Arden and Greater East Midlands Commissioning Support Unit in association with Lincolnshire Clinical Commissioning Groups

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Policy Relating to the Prescribing, Supply, Storage and Disposal of Controlled Drugs in Primary Care

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Version Control Sheet

Version	Section/Para/ Appendix	Version/Description of Amendments	Date	Author / Amended by
1				
2				
3				
4			March 2007	Stephen Gibson / Sharon Hayler
5	1 and 2.3 2.5 3.8.3, 3.8.5 and 3.10.2 5.1.2, 5.4 and 5.6 9	Change in schedule for midazolam Changes to the requirements for requisitions Changes to record keeping requirements Amended guidance on the destruction of controlled drugs Role of the Accountable Officer	November 2008	Stephen Gibson / Sharon Hayler
6	Summary table p7-8 2.5.5, 2.5.6 3.7.4 3.9 5.7 7 11	Formatting and date changes throughout Updated information Additional information about ordering CDs Updated information Additional information on running balances and stock reconciliation New section More detail about SOPs Updated references	February 2010	Sharon Hayler
7	1.1 Summary Table p7-8 2.1.2 2.4 3.7.1 3.8.7 3.9.2 5.1.3 5.2.2 5.4.1	Updated to reflect change of pharmacy regulatory body Updated information on Sativex Change in license arrangements New section on Paramedics Added exception for veterinary prescriptions Additional information added Removal of information and link relating to guidance on running balances New paragraph on changes to waste regulations Removal of link and referral to local guidance in Appendix 1 Change in definition of ‘expired stock’ and updated contact details	December 2011 / January 2012	Sharon Hayler

	'Expired stock' CDs – good practice 7.4 7.5 9 &10 11 Appendix 1	Section removed and information added to 5.4.2 and 5.4.3 Removed ref to check list and added detail on SOP policy Removed check list Updated contact details References updated Procedures for destruction of CDs		
8	Whole document Page 8/9 2.2 2.5.1 3.5.3 3.8.6 3.10.7/8 and 4.5.2/3 and 6.7 5.2.5 5.4.1.1 & 5.4.1.2 5.6.1 7.2 9 10	Updated to reflect changes to NHS organisations from 1st April 2013 Sativex change from S1 to S4 part 1 Change in regulations for nurse & pharmacist independent prescribers Change in PGD legislation Prescribing a dose range in palliative care Addition for LCHS staff Addition reflecting HO advice against CDs being held at collection points Addition for community hospitals – destruction of patient's own CDs Expired stock CDs – contact details for witnessed destruction Update to responsibilities for CDs after patient's death New regulations on SOPs New regulations on CDAOs and updated contact details Care Quality Commission – new section	January / February 2014	Sharon Hayler
9	Whole document 2.5.1 2.6 2.7 3.1.1 3.2.5 3.5.3 3.7.2 3.9.2/5.4.3 3.9.6/5.4.1/9.4/9.6 4.2.1 & Summary table 5.4 / 9.6 References	Updated in line with legislative changes up to Dec 2015; updated link to PACEF website; removed Addition of ketamine Updated in line with mandatory use of FP10 CDF Security of prescription stationery Home Office guidance on CD storage Improving audit around access to CD keys Update on EPS for CD prescriptions Accessing private prescriber codes Including out of date CDs in running balance Updates including new online cd reporting tool Removal of temazepam as an exception to prescription requirements Updated contact details CDAO Updated	February & March 2016	Sharon Hayler

Policy Relating to the Prescribing, Supply, Storage and Disposal of Controlled Drugs in Primary Care

Policy Statement

Background	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 (version nine) replaces version eight issued in April 2014.
Statement	This policy incorporates all the legislative changes published by the Department of Health up to the end of December 2015. It also recommends areas of good practice to strengthen the governance arrangements for controlled drugs.
Responsibilities	Implementation and compliance with the policy will be the responsibility of all staff.
Training	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.
Dissemination	Lincolnshire Clinical Commissioning Groups Website: www.lincolnshire-pacef.nhs.uk
Resource implication	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.

Policy Relating to the Prescribing, Supply, Storage and Disposal of Controlled Drugs in Primary Care

Contents

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. Community pharmacies will be inspected to similar standards by the General Pharmaceutical Council Inspectorate. The current edition of this policy incorporates all of the updated Department of Health material published up to the end of December 2015. The June 2006 guidance from the Department of Health (DoH) clarified arrangements around private prescribing of CDs, validity of CD prescriptions and quantities of CDs to be prescribed. In addition, it was confirmed that pharmacists are now able to amend minor errors on prescriptions for Schedule 2 and Schedule 3 CDs. There have also been changes to record keeping requirements and the introduction of a requirement to ensure that the identity of persons collecting Schedule 2 CD prescriptions is confirmed if not already known. Subsequent material published by the DoH in October 2006 provided interim guidance on issues relating to destruction and disposal of CDs and final guidance on changes to record keeping requirements. Guidance on Standard Operating Procedures for Controlled Drugs was published in January 2007. Guidance followed in December 2007 detailing changes to the requirements for requisitions and amended guidance on the destruction of CDs. Further changes to record keeping requirements were published in January 2008. Changes in November 2015 included making use of the standard requisition form mandatory, introducing new approved wording for instalment prescribing and rescheduling ketamine as a Schedule 2 CD.

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 Changes to the Misuse of Drugs Regulations 2001 have been made in the wake of the Shipman Reports. The requirement that Controlled Drug prescriptions should be written in the prescriber's own handwriting has been removed. Prescriptions will be valid as long as they are written indelibly and include all of the legally required elements. This means that CD prescriptions can be type-written, hand written or computer printed; only the signature of the prescriber needs to be handwritten.

1.4 The definition of CD register has been amended to include a computerised system which is in accordance with best practice guidance endorsed by the Secretary of State under section 2 of the National Health Service Act 1977.

1.5 The Misuse of Drugs Regulations 2012 allow nurse and pharmacist independent prescribers to prescribe any schedule 2-5 controlled drug within their clinical competence but do not allow the prescribing of cocaine, diamorphine or dipipanone for the treatment of addiction.

1.6 The Controlled Drugs Regulations 2013 update and replace the 2006 Regulations to reflect the changes in the NHS in England from April 2013.

Summary Table

Schedules	Definition	Drugs included
Schedule 1 (CD Licence)	These drugs have virtually no therapeutic use. Production, possession and supply are only allowed for the purposes of research or other special purposes. A Home Office License is required.	Hallucinogenic drugs (e.g. LSD), ecstasy-type substances, cannabis etc.
Schedule 2 (CD POM)	These drugs are used medicinally, but prescribing, dispensing, administration and disposal are all tightly controlled. Enhanced prescription requirements are in place as are safe custody requirements (except secobarbital (quinalbarbitone)), record keeping requirements and tight controls on disposal. Prescriptions are valid for 28 days. Changes to legislation have removed the prescribers own handwriting requirement; prescriptions for Schedule 2 CDs can be computer, type or hand written.	Cocaine, dexamfetamine, diamorphine, dipipanone, fentanyl, hydromorphone, ketamine, methadone, methylphenidate, morphine, nabilone, oxycodone, pethidine, secobarbital (quinalbarbitone), tapentadol etc.
Schedule 3 (CD No Register)	These drugs are used medicinally and are liable to abuse. Controls are less rigorous than with Schedule 2. Schedule 3 CDs are exempt from safe custody requirements (except flunitrazepam, temazepam, buprenorphine and diethylpropion) and special record keeping requirements. Prescriptions are valid for 28 days. Invoices should be kept for two years. Changes to legislation have removed the prescribers own handwriting requirement; prescriptions for Schedule 3 CDs can be computer, type or hand written.	Barbiturates (e.g. amobarbital, butobarbital, phenobarbital), buprenorphine, diethylpropion, flunitrazepam, meprobamate, midazolam, pentazocine, phentermine, temazepam, tramadol etc
Schedule 4 Part I (CD Benzodiazepines)	This schedule has a lower level of control than those described above. Possession of a drug from this schedule is an offence without the authority of a prescription. Possession by practitioners or pharmacists acting in their professional capacity is authorised. There are no special prescription or handwriting requirements, nor is there a requirement for special record keeping. Prescriptions are valid for 28 days.	Benzodiazepines (except flunitrazepam midazolam and temazepam), zolpidem and ketamine (e.g. chlordiazepoxide, clonazepam, diazepam, loprazolam, lorazepam, lormetazepam, nitrazepam, oxazepam etc). *Sativex®
Schedule 4 Part II (CD Anabolic	There is no restriction on the possession of a drug from this Schedule when it is part of a medicinal product. There are no special	Anabolic and androgenic steroids and growth hormones e.g. testosterone, mesterolone,

Steroids)	prescription requirements, nor is there a requirement for special record keeping. Prescriptions are valid for 28 days.	nandrolone (Deca-Durabolin), chorionic gonadotrophin and somatropin.
Schedule 5 (CD Invoice: CD Inv P or CD Inv POM)	Schedule 5 contains preparations of certain CDs which are exempt from full control because they are present in these formulations in such low strength that their risk of misuse is reduced. There are no special prescription requirements, nor is there a requirement for special record keeping. Some Schedule 5 CDs (CD Inv P) are available for over the counter sale in registered pharmacies. Prescriptions are valid for six months. Invoices should be kept for two years.	Co-codamol, co-codaprin, codeine linctus BP, codeine phosphate tablets, co-dydramol, co-phenotrope, dihydrocodeine tablets, Gee's Linctus BPC, kaolin and morphine mixture, Oramorph® oral solution 10mg in 5ml.

*Sativex has been moved from Schedule 1 to Schedule 4 Part 1 in April 2013. Records should be kept for the receipt, supply and destruction of Sativex®, preferably 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 degrees. Once opened, it can be stored upright at room temperature for a maximum of 42 days.

2. Prescribing, Supply and Administration of Controlled Drugs

2.1 Medical Prescribers

2.1.1 Doctors, dentists and veterinary surgeons may prescribe all CDs in Schedules 2, 3, 4 and 5.

2.1.2 Doctors are only able to prescribe diamorphine, dipipanone and cocaine to substance abusers for addiction if they are approved by the Department of Health; they are covered by a general 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.

2.1.3 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

2.2.1 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. 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.

2.2.2 The details in paragraph 2.2.1 do not apply to the prescribing of cocaine, diamorphine or dipipanone for the treatment of addiction. This is restricted to Home Office licensed doctors, see paragraph 2.1.2.

2.2.3 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.

2.2.3.1 Chiropodists, podiatrists, physiotherapists, radiographers and optometrists who are supplementary prescribers are also able to prescribe CDs, in partnership with a doctor and according to the patient's CMP.

2.3 Midwives

2.3.1 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

2.4.1 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 of injured persons.

2.5 Patient Group Directions

2.5.1 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 (from 30th November 2015).
- 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 Requisitions for Controlled Drugs

2.6.1. Supplies of CDs as practice stock or stock for doctor's bags must not be acquired through the issue and collection of a named-patient prescription from a pharmacy/dispensary that is not destined for supply to that patient, even if the stock was used for that patient initially.

2.6.2 The standard requisition form, FP10 CDF for Schedule 2, and 3 CDs is available from the NHSBSA website (http://www.nhsbsa.nhs.uk/PrescriptionServices/1120.aspx). The use of this form became a legal requirement from 30th November 2015. The form can be completed electronically before printing or a blank copy can be printed and completed manually. Either way, a paper copy must be signed manually by the authorising prescriber.

2.6.3 Sections B and C of the requisition form must be completed 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
- prescriber code and profession/occupation of the authorising prescriber
- signed by the authorising prescriber (must be handwritten)
- name address and practice code

2.6.4 The supplier of the CD (for example a community pharmacy) must add their name and address indelibly onto the requisition at the time the supply is made e.g. using a stamp or complete the details in Section A. The supplier must submit all requisitions to the NHSBSA using form FP34PCD.

2.6.5 Pharmacists or doctors, who are purchasing Schedule 2 or 3 CDs from wholesalers for their dispensary, can order them electronically.

2.6.6 Doctors, other independent prescribers and pharmacists must provide the wholesaler/supplier with a signed requisition form, FP10 CDF, on receipt of the CDs.

2.7 Prescription Stationery

2.7.1 Prescription stationery for CDs, including blank prescription forms, must be stored securely to prevent theft and misuse to fraudulently obtain controlled drugs. More advice and information about the security of prescription forms is available on the CQC website www.cqc.org.uk.

3. Schedule 2 Controlled Drugs (CD POM)

3.1 Storage: 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.

3.1.1 Schedule 2 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 CDs in retail pharmacies, private hospitals and care homes. In such premises, Schedule 2 and 3 CDs must be stored in an appropriate CD cabinet or approved safe. When purchasing a safe or cabinet, check that the product complies with the requirements stated in the Misuse of Drugs Regulations 1973. Alternatively, the police can provide an exemption certificate, which certifies that the safe or cabinet provides adequate security for holding CDs. Additional guidance is available from the Home Office. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/271565/SecurityGuidanceBusinessesOrganisationsJan14.pdf

3.2 Storage: Good Practice

3.2.1 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.) Nonetheless, these regulations are considered minimum standards for safe custody and good practice recommendations should be followed.

3.2.2. All CDs must be stored in a locked secure container that is not portable. Ideally this should be an appropriate CD cabinet or approved safe.

3.2.3 The room containing the locked secure container should be lockable.

3.2.4 Access to the CD cabinet/safe should be restricted to authorised persons only.

3.2.5 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).

3.2.5.1 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.

3.2.5.2 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.

3.2.6 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.

3.2.7 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.

3.2.8. All dispensed CDs should be stored in the CD cabinet or designated safe until they are collected.

3.3 Storage in a Doctor's Bag: Legal Requirements

3.3.1. Legally, a doctor's bag is regarded, once locked, as a suitable receptacle for the storage of CDs. A locked car is not regarded as a suitable receptacle.

3.4 Storage in a Doctor's Bag: Good Practice

3.4.1. A doctor's bag containing CDs should not be left in a vehicle overnight or in a vehicle left unattended for a long period of time.

3.4.2 The bag can be lockable either by key or by combination lock.
3.4.3 Stock levels of CDs stored in the doctor's bag should be kept to a minimum.

3.4.4 Oral preparations of CDs are not considered as essential components of a doctors' 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.

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

3.5 Prescription Requirements: Legal Requirements

3.5.1 The prescription must:

- be signed by the prescriber issuing it with his/her usual signature (this must be hand written).
- be dated (this does not have to be handwritten).
- be in ink or otherwise so as to be indelible.
- specify the address of the person issuing it.
- if issued by a dentist, have written on it the words 'for dental treatment only'.
- specify the full name and address of the patient for whom the treatment is issued.
- specify 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.
- specify 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.
- specify the strength of the preparation where appropriate (e.g. if the medicine is available in more than one strength).
- specify either the total quantity of the preparation (in both words and figures) or the number of dosage units (in words and figures) to be supplied.
- specify, 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.

NB The name of the medicine is also necessary to identify which medicine is being requested, however this is not a legal requirement.

In order for a Schedule 2 CD to be supplied the prescription must fulfil all of the legal requirements outlined above. In addition, the pharmacist/dispensing assistant must ensure that the address of the prescriber is within the United Kingdom and that they are familiar with the prescriber's signature or have no reason to suppose that it is not genuine.

3.5.2 Prescriptions will be valid as long as they are written indelibly and include all of the legally required elements. This means that CD prescriptions can be type-written, handwritten or computer printed. Only the signature of the prescriber now remains to be handwritten.

3.5.3 Prescriptions for Schedule 2 and 3 CDs can now be sent electronically via the Electronic Prescription Service (EPS) and signed with an Advanced Electronic Signature (AES) as well as handwritten. This follows changes to Home Office legislation on 1 June 2015 and to NHS and Human Medicines Regulations on 1 July 2015. NB The implementation of this change will not be possible until all suppliers have updated their systems to enable dispensing of CDs via EPS.

3.5.4 Prescribing a dose range for a CD in Palliative Care

3.5.4.1 If prescribing a dose range, ensure that the direction on the prescription and the Gold CD1 Form always reflects 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.

3.6. Prescription Requirements: Good Practice

3.6.1. 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.

3.6.2 It is good practice (and will eventually become mandatory) 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.

3.7 Prescription Requirements: Private Prescribing

3.7.1 Special forms (FP10PCD) have been introduced for any **private prescription** issued by any prescriber (except veterinary prescriptions) for a Schedule 2 or 3 CD. It is a statutory requirement for private prescriptions for Schedule 2 or 3 CDs to be prescribed only on the FP10PCD form. 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 the FP10PCD form. NHS patients prescribed CDs will continue to receive their prescriptions on standard FP10 prescription forms, except in the case of instalment dispensing where the FP10MDA form will continue to be used.

3.7.2 Private prescribers are allocated a unique 6-digit private CD prescriber code by the Prescription Pricing Division of the NHS Business Services Authority. This code will differ from the current NHS prescribers' code and will start with the figure '6'. A prescriber who operates both within the NHS and privately will have two identifier codes (one NHS and one private). Community pharmacists and dispensing practices can only dispense private prescriptions for Schedule 2 and 3 CDs on FP10PCD forms that specify the prescriber's identification number.

> 3.7.2.1 If a prescriber requires a 6-digit private prescriber code, please contact the Controlled Drugs Accountable Officer by email (England.centralmidlands-cd@nhs.net) with a brief explanation why the code is required.

3.7.3 FP10PCD forms are obtainable from the Post Room, Cross O'Cliff, Bracebridge Heath, Lincoln.

3.7.4 Pharmacies and dispensing practices are required to send all original dispensed FP10PCDs to the NHS Business Services Authority on a monthly basis.

3.7.5 The private CD prescription dispensing submission form (FP34PCD), for use by community pharmacists and dispensing practices that dispense private prescriptions, will summarise the number of FP10PCD forms and private items submitted by each contractor to the NHS Business Services Authority each month.

3.7.6 It is the responsibility of the NHS England Area Teams to monitor the prescribing patterns of private prescribers using FP10PCDs using information from the NHS Business Services Authority and other local information as appropriate.

3.8. CD Register (CDR): Legal Requirements

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

3.8.1.1 All healthcare professionals who hold personal Schedule 2 CD stock must keep their own CDR and are personally responsible for keeping it accurate and up to date; this includes Schedule 2 CDs stored in doctors' bags.

3.8.2. Each doctor's bag carrying stocks of Schedule 2 CDs should have a separate CDR relating to the bag which is organised as detailed below and within which the information detailed below is recorded. E.g. within a dispensing practice, the transfer of a Schedule 2 CD from the dispensary stock to the doctor's bag should entail a record in the dispensary CDR, detailing the supply, and a record in the doctor's bag CDR detailing the receipt. This process should be checked by a second member of staff.

3.8.3. 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.

3.8.4. 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.

3.8.5. 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.

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

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

3.8.7. 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:

- the date on which the supply was made

- the name and address of the patient or firm supplied
- 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)
- quantity supplied
- person collecting the CD (patient/ patient's representative/ healthcare professional) and if it is a healthcare professional, their name and (work) address
- was proof of identity requested of patient/ patient's representative? (Yes/No)
- was proof of identity of person collecting provided? (Yes/No)
- in the case of a healthcare professional, proof of identity should be their professional registration number

These record keeping requirements are a minimum and do not prevent any person required to keep a register from including additional related information.

3.9. CD Register: Good Practice

3.9.1. 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.

3.9.2. 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.

3.9.3 Wherever CDs are being stored, it is good practice for the accountable professional to carry out a regular stock check (e.g. weekly).
3.9.4 Regular stock checks should be carried out in line with any guidance from professional representative bodies and undertaken after a risk assessment has been carried out. Frequency of CD stock reconciliation will vary according to local circumstances, volume and frequency of CD 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.

3.9.5. 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.

3.9.6. Wherever 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. 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.

3.9.7. 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.

3.9.8 For CD stock held within any type of premises, the CDR should be stored safely outside the cabinet or safe, near to it but not easily visible or accessible.

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

3.10.1. 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.

3.10.2. 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 CDs 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.

3.10.3 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.

3.10.4. 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.

3.10.5. 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.

3.10.6. 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.

3.10.7 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.

3.10.8 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.

3.11 Validity of Prescription

3.11.1 The validity period for prescriptions for Schedule 2, 3 and 4 CDs is 28 days from the date on which the prescription was signed and dated. This should minimise the risk of individuals accessing supplies of CDs a significant time after the clinical need was originally identified.

3.11.2 Arrangements for FP10MDA (instalment prescriptions) continue as before, but 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.

3.11.3 Schedule 2 and 3 CDs can not 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.

3.11.4 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.

3.12 Quantities to be Supplied: Good Practice

3.12.1 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.

3.13 Preservation of Records

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

3.13.2 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.

4. Schedule 3 Controlled Drugs (CD No Register)

4.1 Storage

4.1.1 Schedule 3 CDs are subject to the same safe custody requirements as detailed in paragraphs 3.1 to 3.4. 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.

4.2 Requisition and Prescription Requirements

4.2.1 All Schedule 3 CDs are subject to the same requisition requirements as designated for Schedule 2 CDs (see section 2.5). Schedule 3 CDs ~~(except temazepam)~~ are subject to the same prescription requirements as designated for Schedule 2 CDs (see section 3.5).

4.3 Prescription Requirements: Private Prescribing

4.3.1 Exactly the same requirements for private prescribing exist for both Schedule 2 and Schedule 3 CDs. See Section 3.7 for full details.

4.4 CD Register

4.4.1 There is no legal requirement to record transactions involving Schedule 3 CDs in a CD Register.

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

4.5.1 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.

4.5.2 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.

4.5.3 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.

4.6 Validity of Prescriptions

4.6.1 The validity period for prescriptions for Schedule 2, 3 and 4 CDs is 28 days from the date on which the prescription was signed and dated. This minimises the risk of individuals accessing supplies of CDs a significant time after the clinical need was originally identified. Further detail is provided in Section 3.11.

4.7 Quantities to be Supplied: Good Practice

4.7.1 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.

5. Disposal of Controlled Drugs

5.1 Background

5.1.1 It is crucial that CDs are 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.

5.1.2 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.

5.1.3 The Environment Agency as part of The Environmental Permitting (England and Wales) Regulations 2010 has exempted pharmacies and GP practices from needing a license to denature CDs prior to disposal. A T28 exemption needs to be registered with the Environment Agency, which can be done on their website (www.environment-agency.gov.uk) and is valid for 3 years.

5.2 Patient-Returned Controlled Drugs

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

5.2.2 All CD destruction should be undertaken using an appropriate CD destruction kit. Destruction kits are available through most wholesalers and from NHS Supply Chain. The Royal Pharmaceutical Society issues professional guidance to pharmacists on the safe destruction of CDs; local guidance based on this can be found in Appendix 1.

5.2.3 Under no circumstances should patient-returned CDs be re-entered into the CDR 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.

5.2.4 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.

5.3 Patient-Returned Controlled Drugs: Good Practice

5.3.1 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.

5.4 ‘Expired Stock’ Controlled Drugs

5.4.1 ‘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.

> **5.4.1.1 If 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.**

5.4.2 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.

5.4.3 ‘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.

5.4.4 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.

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

5.5 Destruction of 'Expired Stock' Controlled Drugs: Authorised Witnesses

5.5.1 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.

5.6 Destruction of Controlled Drugs in the community following a Patient's Death

5.6.1 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.

6. Transportation of Controlled Drugs

6.1 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.

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

6.3 Health care professionals involved in the delivery of patient care should not routinely transport CDs to and from the patient's home. It is recognised that in some circumstances this will be the only practical solution to collection and delivery problems.

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

6.5 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.

6.6 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.

6.7 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.

7. Standard Operating Procedures (SOPs)

7.1 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).

7.2 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. There is no longer a minimum list of SOPs that every organisation has to have in place; instead, 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.

7.3 It is recommended that SOPs cover all areas of CD management relevant to the service provided, for example
(1) ordering and receipt of CDs;
(2) assigning responsibilities;
(3) where CDs are stored;
(4) who has access to CDs;
(5) record keeping;
(6) administration;
(7) incidents / concerns;
(8) transport of CDs;
(9) destruction of CDs and
(10) clinical monitoring.

SOPs must be specific for the premises to which they apply.

7.4 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.

7.5 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.

8. Summary Table

	Schedule 2	Schedule 3	Schedule 4, Part I	Schedule 4, Part II	Schedule 5
Designation	CD POM	CD No Reg POM	CD Benz POM	CD Anab POM	CD Inv P or CD Inv POM
Safe custody	Yes, except secobarbital (quinalbarbitone)	No, except temazepam, diethylpropion, buprenorphine and flunitrazepam	No	No	No
Prescription requirements	Yes	Yes	No	No	No
Requisitions necessary	Yes	Yes	No	No	No
Records to be kept in a CD register	Yes	No	No (NB records are required to be kept for Sativex preferably in a CDR)	No	No
Repeats allowed on prescription (applies to private prescriptions only)	No	No	Yes	Yes	Yes
Dispensing by instalments (NHS)	Yes	No, except buprenorphine but only on FP10 (MDA)	No, except diazepam but only on FP10(MDA)	No	No
Stock destruction to be witnessed	Yes	No	No	No	No
Invoices to be retained for 2 years	Yes	Yes	No	No	Yes
Address of prescriber must be in the UK	Yes	Yes	No	No	No
Validity of prescription	28 days	28 days	28 days	28 days	6 months (if POM)

9. Accountable Officer for Controlled Drugs

9.1 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.

9.1.1 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.

9.2 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.

9.3 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.

9.4 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. The declaration and self-assessment is completed online at www.cdreporting.co.uk.

9.5 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.

9.6 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.

- The CDAO 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.

10. Care Quality Commission (CQC)

10.1 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

11. Further Information

For advice and further information on all aspects of Controlled Drug prescribing and dispensing please contact the CDAO (details in 9.6 above) or Sharon Hayler, Prescribing Advisor, Arden&GEMCSU on 01205 366273 ext 227, sharon.hayler@nhs.net.

12. References

a. Department of Health, Safer Management of Controlled Drugs: Guidance on Strengthened Governance Arrangements, January 2007

b. Department of Health, Safer Management of Controlled Drugs: Private CD Prescriptions and Other Changes to the Prescribing and Dispensing of Controlled Drugs, July 2006 (Final Guidance)

c. Department of Health, Safer Management of Controlled Drugs: Changes to Record Keeping Requirements: Guidance for implementation, October 2006 (Final Guidance)

d. Department of Health, Safer Management of Controlled Drugs: Guidance on Standard Operating Procedures for Controlled Drugs, January 2007

e. National Prescribing Centre, A guide to good practice in the management of controlled drugs in primary care (England), Third Edition, December 2009 (available from www.evidence.nhs.uk)

f. Department of Health, Safer Management of Controlled Drugs: Changes to Requirements for Requisitions for the Supply of Schedule 1, 2, and 3 Controlled Drugs, December 2007 (Final Guidance)

g. Department of Health, Guidance on the destruction of controlled drugs – new role for accountable officers – Guidance amended, December 2007

h. Department of Health, Safer Management of controlled drugs: changes to record keeping requirements, February 2008 (Final Guidance)

i. NHS England, Central Midlands Area, Standard Operating Procedure for witnessing the destruction of Controlled Drugs, Lincolnshire Update January 2016

j. NHS Lincolnshire, Policy on the Development of Standard Operating Procedures (SOPs) for the Safe and secure handling of Medicines, January 2015

k. Department of Health, Controlled Drugs (Supervision of Management and Use) Regulations 2013, Information about the Regulations, February 2013

l. Care Quality Commission, Management of Controlled Drugs, at www.cqc.org.uk

m. 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

Appendix 1

Destruction of Controlled Drugs (based on Royal Pharmaceutical Society Guidance for Pharmacists on the safe destruction of Controlled Drugs)

Methods and procedures for destruction	
Tablets, capsules and other solid dose forms	Remove from blister packaging (ensure gloves are worn) or bottle and place in a CD denaturing kit. Best practice would be to grind (using grinder in the box) or crush tablets and capsules before adding to the CD denaturing kit. NB if grinding or crushing solid dosage forms, ensure any particles of CD dust released into the air are minimised. Wear a suitable face mask, gloves and ensure the area is well ventilated.
Liquids	Liquids can be poured straight into the CD denaturing kit. Large quantities of liquids may need to be added and adsorbed into an appropriate amount of cat litter and then disposed of via the usual waste disposal method for medicines.
Suppositories	Suppositories can be dissolved in a small quantity of hot water. The resulting liquid should be poured into the CD denaturing kit or added to an appropriate amount of cat litter as for liquids above.
Fentanyl patches	Remove the backing and fold the patch over onto itself and place in the CD denaturing kit. Suitable gloves must be worn.
Fentanyl lozenges	Dissolve in a small quantity of warm water. The resulting liquid should be poured into the CD denaturing kit or added to an appropriate amount of cat litter as for liquids above.
Liquid ampoules	Liquid ampoules should be opened, the liquid placed in the CD denaturing kit and the ampoule itself placed into a sharps bin which is labelled “contains mixed pharmaceutical waste and sharps – for incineration”. Suitable gloves should be worn.
Powder ampoules	Powder ampoules should have water added to dissolve the powder; the resulting mixture should be poured into the CD denaturing kit. The ampoule should be placed into a sharps bin which is labelled “contains mixed pharmaceutical waste and sharps – for incineration”. Suitable gloves should be worn.
Multiple use vials	The contents should be removed from the vial (using a syringe and needle) and added to the CD denaturing kit. The vial should be placed into a sharps bin which is labelled “contains mixed pharmaceutical waste and sharps – for incineration”. Suitable gloves should be worn.
Aerosol formulations	Aerosols should be expelled into water (to prevent droplets of drug entering the air) and the resultant liquid poured into the CD denaturing kit.