

Controlled drugs guidance and self-assessment documentation for contracted services in primary care

Approval Process

Lead Author: Clare Moody

Developed by: Sati Ubhi, Wendy Lefort, Clare Moody,
Caroline Houlton

Approved by: Controlled Drug Monitoring Group

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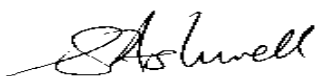
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Signatures for Ratification

1. Name: Christine Macleod Title: Accountable Officer
Signature:  Date: 24/10/2011

2. Name: Sue Ashwell Title: Chief Pharmacist
Signature:  Date: 24/10/2011

Document Control Sheet

Development and consultation:	Guidance supersedes that developed by Sati Ubhi and Wendy Lefort 2007, reviewed by Clare Moody and Caroline Houlton 2009. Approved by the Controlled Drug Monitoring Group.
Dissemination:	Guidance will be disseminated to PCT contracted services.
Implementation:	It is recommended that contracted services in primary care implement this guidance. Separate national guidance is available for community pharmacists.
Training:	No training required.
Audit:	The management of controlled drugs will be monitored as required by the Regulations, Jan 2007.
Review:	Integrated Quality and Patient Safety
CQC Compliance	This guidance supports compliance with Outcome 9 Management of Medicines.
Links with other DtGP:	Not applicable.
Equality and Diversity:	The Medication Safety Group has carried out a Rapid Equality & Diversity Impact Assessment and concluded the guidance is compliant with the PCT Equality and Diversity policy.

Controlled Drugs Guidance for Primary Care

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1. Introduction

- 1.1. The guidance summarises the current legal and good practice requirements to ensure the safe use and management of controlled drugs in Cambridgeshire and shares cumulative learning by the PCT and its contractors.
- 1.2. The Controlled Drugs (Supervision of Management and Use) Regulations 2006 stipulate that NHS Cambridgeshire appoint an Accountable Officer (AO) to ensure the safe and effective use of CDs both within the PCT and by any body or service providing services to their organisation e.g. general practitioners, community pharmacies.
- 1.3. To avoid confusion with the accountable officer in the Government's White Paper "Equity and excellence: Liberating the NHS" the CD Accountable Officer will hereafter be referred to as CDAO.

Table 1 Summary of controlled drugs by schedule, prescribed in Cambridgeshire

Schedule 1	Schedule 2	Schedule 3	Schedule 4 part 1	Schedule 5
Sativex®	Alfentanil Cyclimorph Dexamphetamine Diamorphine Dipipanone Fentanyl Hydromorphone Methadone Methylphenidate Morphine Nabilone Oxycodone Pethidine	Buprenorphine Meprobamate Midazolam Pentazocine Phenobarbital Sodium Amytal Temazepam	Chlordiazepoxide Clobazam Clonazepam Diazepam Ketamine Loprazolam Lorazepam Lormetazepam Nitrazepam Oxazepam Sodium Oxybate Zolpidem	Co-codamol Codeine (oral) Co-dydramol Co-phenotrope Co-proxamol Dihydrocodeine Migralveve® Morphine (low strength) Pholcodine
			Schedule 4 part 2	
			Danazol Mesterolone Somatropin Testosterone	

A full list of controlled drugs is held by the [Home Office](#)

2. Possession of controlled drugs

- 2.1. The following health care professionals are authorised under the Misuse of Drugs Regulations 2001 to possess, supply and compound CDs in Schedules 2, 3, 4 and 5.
 - a. Doctors
 - b. Dentists
 - c. Pharmacists
- 2.2. These people may only supply CDs to those who may lawfully possess them, including patients for whom they are prescribed.
- 2.3. **Standard operating procedures**
 - 2.3.1. All contracted services that hold or prescribe CDs are required to have standard operating procedures (SOPs). These should cover all activities which involve CDs,

including ordering, storing, prescribing, dispensing, recording, supplying, administering and destruction.

2.4. Controlled drugs declaration statement and self-assessment

2.4.1. All contracted services that hold CDs are required to carry out a self assessment, which will inform other monitoring and inspection activities.

3. Standard Operating Procedures (SOPs)

3.1. A SOP is an unambiguous document, describing the responsibilities and the procedures, including audit, necessary to safely and accountably manage any set of processes, in the case around the total management of CDs. A SOP is a working document detailing the current agreed working practice that takes account of all the areas that are applicable to the management of CD in an individual setting.

Tip: SOPs need not be large documents and should not be confused with policy or guidance. Consider a step wise approach.

3.2. All healthcare providers holding stocks of CDs must have SOPs, which will be monitored as part of the strengthened governance arrangements for CDs.

3.3. SOPs should be available to the CDAO upon request.

3.4. Minimum requirements for SOPs are outlined in the Controlled Drugs (Supervision of Management and Use) Regulations 2006.

3.5. It is a legal requirement that:

3.5.1. All healthcare providers will have and comply with an approved SOP.

3.5.2. SOPs for organisations will be agreed by the relevant Accountable Officer.

3.5.3. Each GP practice or pharmacy should have clear, written SOPs in place that are known, understood and followed by doctors, pharmacists and their staff.

3.5.4. Every PCT should have SOPs for handling CDs for all its directly managed services and staff.

3.6. The Regulations state that SOPs must cover the following:

- a. Who has access to CDs
- b. Where the CDs are stored
- c. Security in relation to storage, and transportation, of CDs as required by the Misuse of Drugs legislation
- d. Disposal and destruction of CDs
- e. Who is alerted if complications arise
- f. Record keeping – maintaining relevant CD registers under Misuse of Drugs legislation
- g. Record keeping – maintaining a record of Schedule 2 CDs that have been returned by patients

- 3.7. 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.
- 3.8. SOPs should highlight the accountabilities and roles of all members of the relevant healthcare teams.
- 3.9. The SOP should state the need to complete an incident form where appropriate.
- 3.10. The Department of Health document published in February 2007 [Safer management of controlled drugs: guidance on Standard Operating Procedures for controlled drugs : Department of Health - Publications](#) provides advice on the areas that might be considered for inclusion in a SOP.
- 3.11. The East of England Senior Pharmacy Managers' Network recommends superseded SOPs should be kept for fifteen years in case of future litigation.

4. Purchasing and supply of controlled drugs

- 4.1. Medicines prescribed for an individual patient must be supplied to, and used for / by, that patient only.
- 4.2. Prescribers must NOT use patient-specific CD prescriptions to replace or "top-up" their bags for home visits or practice stock even if the stock was used for that patient initially.
- 4.3. Prescribers should replenish their bags either through written requisitions presented at community pharmacies or from the practice stock, ensuring that the appropriate registers are completed.
- 4.4. Any person or organisation that holds stocks of CDs should keep stock levels to a minimum but enough to meet clinical need. CD usage, for example, over the last two years, should be reviewed when assessing current stock requirements. The level of stock held should then be reviewed on an appropriate / annual basis.
- 4.5. Requisitions and invoices for CDs should ideally be kept for longer than the mandatory two years, as cases often come to court at a much later date.
- 4.6. Pharmacies and dispensing doctor practices may order CDs electronically from wholesalers.
- 4.7. Some services require a Home Office licence to hold CDs. Further information is available from the CDAO's office on 01480 354 377.

Tip: Document frequency of stock review and stock levels in standard operating procedure.

4.8. Requisition requirements

- 4.8.1. Requisition for Schedule 1, 2 and 3 CDs for human use should be made on the standardised form FP10CDF (Figure 1). The regulations permit requisitions for CDs to be computer generated or handwritten. The signature of the recipient (i.e. the person ordering the CDs) must be hand written.

Requisitions must:

- a. Be signed by the requisitioner
- b. State the requisitioner's name and address

- c. State the requisitioner's profession or occupations
- d. Specify the total quantity of the drug (this does not have to be in words and figures)
- e. Specify the purpose for which it is required, such as "for practice use"
- f. The requisitioner's identification number (i.e. their professional registration number) should be included
- g. The date on which the requisition is supplied

4.8.2. A wholesaler or pharmacy supplying CDs to a prescriber must be reasonably satisfied that the requisition is a genuine document. This means that it should be the original document, hence faxed or other electronically transmitted requisitions are not currently permitted. If a messenger is sent to collect the CD they must carry a bearer's note, signed and dated by the prescriber, stating that they are authorised to collect the CD.

4.8.3. The name and address of the supplier must be recorded indelibly on the requisition. A pharmacy or dispensary stamp will suffice.

4.9. Supply of CDs on receipt of a requisition

4.9.1. Standardised requisition forms FP10CDF, figure 1, should be used to obtain CDs within the community. Prescribers or organisations who require these should contact the NHS Cambridgeshire Medicines Management Team on 01480 354 377.

4.9.2. Supplies made against requisitions are wholesale transactions. As such only unlabelled whole packs can be supplied.

Figure 1

Account number:
The supplying pharmacy's private account code

Organisation code: individuals NHS or private prescriber code or the account code of the pharmacy raising requisition

PCT code: 5PP

Practice code: NMP must also include relevant practice code

Part A Supplier Details

Stamp:	Account Number:
Name of business:	
Address:	
Address:	

Part B Controlled Drugs Requisitioned

Drug Name & Form	Strength	Quantity

Part C Customer Details

Name of customer:	Date of order:
* Organisation Code:	
* PCT Code:	
* Practice Code:	
Individual's Name (Printed):	
Professional Qualification:	
Address:	
Address:	

Part D Purpose for which drugs are required

(Tick the relevant box that applies)

1	For use within Pharmacy
2	For use within Practice/Surgery
3	For use within Hospice
4	For onward distribution
5	For stock
6	Other (please state reason briefly below)

Part E Notes on using/obtaining FP10CDF forms

- The person raising the requisition (customer) **must** –
 - Write the controlled drugs to be requisitioned (including form, strength & quantity) in Part B overleaf
 - Sign their name at the bottom of Part B overleaf. Signature must be hand-written in ink
 - Write their name, individual/organisation code*, occupation/profession/qualification (e.g. GP, pharmacist), and address of premises that they represent on Part C overleaf
 - Complete Part D above, indicating the purpose for which the drugs are required.
- The organisation code can either be the individual prescriber code, or the account code of the pharmacy raising the requisition. If an individual prescriber code is used which is not affiliated to one practice/PCT (e.g. Nurse Independent Supplementary Prescriber), then the relevant practice code and PCT code must also be included.
- The person/organisation supplying the controlled drugs (supplier) should either:
 - Write their account/business code, name of organisation, and address in Part A overleaf
 - OR
 - Include a legible stamp in the top left section of Part A, confirming their details
 - Ensure that the customer has completed their relevant sections with correct data.

The supplier **must** then submit all CD requisitions that they have processed to the PPD, using the FP34PCD form which should be downloaded from – <http://www.ppa.org.uk/pdfs/FP34PCD.pdf>

3. Supplies of the FP10CDF form can be obtained from your allocated Primary Care Trust.

Part F Data Protection Statement

This requisition will be passed to the NHS Business Services Authority (NHSBSA), a Special Health Authority in the National Health Service (NHS), for the purposes of statistical analysis of what has been supplied. The information may also be used within the NHS to prevent incorrect usage of controlled drugs, and may be disclosed to organisations outside the NHS that have a lawful entitlement to receive it. This requisition will be confidentially destroyed 24 months after the month in which it was received by the NHSBSA, unless it has been disclosed to another organisation.

4.9.3. Suppliers of CDs are required to submit the original requisitions for schedule 1, 2 and 3 CDs written in England to the NHS Prescription Pricing Division ([NHS BSA PPD](#)) with their private CD prescription account using their private CD submission F code. Suppliers who need to submit requisitions who do not already have a private CD prescription F code, must contact the Medicines Management Team 01480 354 377.

Tip: Ensure you have a SOP for using and processing FP10CDF requisition forms.

4.9.4. The PPD will accept from suppliers of CDs, requisitions written by authorised practitioners using either their NHS or private prescriber code. Authorised practitioners include pharmacists working in community pharmacies. Although not a legal requirement, it is good practice, where one pharmacy orders a CD from another pharmacy, for written requisitions to be used.

4.10. **Emergency supply – urgent supplies to prescribers**

4.10.1. A prescriber who requires a Schedule 2 or 3 CD urgently and who is unable to supply a signed requisition can request the drugs to be supplied in an emergency. The prescriber may be supplied with the CD provided he or she gives an undertaking to supply a written, signed requisition within 24 hours. Failure to do this is a criminal offence on the part of the prescriber.

4.11. **Purchasing by doctors from wholesalers**

4.11.1. Dispensing doctors, when purchasing CDs from wholesalers for their dispensary, can order them electronically. Non-dispensing doctors, however, must provide the wholesaler with a requisition.

4.11.2. It is the responsibility of the prescriber, when receiving a supply of CDs from the wholesaler, to ensure that the correct item and quantity is delivered and that all appropriate entries are made in the CD register on the day of supply, or the day following the day of supply. The task of completing the register can be delegated, but the doctor retains full accountability for this process.

4.11.3. The person receiving the CDs from the wholesaler should be authorised in writing in advance to do so by the pharmacist or doctor, and should sign the supplier's delivery note on receipt of these CDs.

Tip: Document delegation of tasks to named personnel in standard operating procedure.

4.11.4. Any tamper-evident seals on packs of CDs should be left intact when they are received from the supplier. This will simplify and speed up routine balance checks, as sealed containers can be assumed to contain the full amount as stated on the pack. A seal should only be broken when the pack is required for dispensing / administration. If, when the tamper-evident seal is broken, the contents do not match the expected amount stated on the manufacturer's pack, the following action should be taken:

- a. Wherever possible the pack and contents should be kept as evidence to present to the manufacturer / supplier and the CD should be dispensed from an alternative pack to the patient.
- b. Where this is not possible because patient care will be compromised, the professional should assure themselves that the contents are suitable for dispensing

and then appropriately repackage them for the patient, keeping the original packaging for evidence and action.

- c. Appropriate records should be made in the CD register and all necessary action taken to resolve the discrepancy.
- d. An incident report should be completed.

5. Prescribing of controlled drugs

5.1. NHS Cambridgeshire have standards of minimum governance for CD prescribing. See Appendix 1. Discussion of the standards will form part of the CD inspection process.

5.2. Except in exceptional circumstances, the person prescribing the CD should not personally undertake all of the following tasks: preparation, dispensing, transportation and administration of the CD.

5.3. CD prescriptions may, but do not have to be, computer generated. Only the signature has to be in the prescriber's own handwriting. The prescriber must sign any manuscript changes.

Tip: There have been incidents of fraud, it may be pertinent to produce a new script rather than make changes to reduce this risk.

5.4. Dosages and frequencies for all CDs should normally be written in full by the prescriber, to aid administration by nurses and carers. Particular care should be taken to ensure clarity of dosage instructions where systems such as syringe drivers are being used. An example prescription is printed in the BNF.

5.5. Any concerns regarding the prescribing of CDs should be notified to the Accountable Officer's office – 01480 372 039.

5.6. Schedule 2 and 3 controlled drugs (except temazepam)

5.6.1. A prescription for Schedule 2 and 3 CDs (with the exception of temazepam and preparations containing it) must:

- a. Contain the following details, written so as to be indelible:
 - I. The patient's full name, address and, where appropriate, age.
 - II. The name and form of the drug, even if only one form exists.
 - III. The strength of the preparation, where appropriate.
 - IV. The dose to be taken.
 - V. The total quantity of the preparation, or the number of dose units, to be supplied in words and figures.
- b. Be signed by the prescriber with their usual signature (this must be hand written) and dated by them (the date does not have to be hand written).
- c. The address of the prescriber must be stated on the prescription and must be within the UK (N.B. the UK does not include the Channel Islands or the Isle of Man).
- d. Dentists: prescriptions issued by a dentist must contain the words "for dental treatment only".

5.6.2. Prescriptions for Schedule 1, 2, 3 and 4 CDs should be limited to a quantity necessary for up to 30 days clinical need. In exceptional circumstances where the prescriber believes a supply of more than 30 days medication is clinically indicated and would not pose an unacceptable threat to patient safety, the prescriber should make a note of the reasons for this in the patient's notes and be ready to justify his / her decision if required.

Tip: MMT monitor the quantity of CDs prescribed as part of the wider monitoring process and will request an explanation of any supply that appears greater than 30 days.

5.7. Temazepam and Schedule 4 and 5 controlled drugs

5.7.1. Prescriptions for temazepam and for Schedule 4 and 5 CDs are exempt from the specific prescriptions requirements (specifying words and figures) of the Misuse of Drugs Regulations 2001. However, they must still comply with the general prescription requirements as specified under the Medicines Act.

5.8. Validity of prescriptions

5.8.1. The validity period of NHS and private prescriptions for Schedule 1, 2, 3 and 4 CDs has been restricted to 28 days. The prescription must not be dispensed if more than 28 days have elapsed since it was signed and dated by the prescriber, or if the prescription has a later start date, not more than 28 days from this date.

Tip: This includes items owing and collected at a later date. Writing the expiry date on the bag at the time of dispensing may be helpful.

5.8.2. When CDs are supplied in monitored dosage systems, if a monthly prescription is used for weekly collections the last supply must be made within 28 days of the prescription date.

5.8.3. In the case of a prescription containing a Schedule 2 or 3 CD, which directs that specified instalments of the total amount may be supplied at stated intervals, the first instalment must be supplied no later than 28 days after the "appropriate date" (see above).

5.8.4. Any space on the prescription form that has not been written on must be blanked off, e.g. by drawing a line through it to reduce the opportunity for fraud.

5.8.5. Computer systems should be used, wherever feasible, as an additional method to record and audit the prescribing of CDs. If a prescriber makes a domiciliary visit, and a CD is administered or a handwritten prescription for a CD is issued, it should be recorded on the patient's computer record as soon as possible after the event.

5.8.6. If a doctor administers CD preparations from their bag to a patient the doctor should also record the administration of the CD in his or her own CD register.

5.9. Non-Medical prescribing

5.9.1. There are restrictions placed on non-medical prescribers prescribing CDs.

5.9.2. Pharmacist independent prescribers are currently unable to prescribe CDs.

5.9.3. Nurse independent prescribers can prescribe any licensed or unlicensed medicine for any condition within their clinical competence. These include specific CDs for specific conditions. See Table 2.

5.9.4. A supplementary prescriber can prescribe any licensed or unlicensed medicine, including CDs, for any condition within their competence, as part of a patient-specific, written clinical management plan agreed with a doctor, and with the patient's agreement.

Table 2 Controlled drugs prescribable by Nurse Independent Prescribers solely for the medical conditions indicated

Drug	Indication	Route of administration
Buprenorphine	Transdermal use in palliative care	Transdermal
Chlordiazepoxide hydrochloride	Treatment of initial or acute withdrawal symptoms caused by withdrawal of alcohol from persons habituated to it	Oral
Codeine phosphate	---	Oral
Co-phenotrope	---	Oral
Diamorphine hydrochloride	Use in palliative care, pain relief in respect of suspected MI or for relief of acute or severe pain after trauma, including in either case postoperative pain relief	Oral, parenteral
Diazepam	Use in palliative care, treatment of initial or acute withdrawal symptoms caused by the withdrawal of alcohol from persons habituated to it, tonic-clonic seizures	Oral, parenteral, rectal
Dihydrocodeine tartrate	---	Oral
Fentanyl	Transdermal use in palliative care	Transdermal
Lorazepam	Use in palliative care, tonic-clonic seizures	Oral, parenteral
Midazolam	Use in palliative care, tonic-clonic seizures	Parenteral, buccal
Morphine hydrochloride	Use in palliative care, pain relief in respect of suspected MI or for relief of acute or severe pain after trauma, including in either case postoperative pain relief	Rectal
Morphine sulphate	Use in palliative care, pain relief in respect of suspected MI or for relief of acute or severe pain after trauma, including in either case postoperative pain relief	Oral, parenteral, rectal
Oxycodone hydrochloride	Use in palliative care	Oral, parenteral

5.10. Anticipatory prescribing for palliative care

5.10.1. Patients with a terminal illness often experience new or worsening symptoms for which they require urgent medication.

5.10.2. The Cambridgeshire Community Services NHS Trust policy for anticipatory prescribing for patients with a terminal illness "[Just In Case](#)" is available from the Arthur Rank House website. It describes an approved process for ensuring patients have the medication they need available when their condition deteriorates.

5.10.3. NHS Cambridgeshire works with Community Pharmacists to ensure that medication commonly required is available promptly. A [map](#) and [list](#) of pharmacies participating in this campaign is available from the CDAO's office and online. A list of the medication held is available from CDAO's office 01480 354 377.

5.10.4. The maximum strength of diamorphine held as stock by these pharmacies is 30mg. Where greater doses are required, diamorphine should be prescribed in multiples of 30mg e.g. 100mg prescribed as 3 x 30mg and 1 x 10mg, until higher strength preparations are obtained from the wholesaler.

5.10.5. It is considered unsafe to keep higher strengths of diamorphine speculatively. **Higher strength** stock e.g. 100mg should only be kept where there is active prescribing for a patient, and destroyed when the patient no longer requires the preparation.

5.11. Prescribing controlled drugs for addiction

5.11.1. Only doctors who hold a licence, issued by the Home Office, are able to prescribe diamorphine, cocaine or dipipanone to substance misusers for treatment of addiction. Prescribers can prescribe such drugs for patients, including substance misusers, for relief of pain due to organic disease or injury, without a specific licence.

Tip: Dipipanone is not recommended for prescribing locally due to concerns about diversion.

5.12. Prescribing in instalments

5.12.1. Some CDs can be dispensed to substance misusers in instalments providing they are prescribed using specific NHS prescription forms. A prescriber writing a private prescription can also ask for the prescription to be dispensed in instalments.

5.13. FP10 (MDA)

5.13.1. In England, GPs must use the form FP10(MDA) to prescribe in instalments Schedule 2 CDs, buprenorphine (Schedule 3) or diazepam (Schedule 4) for drug addiction. This form must not be used for any other purposes, e.g. when the total quantity needs to be dispensed at one time – in this case the normal FP10 form must be used.

5.14. Details to be specified

5.14.1. If a CD prescription is to be dispensed in instalments, e.g. daily, then the prescriptions must specify the following details:

- a. The number of instalments.
- b. The intervals to be observed between instalments, if necessary, instructions for supplies at weekends or bank holidays should be included.
- c. The total quantity of CD that will provide treatment for a period not exceeding 14 days.
- d. The quantity to be supplied in each instalment.

Tip: Check bank holiday opening times of client's community pharmacy.

5.15. Collection of instalments

5.15.1. The prescription must be dispensed on the date on which it is due. If the client does not collect an instalment when it is due that supply is no longer valid. The client cannot collect that supply the following day.

5.15.2. If a prescriber has ordered several days' instalments to be collected on one day and the client does not come in on the specified day, then the client loses the complete instalment, the client cannot have the remainder of the instalment.

5.15.3. However, the use of specific wording on the prescription can overcome this and will enable those supplying CDs to issue the remainder of an instalment prescription when the client has failed to collect the instalment on the specified day.

5.15.4. The wording below can be used by those prescribing CDs by instalment in accordance with the Misuse of Drugs Regulations 2001. If a prescription does not contain such wording the Regulations only permit the supply to be made in accordance with the prescribers instalment direction.

Approved wording for missed dose – supervised consumption:

“Supervised consumption of daily dose on specified days; the remainder of supply to take home. If an instalment prescription covers more than one day and is not collected on the specified day, the total amount prescribed less the amount prescribed for the day(s) missed may be supplied”

Approved wording for missed dose – unsupervised consumption:

“Instalment prescriptions covering more than one day should be collected on the specified day; if this collection is missed the remainder of the instalment (i.e. the instalment less the amount prescribed for the days missed) may be supplied.”

Or:

“If an instalment prescription covers more than one day and is not collected on the specified day, the total amount prescribed less the amount prescribed for the days missed may be supplied.”

5.15.5. The client should collect the CD in person. If the client is unable to collect prescriptions personally, the client may arrange in advance for a representative to collect it. The representative should bring a suitable note on each occasion to ensure they have the authority to collect.

5.15.6. The requirements to see identification on collection only apply to the first dispensing of an instalment prescription. It is good practice to request ID if the client is unknown to the supplying pharmacist.

5.16. **Emergency supplies**

5.16.1. Emergency supplies (as defined in the Medicines Act) of Schedule 2 and 3 CDs for a specific patient, are not permitted either at the request of the patient or a prescriber. The only exception to this rule is phenobarbital for the treatment of epilepsy.

5.17. **Prescribing to self and family**

5.17.1. Other than in emergencies, no prescriber should prescribe any drug for themselves or anyone with whom they have a close personal or emotional relationship.

5.18. **Private prescribing**

5.18.1. When writing private prescriptions, prescribers must comply with all legal requirements, including appropriate record keeping when ordering, prescribing, dispensing, administering and destroying CDs. CDs can only be prescribed on the approved private prescription form. If private prescription pads are required, please contact the Medicines Management Team 01480 354 377.

5.19. **Standardised private prescription form (FP10PCD)**

5.19.1. All private prescriptions for human use of Schedule 1, 2 and 3 CDs (including temazepam) that are presented for dispensing in the community (not the hospital) must be written on a standard private prescription form, FP10PCD, see Figure 2. The prescription must include the private prescriber’s unique (six digit) identification number,

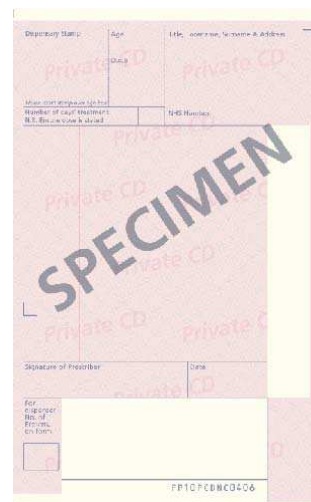
issued specifically for their private prescribing activity. For further information, please contact the Medicines Management Team 01480 354 377.

Figure 2

5.19.2. The National Clinical Assessment Service (NCAS) and the NHS Clinical Governance Support Team have suggested the following good practice for private prescribers:

Private prescribers should produce their own guidance for use in their services with respect to:

- a. Treatment, prescribing and review policies
- b. Clinical governance systems
- c. Training and continuing professional development



6. Dispensing of Controlled Drugs

- 6.1. Details of supplies of Schedule 2 CDs must be entered into the CD register as soon as possible and at the latest the day following the day of supply.
- 6.2. The date entered in the CD register should be the date of supply (i.e. the date on which the CD is handed to the patient / patient's representative) and not the date when it is assembled.
- 6.3. The pharmacist / dispensing doctor must endorse the prescription for Schedule 2 and 3 CDs with the date of supply to the patient.
- 6.4. As with all dispensed medicinal products (except unlicensed medicines), it is a legal requirement to provide a manufacturer's patient information leaflet.
- 6.5. Patients, or their representatives collecting Schedule 2 and 3 CDs should sign for receipt of the medication. This applies to both NHS and private prescriptions. Patients, or their representative should be asked to sign the back of the prescription on collection of the above dispensed medicines.
- 6.6. If a prescription for a CD is presented for dispensing, but is not due to be collected until a future date or time, the prescription can be assembled in advance. However, the details should not be entered in the CD register until after the CD has been supplied to the patient / patient's representative.
- 6.7. It is good practice for a second person to check the quantity / volume and strength of a CD being dispensed, although this may not be practical in all situations. If a second person is not available a mental break between assembly and check should be taken.
- 6.8. The National Patient Safety Agency has issued a rapid response report "[reducing errors with opioid medication](#)" that includes a dispensing algorithm, as well as algorithms for prescribing and administration. The actions in the report should have been incorporated into practice by 30th January 2009.
- 6.9. As with all prescribed medicines, the dispenser should ensure that CDs are normally dispensed in child resistant containers, or with child resistant closures.

6.10. **Dispensing against instalment prescriptions FP10(MDA)**

- 6.10.1. For instalment prescriptions of Schedule 2 CDs each supply must be entered on the day of supply into the relevant section of the CD register. The task must not be left until the end of the prescription period or carried out in advance.
- 6.10.2. Instalments must only be supplied on the day that they are due, as specified on the prescription. See section 5.15.
- 6.10.3. NHS (General Medical Services Contract) Regulations 2004 specify that no more than 14 days treatment can be prescribed on NHS instalment prescriptions.

6.11. **Validity**

- 6.11.1. Prescriptions for Schedule 1, 2, 3 and 4 CDs are valid for 28 days. The 28 day period starts on the applicable date entered on the prescription form. This date will be the date of signing or a start date specified by the prescriber on the form. The first instalment must be dispensed within the 28 day limit, with the remaining instalments dispensed in accordance with instructions.

6.12. **“Owing” prescriptions for controlled drugs**

- 6.12.1. If the pharmacist / dispensing doctor is unable to supply the total quantity of the drug requested, the entry made in the CD register must only be for the quantity of drug actually supplied. A further entry must be made when the balance is supplied. If the patient no longer requires the balance of the prescription, the prescription should be endorsed with the amount dispensed. It is good practice to record the reason why the remainder was not dispensed. It is good practice to record the reason why the remainder was not dispensed e.g. the patient has died.

- 6.12.2. The balance can not be supplied if more than 28 days have elapsed since the prescription was dated even if the original supply was made within that time.

Tip: Ensure you have robust mechanisms for identifying date expired prescriptions.

6.13. **Dispensing private prescriptions**

- 6.13.1. Private prescriptions for Schedule 2 and 3 CDs must be written on FP10PCD prescription forms.
- 6.13.2. The prescription must include the private prescriber's identification number.
- 6.13.3. The prescription must be submitted to the NHS Prescription Pricing Division [NHS BSA PPD](#) with their private CD prescription account using their private CD submission F code.

Tip: Ensure you have a SOP for using and processing FP10PCD prescription forms.

6.14. **Dispensing doctors**

- 6.14.1. Practice and partners carry vicarious liability for errors made, or for any breach of the law. A dispenser or other dispensing doctor employee should not dispense a Schedule 2 or 3 CD with out first checking the dispensed items with a doctor.
- 6.14.2. Contracted dispensing services restrictions apply equally to the supply of CDs. Please contact the CDAO's office if the practice receives requests to dispense CDs to non-dispensing patients.

6.15. **Diamorphine**

6.15.1. It is considered unsafe to keep higher strengths of diamorphine e.g. 100mg speculatively. Pharmacies keeping palliative care drugs, see anticipatory prescribing, do not keep more than 30mg diamorphine in stock.

6.15.2. Where greater doses are required, diamorphine should be prescribed in multiples of 30mg e.g. 100mg prescribed as 3 x 30mg and 1 x 10mg, until higher strength preparations are obtained from the wholesaler.

6.15.3. Higher strength stock should only be kept where there is active prescribing for a patient, and destroyed when the patient no longer requires the preparation.

7. Recording of Controlled Drugs

7.1. This section applies to all CD registers, whether held by a doctor, a pharmacist or other healthcare professional (personally or as part of the activities of an organisation).

7.2. Records for Schedule 2 CDs must be kept in a CD register. This is not a legal requirement for Schedule 3, 4 or 5 CDs.

7.3. All premises must have a CD register. Each premises must only have one register.

7.4. All healthcare professionals who hold personal CD stock must keep their own CD register, and they are personally responsible for keeping this accurate and up-to-date.

7.5. Currently the register must:

- a. Be bound (not loose-leaved) or a computerised system which is in accordance with best practice guidance.
- b. Contain class sections for each individual drug.
- c. Have the name of the drug specified at the top of each page.
- d. Have entries in chronological order and made on the day of the transaction or the next day.
- e. Have entries made in ink or otherwise so as to be indelible or in a computerised form which every such entry is attributable and capable of being audited and is in accordance with best practice guidance endorsed by the Secretary of State under section 2 of the NHS Act 1977.
- f. 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.
- g. Be kept at the premises to which it relates and be available for inspection at any time. A separate register must be kept for each set of premises (for example, not just the main surgery).
- h. Be kept for a minimum of two years after the date of the last entry, once completed.
- i. Not be used for any other purpose.

Tip: You may like to include an explanation to aid audit.

7.6. Computerised controlled drug registers

7.6.1. The definition of a CD register in the 2001 Regulations was amended in November 2005 to allow (not require) the register to be held on a computerised system which

complies with specified best practice guidance. The Regulations require that entries in computerised register must be attributable and capable of being audited.

- 7.6.2. If the CD register is held in computerised form, the following should be put in place:
- a. Safeguards should be incorporated in the software to ensure the author of each entry is identifiable.
 - b. Entries cannot be altered at a later date.
 - c. A log of all data entered is kept and can be recalled for audit purposes.

7.7. Record keeping requirements

7.7.1. For CDs received into stock the following details must be recorded in the CD register:

- a. The name, form and strength of the CD (at the top of the page).
- b. The date on which the CD was received.
- c. The name and address of the supplier, e.g. wholesaler, pharmacy.
- d. The quantity received.

7.7.2. For CDs supplied to patients (via prescriptions) or to prescribers (via requisitions), the following details must be recorded in the CD register:

- a. The name, form and strength of the CD (at the top of the page).
- b. The date on which the supply was made.
- c. The name and address of the patient or prescriber receiving the CD.
- d. Particulars of the authority of the person who prescribed or ordered the CD.
- e. The quantity supplied.
- f. Details of the person collecting the CD – patient, patient's representative, or healthcare professional (if the latter, also record their name and address).
- g. Whether proof of identity was requested of the person collecting (Yes/No).
- h. Whether proof of identity was provided (Yes/No).

Tip: It is illegal to record "not applicable" in either proof of identity fields.

7.7.3. The 2001 Regulations were amended in July 2006 to make clear that the record keeping requirements of the CD Regulations are a minimum and do not prevent any person required to keep a CD register from including additional related information.

7.8. Proof of identity: prescriptions for Schedule 2 controlled drugs

7.8.1. Organisations supplying Schedule 2 CDs on prescription should establish whether the person collecting the drug is the patient, the patient's representative or healthcare professional acting in his professional capacity on behalf of the patient.

7.8.2. **Patient or patient representative** – where the person is the patient's representative, e.g. a friend, neighbour etc., the dispenser:

- a. May request evidence of that person's identity; and

- b. May refuse to supply the drug if he is not satisfied as to the identity of that person

7.8.3. **Healthcare professional** – where the person collecting the prescription is a healthcare professional acting in his professional capacity on behalf of the patient, the dispenser:

- a. Must obtain that person's name and address;
- b. Must, unless he is acquainted with that person, request evidence of that person's identity; but
- c. May supply the drug even if he is not satisfied as to the identity of that person.

Tip: Record the HCP home address. GP dispensers to request I.D. of external HCP e.g. locums, community nurses.

7.8.4. When a Schedule 2 CD is supplied on prescription it must be recorded whether the person who collected the drug was the patient, the patient's representative or a healthcare professional acting on behalf of the patient.

7.8.5. When the person who collected the drug was a healthcare professional acting on behalf of the patient, that person's name and address must be recorded.

7.8.6. If that healthcare professional is also the prescriber the CDAO should be notified.

7.8.7. When the person who collected the drug was the patient or their representative whether evidence of identity was requested (annotate in the yes / no column) must be recorded. As a matter of good practice a note as to why the dispenser did not ask may be included but this is not mandatory.

7.8.8. Discretion can be exercised by the dispenser whether or not you ask patient representatives for identification if to do so would compromise patient confidentiality or deter patients from having their medicine dispensed.

7.8.9. Whether evidence of identity of the person collecting the drug was provided, or not, must be recorded.

7.8.10. It is good practice to record information to support the proof of identity requirements, for healthcare professionals this may be their registration number.

7.9. Prescriber and dispenser details

7.9.1. CD registers are allowed but not required to include:

- a. The prescriber identification number (six digit private prescriber code or the NHS prescriber code) and / or professional registration number of the prescriber where known.
- b. The name and professional registration number of the pharmacist or dispensing doctor.

7.9.2. As the dispensing of a prescription can involve several pharmacists, it should be the pharmacist who makes the supply of CDs to a patient or his/her representative whose name and professional number are entered in the CD register.

7.10. Maintaining a running balance of stock

7.10.1. Pharmacists and other healthcare professionals who supply CDs should maintain a running balance of stock in their CD registers as a matter of good practice.

7.10.2. The aim of the running balance is to identify irregularities or discrepancies as quickly as possible.

7.10.3. The running balance of drug remaining should be calculated and recorded after each transaction. Wherever possible, two members of staff should check all stock received or removed, and both individuals should initial the entry in the CD register, where the format of the register allows this.

7.10.4. The running balance must include all stock, include stock which is date expired or otherwise not suitable for dispensing.

7.10.5. The running balance should be reconciled with the physical amount of stock at regular intervals. The interval should be stated in the standard operating procedure. The interval should reflect the level of activity. This is normally weekly but may be more frequent if volume of CD dispensing is high.

Tip: Reconcile the running balance working from the CD register rather than from the cabinet to ensure that all records are checked including those of low use products.

7.10.6. It is good practice for a pharmacist, doctor or other HCP, when first taking over accountability for premises that hold CD stock, and where they will be in regular attendance, to ensure CD stock levels are correct.

7.10.7. The reconciliation should be recorded in the CD register as a chronological entry.

7.10.8. Accountability for maintaining the running balance of CD stock and dealing with any discrepancies lies with the healthcare professional in charge (pharmacist, doctor) of the healthcare working environment.

7.11. Dealing with discrepancies

7.11.1. Standard operating procedures (SOPs) held by each organisation should clearly define the action to be taken if a discrepancy arises.

7.11.2. If a discrepancy can be resolved following checks a marginal note or footnote should be made in the CD register and the discrepancy corrected.

Tip: Running balances for liquids can be affected by overage, residue and spillage. Tolerance of 5% loss has been agreed by Cambs LIN.

7.11.3. It is advisable to keep appropriate records of the action taken when discrepancies arise. If the source of the discrepancy cannot be identified during the checks a nominated member of the relevant organisation should be informed and a formal internal investigation undertaken. This process may include discussion with the relevant professional body, or other inspectors. If this still does not resolve the issue satisfactorily the CDAO and police should be informed.

7.11.4. The CDAO will request a list of all personnel who were present during the relevant time period.

7.11.5. An incident form should be completed. The CDAO should be informed of the outcome of any internal investigations undertaken within an organisation. In addition, any investigation should be referenced in the annual CD declaration and self-assessment.

7.11.6. Advice is available, and expected to be sought, from the CDAO's office if concerns relating to the management and use of CDs are identified at any time.

7.12. **Preservation of records**

- 7.12.1. Registers of Schedule 2 CDs must legally be preserved for two years.
- 7.12.2. Where registers contain a record of a destruction, the East of England Senior Pharmacy Managers' Network recommends these should be kept for seven years.
- 7.12.3. Invoices for Schedule 3 and 5 CDs must legally be retained for two years.

7.13. **Doctor's bag**

- 7.13.1. All healthcare professionals who hold personal CD stock must keep their own CD register, and they are personally responsible for keeping this accurate and up to date.
- 7.13.2. A doctor's bag is a lockable bag containing medicines and medical equipment, occasionally including CDs, that doctors use when outside, and sometimes inside, their surgeries.
- 7.13.3. Where a doctor carries a bag containing CDs for home visits, etc., a separate CD register must be kept for the CD stock held within that bag.
- 7.13.4. Restocking of the bag from practice stock should be witnessed by another member of the practice staff, as should appropriate entries into both the bag and practice CD registers.
- 7.13.5. Where a prescription is written by a doctor following the administration of a CD to a patient, the doctor should endorse the prescription with the word "administered" and then date it. This aims to avoid unauthorised individuals attempting to reuse such "prescriptions" to obtain CDs illegally. Information should also be entered into the patient's record as soon as possible.
- 7.13.6. Doctors must NOT use patient-specific CD prescriptions to replace or 'top-up' their bags for home visits or practice stock, even if the stock was used for that patient initially. This may be considered as an offence under the Theft Act 1968 and could be seen as a means of obtaining CDs by deception.
- 7.13.7. If a doctor does not carry CDs in his bag, but occasionally takes stock from the surgery to a patient's home, the doctor should transfer the stock from the surgery's CD register into his own register whilst he is carrying the CD in his bag. If the CD is not used the stock should be re-entered into the main surgery register and out of his own register.
- 7.13.8. Although the Fourth Report of the Shipman Enquiry (chapter 14) showed there was strong support for the suggestion that GPs within the same practice who shared the use of an emergency bag should be allowed to keep one CD register which identified who administered or otherwise disposed of the drugs, this has not yet been legally tested.

7.14. **Recording of patient returned controlled drugs**

- 7.14.1. When CDs are dispensed they become the property of the patient they were dispensed for. In the event of a patient's death they become property of the patient's estate.
- 7.14.2. Patients can return unwanted or unused CDs to a doctor or pharmacist for the purpose of destruction.
- 7.14.3. CDs returned from patients must not be returned to stock or reused.

7.14.4. CDs returned from patients are still subject to safe custody requirements and must be kept in the CD cabinet until such time that they are destroyed.

7.14.5. The Controlled Drugs (supervision of Management and Use) Regulations require standard operating procedures to be in place for maintaining a record of Schedule 2 drugs that have been returned by patients.

7.14.6. It is good practice for pharmacists and doctors to keep a separate book to record all CDs returned by patients (drug, formulation, strength and quantity). Patient returned CDs must not be recorded in the main CD register and do not form part of the running balance.

7.14.7. Although it is not a legal requirement to destroy patient returned CDs in the presence of an authorised witness, good practice recommends that they are witnessed by another member of staff. The signature of both the person witnessing and the person destroying should be entered in a separate book set aside for this purpose.

Tip: Pre-printed patient returned CDs registers are available.

7.15. Recording of expired controlled drugs stock

7.15.1. Expired stock should be quarantined from working stock but must not be entered out of the register until physically destroyed in the presence of an authorised witness.

7.15.2. When CDs kept in a doctor's bag expire they should be returned to central practice stock and quarantined from working stock until physically destroyed in the presence of an authorised witness.

7.15.3. If the practice does not hold central stock, the CDs need to be destroyed directly from the bag in the presence of an authorised witness and records made in the CD bag register.

8. Destruction of Controlled Drugs

8.1. Stock controlled drugs

8.1.1. Stock refers to CDs that have not been issued / dispensed to a patient.

8.1.2. The possession, storage and destruction of CD stocks are governed by the Misuse of Drugs Act 1971 and Misuse of Drugs Regulations 2001 as amended.

8.1.3. Safe custody applies to date expired CDs as well as useable stock. When Schedule 2 CDs, plus temazepam, flunitrazepam, buprenorphine and diethylpropion pass their expiry date, they should remain in the CD cabinet until destruction takes place. They should be segregated and clearly marked as "date expired" stock to prevent them being issued to patients erroneously.

Tip: The frequency at which destruction of CD stock takes place should be documented in SOPs and reflect availability of safe storage space.

8.1.4. Those healthcare professionals and service providers required by law to maintain a CD register e.g. pharmacists, doctors, care homes (with nursing) are not allowed to destroy expired Schedule 2 CDs from their stock without the destruction being witnessed by an authorised person.

8.1.5. All Schedule 2, 3 and 4 (part 1) CDs require denaturing as part of the destruction process.

8.1.6. Denaturing usually requires an appropriate licence from the Environment Agency. Doctors dispensaries and pharmacies can apply for an exemption to the licence, a T28 exemption, allowing them to sort and dispose of CDs and to comply with the 2001 Regulations by denaturing them prior to disposal. The exemption needs to be registered with the [Environment Agency](#) .

8.2. Records of destruction

8.2.1. When a stock CD is destroyed details of the drug must be entered in to the CD register.

8.2.2. This should include the name, form and strength of drug, the quantity, the date it was destroyed and the signature of the authorised person who witnessed the destruction and the professional destroying it i.e. two signatures.

8.2.3. When signing the CD register it is good practice for the authorised witness to state their authority e.g. professional registration number.

8.3. Persons currently authorised to witness the destruction of controlled drugs

8.3.1. The Accountable Officer has delegated the responsibility to witness the destruction of stock CDs to appropriately trained members of the NHS Cambridgeshire Medicines Management Team.

8.3.2. The list is held and maintained by the CDAO's office.

8.3.3. Doctors and independent pharmacists requiring the presence of an authorised witness to stock destruction should contact the CDAO's office on 01480 354 377.

8.3.4. Witnesses for larger chain community pharmacies (multiples) are authorised by the PCT hosting the pharmacies' head office. These community pharmacies should contact their Superintendent Pharmacist's office to arrange an authorised witness.

8.4. Patient returned controlled drugs

8.4.1. When CDs are dispensed they become the property of the patient they were dispensed for. In the event of a patient's death they become property of the patient's estate.

8.4.2. Patients can return unwanted or unused CDs to a doctor or pharmacist for the purpose of destruction.

8.4.3. Community pharmacies can accept CDs returned by patients from their own homes, including care homes, for safe destruction and onward disposal even if they did not originally dispense them. Further information can be found on the Pharmaceutical Services Negotiating Committee (PSNC) website [Essential Services: Waste Management](#) .

Tip: It is unwise for a non-dispensing practice to accept patient returns as they will not have the resources to process them.

8.4.4. CDs returned from patients must not be returned to stock or reused.

8.4.5. CDs returned from patients should be destroyed as soon as practicable.

8.4.6. There is currently no requirement for patient returned CDs to be destroyed in the presence of an authorised witness. It is good practice and strongly recommended that doctors and pharmacists have the destruction of these returns witnessed by another member of staff (preferably by a registered healthcare professional).

8.4.7. A record of the destruction should be made in a separate book set aside for this purpose. This must not be the main CD register.

8.4.8. It is good practice for both the person denaturing and the person witnessing to sign that this has taken place.

8.5. Methods of destruction of controlled drugs

8.5.1. Before disposing of Schedule 2, 3 and 4 (part 1) CDs they must be denatured so as to make them unrecoverable.

8.5.2. A CD denaturing kit should be used for the purpose. Kits are available from waste contractors, pharmaceutical wholesalers and NHS Supply Chain.

8.5.3. CD denaturing kits are non-hazardous. However, COSHH data sheets should be available and reference in case of accidental exposure to denaturing material.

8.5.4. The instructions for adding drugs, and final volume of water, stated on the kit label should be followed. These may differ depending on the manufacturer.

8.5.5. The filled denaturing kit should be placed in the pharmaceutical waste bin for collection by waste contractor. Some kits require storage in the CD cabinet for 24 hours after filling.

8.5.6. **Solid dose formulations**

a. Tablets and capsules should be removed from their outer packaging, removed from blister packaging and placed in the denaturing kit.

b. Gloves should be worn.

c. If kit instructions require tablets to be crushed, or capsules opened, care must be taken to ensure particles of drug “dust” are not released into the air. The use of a small volume of water while crushing may assist. A face mask should be worn and the area well ventilated.

Tip: Where possible, it is advisable to use kits where tablet crushing is not required.

8.5.7. **Liquid dose formulations**

a. CD liquids should be poured from the original container into the denaturing kit.

b. CD liquids should not be used to make up the final volume of the kit. Use water as instructed on the label.

8.5.8. **Parenteral formulations (injections)**

a. Ampoules containing liquid should be opened and as much of the content as possible emptied into the denaturing kit.

b. Ampoules containing the CD in powder form should be reconstituted with water and as much of the resultant solution as possible emptied into the denaturing kit.

c. A needle and syringe may be used for drawing up the liquid. The practice should have a sharps injury policy.

d. Gloves should be worn.

- e. The empty ampoule should be disposed of in a sharps bin. The sharps bin should be appropriately labelled as per waste disposal regulations and contract.
- f. Whole ampoules should not be added to the denaturing kit.

8.5.9. ***Transdermal patches e.g. fentanyl***

- a. The active ingredient in a patch can be rendered irretrievable by removing the backing and folding the patch over on itself and then placing in the denaturing kit.
- b. Gloves should be worn.

8.5.10. ***Aerosol formulations***

- a. Aerosol formulations should be expelled into water to prevent droplets of drug entering the air.
- b. The resultant solution should then be transferred to the denaturing kit.
- c. A face mask should be worn and the area well ventilated.

9. Storage of Controlled Drugs

9.1. Controlled drugs in premises

9.1.1. The Misuse of Drugs (Safe Custody) Regulations 1973 impose controls on the storage of Schedule 1, 2 and 3 CDs. The Regulations apply to all Schedule 2 CDs (except quinalbarbitone) and the Schedule 3 drugs buprenorphine, diethylpropion, flunitrazepam and temazepam.

Tip: Temazepam must be stored in a CD cabinet. Midazolam need not be stored in a CD cabinet.

9.1.2. The Regulations state that such CDs must be stored in a cabinet or safe, locked with a key. The lock should have at least 5 differing levers or, in the case of a pin and tumbler mechanism, at least 6 pins. The cabinet should be made of metal, with suitable hinges and fixed to a wall or the floor with rag bolts that are not accessible from outside the cabinet.

9.1.3. In residential and healthcare settings it is recommended that the specification of cabinets and safes set out in Schedule 2 of the Misuse of Drugs (Safe Custody) Regulations 1973 should be regarded as a minimum standard for the storage of CDs.

9.1.4. Regulation 5 of the Regulations requires CDs (other than those specified in Schedule 1 of that Regulation) to be kept in a locked receptacle which can only be opened by the person to whom the Regulation applies (or a person authorised by him/her). The exceptions to this are drugs prescribed to persons for treatment purposes i.e. the patient and carriers (including the Post Office).

9.1.5. The Controlled Drugs (Supervision of Management and Use) Regulations 2006 specify that arrangements for CD storage must be covered in SOPs.

9.1.6. Where practicable different strengths of the same medication should be segregated. The National Patient Safety Agency safer practice notice [Ensuring safer practice with high dose ampoules of diamorphine and morphine](#) also requires separate storage for low and high strength products.

9.1.7. If a safe is used to store CDs there should be a separate receptacle within the safe that keeps the CDs apart from other items, e.g. money, valuables.

- 9.1.8. Nothing should be displayed on the outside to indicate that CDs are kept within the container.
- 9.1.9. The room housing the container should be lockable and tidy, to avoid drugs being misplaced.
- 9.1.10. The room housing the container should not normally be accessible to patients, nor should the keys required for access. If patients do have to enter the area where CDs are stored, it is good practice that they should be continuously supervised until such time as they leave the area.
- 9.1.11. One designated person within the premises should take overall responsibility for the keys / digital key codes.
- 9.1.12. The number of sets of keys to the container, and who holds them, or who has access codes for digital key pads, must be known at all times by the designated person.
- 9.1.13. The keys should always be kept separate from the container and should never be accessible to unauthorised persons.
- 9.1.14. The container should only be opened by the designated person, or by a person authorised by them, e.g. a locum. The designated person remains ultimately accountable for the management of the CDs.
- 9.1.15. Other drugs that are liable to misuse can be locked in the container if this is deemed appropriate by the relevant healthcare professional.
- 9.1.16. For CD stock held within any type of premises, the CD register should be stored safely outside the CD cabinet but near to it and not easily visible or accessible.
- 9.1.17. All CDs should be stored out of sight and reach of children.

Tip: Keys should never be left unattended. When keys are not in personal possession of a designated person a digital key safe provides appropriate security.

9.2. Controlled drugs in a doctor's bag

- 9.2.1. A doctor's bag is a lockable bag containing medicines and medical equipment, occasionally including CDs, that doctors use when outside, and sometimes inside, their surgeries.
- 9.2.2. A doctor's bag should be kept locked at all times, except when in immediate use.
- 9.2.3. The person in lawful possession of this bag, or an individual authorised by them, must always retain the keys.
- 9.2.4. For a bag for home visits, etc., a digital combination lock on a case is often the most practical and convenient solution and avoids problems with keys.
- 9.2.5. Legal precedent (Rao v Wyles 1949) holds that such a bag is regarded, once locked, as a suitable receptacle for storing CDs, but a locked car is not.
- 9.2.6. Bags containing CDs should not be left in a vehicle overnight, or in a vehicle left unattended for long periods of time. The bag should be out of sight during transit.
- 9.2.7. When a bag for home visits, etc., containing CDs is in the practice, it should be stored in a safe place, away from patient areas, preferably in a locked room.

- 9.2.8. The stock levels held in this bag should be kept to a minimum and informed by previous requirements.
- 9.2.9. Normally, only one strength of each CD should be kept in a bag for home visits, etc., in order to minimise the risk of confusion, error and inappropriate administration.
- 9.2.10. The NPSA safer practice notice [Ensuring safer practice with high dose ampoules of diamorphine and morphine](#) recommends that where opioids are carried sufficient naloxone injection should be available to treatment accidental overdose.
- 9.2.11. Oral preparations of CDs would not routinely be considered essential items to be carried in such a bag.
- 9.2.12. It is good practice for the doctor, or a delegated member of staff, to undertake a monthly stock check of CDs held within each bag for home visits. This process also provides a good opportunity to check for any date expired (or soon to expire) stock. This needs to be included in the SOP.

10. Transportation of Controlled Drugs

- 10.1. Nurses, midwives, doctors, pharmacists, pharmacy staff and other healthcare professionals, plus formal carers and patients' representatives, are legally allowed to transport CDs to a patient, provided the CDs have been prescribed, by an appropriate prescriber, for that patient.
- 10.2. Any nominated individual is also allowed to return CDs from the patient to the pharmacy, or the practice for destruction.
- 10.3. Healthcare professionals involved in the delivery of patient care should not routinely transport a patient's own CDs to and from that patient's home. Where this is essential, part of an organised service, or where pharmacists operate collection and delivery schemes to the housebound and other vulnerable patients, the CDs should be kept out of view during transit.
- 10.4. The CDs should preferably be transported in a locked box.
- 10.5. A full audit trail should be maintained.
- 10.6. CDs should not generally be transported via mail, taxi services or equivalent. However, in exceptional circumstances, where urgent clinical need dictates, dispensed CDs can be sent to a patient, or stock CDs to premises, via such routes. Where the mail route is used, the CD should always be sent as a special delivery item to ensure the entire pathway is auditable (i.e. not just signed on receipt).
- 10.7. Prescription forms for Schedule 2 CDs should not routinely be sent to the patient's pharmacy via the postal system, but should be collected from the surgery by a healthcare professional, a member of their staff, the patient or their representative.
- 10.8. Prescription forms for treatment of drug addiction are often sent to pharmacies as it is not always practicable for the pharmacist to collect prescriptions from practices or addition service premises, and it is not always desirable for the patient to be handed the prescription.
- 10.9. Where such prescriptions are transported via mail, taxi service or equivalent a robust SOP must be developed reflecting a risk managed assessment. There should be a full audit trail. Where the mail route is used, the CD should always be sent as a special delivery item to ensure the entire pathway is auditable (i.e. not just signed on receipt).

11. Overseas Travel

- 11.1. The [Home Office | Personal licences](#) advises travellers who are carrying CDs from the UK, or into the UK for personal use may need a personal licence.
- 11.2. Travellers will require a person import or export licence if:
 - a. They are travelling for three calendar months or more
 - b. They are carrying more than three months supply of CDs
- 11.3. Personal licences should be applied for at least ten working days before the travel date.
- 11.4. A personal licence has no legal standing outside the UK and is intended to allow travellers to pass through UK customs unhindered.
- 11.5. Some countries have their own importation regulations for CDs. It is recommended that travellers contact the country's Embassy to check these regulations.
- 11.6. CDs should be carried in their original packaging and in hand luggage. However travellers should check with their carrier in advance of travel date that carrying the entire amount in hand luggage is allowed.
- 11.7. The traveller should be provided with a copy of their prescription and a letter stating:
 - a. Their name
 - b. Travel itinerary
 - c. Names of the prescribed CDs
 - d. Dosages
 - e. Total amounts to be carried
- 11.8. If a person is staying outside their resident country for a period exceeding three months, they are advised to register with a doctor in the country they are visiting for the purpose of receiving further prescriptions, appropriate follow-up and monitoring.
- 11.9. Furthermore, the [GMS contract](#) states that the PCT shall remove a patient from the contractor's list of patients where it receives notification that the patient intended to be away from the UK for a period of at least three months (paragraph 216.1) or has been absent from the UK for a period of more than three months (paragraph 216.4).

12. Governance, Inspections and Monitoring

- 12.1. The Health Act 2006 introduced the requirement for relevant authorities to appoint Accountable Officers (CDAO) to ensure the safe use and management of CDs.
- 12.2. The Controlled Drugs (Supervision of Management and Use) Regulations require that PCTs, as a designated body, appoint a CDAO and provide detail on the role and responsibilities of the Accountable Officer.
- 12.3. **Responsibilities of Accountable Officers**
 - 12.3.1. The CDAO must ensure the safe and effective use of CDs within the PCT and by any body or service providing services to their organisation e.g. general practitioners, community pharmacies.

12.3.2. The CDAO must establish and ensure appropriate arrangements to comply with the Misuse of Drugs legislation.

12.3.3. The CDAO must ensure adequate and up-to-date SOPs are in place in relation to the management and use of CDs.

12.3.4. The CDAO must also have regard to best practice in relation to the management of CDs:

- a. Ensure adequate destruction and disposal arrangements for CDs
- b. Ensure monitoring and auditing of the management and use of CDs
- c. Ensure relevant individuals receive appropriate training
- d. Maintain a record of concerns regarding relevant individuals
- e. Assess and investigate concerns
- f. Take appropriate action if there are well founded concerns
- g. Establish arrangements for sharing information

12.3.5. In addition, CDAO in PCTs are responsible for:

- a. Running the Local Intelligence Network (LIN) where CDAOs and other appropriate representatives from across the local health and social care economy to share concerns about the activities of relevant individuals.
- b. Analysing NHS and private prescribing of CDs.
- c. Requesting a periodic declaration and self-assessment from a general medical practitioner on the PCT medical performers list regarding their CD management and use.
- d. Ensuring the PCT operates arrangements for periodic inspections of premises used in connection with management or use of CDs which may not be subject to inspection by CQC or GPhC.

12.4. **Training**

12.4.1. The CDAO's office provide education, training and information to practices, community pharmacies and other healthcare professions in Cambridgeshire.

12.4.2. In addition to this document the CDAO's office, in conjunction with the Medicines Management Team, offer support and information in the following ways:

- a. Dispensing Services Quality Scheme workshops
- b. Clinical governance workshops
- c. Newsletters e.g. Prescribing Matters, Pharmacy Matters
- d. Signposts to national support materials

12.5. **Prescription and requisition monitoring**

12.5.1. The CDAO's office use the NHSBSA PPD databases to monitor, on a monthly basis:

- a. NHS CD prescribing by general practitioners
 - b. NHS CD prescribing by non-medical prescribers
 - c. Private CD prescribing
 - d. Requisitions for stock CDs
- 12.5.2. The CDAO's office will request further information from prescribers or dispensers where:
- a. The quantity on the prescription appears to be in excess of 30 days supply
 - b. An unusual drug or formulation has been prescribed / requisitioned
 - c. A prescription / requisition does not correlate with the prescribing service
 - d. A prohibited item has been prescribed by a non-medical prescriber
 - e. Local prescribing advice appears not to have been taken into consideration
- 12.6. Identifying and reporting concerns**
- 12.6.1. Organisations should have clearly established protocols for incident reporting and investigation.
- 12.6.2. Organisations should cultivate an atmosphere conducive to reporting incidents and near misses to ensure the safe use and management of CDs, patient safety and maintain a safe working environment.
- 12.6.3. Each SOP held by an organisation should clearly define the action to be taken should deviation from the procedure arise including, who to report to, how to investigate and what documentation requires completion.
- 12.6.4. Clinical incidents or significant events include:
- a. Any incident where a patient is harmed or nearly harmed and includes "near misses", when things almost go wrong;
 - b. Deviation from the SOP or unsafe / illegal practice;
 - c. Incomplete records;
 - d. Stock that is unaccounted for.
- 12.6.5. An investigation should be carried out and a root cause analysis report prepared. The NHS National Patient Safety Agency has developed [Root Cause Analysis \(RCA\) report-writing tools and templates](#) to use for this purpose.
- 12.6.6. This process may include discussion with the relevant professional body, or other inspectors. If this still does not resolve the issue satisfactorily the CDAO and police should be informed.
- 12.6.7. The CDAO should be informed of the outcome of any internal investigations undertaken within an organisation. In addition, any investigation should be referenced in the annual CD declaration and self-assessment.
- 12.6.8. Advice is available, and expected to be sought, from the CDAO's office if concerns relating to the management and use of CDs are identified at any time.

12.6.9. Concerns may be related to legal, clinical, practical, contractual or ethical use of CDs.

12.6.10. There may be occasions when the CDAO's office will identify concerns at a practice or pharmacy, e.g. while witnessing a CD destruction. A letter of advice will be sent to the contractor to advise of necessary improvements.

12.7. **Self-assessment and controlled drug declaration**

12.7.1. All healthcare organisations providing clinical services are required to complete a periodic declaration on their use and stock holding of CDs, see Appendix 2.

12.7.2. If the organisation uses or holds stocks of CDs it is required to complete a self-assessment, see Appendix 3.

12.7.3. The declaration and self-assessment have been adapted for use by NHS Cambridgeshire from the models of good practice provided by the Department of Health.

12.7.4. The declarations and self-assessment questionnaires are sent to organisations by the relevant agency, and may be included in other assessments or planning tools.

12.7.5. NHS Cambridgeshire require annual completion of declarations and self-assessments, in accordance with regional guidance, from general medical and dental practices and practitioners, and specialist contractors e.g. substance misuse.

12.7.6. Declarations and self-assessments will be requested each autumn. Any change of circumstance in the period in-between returns should be notified to the CDAO's office within fourteen days of commencement.

12.7.7. Community pharmacist provide declarations and self-assessments to the General Pharmaceutical Council.

12.7.8. Declaration and self-assessments will be sent to practices for completion by the practice team, including clinical, technical and administrative personnel.

12.7.9. Individuals, including locums, GPSI, or others who work outside of the practice scope, e.g. by keeping personal stock of CDs, are required to complete a return separate from that of the practice.

12.7.10. The assessments, along with other monitoring information, will inform inspections on a risk assessed basis to provide an additional reassurance that CDs are managed safely.

12.7.11. Failure to return a declaration or self-assessment to the CDAO will result in automatic short listing for inspection. See figure 3.

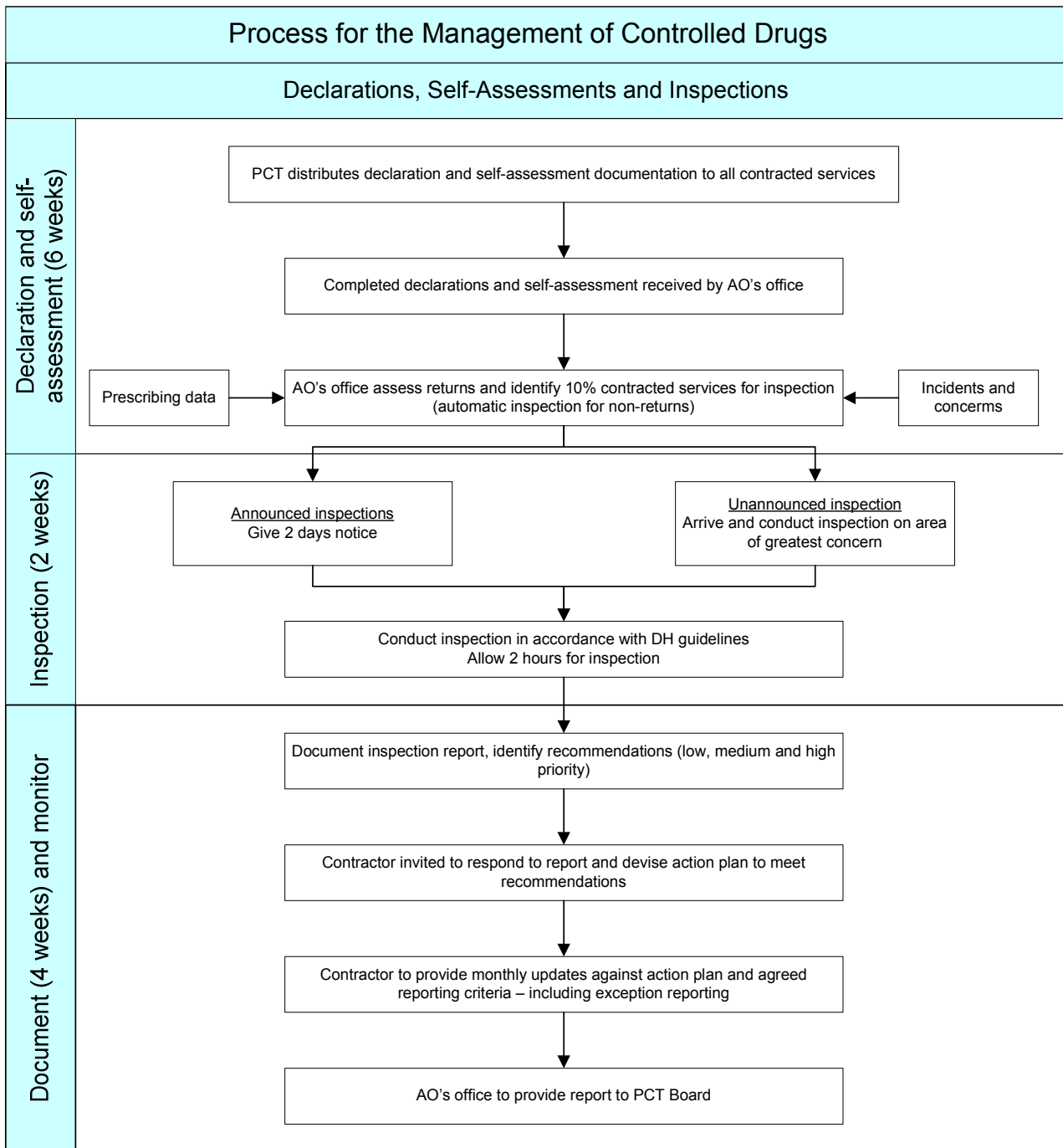
12.7.12. Other health and social care organisations will find the self-assessment a useful checklist of areas which will be monitored and inspected by the body overseeing their management of controlled drugs.

12.8. **Inspection**

12.8.1. The CDAO must undertake period inspections of premises used in connection with the management of CDs which are not subject to inspection by other bodies, e.g. GPhC, CQC.

- 12.8.2. The CDAO authorises an inspection team consisting of an Associate Medical Director, Specialist Pharmacy Technician and Principal Pharmacist to inspect premises on her behalf.
- 12.8.3. The inspection team is not required to give notice of the inspection to the owner or occupier of the premises.
- 12.8.4. NHS Cambridgeshire reserve the right to unannounced inspections to address pressing concerns throughout the year.
- 12.8.5. Practices will receive two days notice of routine inspections.
- 12.8.6. Inspections will comply with the ten principles of inspections set out in the Government's policy on Inspection of Public Services.
- 12.8.7. The Inspection team will document the inspection and provide the practice with low, medium or high priority recommendations. The practice will be invited to comment on the inspection process and report.
- 12.8.8. The practice will be asked to produce an action plan to meet the recommendations and will provide monthly updates to the CDAO.
- 12.8.9. Inspection is a useful tool to check physical arrangements for the storage, record keeping and management of CDs to support individual and organisational development and to identify and investigate concerns.
- 12.8.10. Learning from inspections will be shared with all contracts to support the safe use and management of CDs in Cambridgeshire.

Figure 3



13. References

[NPC A guide to good practice in the management of controlled drugs in primary care, Third edition, December 2009](#)

Safer Management of Controlled Drugs: (1) Guidance on Strengthened Governance arrangements DH January 2007

Safer management of controlled drugs: Guidance on Standard operating procedures for controlled drugs DH January 2007

Guidance on the destruction of controlled drugs – New role for Accountable Officers – Authorising people to witness the destruction of controlled drugs DH August 2007

Monitoring and Inspections Guidelines: Core Activities for CD Monitoring and Inspection Work – Primary Care – DH March 2006

Medicines Ethics and Practice – The professional guide for pharmacists – July 2011

Recommendation for the retention of pharmacy records, East of England Senior Pharmacy Managers Network – July 2010

Safer management of controlled drugs: changes to record keeping requirements DH January 2008

Safer management of controlled drugs: changes to the requirements for requisitions for the supply of Schedule 1, 2 and 3 controlled drugs DH December 2007

Professional Advice: The safe management of controlled drugs in care homes CSCI January 2008

14. Contacts

Accountable Officer:	Dr Christine Macleod Accountable.officer@cambridgeshire.nhs.uk
Specialist Pharmacy Technician:	Clare Moody Clare.moody@nhs.net 01480 354 377 (administrator, Louise Gregory) 01480 354 369 (fax) 01480 372 039 (direct line) 07904 967 236 (mobile)
Deputy Chief Pharmacist:	Sati Ubhi 01480 354 377 (PA, Louise Gregory)
CDAO Office:	c/o Medicines Management Team Hunts Area Offices California Road Huntingdon Cambridgeshire PE29 1BN

	Minimum Standards	Good Practice Suggestions – in addition to minimum standards
Prescribing – general processes		
<ul style="list-style-type: none"> Initiation of CDs 	<ul style="list-style-type: none"> Controlled drugs should only be prescribed after careful consideration of the risks and benefits CDs are preferably only initiated by a doctor that knows the patient well Locums, registrars and nurse independent prescribers are encouraged to discuss acute prescriptions for CDs (S2,3,4) with a senior partner 	<ul style="list-style-type: none"> Locums, registrars and nurse independent prescribers only rarely / never add CDs (S2,3,4) to the “repeat medication list”
<ul style="list-style-type: none"> Monitoring of CD prescribing 	<ul style="list-style-type: none"> The culture of the practice allows open peer review and scrutiny of CD prescribing at clinical meetings. Usual trigger for this will be anecdotal The practice aims to prescribe only monthly quantities The practice aim to minimise prescribing of low strength / high volume formulations Those practices that prescribe diconal[®] stop this, this should be audited 3 monthly, with the aim of stopping 	<ul style="list-style-type: none"> The practice does regular audits of CD prescribing to look for unusual products, quantities, dose, formulations and strength Annual benzodiazepine audits
<ul style="list-style-type: none"> Integration of Out of Hours requests for prescriptions for CDs into the medical record 	<ul style="list-style-type: none"> Each OOH CD request / prescription triggers a review of the medical records and the medication record The reviewing clinician makes an entry in the medical records of this review 	<ul style="list-style-type: none"> In addition, the medication is also added to the medication record as given outside so the total consumption is obvious (not possible on all clinical systems)
<p>Prescribing – Repeat Prescribing</p> <p><i>Current legislation does not allow Schedule 2 and 3 CDs to be prescribed as repeat prescriptions (i.e. to be part of the repeat prescribing or dispensing system, also called “batch prescribing”).</i></p> <p><i>It is common practice to allow patients to receive a prescription for Schedule 2, 3 or 4 CDs (hand signed by a practitioner) without a consultation. This is not subject to legislation, but is a clinical decision made on a case by case basis.</i></p>		
<ul style="list-style-type: none"> Repeat Prescribing 	<ul style="list-style-type: none"> Practices with attached dispensary or pharmacy do not allow patients to collect “repeat prescriptions” for S2 or 3 CDs without a doctor signature 	
<ul style="list-style-type: none"> Allowing patients to receive a prescription for Schedule 2, 3 or 4 CDs (hand signed by a prescriber) without a consultation 	<ul style="list-style-type: none"> CDs are not routine added to the “repeat medication list” unless the prescribing clinician considers the patient stable, with full consideration of the risks and benefits. Patients with CDs on repeat have a half yearly medication review. Repeat requests for CDs are subject to a strict Standard Operating Procedure within the practice with clear lines of accountability and responsibility for admin staff and clinical staff Prescriptions for CDs are preferably signed by the doctor that knows the patient the best. 	<ul style="list-style-type: none"> Medication review is auditable with clear evidence in the medical records that total quantities issued have been reviewed and found to be clinically appropriate by the doctor that knows the patient best.
Interaction with PCT, MMT and the Accountable Officer		
<ul style="list-style-type: none"> The practice deals with medicines management team updates appropriately 	<ul style="list-style-type: none"> The updates are circulated in the clinical team and discussed at eth clinical meetings and easily available electronically for reference 	<ul style="list-style-type: none"> These updates are incorporated into the practice prescribing policies
<ul style="list-style-type: none"> MMT/CDAO requests for information are dealt with appropriately 	<ul style="list-style-type: none"> The request is acknowledged and answered promptly The yearly self-assessment is filled in by the most appropriate senior clinician, and not delegated without clinical input The practice understands the role of the Accountable Officer and it’s own obligations with regard to CDs 	<ul style="list-style-type: none"> Information requests and the annual self-assessment declarations are discussed at the clinical meeting
<ul style="list-style-type: none"> Requesting advice from MMT for difficult cases 	<ul style="list-style-type: none"> The practice knows how to obtain advice from MMT 	<ul style="list-style-type: none"> The practice has active interaction and dialogue with MMT. MMT attend meetings frequently.

Essential Process	Minimum Standards	Good Practice Suggestions – in addition to minimum standards
Prescribing – Palliative Care		
<ul style="list-style-type: none"> Awareness of local palliative care formularies and guidelines 	<ul style="list-style-type: none"> The practice is aware of local palliative care guidelines and can obtain timely advice 	<ul style="list-style-type: none"> A copy of the palliative care guidelines is in the practice and available to all
<ul style="list-style-type: none"> Liaison with local palliative care / DN team 	<ul style="list-style-type: none"> QOF quarterly meetings 	<ul style="list-style-type: none"> The practice has signed up to the Gold Standard Framework principles All patient deaths (including non-expected, OOH and hospital deaths) are reviewed with dissemination of good practice and lessons learned.
<ul style="list-style-type: none"> Anticipatory prescribing 	<ul style="list-style-type: none"> The practice closely cooperates with district nurses The practice follows local “Just in Case” policy (or it’s own if none local) 	<ul style="list-style-type: none"> Anticipatory prescribing is audited annually
Prescribing – Analgesia – especially chronic non malignant pain		
<ul style="list-style-type: none"> The practice has a prescribing policy and formulary which covers analgesia 	<ul style="list-style-type: none"> The practice adheres to the local PCT formulary and the principles of the “analgesic ladder” Where possible regular dosing for CDs is done with modified release preparations 	<ul style="list-style-type: none"> Patient given regular CDs for analgesia are given a patient leaflet
<ul style="list-style-type: none"> Awareness of creating secondary dependency by excessive / prolonged prescribing 	<ul style="list-style-type: none"> Patients are given information and are counselled before starting strong opioid medication 	<ul style="list-style-type: none"> The practice has a “patient contract” available for patients on CDs if necessary
Prescribing – Emergencies		
<p><i>Administering CDs in an emergency is becoming rare in NHSC general practice.</i></p> <p><i>Any practice that chooses to have available CDs to be given in emergencies either in the practice or during home visits must have available sufficient quantity of naloxone (as defined in the BNF) both in the practice and during home visits.</i></p>		
<ul style="list-style-type: none"> Administering CDs in emergencies 	<ul style="list-style-type: none"> The practice reviews annually the frequency and indications for which emergency CDs are administered 	<ul style="list-style-type: none"> Situations that have needed emergency CDs are discussed afterwards at the practice clinical meetings
<ul style="list-style-type: none"> Availability of naloxone 	<ul style="list-style-type: none"> The practice has sufficient quantity of naloxone available (as defined in the BNF) both in the practice and during emergency visits 	
Prescribing – Substance Misuse		
<ul style="list-style-type: none"> Tight control of prescriptions for patients on CDs for substance misuse problems 	<ul style="list-style-type: none"> The practice has a register of these patients The practice is aware of local substance misuse services and referral pathways and when to use them Any patient on CDs for substance misuse problems have their requests dealt with by a dedicated clinician with support from a dedicated admin team member is appropriate There is written Standard Operating Procedure in place describing the above process in detail which includes arrangements to cover absence or leave The care of these patients is subject to an annual audit and review, the results of which are shared with the whole clinical team 	<ul style="list-style-type: none"> The practice takes part in clinical governance arrangements with local substance misuse service
Prescribing - Psychiatry		
<ul style="list-style-type: none"> Adult ADHD 	<ul style="list-style-type: none"> Prescribing for adult ADHD is monitored 	
<ul style="list-style-type: none"> Benzodiazepines 	<ul style="list-style-type: none"> The practice has a guideline that covers benzodiazepine use in this patient group 	<ul style="list-style-type: none"> Benzodiazepine use in monitored

Appendix 2 Controlled Drugs Declaration

The model was produced by a working group involving key stakeholders and chaired by the RPSGB on behalf of the Department of Health.

Name of Organisation / Prescriber	
Address of Organisation / Prescriber	

Please complete the relevant parts of the questionnaire below. This questionnaire relates to activities within the last 12 months and relates to controlled drugs (CDs) Schedule 1, 2 and 3 only as these are subject to a higher level of control.

	Area of activity	
Q1	Do you prescribe CDs?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Q2	Do you supply / dispense CDs?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Q3	Do you administer CDs (or supervise or assist patients' own administration)?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Q4	(i) Do you hold stock CDs either on the premises or off site e.g. in doctors' bags? (ii) Do you hold patients' own CDs?	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>
Q5	Do you destroy or dispose of CDs (patient returns/stock)	Yes <input type="checkbox"/> No <input type="checkbox"/>

If you have answered **YES** to any of these questions, please sign declaration **A** overleaf.

If you have answered **NO** to all questions, please sign declaration **B** overleaf.

Declaration A

I declare that to the best of my knowledge and belief that this **organisation / prescriber / does / does not** comply (please delete as appropriate) with the provisions of the Misuse of Drugs Act 1971 and the associated Regulations in its handling, use and management of Schedule 1, 2 and 3 CDs.

Signature*	
Name (and registration number, if healthcare professional)	
Position within the organisation* *This form must be signed by appropriately authorised personnel, who have responsibility for the management and use of CDs within the organisation	
Date of signing	

Declaration B

I declare to the best of my knowledge and belief that this **organisation / prescriber** does not handle, use or manage Schedule 1, 2 or 3 CDs on any premises of this **organisation / prescriber** (please delete as appropriate).

Signature*	
Name (and registration number, if healthcare professional)	
Position within the organisation* *This form must be signed by appropriately authorised personnel, who have responsibility for the management and use of CDs within the organisation	
Date of signing	

Please note that you must notify us of any material changes to the answers to Q1 – Q5 above within 14 days of the change.

Please return your completed declaration / self-assessment to:

Clare Moody, Specialist Pharmacy Technician

Clare.moody@cambridgeshire.nhs.uk

or

Medicines Management Team
Hunts Area Offices
California Road
Huntingdon
PE29 1BN

Please fill in the relevant tables below if you / your organisation prescribes, manages, uses or handles Schedule 1, 2 or 3 CDs. Please ensure that the information is accurate. **Please complete one return for each premises your organisation operates from, including branch surgeries.**

Name of organisation / prescriber	
Person completing self-assessment (if organisation) and designation	
Date of self-assessment	

	Area of activity	Yes / No	
Q1	Do you prescribe CDs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Please complete table A and section 1
Q2	Do you supply / dispense CDs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Please complete table A and section 2
Q3	Do you administer CDs (or supervise or assist patients' own administration)?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Please complete table A and section 3
Q4	Do you hold stock CDs either on the premises or off site e.g. in doctors' bags? Do you hold patients' own CDs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Please complete table A and section 4
Q5	Do you destroy or dispose of CDs (patient returns/stock)	Yes <input type="checkbox"/> No <input type="checkbox"/>	Please complete table A and section 5

Table A: General information: please complete if answered Yes to Q1 – Q5

	Yes / No	Details
1. Do you have written standard operating procedures (SOPs) covering the handling and management of CDs, appropriate to the activities carried out at the premises, which include guidance on how to escalate concerns?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
2. Do you audit and review the SOPs at regular documented intervals?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
3. Do you have in place a SOP for dealing with a significant event* involving CDs including escalation to the CDAO?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
4. Do you have appropriate SOPs for the initial and continuing training or development of all staff, including clinicians, involved in prescribing, handling, supply and administration of CDs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
5. Are there any special factors which influence the prescribing or use of CDs by your organisation? If yes please give details.	Yes <input type="checkbox"/> No <input type="checkbox"/>	Please submit separate returns for GPSIs.

*Significant event includes any incident where a patient is harmed or nearly harmed, and includes “near misses”, when things almost go wrong.

Section one (only complete if the answer to Q1 is yes)

Prescribing CDs

	Yes / No	Details (where applicable)
6. Do you have a written prescribing policy? Does it include specific details relating to prescribing CDs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
7. Are there any specific restrictions on the CD prescribing abilities of any of the healthcare professionals at the organisation?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
8. Do you employ Independent Nurse Prescribers?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
9. Do you employ Independent Pharmacist Prescribers?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
10. Do you prescribe CDs to addicts? This may include patients with addiction secondary to clinical use e.g. opioids, benzodiazepine	Yes <input type="checkbox"/> No <input type="checkbox"/>	If yes, give details of any service level agreements
11. Do you prescribe CDs privately? Please include Schedule 1, 2, 3, 4 and 5 CDs.	Yes <input type="checkbox"/> No <input type="checkbox"/>	
12. Have there been any patient or carer complaints* involving the prescribing of CDs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
13. Have there been any concerns expressed by colleagues, police, CDAO, drugs misuse services or others about unusual, excessive or inappropriate prescribing of CDs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
14. Have there been any significant events** involving the prescribing of CDs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	

*This includes complaints about failing to prescribe appropriate dose and/or appropriate medicines.

**Significant event includes any incident where a patient is harmed or nearly harmed, and includes “near misses”, when things almost go wrong.

Section Two (only complete if the answer to Q2 is yes)

Supply of CDs

	Yes / No	Details (where applicable)
15. Do you have SOPs for the supply / dispensing of controlled drugs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
16. Are you enrolled in the Dispensing Services Quality Scheme?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
17. Do you supply CDs to addicts? This may include patients with addiction secondary to clinical use e.g. opioids, benzodiazepine	Yes <input type="checkbox"/> No <input type="checkbox"/>	
18. Do you supply CDs against private prescriptions a) from addiction services? b) else where?	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>	
19. Do you supply CDs a) to doctors? b) to others (not including patients)?	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>	
20. From where do you obtain your stocks of CDs?		
21. Do you provide advice to patients on the safekeeping and disposal of unwanted CDs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
22. Are patient returned medicines ever re-used?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
23. Are patient information leaflets supplied to all patients receiving CDs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
24. Have there been any patient or carer complaints* involving the supply of CDs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
25. Have there been any concerns expressed by colleagues, police, CDAO, drugs misuse services or others about the supply of CDs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
26. Have there been any significant events** involving the supply of CDs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	

*This includes complaints about failing to supply appropriate dose and/or appropriate medicines.

**Significant event includes any incident where a patient is harmed or nearly harmed, and includes "near misses", when things almost go wrong.

Section three (only complete if the answer to Q3 is yes)

Administration of CDs (excludes supervised consumption by addicts)

	Yes / No	Details (where applicable)
27. Do you have SOPs for the administration of CDs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
28. Are the CDs used for administration a) stock CDs? b) patient's own CDs?	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>	
29. Do you have any syringe drivers used for continuous subcutaneous infusions?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
30. Do you maintain records of administration? If yes, where? (CD register, MAR chart etc)	Yes <input type="checkbox"/> No <input type="checkbox"/>	
31. Is administration of CDs witnessed? If not, what risk management policies are in place to cover administration	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	
32. Have there been any patient or carer complaints* involving the administration of CDs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
33. Have there been any concerns expressed by colleagues, police, CDAO, drugs misuse services or others about the administration of CDs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
34. Have there been any significant events** involving the administration of CDs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	

*This includes complaints about failing to administer appropriate dose and/or appropriate medicines.

**Significant event includes any incident where a patient is harmed or nearly harmed, and includes "near misses", when things almost go wrong.

Section four (only complete if the answer to Q4 is yes)

A) Security and safe custody of CDs (S1, 2 and 3) on premises

	Yes / No	Details (where applicable)
<p>35. Do you store CDs in:</p> <p>(a) a central store?</p> <p>(b) doctor's bag?</p> <p>(c) other places (please specify)?</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>	<p>Doctors who keep personal stock should complete a separate return.</p>
<p>36. Do you have any current Chief Constable exemption certificates in operation for your CD storage facilities? (NB not required for some premises)</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>N/A <input type="checkbox"/></p>	
<p>37. Are all CDs kept under lock and key (including patient returned CDs or unwanted/obsolete CDs)?</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>	
<p>38. Is access to CDs controlled?</p> <p>If yes, describe how</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>	
<p>39. Do you utilise the CD storage facilities for storage of anything other than CDs?</p> <p>If yes, please state</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>	
<p>40. How often does date checking of CD stock take place?</p> <p>Give details of date checking procedure</p>	<p>Weekly <input type="checkbox"/></p> <p>Monthly <input type="checkbox"/></p> <p>Other <input type="checkbox"/></p>	
<p>41. How often does date checking of CD stock in doctor's bags take place (where applicable)?</p> <p>Give details of date checking procedure</p>	<p>Weekly <input type="checkbox"/></p> <p>Monthly <input type="checkbox"/></p> <p>Other <input type="checkbox"/></p>	
<p>42. Are all stock CDs kept in the original container?</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>	
<p>43. Are dispensed patient's medicines appropriately labelled? (in accordance with Medicines Act 1968)</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>	
<p>44. Do you keep stock of high dose morphine or diamorphine?</p> <p>e.g. diamorphine 30mg, 100mg or 500mg</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>	
<p>45. Are different strengths of the same medicines segregated in any way?</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>	

46. Do you stock sufficient naloxone (10mg) in every location where opioids are stored i.e. doctor's bag, treatment room for treatment of overdose?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
47. Do you have any out of date or obsolete stock CDs currently stored?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
48. Are out of date / obsolete / patient returned CDs segregated from other CDs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
49. Are patient returned medicines ever reused?	Yes <input type="checkbox"/> No <input type="checkbox"/>	

B) Security and safe custody if CDs in transport

	Yes / No	Details (where applicable)
50. Do you transport or are you responsible for the transport of CDs (this includes doctor's bags, practice delivery to patients, third party carriers e.g. delivery drivers, postal system)	Yes <input type="checkbox"/> No <input type="checkbox"/>	
51. Do you offer delivery of CDs to patients?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
52. What procedure do you have in place for the transport of CDs (not doctor's bags)?		
53. Do you have a protocol for transporting CDs in doctor's bags or emergency packs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
54. Are CDs routinely kept under lock and key during transit? If no, please provide details	Yes <input type="checkbox"/> No <input type="checkbox"/>	
55. What records are maintained of CDs in transit?		

C) Registers (S2)

	Yes / No	Details (where applicable)
56. Do you keep an up to date CD register?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
57. Do you keep an up to date register in the doctor's bag?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
58. Do you keep running balances of stock CDs held? If yes: (a) Do you audit / reconcile the running balance? (b) How often does your SOP state you should reconcile the running balance? Weekly <input type="checkbox"/> Monthly <input type="checkbox"/> Other <input type="checkbox"/> (c) Are the running balances audited by outside management staff?	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>	

<p>59. Have you identified any discrepancies between the running balance and actual CDs held in the last 12 months?</p> <p>If yes, what was the explanation for the discrepancy?</p> <p>What action was taken?</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>	
<p>60. For how long do you keep records of all receipts and supplies of CDs?</p>		
<p>61. Have there been any patient or carer complaints* involving the storage, transport or recording keeping of CDs?</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>	
<p>62. Have there been any concerns expressed by colleagues, police, CDAO, drugs misuse services or others about the storage, transport or recording keeping of CDs?</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>	
<p>63. Have there been any significant events** involving the storage, transport or recording keeping of CDs?</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>	

*This includes complaints about failing to store, transport or record appropriately.

**Significant event includes any incident where a patient is harmed or nearly harmed, and includes "near misses", when things almost go wrong

Section Five (only complete if the answer to Q5 is yes)

Destruction or disposal of CDs

	Yes / No	Details (where applicable)
Patients' CDs		
64. Do you have SOPs for the destruction of patients' returned CDs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
65. Do you routinely destroy patients' old or obsolete CDs? What	Yes <input type="checkbox"/> No <input type="checkbox"/>	
66. records do you keep of CDs returned to you by patients for disposal?		
67. What systems do you have in place to dispose of patients' old or obsolete CDs?		
68. Is the destruction of patients' old of obsolete CDs witness? If yes, by whom?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
69. Do you keep records of the destruction of patients' old or obsolete CDs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Stock CDs (if applicable)		
70. Do you have SOPs for the destruction of stock CDs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
71. How often do you aim to destroy out of date or obsolete CD stock?	Quarterly <input type="checkbox"/> Annually <input type="checkbox"/> Other <input type="checkbox"/>	
72. Do you have any out of date or obsolete stock CDs currently awaiting destruction?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
73. Who usually witnesses your stock destruction?		
74. When was the last witnessed CD stock destruction?		
75. Are records of stock destruction kept in the CD register?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
76. Have there been any patient or carer complaints* involving the destruction or disposal of CDs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
77. Have there been any concerns expressed by colleagues, police, CDAO, drugs misuse services or others about the destruction or disposal of CDs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
78. Have there been any significant events** involving the destruction or disposal of CDs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	

*This includes complaints about failing to dispose of medicines appropriately.

**Significant event includes any incident where a patient is harmed or nearly harmed, and includes "near misses", when things almost go wrong