

Guidance on the Management of Controlled Drugs in GP Practices

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Document History

Date	Version	Author	Changes
November 2015	1	Jo Bark-Jones (NWCSU)	
July 2018	2	Mariah Zavery (MLCSU)	Updated Definitions Added new CD monitoring and incident reporting process. SOPs updated.
December 2019	3	Emma Jaeger (MLCSU)	Updated schedule 3 changes for gabapentin and pregabalin inc EPS definitions.

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1. Purpose and Objectives

The Controlled Drug Regulations highlight the need for Standard Operating Procedures for the handling of CDs and to ensure that robust systems and audit trails are in place for all stages in the handling of controlled drugs in primary care.

This guidance sets out procedures to ensure the safe care, custody, administration and destruction of controlled drugs in accordance with current legislation.

DISCLAIMER:

This guidance has been produced to support GP practices in managing processes relating to controlled drugs. All information is correct at time of review. It is the GP practice and prescribers' responsibility to ensure they are acting and adhering to the current lawful regulations and requirements relating to the use of controlled drugs. The authors of this guidance do not have any responsibility for the actions taken.

2. Introduction

The Misuse of Drugs Act 1971 identifies a range of drugs with the potential for misuse and diversion and divides them into three classes A, B and C. Many of these drugs have legitimate medical uses so the Act has Regulations to enable their legal use. The main purpose of the Misuse of Drugs Act is to prevent the misuse of Controlled Drugs by imposing restrictions on their possession, supply, manufacture, import and export.

The CCG is responsible for ensuring the quality of patient care. Each practice has a duty to ensure the safe care, custody, administration and destruction of medicines by employees, for the safety of employees, those receiving services and the population at large, and to comply with current legislation pertaining to controlled drugs and their use. [The Department of Health Controlled Drugs \(Supervision of Management and Use\) Regulations 2013](#) set out governance arrangements for Controlled Drugs used as medicines.

3. Legislation

[The Misuse of Drugs Regulations \(MDR\) 2001](#) govern the possession and supply of the drugs controlled under the Misuse of Drugs Act 1971

The Regulations and their amendments also govern prescribing, safe custody, importation, exportation, production and record keeping. The Schedules define who may be in possession of or supply each drug, and under what conditions.

As a consequence of the Health and Social Care Act 2012, the Regulations have been revised to reflect the new architecture for the NHS in England from April 2013. These legal changes are in place to encourage good practice in the use and management of CDs and to help detect unusual or poor clinical practice systems, criminal activity or risk to patients.

4. Definitions

<p>Controlled Drugs Accountable Officer (CDAO)</p>	<p>The Accountable Officer (AO) is the designated member of NHS England who is responsible for ensuring the safe and effective use and management of controlled drugs (CDs) within local organisations subject to their oversight.</p> <p>The responsibilities of the Accountable Officer are fully detailed in The Controlled Drugs (Supervision of Management and Use) Regulations 2013 (S.1. 2013/373)</p> <p>The Controlled Drugs Accountable Officer contact details can be found via the CQC website http://www.cqc.org.uk/content/controlled-drugs-accountable-officers</p> <p><u>CDAO for NHS England Cheshire and Merseyside Area Team.</u> Dr Devina Halsall email: england.cmcd@nhs.net</p> <p>Alternatively call the medical directorate at Regatta House reception 0151 285 4777</p> <p><u>CCG CD Lead:</u> Wirral: Lorna Quigley (Director of Quality and Safety)</p>
<p>Controlled Drug Register</p>	<p>A register meeting the requirements of the Misuse of Drugs Regulations 2001, as amended, for entering records of Schedule 2 CD receipt, administration, return or destruction.</p>
<p>Controlled Drugs</p>	<p>The Misuse of Drugs Regulations 2001 divides CDs into five schedules which dictate the degree to which a CD is regulated.</p> <p><u>Schedule 1 e.g. lysergide, raw opium, coca leaf</u></p>

	<p>Drugs in Schedule 1 have no recognised medicinal use. Their production, possession and supply are strictly limited.</p> <p>Practitioners may not lawfully possess them except under licence from the Home Office.</p> <p><u>Schedule 2</u> e.g. morphine, diamorphine, methylphenidate</p> <p>Drugs in Schedule 2 are subject to safe custody requirements i.e. must be stored in an approved, locked receptacle. Their possession, supply and destruction are strictly controlled.</p> <p>Full records of receipt, supply and destruction must be kept in an approved CD register and strict CD destruction requirements apply. Destruction of expired Schedule 2 drugs must be observed by an authorised witness.</p> <p><u>Schedule 3</u> e.g. phenobarbitone, pentazocine, tramadol, buprenorphine, temazepam, gabapentin, pregabalin</p> <p>These drugs are less likely to be abused than those in Schedule 2 and the majority are exempt from safe custody requirements (exceptions are temazepam, buprenorphine, flunitrazepam and diethylpropion).</p> <p>Entries in a CD register entries are not mandatory. All S3 CDs must be denatured before destruction. An authorised witness is not required, but a second witness and record of destruction is good practice.(NICE NG46)</p> <p><u>Schedule 4</u></p> <p>Part 1 (CD Benzodiazepines) e.g. diazepam, zolpidem, Sativex</p> <p>Their possession is an offence without the authority of a prescription.</p> <p>These drugs are exempt from safe custody requirements and CD register entries for receipt and supply are not required. S4 (1) CDs must be denatured before destruction.</p> <p>Sativex® is a cannabis-based medicine. Under the 1961 UN Convention on Narcotic Drugs, a record of the amount possessed and destroyed must be kept for two years. Consider adding a section for Sativex® to the CD Register.</p>
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	<p>Part 2 (CD Anabolic steroids) e.g. testosterone, clenbuterol, growth hormones</p> <p>There are no restrictions on their possession and are exempt from safe custody, CD destruction and CD register entry requirements. They do not require denaturing before destruction. Dispose as hazardous waste.</p> <p>Schedule 5 e.g. codeine, pholcodine, are exempt from full control when that are present in medicinal products of low strengths. They are exempt from virtually all CD requirements except the retention of invoices for two years.</p> <p>The full list of Controlled Drugs is available from the Home Office (updated 2/12/19) https://www.gov.uk/government/publications/controlled-drugs-list--2</p> <p>A list of commonly used controlled drugs by generic and brand name in each schedule is listed in section 14.</p>
<p>Designated Person(s) or Responsible Person for Controlled Drugs</p>	<p>Nominated Person(s) authorised within a GP practice to lead matters related to CDs.</p> <p>NICE NG46 (2016) defines a nominated person as “a person who is not involved in the day-to-day handling of controlled drugs who has been appointed to oversee the management and governance of activities related to controlled drugs.”</p>
<p>Relevant Individual</p>	<p>Clinician responsible for the prescribing, monitoring, storage and record keeping as defined in The Controlled Drugs (Supervision of Management and Use) Regulations 2013.</p>
<p>FP10, FP10MDA, FP10PCD, FP10CDF</p>	<p>Forms on which CDs must be prescribed or requisitioned (ordered) in England to be legally valid.</p> <p>Electronic prescribing (EPS) for CDs was rolled out nationally for TPP, Vision and EMIS in March 2019.</p> <p>Instalment prescribing: EPS cannot be used for prescribing in instalments (FP10MDA prescribing), therefore a paper prescription for oral methadone must be generated.</p>
<p>Private CD Prescriber code</p>	<p>Identification code for a prescribing clinician obtained via application to england.cmcd@nhs.net.</p> <p>This code allows a clinician to requisition Schedule 2 and 3 CDs on FP10CDF or prescribe CDs privately on FP10PCD.</p>

	<p>The CDAO must be notified if there are any changes to the prescribing profile for the clinician or if they leave the organisation. For more details refer to: The Controlled Drugs (Supervision of Management and Use) Regulations 2013 NHS England Single Operating Model. November 2013</p>
Authorised Witness	<p>Person authorised by the CDAO to witness the safe destruction of expired CD stock. Contact england.cmcd@nhs.net to ask for an authorised witness to attend the practice.</p>
Local Intelligence Network (LIN)	<p>A group of members organised by the CDAO to discuss and share information regarding controlled drugs.</p>
Controlled Drug Liaison Officers	<p>Police officers who can provide advice and information related to controlled drugs incidents. Also, can certify a 'secure custody' environment.</p> <p><u>Cheshire CDLOs</u> DC Paul Corteen Controlled Drug Liaison Officer 0160 636 5183 07717761261 paul.corteen@cheshire.pnn.police.uk</p> <p><u>Merseyside CDLOs</u> DS Paul Storey D/Sgt 1424 0151 777 2559 07870916819 paul.storey@merseyside.pnn.police</p>

5. Roles and responsibilities

Each GP Practice should have a designated senior health professional (the Senior GP Partner or Prescribing Lead) who has overall responsibility for controlled drugs in their Practice to ensure:

- Prescribing, storage and record keeping complies with current regulations and good practice
- Where appropriate, authorising other staff to conduct specific processes regarding CDs at the Practice
- Any CPD requirements that are highlighted are addressed immediately
- Up to date SOPs are in place for all processes involving CDs
- Providing the link for the investigation of any CD discrepancies

- Reporting unresolved discrepancies or other concerns to the NHS England Controlled Drugs Accountable Officer (CDAO).

Registered practitioners in legal possession of CDs have a professional duty of care to take all reasonable steps to maintain safe custody of that CD at all times and to ensure that storage and records of controlled drugs are in line with all legal requirements.

Registered practitioners have a professional and legal duty to ensure that prescriptions for the supply of controlled drugs to patients are in line with all relevant legal requirements and are clinically appropriate.

All registered practitioners administering controlled drugs have a professional duty of care to ensure administration is clinically appropriate and that legally required record keeping is completed following administration.

Only a clinician can:

- Write a requisition order for a controlled drug
- Write in the controlled drugs register
- Check the controlled drug stock

Only authorised individuals in the Practice should have responsibility for:

- Collecting controlled drugs requisitioned from a pharmacy
- Witnessing stock checks and witnessing restocking of doctors' bags.

6. Training

All Practice staff involved in the handling of medicines should be appropriately trained to use the Standard Operating Procedures (SOPs) to ensure the safety and security of medicines as well as safeguarding themselves and those under their supervision from any risks. The relevant staff should sign the Staff Compliance form for each Standard Operating Procedure that they are involved with, to record that they have read and understood it. If the SOP is updated, the relevant staff must sign the revised version. A record of staff training, and competency checks should be held at the Practice.

All health professionals must work within their Code of Professional Conduct, and acknowledge any limitations in their knowledge and competence, and decline any duties or responsibilities unless able to perform them in a safe and skilled manner.

7. Audit

The Senior GP leading on controlled drugs is responsible for ensuring regular stock reconciliation of controlled drugs in the Practice takes place and involves two clinicians. Any

issues arising should be dealt with via the Practice's procedure for dealing with controlled drug errors or concerns.

NHS England (Cheshire & Merseyside) requires the completion and periodic submission of a declaration form in relation to the control, safe use and management of Schedule 1, 2 and 3 controlled drugs. A good practice model declaration and self-assessment can be found in Appendix 1 for use as a self-audit tool. It provides a useful checklist of areas that may be monitored and inspected to ensure the safe management of controlled drugs. An online declaration should also be completed and submitted at www.cdreporting.co.uk

8. CD Monitoring

Practice Responsibilities

- Practice designated person or CD Prescribing Lead should ensure that practice CD policy is adhered to, CDs stocked by the practice are done so in a safe and legal manner, prescribing is monitored, and processes are in place to mitigate risks and provide assurance in the management of controlled drugs and incidents. See Appendix 1 for Example of a Controlled Drug Self-assessment and Declaration form.
- GP Practices should have a system for monitoring and assessing individual health professional (Relevant Individual) performance in relation to the safe management of controlled drugs as per Regulations 11 and 13 of the Controlled drugs (Supervision of management and use) 2013 Regulations.
- Clinicians are responsible for prescribing within their authority and ensuring patients who are prescribed controlled drugs are monitored and followed up and to ensure that risk of diversion and/or stock piling by patients is minimal.

CCG responsibilities

- CCGs are responsible for monitoring the prescribing of controlled drugs in accordance with the CD monitoring requirements as set out by NHS England.
- Analyse practice and prescriber level controlled drug prescribing trends.
- Support CDAO in ensuring adequate steps are taken to protect patients and the public and provide assurance that prescribing at local level is safe.
- Attend Controlled Drug Local Intelligence Network (CD LIN) meetings.
- Submit quarterly Controlled Drugs (CD) Occurrence Reports to CDAO if required.

CDAO Responsibilities

- CDAO is responsible for analysing trends in controlled drug incidents and overall prescribing at local and national level and facilitate shared learning via CD LIN and CCG meetings.
- CDAO is responsible for requesting a self-assessment Declaration form for the management of controlled drugs by the Practice via the CD online reporting tool.

Organisations must register with the online tool at www.cdreporting.co.uk or by emailing england.cmcd@nhs.net

9. Incident Reporting

All organisations providing healthcare services within the NHS England Area Team boundary are required to report incidents regarding CDs.

All controlled drug related incidents should be reported via Datix or other local incident reporting systems in a timely manner (ideally within 48 hours). The report should include details of the incident, the learning, the mitigating factors put in place by the Practice to prevent recurrence and demonstration of the wider sharing of lessons learned (see SOP 8 – Process for dealing with CD concerns and errors)

Serious incidents/concerns (category RED incidents) should be notified to the NHS England CDAO immediately via the online CD reporting tool: www.cdreporting.co.uk. It should be noted that the reporting of serious incidents and/or concerns to the CDAO is for information only. It does not follow that any internal or external investigation being conducted will be taken over, or assisted, by NHS England. Organisations are required to have their own internal policies and procedures in place to investigate such occurrences.

Individual Incident Reporting forms (e.g. Datix) submitted ad hoc by Practices will be collated quarterly at CCG level and submitted to NHS England via the quarterly CD Occurrence Report.

10. Templates

The following templates include Standard Operating Procedures for:

1. Accessing the controlled drugs cabinet and Doctor's bag
2. Requisition of controlled drugs
3. Receipt, Storage and Record Keeping of controlled drugs
4. Transfer of Stock Controlled Drugs to/from the Doctors Bag.
5. Prescribing and Collecting controlled drugs.
6. Administration of controlled drugs.
7. Destruction of out of date, unwanted or damaged controlled drug

8. Process for dealing with controlled drug errors or concerns.

9. Reporting Lost/Stolen/Forged Controlled Drug Prescriptions

The templates are available on the CCGs and/or Medicines Management websites for Practices to download and adapt to produce an individual Practice Standard Operating Procedure defining the staff responsible for the process. Any person assuming responsibility should be appropriately trained and must sign that they have read and understood the Practice's SOPs.

All SOPs should be dated with a review date included. Tasks should not be delegated to members of staff who have no responsibility or training for the specific procedure.

Please be aware that neither the CCG nor the Commissioning Support Unit is responsible for any changes made locally to these templates by Practices/ All Standard Operating Procedures must be dated and the date of review included.

11. References

1. Misuse of Drugs Act 1971. London: HMSO.
2. Misuse of Drugs regulations 2001 (amended). London:HMSO
<http://www.legislation.gov.uk/ukxi/2001/3998/introduction/made>
3. Safer management of controlled drugs NHSBSA from
<https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/prescribing-and-dispensing/safer-management>
4. [Department of Health The Controlled Drugs \(supervision and management of Use\) Regulations 2013. London:HMSO](#)
5. [The National Institute for Health and Care Excellence \(NICE\). Controlled drugs: safe use and management. NG46. April 2016](#)
6. License guide
<https://www.gov.uk/guidance/controlled-drugs-licences-fees-and-returns>
7. Dame Janet Smith DBE. Harold Shipman Fourth Report - The Regulation of Controlled Drugs in the Community. Published 15 July 2004.
8. Human Medicines Regulation 2012 – who and what can be supplied on a requisition.
<http://www.legislation.gov.uk/ukxi/2012/1916/schedule/17/made>
9. Safe transportation guidance by the Home Office (2016).
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/526536/Tra nsit guidance - Final- May 2016.pdf
10. PSNC, Controlled Drug Prescriptions and Validity <http://psnc.org.uk/dispensing-supply/dispensing-controlled-drugs/controlled-drug-prescription-forms-validity/>

Appendix 1: Example of a Controlled Drug Self-assessment and Declaration form

Practice Name and Address:

The following questionnaire is a useful self-audit tool for Practices to use for assurance purposes.

Section 1

	<u>Area of Activity</u>	<u>Yes/No</u>	<u>If the answer is 'yes'</u>
Q1	Do you prescribe CDs?		Please complete Table A and Section 2
Q2	Do you supply CDs?		Please complete Table A and Section 3
Q3	Do you administer CDs (or supervise or assist patients own administration)?		Please complete Table A and Section 4
Q4	(i) Do you hold stock CDs either on the premises or off site e.g. doctor's bags? (ii) Do you hold patient CDs?		Please complete Table A and Section 5
Q5	Do you destroy or dispose of CDs (patient returns/stock)?		Please complete Table A and Section 6

If you have answered YES to any of the above questions, then complete the appropriate Sections. The following declaration should then be signed.

In **ALL** cases please **delete** as applicable and sign the declaration below:

i) I declare to the best of my knowledge and belief that this Practice does not handle, use or manage Schedule 2 or 3 CDs on any premises of this Practice

Or

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

Signature*	
Name (and registration number, of healthcare professional)	
Position within the Practice*	
Date of signing	

*This form must be signed by appropriately authorised personnel, who have responsibility for the management and use of CDs within the organisation.

Please fill in the relevant tables below if your organisation prescribes, manages, uses or handles CDs. Please ensure that the information is accurate.

Table A: General Information: Please complete in ALL cases

	Yes/No	Details
1. Do you have written standard operating procedures or written policies covering the handling and management of CDs, appropriate to the activities carried out at the premises?		
2. Do you have in place a local procedure for dealing with a significant event* involving CDs?		
3. Do you have appropriate procedures for the initial and continuing training or development of all staff involved in the prescribing, handling, supply and administration of CDs?		
4. Do you have a process in place to ensure safety alerts regarding CDs are acknowledged, disseminated and actioned upon?		
5. Are there any special factors which influence the prescribing or use of CDs by your organisation? If yes, please give details		

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

Section 2: Prescribing CDs

	Yes/No or N/A	Details
1. Are there any specific restrictions on the CD prescribing abilities of any of the healthcare professionals involved?		
2. Have there been any patient or carer complaints* involving the prescribing of CDs?		
3. Have there been any concerns expressed by colleagues, police, drugs misuse services or others about unusual, excessive or inappropriate prescribing of CDs?		
4. Have there been any significant events** involving the prescribing of CDs?		

*This includes complaints about failing to prescribe appropriate doses 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 3: Supply of CDs

	Yes/No or N/A	Details
1. Do you supply CDs to addicts?		
2. Do you supply CDs against private prescriptions: (a) from addiction services? (b) elsewhere?		
3. Do you supply controlled drugs: (a) to doctors? (b) to others (not including patients)?		
4. From where do you obtain your stocks of CDs?		

5. Do you provide advice to patients on the safekeeping and disposal of unwanted CDs?		
6. Are patient returned medicines ever re-used?		
7. Are patient information leaflets supplied to all patients receiving CDs?		
8. Have there been any patient or carer complaints involving the supply of CDs?		
9. Have there been any concerns expressed by colleagues, police, drugs misuse services or others about the supply of CDs from the organisation/pharmacy?		
10. Have there been any significant events** involving the supply of CDs?		

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

Section 4: Administration of CDs (This excludes supervision of CDs consumed by addicts)

	Yes/No or N/A	Details
1. Are the CDs used for administration: (a) stock CDs? (b) patient's own CDs? (c) both (a) and (b)?		
2. Do you maintain records of administration? If yes, where? (Register etc.)		
3. Is administration of CDs witnessed? If not, what risk management policies are in place to cover administration?		

4. Have there been any patient or carer complaints involving the administration of CDs?		
5. Have there been any concerns expressed by colleagues, police, drugs misuse services or others about the administration of CDs?		
6. Have there been any significant events** involving the administration of CDs?		

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

Section 5:

A. Security and safe custody of CDs on premises		
	Yes/No or N/A	Details
1. Do you store CDs in: (i) A central store? (ii) Doctors' bags? (iii) Other places (please detail)?		
2. Do you have any current Chief Constable exemption certificates in operation for your CD storage facilities?(NB Not all premises will need exemption certificates for CD storage facilities)		
3. Are all CDs kept under lock and key (including patient returned CDs or unwanted/obsolete CDs)?		
4. Is access to CDs controlled? If yes, then how?		

5. Do you utilise the CD storage facilities for storage of anything other than CDs? If so, please state.		
6. How often does date checking of CD stock take place? Give details of date checking procedures		
7. How often does date checking of CD stock in doctors' bags take place? (where applicable) Please give details of date checking procedures.		
8. Are all stock CDs kept in the original container?		
9. Are dispensed patients' medicines appropriately labelled?		
10. Are different strengths of the same medicine segregated in any way?		
11. Do you have out of date or obsolete stock CDs currently stored?		
12. Are out of date/obsolete/patient returned CDs segregated from other CDs?		
13. Are patient returned medicines ever reused?		

B <u>Security and safe custody of CDs in transport</u>		
	Yes/No or N/A	Details
14. Do you transport or are you responsible for the transport of CDs (this includes sending CDs using third party carriers such as delivery drivers and postal system)? If NO, please move on to section C.		

15. What procedure do you have in place for the transport of CDs?		
16. Are CDs kept in a locked Doctor's Bag during transport? If no, then please provide details.		
17. What records are maintained of CDs in transport?		

C Registers

	Yes/No or N/A	Details
18. Do you keep an up to date CD register?		
19. Do you keep running balances of stock CDs held? If yes: (a) Do you audit your running totals? (State how often and date of last audit) (b) Are the running totals audited? (State how often and date of last audit)		
20. Have you identified any discrepancies between running totals and actual CDs held in the last 12 months? If yes, what was the explanation for the discrepancy? What action was taken?		
21. Do you maintain records of all receipts and supplies of CDs? If yes, for how long do you keep records?		
22. Have there been any patient or carer complaints involving the storage, transport or record keeping of CDs?		

23. Have there been any concerns expressed by colleagues, police, drugs misuse services or others about the storage, transport or record keeping of CDs?		
24. Have there been any significant events** involving the storage, transport or record keeping of CDs?		

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

Section 6: Destruction or disposal of CDs

Patient's CDs		
	Yes/No or N/A	Details
1. Do you routinely destroy patients' old or obsolete CDs? If Yes, what systems do you have in place?		
2. Is there an appropriate process in place to destroy Schedule 2 CDs?		
Stock CDs (if applicable)		
1. How often do you aim to destroy out of date or obsolete stock CDs?		
2. Do you have any out of date or obsolete stock CDs currently awaiting destruction?		

3. Who usually witnesses your stock destruction?		
4. When was the last-witnessed CD stock destruction?		
5. Are records of stock destruction kept in the CD register?		
6. Have there been any patient or carer complaints involving the destruction or disposal of CDs?		
7. Have there been any concerns expressed by colleagues, police, drugs misuse services or others about the destruction or disposal of CDs?		
8. Have there been any significant events** involving the destruction or disposal of CDs?		

SOP 1: Template Standard Operating Procedure for Accessing the Controlled Drugs Cabinet

Objectives

To ensure the cabinet storing Controlled Drugs (CDs) is appropriate and accessed by appropriate staff only.

Scope

This SOP encompasses the requirements of the cabinet to store controlled drugs, the security of the keys and access to the CD cabinet. For the purposes of this procedure, the storage receptacle may be a cabinet or safe and access may be using keys or a digital key pad system.

Responsibilities

- The Clinician with lead responsibility for controlled drugs has overall responsibility for the keys to the controlled drug cabinet but may authorise a named member of staff to ensure the security of the cabinet and keys on a day to day basis.
- The Practice Manager is responsible for ensuring strict controls are in place if there is more than one set of keys and for ensuring it is known who is in possession of the key(s) at all times.

Process and Records

- CDs requiring safe custody should be stored under lock and key in a cabinet. The cabinet must conform to the requirements of the Misuse of Drugs (Safe Custody) Regulations 1973 and be made of steel, with suitable hinges, and fixed to a wall or the floor with rag bolts (these bolts should not be accessible from outside the cabinet).
- The cabinet should not be easily identifiable as a CD cabinet to avoid easy detection by intruders.
- The Lead Clinician for controlled drugs or delegated staff member authorised to ensure the CD key(s) is secure at all times must ensure the key is kept separate from the cabinet and is only accessible to staff authorised to handle CDs.
- The use of several sets of keys for the CD cabinet/safe should be avoided. An emergency spare key to the CD cabinet should be available but not stored with the normal set of keys.

- Access to key cupboards should be restricted and removal of the key for the CD cabinet should be logged, so that it is known at all times who is in possession of the key.
- Access to the cabinet must always be witnessed by a second authorised person.
- If a safe is used to store CDs, then there should be a separate receptacle within the safe that keeps the CDs apart from other items, e.g. money, valuables, etc.
- The room containing the safe/cabinet should be lockable and tidy around the safe/cabinet area to avoid drugs being misplaced.
- The walls of the room should be constructed to a suitable thickness using suitable materials.
- A controlled drug register must be kept and maintained according to Misuse of Drug Regulations and good practice requirements. Refer to the appropriate SOP.
- The CD register should be stored safely outside the CD cabinet, in an appropriate location near the CD cabinet; care should be taken to choose a location that does not advertise the location of the CDs.

References

1. The Misuse of Drugs Regulations 2001
<http://www.legislation.gov.uk/ukxi/2001/3998/regulation/19/made>
2. Misuse of drugs (Safe custody) Regulations 1971
<http://www.legislation.gov.uk/ukxi/1973/798/made?view=plain>
3. The Controlled Drugs (Supervision of Management and Use) Regulations 2013
<http://www.legislation.gov.uk/ukxi/2013/373/contents/made>

SOP 2: Template Standard Operating Procedure for the Requisition of Controlled Drugs.

Objectives

Ensure ordering of controlled drugs by the Practice is carried out by appropriate personnel and conforms to all legal requirements.

Scope

This SOP encompasses all requisitions for schedule 2 and 3 controlled drugs made by the Practice.

Responsibilities

- An authorised practitioner (i.e. a doctor, dentist, supplementary prescriber, nurse independent prescriber or pharmacist independent prescriber with an NHS or private CD prescriber code) only should requisition controlled drugs in line with this SOP.
- Clinicians are responsible for signing the requisition for the drugs they will be prescribing or administering within their competence.
- An authorised member of practice staff is responsible for collecting controlled drugs for the Practice from a community pharmacy using a headed notepaper bearer's note signed by the prescriber.

Process and Records

1. A requisition on form **FP10CDF** is required for Schedule 2, and 3 controlled drugs, either handwritten in indelible ink or computer generated with a handwritten signature.
2. Form FP10CDF can be ordered from the NHS England local Area Team at england.cmcd@nhs.net or it can be downloaded at: http://psnc.org.uk/sunderland-lpc/wp-content/uploads/sites/89/2015/11/CD-Requisition-form-FP10CDF_v5_final.pdf
3. Parts B, C and D of form FP10CDF should be completed.
 - **Part B** - complete the name of the CD to be requisitioned including the form, strength and quantity. **The signature should be hand-written in ink.**
 - **Part C** - the organisation code can be either the NHS or private prescription code of the prescriber. Non-medical prescribers (e.g. nurse and pharmacist prescribers) must also

include the relevant practice code (which will be on their normal prescriptions). The person raising the requisition should also complete the form with their name, occupation/professional qualification and the address of the premises that they are working out of.

- **Part D** - indicate the purpose for which the drugs are required by ticking the relevant box and, if applicable, providing further details.
4. Retain a copy of the requisition order (both sides) in the Practice.
 5. The requisition order is taken to the pharmacy. It is not permitted to be faxed or electronically transmitted.
 6. If ordering from a wholesaler, the GP must provide the wholesaler with a requisition, as described above, on receipt of the CDs.
 7. A bearer`s note which is signed and dated is prepared by the GP to authorise a member of staff to collect the controlled drugs from a pharmacy, if they are not legally entitled to do so independently. The staff member should carry formal ID.
 8. An authorised member of the practice staff takes the bearer`s note and requisition to the community pharmacy and collects the controlled drug. They should be stored out of sight during transport, ideally in a locked container
 9. The authorised member of staff should bring the controlled drugs back to the practice immediately. CD stock should be checked and transferred to secure storage in the practice as soon as possible.
 10. All requisitions, invoices and other paperwork, including signed delivery or collection notes relating to CD ordering and receipt, need to be retained for 2 years.
 11. The pharmacy is required to send the FP10CDF to NHSBSA at the end of each month. The CDAO will receive notification of FP10CDF requisitions made from NHSBSA and will monitor levels of requisitioned controlled drugs.

IMPORTANT TO NOTE: In an emergency a practitioner may obtain a CD **without** a requisition form **provided** they undertake to supply one within 24 hours. **Failure to then provide the requisition is a criminal offence.**

References

1. **NHS Counter Fraud Authority:** Management and control of prescription forms A guide for prescribers and health organisations, March 2018.
https://cfa.nhs.uk/resources/downloads/guidance/Management%20and%20control%20of%20prescription%20forms_v1.0%20March%202018.pdf
2. **Safer management of controlled drugs NHSBSA from**
<https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/prescribing-and-dispensing/safer-management>
3. **Misuse of Drugs Regulations 2001**
<http://www.legislation.gov.uk/ukxi/2001/3998/contents/made>
License guide: <https://www.gov.uk/guidance/controlled-drugs-licences-fees-and-returns>
4. **Human Medicines Regulation 2012** – who and what can be supplied on a requisition.
<http://www.legislation.gov.uk/ukxi/2012/1916/schedule/17/made>
5. **Safe transportation guidance by the Home Office (2016).**
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/526536/Transit_guidance_-_Final_-_May_2016.pdf
6. **PSNC, Controlled Drug Prescriptions and Validity**
<http://psnc.org.uk/dispensing-supply/dispensing-controlled-drugs/controlled-drug-prescription-forms-validity/>

SOP 3: Template Standard Operating Procedure for Receiving, Supplying, Storage and Record Keeping of Controlled Drugs

Objectives

- To enable Controlled Drugs (CDs) to be received/supplied and the legally required records to be kept and maintained.
- To ensure appropriate, safe and legal storage of controlled drugs.
- To ensure appropriate stock levels of controlled drugs in a Practice.

Scope

This SOP encompasses the receipt and supply of all controlled drugs for the Doctor's bag/Practice stock and the storage and record keeping requirements. For information on access to the CD cabinet, refer to the appropriate SOP.

The Misuse of Drugs (Safe Custody) Regulations 1973 (SI 1973 No. 798) apply to Schedule 2 CDs (except quinalbarbitone (secobarbital), some liquid formulations and the commonly used Schedule 3 CDs e.g. temazepam, flunitrazepam, diethylpropion and buprenorphine.

All other S3 CDs such as tramadol, midazolam, phenobarbital, gabapentin, pregabalin and all S4 and S5 CDs are exempted for the Safe Custody Regulations.

Responsibilities

- All healthcare professional in legal possession of CDs have a professional duty of care to take all reasonable steps to maintain safe custody of CDs at all times and to ensure that storage and records of controlled drugs are in line with all legal requirements
- A designated Clinician in the Practice, such as the Senior GP or Prescribing Lead, will have overall responsibility for the stock control of controlled drugs, maintaining the controlled drug register and ensuring the room and cabinet are fit for purpose.
- The practice CD Lead is responsible for ensuring that CDs are stored to the legal standard specified in The Misuse of Drugs (Safe Custody) Regulations 1973 (SI 1973 No. 798) and updated Home Office Security Guidance May 2016
- A named person(s) will be responsible for the keys to the CD cabinet/safe and ensure they are secure at all times. Refer to the SOP for Accessing the CD cabinet.

- The practice CD Lead should manage the audit trails for movement and secure storage of CDs in the practice and for the regular stock checks.

Process

Receipt and Supply

1. For receipt of controlled drugs, practice staff authorised by the designated Clinician for controlled drugs should check the order contents:
 - a. Check the quantity of the product received matches that of the requisition.
 - b. Check the expiry date of the product and check that all seals are intact if a whole pack has been supplied then sign the delivery note. If there is any discrepancy, decline the delivery, do not sign the delivery note and inform the designated Clinician for CDs.
2. The copy of the requisition and delivery note should be retained with the Controlled Drug register (e.g. in an envelope fixed to the inside back cover of the register) for a minimum of 2 years. This includes CD requisitions, collection authorisation notes, S3 (CD No Reg) invoices and S5 (CD Inv P, CD Inv POM) invoices.
3. If the item is a Schedule 2 or 3 controlled drug these should be stored in a CD cabinet. *NB. All Schedule 2 drugs are required to be kept in safe custody, but legally only the Schedule 3 drugs temazepam, flunitrazepam, buprenorphine and diethylpropion are required to be kept in safe custody.*
4. Other drugs that are liable to misuse can be locked in the cabinet if this is deemed appropriate by the relevant health professional.

Storage of controlled drugs

The CDs should be stored to the standard specified in the updated Home Office Security Guidance May 2016. This can be a locked cabinet or safe bolted to a solid wall or floor and in an area protected by an alarm system. The size of the stocks will determine which of the following is most suitable:

- a. safe that has been certified to an appropriate CEN Grade (e.g. I to XIII) of BS/EN 1143-1

- b. A small safe that has been certified to Grades S1 or S2 of BS/EN 14450
 - c. A cabinet that complies with the specifications set out in the Misuse of Drugs (Safe Custody) Regulations 1973.
 - d. Alternatively, apply for an exemption certificate from the police which certifies the safe, cabinet or room used by the practice provides an adequate level of security for storing CDs. Contact the Police Controlled Drugs Liaison Officers for advice.
6. The key to the controlled drugs cupboard should be kept separate from any other keys and should only be accessed by authorised staff. Spare keys should be kept in a separate safe to which only a few authorised staff have access. A log of access to the CD store keys at all times should be available for CQC inspection.
 7. Controlled drugs can be transported in a Clinicians bag/box/case during home visits, which must be locked. A locked car is not considered suitable for storing CDs. The bag must be kept locked at all times except when in immediate use. The clinician must always retain the keys. Ideally use a digital combination lock which avoids handling keys.
 8. If patients or staff members not authorised to have access to CDs need to enter the room where CDs are stored, it is good practice that they should be continuously supervised until such time as they leave the room.
 9. Out of date Schedule 2, Schedule 3 and Schedule 4(1) CDs should be clearly labelled as 'out of date' and segregated from the rest of the CD stock. Schedule 2 controlled drugs should be stored in the locked CD cupboard and included in the running total until disposed.
 10. Patients or carers should be advised to return their expired/unwanted CDs to a community pharmacy. Dispensing GP Practices can accept patient returns which should be stored under Safe Custody Regulations, segregated from expired and other CD stock.

Record Keeping

11. A record should be made of the receipt/supply of Schedule 2 controlled drugs in the CD register which should be a bound (not loose-leaved) book. The record should be made on the appropriate page of the register, with a separate page used for each strength and form of a drug. The name and strength of the CD should be written on top of each page.

For S2 CDs received into stock

- a. Name and address of supplier e.g. wholesaler or Pharmacy
- b. Name of drug, including strength and formulation

- c. Quantity
- d. Date received/supplied
- e. A running total balance.

For S2 CDs supplied to patient

- a. Name and address of patient
 - b. Authority of prescriber
 - c. Name of drug, including strength and formulation
 - d. Quantity
 - e. Date supplied
 - f. Who was collecting the CD, whether their identity was requested and was it supplied
 - g. A running total balance.
12. All entries into the register must be legible and permanent, in chronological order and made as soon as possible, either on the day of the receipt/supply or the next day. If a mistake is made, the error should be bracketed and initialled and dated, not crossed through. A footnote should be entered to explain the error. Entries **MUST NOT** be altered, erased or obliterated (to do so is a criminal offence).
13. Ensure that expired stock of schedule 2 controlled is included in the running total until disposed by an authorised witness.
14. Record patient returned Schedule 2 CDs in a separate record book to the CD register for purchased stock. Record the date returned, patient name & address, dispenser details (if on label), name, quantity and form of the CD, role of person returning the CD, signature of staff receiving the CD.
15. Stock levels must be checked with the register and the balance signed on receipt or supply of a controlled drug.
16. A separate register must be kept for each place CDs are stored (for example, the main surgery CD cabinet and a Doctor's bag for home visits **MUST** have separate registers).
17. Details of the administration of a CD to a patient should be recorded in the clinician's CD register and patient's electronic health register.
18. An audit of all CD stock, in the practice and clinician's bags should be done at regular intervals, ideally weekly. This should be undertaken by authorised staff and a clinician. **Both should sign and date the CD Register for S2 CDs and the separate record book for S3, S4 and S5 CDs (good practice).**

19. All stock discrepancies must be reported immediately to the Lead GP and the practice designated person(s) for controlled drugs. Thorough investigation must be undertaken.
- If a reason for discrepancy is identified, rectify the register; make a * and a margin or foot note for the amendment; Entrant and a clinician should sign and date the record.
 - If the discrepancy cannot be resolved or fully explained this must be reported to the CDAO of NHS England via the www.cdreporting.co.uk website (refer to SOP 8: Dealing with CD Concerns and Errors)
20. All CD registers must be retained for a minimum of 2 years after the last date of entry, once completed. If it contains a record of CD destruction, it should be kept for seven years.
21. The CD register, requisitions, collection notes and invoices can be kept in an electronic or paper format. An electronic register should have data safeguarded so the dates cannot be altered later, should be attributable, capable of being audited and compliant with data protection practice. Further information is available in sections 9-11 at <http://www.bipsolutions.com/docstore/pdf/13741.pdf>. Electronic records should be retained securely for 11 years and regularly backed up to prevent data loss.

References

- The Misuse of Drugs (Safe Custody) Regulations 1973 (SI 1973 No. 798)**
<http://www.legislation.gov.uk/uksi/1973/798/made?view=plain>
- Security Guidance for Controlled Drugs Home Office (May 2016)**
<https://www.gov.uk/government/publications/general-security-guidance-for-controlled-drug-suppliers>
- NHSBSA: Safer Management of Controlled Drugs**
<https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/prescribing-and-dispensing/safer-management>
- Safe transportation guidance by the Home Office (2016).**
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/526536/Transit_guidance_-_Final_-_May_2016.pdf
- NHS Counter Fraud Authority: Management and control of prescription forms. A guide for prescribers and health organisations, March 2018.**
https://cfa.nhs.uk/resources/downloads/guidance/Management%20and%20control%20of%20prescription%20forms_v1.0%20March%202018.pdf

6. **Transporting controlled drugs: guidance on security measures** for transporting controlled drugs in the UK or internationally.
<https://www.gov.uk/government/publications/transporting-controlled-drugs-guidance-on-security-measures>

SOP 4: Template Standard Operating Procedure for Transfer of Stock Controlled Drugs to/from the Doctors Bag

Objectives

Ensure that controlled drug (CD) stock held in GP bags is in date and the stock holding level reflects demand and is appropriate.

- Ensure the transfer of stock CDs to/from the doctor's bag is managed safely and securely.
- Ensure that the documentation is accurate and reflects the current stock position in both the doctor's bag and the Practice's stock.

Scope

This SOP encompasses the process and record keeping of transferring controlled drugs to/from the doctor's bag.

Responsibilities

The GP is responsible for:

- Stocking his/her bag with controlled drugs.
- Security of his/her bag in their possession, ensuring it is locked and they retain the key. Note: a digital combination lock on the bag may be more practical and convenient.
- Completing the appropriate CD registers following the transfer of CDs to/from the doctor's bag.

Authorised members of staff are responsible for:

- Witnessing the stocking of controlled drugs in doctor's bags.
- Completing stock checks and completing the controlled drugs register.

Process and Records

If a GP wishes to carry controlled drugs in his/her bag, the following should take place:

1. An authorised staff member should witness both the GP stocking the bag from the Practice CD stock **and** the appropriate entry being made into the **Practice's** CD register of the drug supplied including:
 - a. Date supplied
 - b. Name of drug, form and strength
 - c. Quantity
 - d. Running balance of stock updated.
2. The CDs should be stored in a locked bag, which can only be opened by the person in lawful possession of the bag i.e. the doctor/prescriber.
3. Bags containing CDs should not be left in a vehicle overnight or for long periods of time.
4. Each doctor is responsible for the receipt and supply of CDs from their own bag and must keep a CD register for the controlled drugs carried in their bag. There must be a separate register for each doctor's bag.
5. When CD stock is transferred from Practice stock to the doctor's bag an entry must be made in the **bag's** CD register on the appropriate page for the drug received including:
 - a. Date received
 - b. Name of drug, form and strength
 - c. Quantity
 - d. Running balance of stock updated.
6. Details of the administration of a CD to a patient from a doctor's bag should be recorded in the doctor's bag CD register. Refer to SOP 6.
7. If a CD in the bag has expired, to avoid misuse, the doctor should return the CD to the practice stock to await future destruction. A record of this transaction should be recorded in both the bag and the Practice CD registers. If there is no Practice stock then the expired CD would need to be destroyed directly from the bag and witnessed by an authorised person. A record should be made.

8. The doctor with a delegated member of staff should undertake monthly stock checks of CDs held within each bag for home visits and a record, signed and dated, made in the register to indicate the stock check has been done.
9. The expiry date on each product should be checked. Any product which is out of date should be clearly marked as “out of date” and segregated from other stock for future destruction. Refer to the SOP for disposal of CDs.
10. The stock levels of controlled drugs should be assessed, and more stock ordered if required. Refer to the SOP 7 for requisition of controlled drugs.
11. Any discrepancy between the stock and the register must be investigated. If the issue cannot be resolved the NHS England CD Accountable Officer must be informed.

References

1. **The Misuse of Drugs (Safe Custody) Regulations 1973 (SI 1973 No. 798)**
<http://www.legislation.gov.uk/ukxi/1973/798/made?view=plain>
2. **Transporting controlled drugs: guidance on security measures** for transporting controlled drugs in the UK or internationally.
<https://www.gov.uk/government/publications/transporting-controlled-drugs-guidance-on-security-measures>
3. **Security Guidance for Controlled Drugs Home Office (May 2016)**
<https://www.gov.uk/government/publications/general-security-guidance-for-controlled-drug-supplier>

SOP 5: Template Standard Operating Procedure for Prescribing a Controlled Drug and the Collection of the Prescription

Objectives

To ensure prescriptions issued for controlled drugs (CDs) are legal, accurate and conform to good practice and there is a process in place for their collection.

Scope

This SOP encompasses all prescriptions produced for controlled drugs within the Practice.

Responsibilities

- **The authorised clinician is responsible for all clinical and legal aspects of prescribing controlled drugs in accordance with the Misuse of Drugs Act 1971 and the Human Medicines Regulation 2012.**
- **CDs should be prescribed according to national and local guidance. Prescribers should be able to justify 'outlying' prescribing.**
- All private prescriptions for CDs must be written on prescription form FP10PCD using a private CD prescriber identifier code obtained from the NHS England CDAO. For more information email england.cmcd@nhs.net
- **Authorised practice staff may be responsible for generating prescriptions.**
- The Practice manager should keep a full list of the prescribers and their scope of prescribing authority. A record of an annual review should be kept of the prescribing authority of clinicians from their professional body's website.
- **Practice staff are responsible for ensuring there is an audit trail for the collection of controlled drug prescriptions.**

Process and Records

1. **The need for a CD prescription is identified and use of non-pharmacological treatment and non-CDs has been considered.**
2. **Only those prescribers legally able to prescribe controlled drugs may prescribe within their own competence.**
3. **All prescribers should be familiar with the security processes of controlled drug prescriptions.** Further guidance can be found in [Management of Prescriptions Forms](#); A guide for prescribers and health organisations.
4. From 1st April 2019 gabapentin and pregabalin were reclassified as schedule 3 CDs. These schedule 3 drugs:
 - a. will be exempt from safe custody requirements
 - b. subject to special prescription writing requirements
 - c. have a prescription validity of 28 days
 - d. do not need to be recorded in the CD register
 - e. do not require a witness for destruction
 - f. invoices need to be retained for 2 years
5. Prescriptions for Schedule 2, 3 and 4 CDs are only valid for **28 days**. The 28 day period of validity runs from the date the prescription was signed unless the prescriber has specified a start date on the prescription. For instalment dispensing prescriptions, the first supply must be made within 28 days of the appropriate date and the remainder of the instalments must be dispensed only in accordance with the directions on the prescription.
6. There is a **good practice requirement** that the quantity of Schedules 2, 3 and 4 CDs be **limited to a quantity for up to 30 days treatment**. In cases where the prescriber believes that a prescription should be issued for a longer period they may do so, but will need to be able to justify that there is a clinical need and that it would not cause an unacceptable risk to patient safety. **This information should be clearly documented in the patient`s notes.**
7. **The generated prescription (either FP10 or private prescription FP10PCD) must be completed on the appropriate form and in accordance with the legal requirements for the relevant schedule.** Information that must be included on both NHS and private prescriptions forms for controlled drugs in **Schedules 2 and 3** is:

- a) The patient's full name, address, age, date of birth and (where possible) their NHS number. Legally an age is required if below 12 years but it is good practice to include the date of birth for all prescriptions.
 - b) The name, form and strength of the drug.
 - c) The dose and frequency to be taken ('as directed' etc. is NOT legal).
 - d) The total quantity of the preparation in both words and figures.
 - e) The prescriber's name and Practice address must be stated on the prescription, together with their registration number and profession.
 - f) The prescription should be signed and dated by the prescriber in indelible ink and include the prescriber's UK address (and contact details). An Advanced Electronic Signature is acceptable for EPS2 prescriptions where Schedule 2 and Schedule 3 CDs are able to be prescribed electronically. The prescriber's name should be legible.
 - g) A prescriber code is necessary for NHSBSA and for private prescriptions.
 - h) Independent and Supplementary prescribers must also include their designation, professional registration number and prescriber code.
8. **A CD may be authorised for issue on repeat but this must only be done by an authorised prescriber. The Practice repeat prescribing SOP should also be followed, in addition to this SOP.**
9. Schedule 2 and Schedule 3 CDs (including gabapentin and pregabalin from 1st April 2019) cannot be prescribed on the repeat dispensing service (RDS). The first supply of Schedule 4 CDs on RDS must be within 28 days of issue and for Schedule 5 CDs within 6 months of issue; after then the prescription is valid for 12 months from the date of issue.
10. **If a prescriber makes a home visit and a controlled drug is prescribed, the electronic patient's medication record should be updated at the earliest opportunity (ideally 48 hours)**
11. **If a prescription for a CD is lost every attempt should be made to locate it and the prescriber should be notified along with the NHS England CD Accountable Officer. Refer to the SOP for dealing with Lost/Stolen/Forged Prescriptions.**

12. Patients / carers should have clear information on how to safely use, store and dispose the prescribed CD; document when the drug driving advice is given. The patient / carer should be informed that identity evidence will be required when collecting dispensed Schedule 2 and 3 CDs.
13. High-dose prescribing should be with reference to appropriate specialist advice. Prolonged prescribing of high doses should involve review by an alternative prescriber within the practice.
14. For patients travelling abroad, prescribers should be aware of the advice from the Home Office at <https://www.gov.uk/travelling-controlled-drugs>

Collecting Controlled Drug Prescriptions

When the patient or their representative comes to collect CD prescription it is good practice to:

1. Identify who is collecting the CD prescription – patient or their representative and confirm and record their identity evidence. **This is a legal requirement for all schedule 2 CDs** and good practice for schedule 3, 4 and 5 CDs. Professional judgement should be used to decide if appropriate to supply without identity evidence and record this in the CD Prescription Collection note.
2. Confirm the patient's address and/or DOB.
3. Ask the patient or representative to sign for the prescription(s) they are collecting. An example of a slip that can be used for this is shown below. It is suggested that the person giving out the prescription countersigns and maintains records as agreed in the practice (e.g. scan to PMR, maintain a CD book). The signature slips should be retained for at least 2 years. Alternatively, Practices can record the collection on a spreadsheet or on patient's record.
4. Check the date on the prescription. Scripts for Schedule 2, 3 and 4 CDs are legally valid for 28 days from the date of issue and for Schedule 5 drugs for 6 months from the date of issue. Refer to a clinician if a CD prescription for schedule 2 or 3 CD is being collected

more than 7 days after date of issue – there is a risk of overdose with some CD doses if not taken regularly.

5. It is good practice for the practice to use this process to monitor access to other drugs liable to abuse for all patients or certain individuals.
6. CD prescriptions should NOT be posted. It is recommended that alternative arrangements are made to allow patient access to their medication; for example arrangement with a nominated pharmacy to deliver the medication. Further guidance from Management and Control of Prescription Forms (March 2018) is published by the Counter Fraud Authority.

Example of CD collection signature slip

SIGNATURE SLIP FOR CONTROLLED DRUGS COLLECTION:	
Patient Name	
Date Prescription issued	Date
Prescription collected	
Name(s) & amount of CD issued:	
Name of person collecting (CAPITALS).....	
Relation to patient if representative	
Signature of person collecting script.....	
Identity of patient or representative confirmed	

References and Useful links:

1. NICE Recommendations on Prescribing Controlled Drugs
<https://www.nice.org.uk/guidance/NG46/chapter/Recommendations#prescribing-controlled-drugs>
2. PSNC Guidance on Dispensing and Supplying of Controlled Drugs.
<http://psnc.org.uk/dispensing-supply/dispensing-controlled-drugs/controlled-drug-prescription-forms-validity/>
3. NICE NG46 (2016) Controlled Drugs: Safe Use and Management.
<https://www.nice.org.uk/guidance/ng46>
4. Summary of NICE NG46 in NICE Bites March 2016:No.87
5. BNF guidance for controlled drugs prescribing. <https://bnf.nice.org.uk/guidance/controlled-drugs-and-drug-dependence.html>
6. NICE KTT21 (2017) Medicines Optimisation in long-term pain.
<https://www.nice.org.uk/advice/ktt21>
7. NICE CG140 (updated 2016) Palliative care for adults; strong opioids for pain relief.
<https://www.nice.org.uk/guidance/cg140>
8. Electronic Prognostic Assessment and Information Guide for End of Life website for Cheshire – includes conversion chart, assessment tools, e-learning & more. <http://www.cheshire-epaige.nhs.uk/Stages/Latest%20News.aspx>
9. Drug driving and medicine advice. <https://www.gov.uk/government/publications/drug-driving-and-medicine-advice-for-healthcare-professionals>
10. NHS England supported information and education about opioid use particularly for non-malignant pain. Opioids Aware <http://www.rcoa.ac.uk/faculty-of-pain-medicine/opioids-aware>
11. Drug Misuse and Dependence guidance July 2017
<https://www.gov.uk/government/publications/drug-misuse-and-dependence-uk-guidelines-on-clinical-management>
12. NHS Choices also have lots of helpful information to support patients to work towards non-pharmacological methods to cope with all types of pain including the Pain Toolkit and mindfulness in the Livewell section: <http://www.nhs.uk/Livewell/Pain/Pages/Painhome.aspx>

13. This video is useful to share with patients when talking about chronic pain:
www.youtube.com/watch?v=gy5yKbduGkc
14. Webinars by GPs to support prescribing and de-prescribing controlled drugs from PrescQIPP <https://www.prescqipp.info/other-comms/media-videos-and-webinars>
15. **NHS Counter Fraud Authority:** Management and control of prescription forms. A guide for prescribers and health organisations, March 2018.
https://cfa.nhs.uk/resources/downloads/guidance/Management%20and%20control%20of%20prescription%20forms_v1.0%20March%202018.pdf

SOP 6: Template Standard Operating Procedure for Administering a Controlled Drug

Objective

To ensure the administration of controlled drugs (CDs) follows appropriate procedures and record keeping in accordance with professional and national guidance.

Scope

The SOP encompasses all controlled drugs administered by authorised practitioners to patients from Practice stock or the doctor's bag stock. Any relevant Pathways/SOPs/Guidelines should be available for reference during the consultation.

Responsibilities

Authorised practitioners are responsible for administering controlled drugs and making appropriate records in the controlled drug register and the patients' records. They should be able to justify any actions taken and be accountable for those actions.

Process and Records

All reasonable endeavours must be made to gain the patient's consent before administration is undertaken.

1. The practitioner administering the CD should be familiar with the therapeutic characteristics of the drug to be administered as well as understand the prescription, and should have knowledge of the common indications, side effects, dosages, formulations and compatibilities of the CDs prescribed.
2. Before administering the CD to the patient, the following checks should be made:
The correct CD (name, form, strength is the same as that on the prescription/PSD) **is given to the correct patient and that the CD is suitable for use** (in date and in good condition) **and safe to administer** (appropriate dose and route for the patient). It is a good idea to also check whether previous doses have been taken or administered and if other controlled drugs have been prescribed to prevent therapeutic duplication and overdose.
3. Once all of the above has been satisfied, the CD may be administered.

4. Record the details of the administration into the appropriate CD register as soon as possible. The record should be made on the appropriate page of the register. Separate page must be used for each, strength and form of that drug. Record the following details:
 - a. Date administered
 - b. Name and address of patient
 - c. Name and professional registration number of the prescriber
 - d. Name and professional registration number of the professional administering the CD
 - e. Name, strength, dose, quantity of drug administered
 - f. Running balance
5. Make a record of the administration in the patient's notes. If a prescriber makes a domiciliary visit, and a CD is administered, an entry must be made by the person administering the CD, into the patient's computer record as soon as possible after the event.
6. If there is an administration error, immediate help/treatment must be given to the patient and the Practice's SOP for dealing with incidents/errors should be followed.
7. If there is an unused portion of the controlled drug, record and dispose of it safely and in accordance with the SOP 7 for CD destruction.

References

1. The Misuse of Drugs Regulations 2001
<http://www.legislation.gov.uk/ukxi/2001/3998/regulation/19/made>
2. Controlled drugs: safe use and management, NICE guideline:
<https://www.nice.org.uk/guidance/ng46>

SOP 7: Template Standard Operating Procedure for the Destruction of out of date, unwanted or damaged Controlled Drugs

Objectives

To ensure the appropriate destruction of expired or damaged controlled drugs (CDs) stored in Doctor's bag and Practice stock and to ensure a record of stock levels is maintained in accordance with all relevant guidance and legislation.

Scope

This SOP encompasses the destruction of out of date, damaged or no longer required controlled drugs from practice stock or doctors' bags. It does not include the destruction of controlled drugs prescribed for a patient as these are the patient's property (even after death). Patients or carers should be advised to return them to a community pharmacy.

All Schedule 2, 3 and 4 (Part 1) controlled drugs must be denatured and rendered irretrievable before disposal. This procedure is in place for the destruction and disposal of these CDs.

Responsibilities

Authorised members of staff are responsible for destroying and witnessing the destruction of Schedule 3 and 4 (Part 1) controlled drugs. For Schedule 2 controlled drugs (e.g. morphine, diamorphine, pethidine) a witness must be present to authorise the destruction as per the Misuse of Drugs Regulations. The local NHS England CD Accountable Officer should be contacted to arrange an authorised witness.

CDs must be denatured (made irretrievable) before disposal. To do this, the practice must first obtain and register a T28 Exemption form from the Environment Agency to avoid the need for a license.

Relevant Trade Effluent Consent must be taken from the sewerage company if rinsing's containing pharmaceutical waste will be disposed via the sewerage system.

Process and Records

1. Two authorised members of staff who have read and signed this procedure can destroy **Schedule 3 and 4(1) CDs**. Schedule 4(2) and 5 CDs do not require denaturing.
2. For Schedule 2 CDs, contact the local NHS England CDAO team at to arrange an authorised witness to observe the destruction. This can be done via online

at www.cdreporting.co.uk or via email england.cmcd@nhs.net. Do not allow expired stock to accumulate for longer than a few months.

3. CDs to be destroyed should be clearly marked for disposal and segregated from other stock in the CD cabinet but must remain part of the running stock balance until destroyed.
4. The expired stock should be counted as part of the balance in the CD register until the drugs are destroyed.
5. The controlled drug should be destroyed in the presence of the members of the Practice who have read and signed this policy or an authorised witness.
6. Expired stock should be destroyed using a denaturing kit. GP Practices are responsible for purchasing their own denaturing kits (available from pharmaceutical wholesalers) and must have them available at the appointed destruction time with the authorised witness.
7. Resulting waste should be stored in accordance with the CD denaturing kit and then placed in the appropriate container for disposal and incineration. This should be stored securely whilst awaiting collection.
8. The person destroying the CD should make the entry into the register and both the person destroying the CD and the authorised witness must sign the register.
9. In the CD register record the date of destruction, the name, formulation strength and quantity of drug. It may be useful to include the reason for disposal e. g. expired, damaged or no longer required.
10. The new running total of the products that have had their entry in the register changed should be calculated and entered into the register.
11. To make corrections surround the mistake with brackets and asterix to a footnote at the bottom of the page stating what the entry should say – initial and date the footnote.
12. Any discrepancy between the stock and the register must be reported immediately to the Practices Designated Person or CD Lead and investigated. If the issue cannot be resolved the NHS England CD Accountable Officer must be informed (see SOP 8 for Reporting CD Concerns).

Method for Destruction of Controlled Drugs

1. Ensure Personal Protective Equipment is worn e.g. gloves, aprons, goggles and face masks as deemed appropriate for product to be destroyed.
2. Ensure adequate access to water, spill kit, first aid kits.
3. Correct number of CD denaturing kits should be available before undertaking destruction.
4. **Liquids** should be emptied into an appropriate CD denaturing kit.
5. **Tablets and capsules** should be removed from their outer packaging and blister packaging and emptied into a CD denaturing kit.
6. **Liquid ampoules** should be opened and as much content as possible emptied into the CD denaturing kit. The ampoule should be disposed of in the sharps bin. The sharps bins should be labelled "contains mixed pharmaceutical waste and sharps for incineration". Ampoules containing the CD in a powder form can be opened, water added to dissolve the powder, and the resultant mixture poured into the CD denaturing kit. The ampule can then be disposed of in the sharps bin. Suitable gloves should be worn when breaking open glass ampoules.

NB: When administering CDs by injection it is quite common place for the patient to only require part of the total quantity contained in a vial/ampoule. Any unused portion remaining after the patient has received the required dose should be discarded along with the other equipment used (needles, syringes etc.) by placing them in a suitable 'sharps bin' for disposal by incineration and labelled 'Contains mixed pharmaceutical waste. For destruction by incineration'
7. **Patches** should have the backing removed and folder over on themselves and then placed in a CD denaturing kit. Reservoir patches should be cut in half and placed in the CD denaturing kit.
8. **Aerosol formulations** should be expelled into water (to prevent droplets of drug entering the air). Face mask may need to be worn; adequate ventilation must be ensured. The resulting solution can then dispose of in an appropriate CD denaturing kit.
9. The CD denaturing kit should be filled with the correct amount of water, sealed and shaken to ensure adequate denaturing of products. Follow instructions provided on the denaturing container. The kit should then be placed in a yellow waste bin for incineration.

References

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3. https://www.unitedutilities.com/globalassets/documents/pdf/trade-effluent-information-pack_acc16.pdf
4. Management of Health and Safety at Work Regulations 1999
<http://www.legislation.gov.uk/ukxi/1999/3242/regulation/3/made>
5. <https://www.gov.uk/how-to-classify-different-types-of-waste/healthcare-and-related-wastes>
6. <http://www.cqc.org.uk/guidance-providers/gps/nigels-surgery-28-management-controlled-drugs>
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8. The Misuse of Drugs Regulations 2001
<http://www.legislation.gov.uk/ukxi/2001/3998/regulation/19/made>
9. Misuse of drugs (Safe custody) Regulations 1971
<http://www.legislation.gov.uk/ukxi/1973/798/made?view=plain>
10. The Controlled Drugs (Supervision of Management and Use) Regulations 2013
<http://www.legislation.gov.uk/ukxi/2013/373/contents/made>

SOP 8: Template Standard Operating Procedure for Dealing with Controlled Drug Incidents and Errors

Objectives

To ensure reporting and escalation processes are in place for the safe management and use of controlled drugs (CDs).

Provide assurance that incidents are reported and dealt with appropriately and ensure timely actions are taken to mitigate risks and share learning from the lessons learnt.

Scope

This SOP encompasses the significant event procedure used to record incidents or discrepancies within the CD procedure and to define when an incident should be reported to the CCG and the local NHS England CD Accountable Officer.

Responsibilities

All clinicians and Practice staff are responsible for the safe management and use of controlled drugs

The CD GP Lead for controlled drugs in the Practice should be informed of all issues relating to controlled drugs in the Practice and depending on the type and seriousness of the incident, reporting may need to be escalated to the CCG, the NHS England Controlled Drugs Accountable Officer and the Police.

Concerns may be raised through any channel, such as routine prescribing data, patient comments or complaints, other clinicians, the police or social services. A decision to refer the matter to other agencies may be taken in consultation with others in the Practice, defence organisations, the CCG etc., and this decision should be taken at the outset.

Process and Records

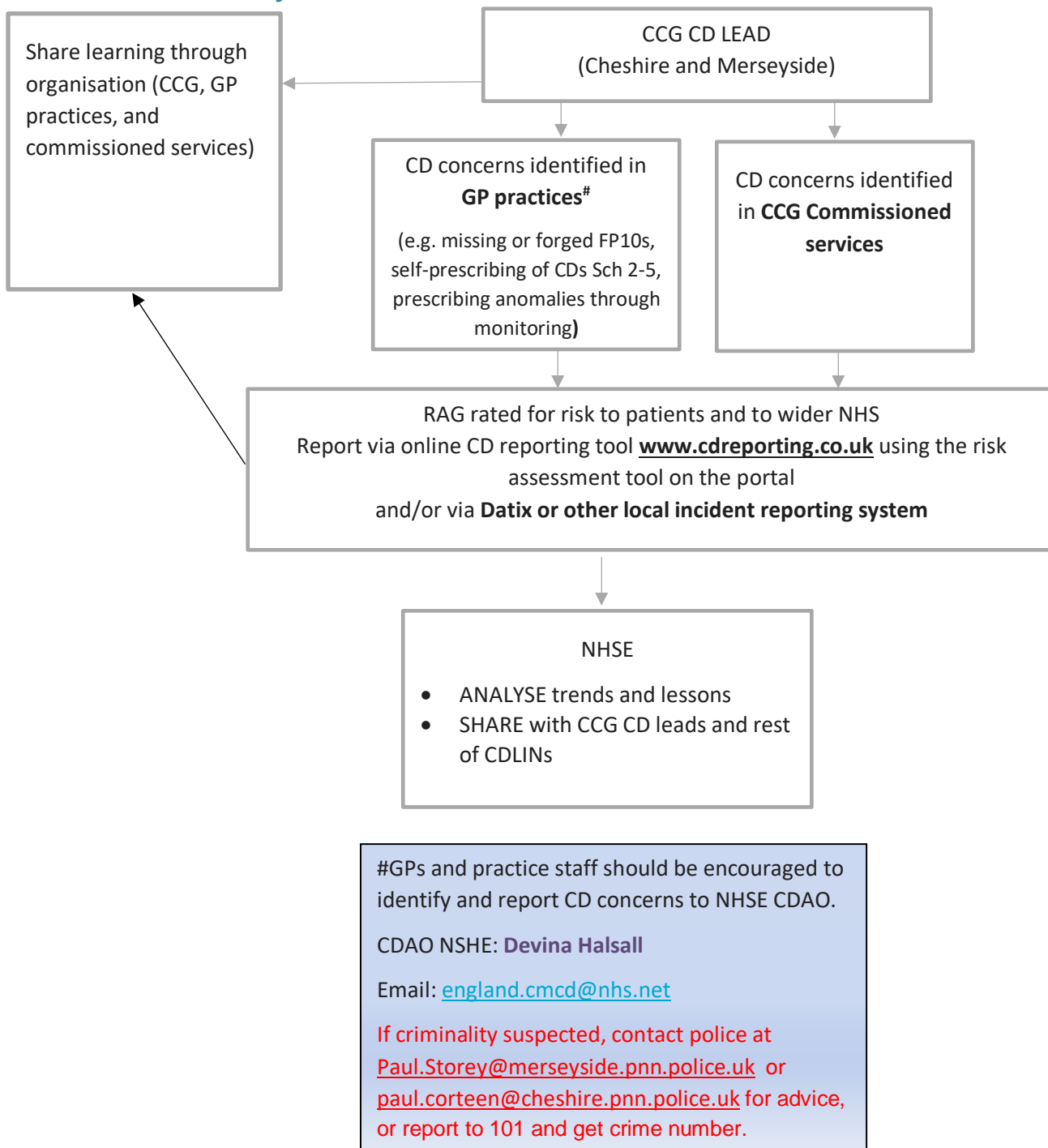
1. All concerns and incidents related to CDs should be reported to the Lead GP and CD Lead within the practice as soon as possible.
2. Follow the practice protocols for Complaints, Concerns and Significant Event.

3. Report CD related incidents, including lost prescriptions and lost controlled stationery, via Datix or other local incident reporting systems (excluding patient identifiable information) to share learning and to identify areas of concern and systems improvement.
4. All category RED incidents (see Appendix 2) should be reported to the NHSE Controlled Drug Accountable Officer immediately. This should be done via online CD reporting tool: www.cdreporting.co.uk
5. Organisations must register with the online tool at www.cdreporting.co.uk or by emailing england.cmcd@nhs.net. This web-based system will also be used for annual declarations for CDs and can also be used to request an authorised witness for destruction of stock CDs.
6. If criminality is suspected contact Police Controlled Drug Liaison Officer for advice or report to 101 and get a crime number.
7. Learning should be shared within the practice and with colleagues.
8. Learning can also be shared nationally on the National Reporting and Learning System at <http://www.nrls.npsa.nhs.uk/report-a-patient-safety-incident/>
9. Serious incidents should also be reported to National Reporting and Learning System (NRLS) and Strategic Executive Information System (STEIS). Refer to CQCs guide https://www.cqc.org.uk/sites/default/files/20160229_briefguide-interpreting_reporting_incident_data.pdf

References

1. The Controlled Drugs (Supervision of Management and Use) Regulations 2013
<https://www.legislation.gov.uk/ukxi/2013/373/contents/made>
2. NICE NG46 (2016) Controlled Drugs: Safe use and management
<https://www.nice.org.uk/guidance/ng46>

Appendix 2: CD Concerns - Reporting, analysis and sharing learning for CCGs in Cheshire and Merseyside



NB: The NHSE Controlled Drug Risk Assessment Tool used to RAG incidents can be found on www.cdreporting.co.uk

SOP 9: Template Standard Operating Procedure for Reporting Controlled Drug Lost/Stolen/Missing/Forged Prescriptions

Objectives

To minimise the risk of prescription forms used illegally to obtain controlled drugs (CDs), as well as other medicines, either for illegitimate personal use or to sell on.

Ensure a standard alerting system is implemented when Incidents and risks are reported to the practice.

Ensure incidents are dealt with in accordance with NHS Protect guidance and NHS England Area Team requirements.

Scope

This SOP encompasses all incidents of missing or stolen prescriptions blank, printed or written for controlled drugs and incidents of forged prescriptions reported to the practice.

Responsibilities

All clinicians and Practice staff are responsible for the safe management and use of controlled drugs prescriptions.

The CD GP Lead and the practice designated person(s) must be informed of any incident involving lost/stolen/forged prescription and a report sent to the NHS England area team.

A named deputy should take over the duties if the primary nominated person is not available for more than 24 hours.

Process and Records

1. FP10, FP10MDA, FP10PCD (for private prescriptions) forms and electronic prescription tokens, FP10DT, are controlled stationery and must be kept secure to avoid diversion. Please refer to the [Management of Prescriptions Forms](#) for further guidance.

Lost/stolen controlled drug prescriptions should be reported to the **NHS England Primary Care** team using the Missing Prescriptions Proforma (see appendix 3).

2. Completed form should be emailed to england.cwwalerts@nhs.net within 24 hours.
3. Contact NHS England CD team on telephone: **011382 48208** or **011382 52355** or email england.cmcd@nhs.net for advice.
4. Lost/stolen prescriptions of controlled drugs (CD) should also be reported to the **police** telephone **101** and get a **crime number**.
5. Record the loss on patient's records.
6. If a replacement prescription is needed, the practice should NOT delete the previous issue but should reprint it and record reason. On EMIS Web system, a pop-up text box will appear which allows the reason for the reprint to be recorded. This record will remain in the drug history.
7. **'Duplicate'** should be printed automatically in capital above the signature box. If unclear, write it on the script in indelible ink where it can be clearly seen.
8. If the original prescription is later found, ask for it to be returned to the practice; report to the police and area team; record in patients' notes and destroy the prescription as per practice protocol.
9. Practice to report the incident on DATIX or other local incident reporting system. For serious or ongoing concerns, the incident should be reported to the CCG CD Lead as well.
10. For incidents within practice, the matter should be recorded as a security incident on the practice's incident reporting system by the designated person and a Significant Event Analysis should be undertaken.
11. Prescriptions should be signed in a different colour ink for a period of time up to 2 months following a missing prescription incident.
12. Review practice protocol for security and audit trail for blank and completed prescriptions. Aide memoire, guidance and templates available from NHS Protect and CQC.

References

1. NHS Counter Fraud Authority: Management and control of prescription forms A guide for prescribers and health organisations, March 2018.
https://cfa.nhs.uk/resources/downloads/guidance/Management%20and%20control%20of%20prescription%20forms_v1.0%20March%202018.pdf
2. Aide Memoire for prescribers from
https://www.nhsbsa.nhs.uk/sites/default/files/2017-03/Aide-memoire_-_Prescribers.pdf
3. The Care Quality Commission (CQC) inspection criteria for prescription security. Accessed online on 25.10.2017 from
<https://www.cqc.org.uk/guidance-providers/gps/nigels-surgery-23-security-blank-computer-prescription-forms>

Appendix 3: Missing/lost/stolen NHS prescription form(s) notification form

*Organisation:	*Date reported:
*Contact name:	*Contact telephone number:
*Contact address:	
The following numbered NHS prescriptions forms have been identified to us as lost or stolen:	
Date of loss/theft:	
Name of person reporting (GP, practice manager, nurse, trust pharmacist)	
Telephone number	
Full details of loss/theft (please fill in details below)	
Date and time of loss/theft:	
Date and time of reporting loss/theft:	
Place where loss/theft occurred:	
Patient details on lost/stolen prescription:	
Drug name, form and strength daily dose and total quantity:	
Details of doctor/department/dentist/nurse etc from whom prescription form(s) have been stolen or lost	
Name:	
Personal dispensing or identification code/number	
Address:	
Serial number(s) lost or stolen	

From		To	
Details of NHS prescription form type lost or stolen (tick appropriate box)			
	Issue	Colour	Please indicate type
	FP10NC	Green	
	FP10HNC	Green	
	FP10SS	Green	
	FP10MDAS	Blue	
	FP10HMDA	Blue	
	FP10MDASP	Blue	
	FP10MDASS	Blue	

Staff compliance form

Template Staff Compliance form

Standard Operating Procedure for.....

.....

Date of review.....

I have read and understood the Standard Operating Procedure and agree to handle medicines in accordance with this procedure.

Name of Practice Employee	Role in relation to controlled drug processes	Signature	Date