctor's bag).

## **ROLES AND RESPONSIBILITIES**

NHS Dorset CCG actively encourages all healthcare professionals to seek advice/guidance from the Controlled Drugs lead for CCG or the Local Area Team CDAO and to share intelligence. The following types of issues regarding controlled drugs and their safe management should be reported:

- discrepancies in balances
- prescribing concerns (e.g. excessive quantities or unusual doses)
- suspected loss or theft of controlled drugs
- suspected loss or theft of a prescription for controlled drugs
- forged prescriptions for controlled drugs

Sometimes a small piece of information can fit into something wider. It is important to report issues or suspicions to the Local Area Team CDAO to assist in identification of potential trends. The information is not used to assign blame, only to ensure that there is safe and secure use of controlled drugs.

It is the responsibility of all healthcare professionals to ensure that they adhere to the legislation covering the safe management of controlled drugs and to report any relevant information to the CDAO.

All healthcare professionals working with controlled drugs must ensure that there are SOPs in place for that activity and that the SOPs are adhered to.

The CDAO is responsible for ensuring that the requirements of The [Health and Social Care Act 2012](#) are implemented.

## **THE ACCOUNTABLE OFFICER**

The Controlled Drugs (Supervision of Management and Use) Regulations 2013 set out the requirements for NHS England to appoint a Controlled Drugs Accountable Officer for each Local Area Team.

NHS England published a [Single Operating Model](#) for the new 2013 regulations that clarify the responsibilities of the CCG and NHS England in Controlled drugs supervision.

The Area Team CDAO is responsible for all aspects of the safe and secure management of controlled drugs (CDs) in the Wessex Area Team locality.

The Controlled Drugs lead for CCG is the Chief Pharmacist and will act as a focal point for liaison with the Local Area Team CDAO. This includes ensuring that safe systems are in place for the management and use of controlled drugs, monitoring and auditing the management systems and investigation of concerns and incidents related to controlled drugs.

Any issues regarding controlled drugs and their safe management (e.g. discrepancies, prescribing concerns, loss, theft etc.) including those that occur in the wider community (e.g. patient's own home) MUST be reported to the Area Team CDAO and also on the relevant adverse incident reporting form.

## **CONTROLLED DRUGS (CD'S)**

All activity related to controlled drugs in all healthcare settings must be subject to standard operating procedures (SOPs). These should reflect the legal requirements and include the information as laid out in the guidance previously published by the Department of Health "[Safer Management of Controlled Drugs: Guidance on Standard Operating Procedures for Controlled Drugs](#)".

## **PRESCRIPTION REQUIREMENTS**

Prescribers should refer to the most recent [BNF](#) for advice on writing prescriptions for controlled drugs.

Schedule 2 and 3 NHS CD prescriptions must be written so as to be indelible (e.g. written by hand, typed or computer generated). From July 2105, the legislation has extended to allow electronic transmission of prescriptions.

All prescriptions for controlled drugs must specify:

- The name and address of the patient and, where appropriate, age
- The name and form of the drug, even if only one form exists
- The strength of the preparation, where appropriate
- The dose to be taken

- The total quantity of the preparation, or the number of dose units, to be supplied in both words and figures
- The prescribers name and address (must be within the UK)
- If the prescriber is a dentist, the words “for dental treatment only” must also be present.

Additionally:

- The prescription must be signed by the prescriber with their usual signature (this must be handwritten) and dated by them (does not have to be hand written).
- Prescriptions for Schedule 4 and 5 CDs are exempt from the specific prescription requirements; however they must still comply with the general prescription requirements.
- It is illegal to issue a CD prescription which does not meet all the CD prescription requirements described above. It is also illegal for a pharmacist to dispense such a prescription.
- It is good practice to include patient’s NHS number where possible.
- The duration of a controlled drug prescription should not exceed 28(30) days.
- Any part of the prescription that has not been written upon should be blanked off to reduce the opportunity for fraud.
- It is inappropriate for a prescriber to prescribe or administer CDs for personal use or for family members, except in a true emergency. Further information on this is available in the [GMC good practice guidance](#).

### **Changes to the Misuse of Drugs Regulations effective from July 2015**

The introduction of electronic prescribing of Schedule 2 and 3 controlled drugs.

This instrument introduces the electronic prescribing of of Schedule 2 and 3 controlled drugs under the National Health Service Electronic Prescribing Service (EPS) structure with its incorporated layers of security, including the use of an Advanced Electronic Signature. The authority granted applies to England, Wales and Scotland and restricts the electronic prescribing of these drugs to EPS only. Private prescribing of Schedule 2 and 3 drugs are also enabled under these provisions, but are also restricted to when such prescribing takes place under EPS.

The provisions introducing electronic prescribing of Schedule 2 and 3 drugs are enabling and not mandatory. Prescribing of these drugs under EPS will run alongside paper prescribing to provide flexibility and ensure prescribers are able to prescribe in settings where access to an electronic system is limited, such as in the community.

The DH as lead department for this policy will progress the necessary structural changes required to implement this policy, including in respect of private prescribing of these drugs under EPS in England. The enablers for this to occur have not been implemented at the time of reviewing this policy.

## **ALTERATIONS TO A CD PRESCRIPTION**

In emergency situations, a doctor or health professional who is allowed to prescribe controlled drugs may amend a prescription written by another prescriber provided that s/he signs and dates the prescription/amendment in addition to the original prescriber.

Changes to a prescription should not be made by third persons e.g. practice manager, receptionist and then passed to a prescriber to sign.

Pharmacists are permitted to make **minor** adjustments to prescriptions for controlled drugs. The only errors that pharmacists may amend are minor typographical errors or spelling mistakes.

Where the total quantity of the preparation of the CD or the number of dosage units as the case may be is specified in either words or figures but not both (i.e. the pharmacist may add the words **OR** the figures to the CD prescription if they have been omitted, but not both)

As a safeguard to these changes the pharmacist must satisfy two pre-condition before amending the prescription and supplying the CD:

- The pharmacist must be satisfied beyond reasonable doubt, having exercised due diligence, that the prescription is genuine and that s/he is supplying the drug in accordance with the intention of the prescriber ;
- Any correction must be marked so as to be attributable to the pharmacist to ensure it is readily identifiable, for the purpose of audit.

## **NON-MEDICAL PRESCRIBERS AND CONTROLLED DRUGS**

### **Supplementary prescribers**

A supplementary prescriber, when in accordance with the terms of an agreed individual clinical management plan (CMP) may prescribe and administer and/or supply or direct any person to administer any controlled drug provided that the controlled drug is included in the CMP.

### **Community Practitioner Nurse Prescribers**

Community Practitioner Nurse Prescribers may only prescribe those products and medicines specified in the Nurse Prescribers' Formulary for Community Practitioners. No controlled drugs are included in this formulary.

## **Nurse Independent Prescribers (formerly Extended Formulary Nurse Prescribers)**

Nurse Independent Prescribers are able to prescribe any licensed medicine for any medical condition within their competence, including controlled drugs.

In 2012, [The Misuse of Drugs \(Amendment No.2\) \(England, Wales and Scotland\) Regulations 2012](#) extended the controlled drug prescribing responsibilities of Nurse and Pharmacist independent prescribers. Restrictions were removed to enable nurse and pharmacist independent prescribers to:

- Prescribe any controlled drug listed in schedules 2-5 for any medical condition within their competence, except diamorphine, cocaine and dipipanone for the treatment of addiction (nurse and pharmacist independent prescribers are able to prescribe other controlled drugs for the treatment of addiction).
- Requisition controlled drugs and are authorised to possess, supply, offer to supply and administer the drugs they are able to prescribe. Persons acting in accordance with the directions of a nurse or pharmacist independent prescriber are authorised to administer any schedule 2-5 drugs that the nurse or pharmacist can prescribe.
- Mix any drugs listed in schedules 2-5 prior to administration. Persons acting in accordance with the written directions of a nurse or pharmacist independent prescriber or, a supplementary prescriber when acting in accordance with the terms of a clinical management plan, are authorised to mix drugs listed in schedules 2-5.

Other non-medical prescribers: Pharmacists, and some Allied health professionals are also able to prescribe within specific restrictions. The relevant legislation and their competences differ slightly so refer to the individual profession rules.

### **PRIVATE PRESCRIPTIONS FOR SCHEDULE 1, 2 AND 3 CDs.**

All private prescriptions for Schedule 1, 2 and 3 CDs that are presented for dispensing in the community must be written on a standardised (pink) private controlled drug prescription form which must include the prescriber's unique six-digit private prescriber code (different from the current NHS prescribers' code) issued specifically for their private CD prescribing activity only.

The private prescriber code can be obtained via the Area Team CDAO. The prescriber will then be permitted to obtain private prescription forms, known as FP10PCD forms, to prescribe CDs privately. A charge may be made for the administration of these prescription pads.

Private prescriptions for schedule 4 and 5 CDs can be issued in the same way as any other private prescription.

## **DISPENSING OF CONTROLLED DRUGS**

Dispensing practices and community pharmacies are required to have in place SOPs for all aspects of controlled drug stock management and dispensing as well as destruction of waste. These must reflect current practice and meet all legal requirements.

Practices that keep stocks of controlled drugs must keep a CD record book (CDRB) and have up to date SOPs. Stocks of CDs held in 'doctor's bags' must also be recorded in a hand-held CDRB for this purpose.

Schedule 2 CDs must be entered into the CD record book (CDRB) as soon as they have been supplied, or within 24 hours of supply. The date of supply must be entered into the register (i.e. the date when the CD is administered / handed to the patient / carer / representative and not the date when it is assembled).

### **Running Balances**

All practices stocking controlled drug should ensure that a running balance is kept. This is a good practice requirement and a minimum expected standard.

After each transaction of controlled drug, the running balance of drug remaining should be calculated and recorded in the CD record book. Balances should be checked with the physical amount of stock, ensuring irregularities are identified as quickly as possible. If discrepancies arise, more frequent reconciliation should be undertaken until the problem is resolved.

When the running balance is entered into the CD record book, ensure that it corresponds to the actual level of physical stock. It should not be assumed that the balance in the CD record book is correct. The running balance must not be initialled as correct without first being sure that it is correct by checking the physical stock.

### **Emergency Supplies**

Pharmacists are unable to make an emergency supply of a Schedule 2 or 3 CD to a patient, other than in the case of the supply of phenobarbital for the treatment of epilepsy.

An emergency supply of Schedule 4 or 5 CDs may be made as long as the other conditions for the supply of a prescription only medicine (POM) to a patient in an emergency are satisfied, including the fact that the patient must request the emergency supply in person.

## **STORAGE OF CONTROLLED DRUGS**

The Misuse of Drugs [Safe Custody] Regulations 1973 set out the rules for safe custody of controlled drugs (CDs). All Schedule 2 and those Schedule 3 CDs that are subject to safe custody requirements must be kept in a locked receptacle, which is so constructed and maintained as to prevent unauthorised access to drugs.

Requirements are that:

- The receptacle should consist of a locked safe/cabinet preferably of steel, with suitable hinges, fixed to a wall or the floor with rag bolts (these bolts should not be accessible from outside the cabinet);
- Ideally the safe/cabinet should be within a cupboard or in such other position as to avoid easy detection by intruders;
- The room containing the safe/cabinet should be lockable and kept tidy around the safe/cabinet area to avoid drugs being misplaced;
- The walls of the room should be constructed to a suitable thickness using suitable materials;
- Nothing should be displayed outside to indicate that controlled drugs are kept within the receptacle and the locked cabinet should not be one that staff routinely access for other items;
- The locked receptacle must only be opened by the person in lawful possession of the CDs, or an otherwise authorised person;
- Stock should be kept to a minimum and the cabinet should not contain anything other than the drugs, or the drugs and the register (the register does not have to be kept locked with the drugs).
- The number of sets of keys to the locked cabinet, and who holds them, must be known at all times. The keys should always be kept separate from the cabinet and should never be accessible to unauthorised persons.

Appropriate controlled drug security cabinets are available from The National Pharmacy Association (NPA) and other medical supplies providers such as Bristol Maid. When purchasing new cabinets, practices should ensure that they meet the BSA standard and are appropriately installed.

Other cabinets can be used, providing they meet with the specifications as laid out in the Safe Custody Regulations. If these cabinets are used then a 'Certificate of exemption' will have to be issued by the Police Controlled Drug Liaison Officer (CDLO) for Dorset, in order to approve their use as a CD storage cabinet.

Additional best practice recommendations for storage and security of controlled drugs:

- Cupboards must be kept locked when not in use;
- Keys to the controlled drug cupboard must only be available to authorised members of staff and at any time the key-holder should be readily identifiable;



- The cupboard should be dedicated to the storage of controlled drugs (i.e. no other medicines or items should normally be stored in the controlled drug cupboard);
- Controlled drugs must be locked away when not in use.

## RECORD-KEEPING

Records of controlled drugs held as practice stock (or in a doctor's bag) must be kept in a controlled drug record book (CDRB). The record book must be kept up to date at all times.

The CDRB should be bound (not loose-leaf) with sequentially numbered pages and it should have separate pages for each drug and each strength, so that a running balance can be kept easily. Entries should be made in chronological order, in ink or be otherwise indelible.

On reaching the end of a page in the CDRB, the balance should be transferred to another page. The new page number should be added to the bottom of the finished page and the index updated.

If a mistake is made in the record book it should be bracketed in such a way that the original entry is still clearly legible. This should be signed, dated and witnessed by another member of practice staff.

In February 2008, the Misuse of Drugs Act regulations required additional information to be recorded in the controlled drug register when CDs are received or supplied. The table below lists the headings that should be available in the register.

Type of entry	Information to record
Receipt of CDs	Date supply obtained Name and address from whom obtained (e.g. wholesaler, pharmacy) Quantity obtained
Supply of CDs	Date supplied Name and address of person or firm supplied Detail of authority to possess – prescriber or license holder's details Quantity and form in which supplied Running balance
Information in relation to the identity of the person collecting a CD supplied on prescription	Whether the person who collected the drug was the patient, the patient's representative or a healthcare professional acting on behalf of the patient; If the person who collected the drug was a healthcare professional acting on behalf of the patient, that person's name and address; If the person who collected the drug was the patient or their representative and whether evidence of identity was requested (annotated in the yes/no columns) Whether evidence of identity was provided by the person collecting the drug

If practice (or doctor's bag) registers do not meet these requirements then a new CD record book that meets the record keeping requirements needs to be obtained.

CD record books for use in GP main CD store cupboards and for doctors bags can be obtained from Sure lines Pharmaceutical Services Ltd: [www.surelines.com](http://www.surelines.com) and Williams Medical supplies: [www.wms.co.uk](http://www.wms.co.uk). There may be other suppliers available. The CCG does not endorse any supplier over another.

If the controlled drugs record is held in computerised form, safeguards should be incorporated in the software to ensure:

- the author of each entry is identifiable
- entries cannot be altered at a later date
- A log of all data entered is kept and can be recalled for audit purpose
- Adequate backups should be made

The register must be retained for a minimum period of two years after the date of the last entry, at the premises to which they relate.

If a practice has more than one set of premises it must keep a register for each premises. In case of a change in premises, the same registers may continue to be used.

#### **EVIDENCE OF IDENTITY: PRESCRIPTIONS FOR SCHEDULE 2 CONTROLLED DRUGS**

Persons asked to supply Schedule 2 controlled drugs on prescription should establish whether the person collecting the drug is the patient, the patient's representative or a healthcare professional acting in his/her professional capacity on behalf of the patient. If the person is the patient or the patient's representative (e.g. a friend, neighbour etc.), the dispenser may:

- Request evidence of that person's identity, *or*
- Refuse to supply the drug if s/he is not satisfied as to the identity of that person

If the person collecting the prescription is a healthcare professional acting in his/her professional capacity on behalf of the patient, the dispenser:

- Must obtain that person's name and address
- Must, unless he is acquainted with that person, request evidence of that person's identity.

#### **CONTROLLED DRUGS AS PRACTICE STOCK**

November 2015 Introduction of mandatory requisition form – England only  
The Home office has introduced a new approved requisition form, in electronic format, which can be [accessed online](#). The requirement to use the mandatory form applies to the professionals listed at regulation 14(4) of the 2001 Regulations, which now include

paramedics and the person in charge or acting person in charge of an organisation providing ambulance services.

The form must be used only when stocks of the relevant controlled drugs are to be obtained in the community, including from wholesalers but outside settings such as hospitals where supply to wards are governed by different provisions. From 1 June 2015, hospices and prisons are exempt from the requisition requirements under the 2001 Regulations, and are not required to use the mandatory form when ordering the relevant controlled drugs. The scope of the form includes pharmacy to pharmacy transfer of controlled drugs stocks.

Professionals can complete the form online or download onto local drives prior to the form being completed, printed and signed in wet ink. However, the form is designed to reset anytime it is saved with added data to prevent confidential details of requisitioners falling into the wrong hands. The form also has an in-built security mechanism which generates a unique code when completed electronically. This facility is not available for forms that are printed blank. It is expected that this facility will in the future further assist the NHS Business Services Authority in its data collection and CD Accountable Officers in their monitoring role.

These changes and the security features highlighted above do not impact on the responsibility placed on suppliers under the 2001 Regulations to ensure that a person requisitioning controlled drugs is either authorised under the 2001 Regulations, or has a Home Office licence, which entitles them to possess the relevant controlled drugs. Any prescriber wishing to requisition controlled drugs (e.g. for practice stock, doctors bags, or private work), that does not yet have a private controlled drug identification number must contact the NHS England Controlled Drug Accountable Officer.

All requisitioned stock is subject to the storage and record keeping requirements laid out in section sections 12 and 13 above. The stock will have been requested in the name of, and continue to be the property of the named practitioner whose name was on the FP10CDF. Record keeping and SOPs should reflect this.

### **STOCK FOR DOCTORS BAGS**

CDs in the possession of a doctor must be kept in a locked receptacle (box or a bag) when in transit and out of sight in a locked car. Keys to the doctor's bag should be kept separate from it and the number of keys and who holds them must be known. A combination lock is recommended.

Each doctor holding their own stock (e.g. doctor's bag) must keep an individual register to record the receipt of the CDs from the practice stock into personal stock, and to record supply/administration patients. The doctor is personally responsible for keeping the register up to date.

Each entry in the doctor's personal CDRB should be signed and dated by them.

The stock balance of all controlled drugs entered in the CDRB should be checked and reconciled regularly (at least monthly), with the amounts in the bag to ensure that discrepancies can be identified in a timely way.

A record indicating that this reconciliation check has been carried out and confirming the stock is correct should be kept in the CDRB. This record should as a minimum state the date and time of the reconciliation check and include wording such as “check of stock level” and be signed by the doctor.

If a discrepancy is found it should be investigated without delay. If the situation cannot be resolved then an adverse incident form must be completed and the Area Team CDAO informed.

Restocking of a ‘doctor’s bag’ from practice stock, should be witnessed by another member of staff, as should the appropriate entries into the practice’s CD register.

## **STOCK CHECKING AND RECONCILIATION**

One person should take lead responsibility for stock control in the GP practice (e.g. senior partner), with another senior member of the practice (e.g. practice manager) to act as a witness and countersign documentation.

All controlled drug stocks and records (including those relating to stocks in doctor’s bags) should be checked for accuracy at least every month. It may be appropriate to do this more often if frequent transactions occur.

Checking of controlled drugs balance involves checking of balance in the CDRB against the contents of the controlled drug cupboard, not the reverse, to ensure all balances are checked.

A record indicating that this reconciliation check has been carried out and confirming the stock is correct should be kept in the CDRB. This record should as a minimum state the date and time of the reconciliation check and include wording such as “check of stock level” and be signed and dated by the person carrying out the check.

Date-expired stock should be marked “expired” and segregated from other stock. It stored securely and destroyed in the presence of an Authorised Witness as soon as possible.

It is not necessary to open packs with intact tamper-evident seals for stock checking purposes.

Stock balances of liquid medicines should generally be checked by visual inspection but periodic volume checks using a measure may be helpful.

If a discrepancy is found it should be investigated without delay. The use of the checklist for investigation of discrepancies is recommended, see [appendix 2](#).

If the situation cannot be resolved then the relevant Adverse Incident Form must be completed and the Local Area Team CDAO informed.

The level of stock of controlled drugs held in the practice should be kept to a minimum and reviewed at least on an annual basis.

Controlled drugs held as stock must be destroyed with an Authorised Witness. Please refer to the CCG policy for the destruction of controlled drugs for more information.

### **PRIVATE PARAMEDICS AND CONTROLLED DRUGS**

Registered private paramedics can requisition controlled drugs from community pharmacies for their possession, providing they are to be used for the 'immediate necessary treatment of sick or injured persons' only. The CDs should be requisitioned on the form for this purpose, an FP10CDF.

Paramedics should enquire with the Local Area Team CDAO for further information.

### **MONITORING AND AUDIT**

The Controlled Drug CD lead at the CCG will carry out regular routine monitoring of prescribing controlled drugs and seek clarification from prescribers of anomalies when necessary.

Where concerns remain, these will be referred to the Local Area Team CDAO as appropriate.

### **STOCK CONTROLLED DRUGS FOR DISPOSAL**

This section applies to controlled drugs, held as stock, which have never been dispensed for a patient, and require disposal because they are unfit for purpose, e.g. passed the expiry date. This includes practice stock and GP Doctors bag stock.

Any expired or unwanted stock CDs should be segregated from the other CD stock within the CD cupboard and clearly labelled as "awaiting destruction".

GPs and dispensing practices may not dispose of stock or Drs Bag controlled drugs without the presence of an Authorised Witness to witness the destruction of those drugs. The practice must make arrangements for the Authorised Witness to visit the practice to carry out the destruction by contacting the Medicines Management Team.

The practice must ensure that appropriate equipment is available for the process to take place, prior to the visit, i.e. Destruction Of Old Medicines (DOOM) kits and pharmaceutical waste bins and/or sharps bins. It is the responsibility of the practice or community pharmacy to ensure that they have the appropriate waste licenses.

## **CONTROLLED DRUGS LABELLED FOR INDIVIDUAL PATIENTS ('PATIENT'S OWN')**

Non-dispensing practices should not normally accept controlled drugs for destruction from patients but should instead direct them to the nearest community pharmacy.

Dispensing practices may accept returned controlled drugs from patients. It is advised that a dedicated register should be kept and entries made at the point of return.

Pharmacies have a contractual obligation to accept controlled drugs returned from patients even if they did not dispense them and NHS England funds the collection and incineration of these patient returned medicines.

Destruction of patient returns in Dispensing GP practices should be witnessed by a registered professional i.e. nurse or doctor, and appropriate entries made in the dedicated patient returns register. It is not currently a requirement to have an Authorised Witness to witness patient own returned controlled drugs but it may become a requirement in the future.

It is advised that destruction of patient returns takes place at regular intervals to prevent build-up of stored controlled drug waste.

## **METHODS OF DESTRUCTION**

All medicines should be disposed of in a safe and appropriate manner, in relevant waste containers, which are then sent to an agency with a waste management licence.

CDs can be placed into waste containers only after they have been rendered irretrievable by denaturing, also known as using a 'DOOM' kit.

The specific method of destruction of the range of formulations (e.g. tablets, patches, liquids) is described the 'Standard operating procedure for witnessing the safe destruction of controlled drugs' ([appendix F](#)).

## REFERENCES

Reference	Link
1	<i>The Shipman Inquiry (15 July 2004) Fourth Report - The Regulation of Controlled Drugs in the Community</i> <a href="http://www.the-shipman-inquiry.org.uk/fourthreport.asp">http://www.the-shipman-inquiry.org.uk/fourthreport.asp</a>
	<i>The Controlled Drugs (Supervision of Management and Use) Regulations 2013</i> <a href="http://www.legislation.gov.uk/uksi/2013/373/contents/made">http://www.legislation.gov.uk/uksi/2013/373/contents/made</a>
2	<i>The Health and Social Care Act 2012</i> <a href="http://www.legislation.gov.uk/ukpga/2012/7/contents">http://www.legislation.gov.uk/ukpga/2012/7/contents</a>
3	<i>Misuse of Drugs Act (1971)</i> <a href="http://www.homeoffice.gov.uk/drugs/">http://www.homeoffice.gov.uk/drugs/</a>
4	<i>Medicines Act (1968)</i> <a href="http://www.legislation.gov.uk/ukpga/1968/67/contents">http://www.legislation.gov.uk/ukpga/1968/67/contents</a>
5	<i>Misuse of Drugs Regulations (2001)</i> <a href="http://www.legislation.gov.uk/uksi/2001/3998/contents/made">http://www.legislation.gov.uk/uksi/2001/3998/contents/made</a>
6	<i>The Misuse of Drugs (Amendment No. 2) (England, Wales and Scotland) Regulations 2013 (to include medicinal cannabis)</i> <a href="http://www.legislation.gov.uk/uksi/2013/625/contents/made">http://www.legislation.gov.uk/uksi/2013/625/contents/made</a>
7	<i>The Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007</i> <a href="http://www.legislation.gov.uk/nisr/2007/348/contents/made">http://www.legislation.gov.uk/nisr/2007/348/contents/made</a>
8	<i>The Controlled Drugs (Supervision of Management and Use) Regulations 2013 NHS England <b>Single Operating Model</b></i> <a href="http://www.england.nhs.uk/wp-content/uploads/2013/11/som-cont-drugs.pdf">http://www.england.nhs.uk/wp-content/uploads/2013/11/som-cont-drugs.pdf</a>
9	<i>The Misuse of Drugs (Amendment No.2) (England, Wales and Scotland) Regulations 2012 (Amendment to Misuse of Drugs Act 2001 - extending the responsibilities of NMPs)</i> <a href="http://www.legislation.gov.uk/uksi/2012/973/contents/made">http://www.legislation.gov.uk/uksi/2012/973/contents/made</a>
10	<i>A guide to good practice in the management of controlled drugs in primary care (England) – 3rd edition (2009)</i> <a href="http://www.npc.nhs.uk/guidance_cd.php">http://www.npc.nhs.uk/guidance_cd.php</a>
11	<i>Department of Health, Safer management of controlled drugs: guidance on Standard Operating Procedures for controlled drugs (Jan 2007)</i> <a href="http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_064824">http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_064824</a>
12	<i>Department of Health, Safer management of controlled drugs: private CD prescriptions and other changes to the prescribing and dispensing of controlled drugs (3 July 2006)</i> <a href="http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4131465">http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4131465</a>
13	<i>National Patient Safety Agency (NPSA) incident decision tree</i> <a href="http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59900">http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59900</a>
14	<i>Drug Misuse and dependence – UK guidelines on clinical management (Department of Health, September 2007)</i> <a href="http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_104819">http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_104819</a>
	<i>Home office circular November 2015</i> <a href="https://www.gov.uk/government/publications/circular-0272015-approved-mandatory-requisition-form-and-home-office-approved-wording/circular-0272015-approved-mandatory-requisition-form-and-home-office-approved-wording">https://www.gov.uk/government/publications/circular-0272015-approved-mandatory-requisition-form-and-home-office-approved-wording/circular-0272015-approved-mandatory-requisition-form-and-home-office-approved-wording</a>

## SUMMARY OF MISUSE OF DRUGS ACT SCHEDULES

Consultations have been undertaken on changing the schedule of some controlled drugs. Prescribers should refer to latest guidance in the BNF.

Legal requirement	Misuse of Drugs Regulations Schedule				
	Schedule 2	Schedule 3	Schedule 4 Part 1	Schedule 4 Part 2	Schedule 5
Prescription writing requirements	Yes	Yes,	No	No	No
Validity of prescription	28 days	28 days	28 days	28 days	6months (if POM)
Address of prescriber must be in UK	Yes	Yes	No	No	No
Repeats allowed?	No	No	Yes	Yes	Yes
Emergency supplies allowed?	No	No, except phenobarbitone for epilepsy	Yes	Yes	Yes
Requisitions necessary?	Yes	Yes	No	No	No
Requisition to be marked by supplier?	Yes	Yes	No	No	No
Requisition to be sent to PPA	Yes	Yes	No	No	No
Invoices to be retained for two years	yes	Yes	No	No	No
Safe custody requirements	Yes, except quinalbarbitone	Yes*	No	No	No
License required for import and export	Yes	Yes	Yes	Yes, unless the drug is in the form of medicine and is for administration for himself.	No
*Schedule 3 exceptions to safe custody – 5,5 disubstituted barbituric acid, cathine, ethchlorvynol, ethinamate, mazindol, meprobamate, methylphenobarbitone, methprylone, midazolam, pentazocine, phentermine or any stereoisomeric form of the above, or any salts of the above). Note: Phenobarbitone (Phenobarbital) does not require safe custody.					



**Checklist for Investigation of CD Register Discrepancy****Practice name:****Contact name:****Date completed:**

Step	Details	Did this resolve discrepancy?	Comments	Initials & date
1	Check maths since last correct balance	Yes / No		
2	Re-check CD cupboard with second person (Remember date expired stock, patients owings, uncollected items, goods awaiting delivery to patients, patient returns, returned items from 'doctors bags', which may have become mixed with stock).	Yes / No		
3	Check other register sections of same/similar drugs for erroneous entries.	Yes / No		
4	Sense checks register (correct pack sizes, patterns of entry for potential missing entries and unusual quantities).	Yes / No		
5.	Search clinical system for the specific drug and cross reference the clinical system data with entries for potential missing entries.	Yes / No		
6.	Check private prescriptions and requisitions have all been entered.	Yes / No		

Step	Details	Did this resolve discrepancy?	Comments	Initials & date
7.	Check all delivery receipts to ensure all have been entered into register.	Yes / No		
8.	Contact suppliers to request a list of deliveries since last correct balance.	Yes / No		
9.	Ensure any stock transfers of CDs to other premises, or 'Doctor's Bags' have been entered	Yes / No		
10.	Check returns to suppliers' notes and/or product recall notes.	Yes / No		
11.	Check access log and contact all staff who have accessed the cupboard during the relevant period	Yes / No		
12.	Contact patients who have been dispensed the medication around the time of the discrepancy to see if there has been a dispensing error	Yes / No Not applicable		

*Any other steps taken to resolve discrepancy / additional notes*

**IF DISCREPANCY REMAINS UNRESOLVED CONTACT THE LOCAL AREA TEAM ACCOUNTABLE OFFICER**

Email: [england.wessexdao@nhs.net](mailto:england.wessexdao@nhs.net) or call 02380 725 537 or 02380 296064

**STANDARD OPERATING PROCEDURE FOR WITNESSING THE DESTRUCTION OF CONTROLLED DRUGS**



Standard operating Procedure for the witnessing of the destruction of controlled drugs



## **NHS England**

*Controlled Drugs*

*Witness of Destruction*

*Standard Operating Procedure*

First published: July 2013

Prepared by

Moira Philpott – Programme Manager NHS England (Wessex)

## Objectives

This procedure outlines the circumstances in which a person Authorised by the Accountable Officer (AO) of NHS England (Wessex Local Area Team) may witness the destruction of controlled drugs, and the governance and safety arrangements that should be employed.

## Scope

- The Authorised Witness will be either subject to a professional code of ethics and or CRB checked by the organisation.
- The Authorised Witness should not normally be involved in the day to day management of controlled drugs.
- The Authorised Witness may witness the destruction of Expired Controlled Drugs (and occasionally patient own/returns) in the following areas:
  - GP personal stock
  - GP Practice Stock
  - Dispensing Practice Stock (NHS England Wessex)
  - Community Pharmacy Stock

## The Stages of the process

Witnessed destruction will take place with a registered member of staff at the premises.

## Equipment

- Destruction of expired controlled drugs (CDs) must be done using a resin based system. The Environment Agency has agreed that where CDs are denatured using one of the specially designed CD denaturing kits (e.g. those that use resin mixtures to render the CD irretrievable), this activity would not normally be regulated as licensable waste treatment.
- It is advisable to ensure that the resin preparation is available at the premises prior to the visit. It can be obtained through most pharmaceutical wholesalers, DOOP and NHS supplies.
- To avoid sharps injury from ampoules, it is advisable to use an ampoule breaker, or otherwise protect the hands from sharps injury. Although most controlled drugs are not hazardous to touch, gloves may be worn for additional protection.

## Checks

- The Authorised Witness should first inspect the Controlled drug register in which the drugs to be destroyed are recorded to ensure that the documentation is accurate and a clear audit trail from receipt to use/destruction is available. If there are any irregularities, with the drugs to be destroyed, the witnessed destruction should not proceed.
- In the case of irregularities, the AO should be informed and the responsible person at the premises asked to carry out an investigation to be forwarded to the AO.
- The running balance of the drug in question should match the actual number, with those to be destroyed easily identified.

## Documentation

- When an expired CD is being destroyed, details of the drug must be entered into the CD register, including the drug name, form, strength and quantity, as well as the date of destruction and the signature of the person in whose presence the drug was destroyed.
- The Authorised Witness should write alongside the entry for the drug to be destroyed “Destruction Witnessed by *name, Registration number/title*”
- This should be countersigned by the staff member present
- The Authorised Witness should then ensure that the running balance can be amended to allow for the number destroyed.
- The Authorised Witness should make a personal record of controlled drugs destroyed.

### Destruction Process

- The jar of resin granules should be opened, and the drugs witnessed as they are put into the jar.
- Ampoules should be opened, tablets and capsules may be removed from their blisters and crushed, and liquids poured directly into the jar. Once a liquid has been added to these resin preparations, they need to be shaken thoroughly otherwise the resin will stick to the bottom, and the top drugs will not be denatured. It is wise to leave liquids until last.
- Patches containing CDs can be managed by removing the backing and folding the patch over on itself and then placing it in the CD denaturing kit
- Aerosol formulations should be expelled into water and the resultant liquid managed as per liquid formulations a mask must be worn during this process.
- Once all the preparations to be destroyed have been entered into the jar of resin, the manufacturers’ instructions should be followed for the denaturing process. In most cases this requires the jar to be filled to a level with water, the lid screwed tightly and the jar shaken vigorously to ensure even distribution of the resin. After shaking for a short time the resin will solidify. The sealed jar of solidified resin may be disposed of in the Pharmaceutical Waste bin on the premises.

### Disposal

The sealed jar may be disposed of in the Pharmaceutical Waste bin on the premises. For prescribing practices they need to arrange collection by their waste contractor.

### **Responsibility**

- It is the responsibility of the Practice/pharmacy or other premises to have adequate safe disposal facilities for controlled drugs.
- It is the responsibility of the Accountable Officer to provide the Authorised Witness with training.
- The Authorised Witness must be familiar with the Guidance for the management of Controlled Drugs in Primary Care (2009), and RPSGB controlled drugs destruction guidance.

- The Authorised Witness is responsible for ensuring that the witnessed destruction of Controlled drugs is done in a manner that adheres to the RPSGB and Environment Agency Guidance for the destruction of waste medicines and should ensure that they are up to date with any changes.
- The Accountable Officer is responsible for ensuring that there are adequate numbers of Authorised Witness available in NHS England (Wessex) to avoid the build-up of expired CDs.
- The Authorised Officer cannot delegate this role to another Pharmacist/Technician, although there are other professionals within NHS England (Wessex) who can witness destruction.
- The Authorised Witness must complete an annual self-declaration for the Accountable Officer to declare their activities involved with controlled drugs.

**Other useful Information**

- The Authorised Witness should report any irregularities or concerns about controlled drugs management, security or prescribing to the Accountable Officer.
- Hampshire and Dorset Police will work to their own Standard Operating Procedure.
- If there are any concerns regarding the management of controlled drugs you should stop what you are doing immediately and call either your AO Manda Copage – 02380 725537 or your AO Support Manager – Moira Philpott -02380 296064
  - If you have concerns of criminal activity call your CDLO Hampshire – Jim Goodacre – 07767664063; Dorset – Bob Sparks - 07770782423

I have read and understood this standard operating procedure and agree to work to it. This SOP has been authorised for use in NHS England (Wessex Area Team) by the Accountable Officer for controlled drugs.

Signature.....

Date.....

Name: .....Head of Medicines Management.

**References**

1. Health Act 2006
2. Controlled Drugs (Supervision of management and use) Regulations 2013 Information about the Regulations:  
[www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/141407/15-02-2013-controlled-drugs-regulation-information.pdf.pdf](http://www.gov.uk/government/uploads/system/uploads/attachment_data/file/141407/15-02-2013-controlled-drugs-regulation-information.pdf.pdf)
3. Controlled drugs governance self-assessment tool for primary care providers.  
[www.cgc.org.uk/organisations-we-regulate/special-reviews-and-inspection-programmes/controlled-drugs](http://www.cgc.org.uk/organisations-we-regulate/special-reviews-and-inspection-programmes/controlled-drugs)
4. National Prescribing centre supporting commissioner and provider organizations.  
[www.npc.nhs.uk/controlled\\_drugs/](http://www.npc.nhs.uk/controlled_drugs/)

5. <http://www.rpsgb.org/pdfs/cdsafedestructionguid.pdf>
6. Manufacturer's instructions, DOOP/DOOM container, Cliniserve
7. Manufacturer's instructions, DENKIT01727 858687 ext 3469, Denward Manufacturing Ltd.01245 492986, Cliniserve 01243 782288

***Acknowledgements:***

*Adapted with thanks to NHS Bournemouth Poole and NHS Dorset*



## SELF DECLARATION FOR AUTHORISED WITNESSES

<b>Name of Witness for CD destruction</b>	
<b>Address</b>	
<b>Contact e-mail address</b>	
<b>Contact telephone number</b>	

Please complete the questions below, for **ALL** controlled drugs (CDs) activities **within the last 12 months**.

	<b>Y / N or N/A</b>	<b>Details (Where applicable)</b>
Have you had any involvement in the handling or management of controlled drugs in the last 12 months? (For example, supply/dispensing, stock control). If yes, please provide details*.		
Are you a registered Healthcare Professional? (ie do you have a GMC, NMC or GPhC registration number?) If yes, please provide registration body and registration number.		<b>Registration body:</b>  <b>Registration number:</b>
If you are a registered HCP, do you have any current restrictions on your practice? If yes, please provide details.		
If you are not a registered HCP, have you had a CRB check in the last 12 months? If yes, please provide a copy.		

*\*If you have had any involvement with controlled drugs in the last 12 months, please provide details about the nature of this activity. The Accountable Officer may ask you to complete a more detailed questionnaire.*

**Any other information you wish to provide**

Please enter any additional information you wish to provide in the space below

**Please sign the declaration in the box below**

**To the best of my knowledge, the information I have supplied is correct. In the event of a change to the information supplied, I will notify the Accountable Officer within 14 days.**

Signature	
Name (PRINT)	
Position	
Date of Signing	

**Thank you for completing this declaration.**

Please post to the following address in an envelope marked "Private and Confidential" to:

Liz Mearns  
Controlled Drug Accountable Officer  
NHS England Wessex Local Area Team  
1st Floor, Oakley Road  
Millbrook  
Southampton  
SO16 4GX