

Management of Controlled Drugs (CDs) in GP Practices

Document Purpose	To ensure GP practices are aware of legal and good practice requirements related to controlled drugs.
Version	4
Title	Management of Controlled Drugs (CDs) in GP Practices
Author/Nominated Lead	Medicines Optimisation Team, NHS Nottingham & Nottinghamshire ICB
Approval Date	March 2023
Approved by	Senior Pharmacy Management Team (SPMT) Medicines Optimisation Governance Group (MOGG)
Review Date	March 2025
Groups/staff consulted	
Target audience	<ul style="list-style-type: none"> • ICB Staff • PCN Staff • GPs • GP practices • Non-Medical Prescribers
Circulation List	As above
Superseded documents	Guidelines for the Management of Controlled Drugs in GP Practices Version 3, 2014

Version Control

Version Control - Management of Controlled Drugs in GP Practices			
Version	Author	Date	Changes
4	Medicines Optimisation Team	March 2023	Organisational name changes, various contact details and general updates as per additional list.

MANAGEMENT OF CONTROLLED DRUGS (CDs) IN GP PRACTICES

Contents:

	Subject	Page No.
1	<u>Introduction</u>	4
	1.1 Responsibilities of NHS England	4
	1.2 Responsibilities of ICBs	5
	1.3 Responsibilities of the Care Quality Commission	5
	1.4 Responsibilities of Practice Staff	5
2	<u>Storage</u>	6
	2.1 Drugs, which require safe storage	6
	2.2 CD Receptacle	6
	2.3 Duties of the designated person	7
	2.4 Stock control	7
3	<u>Doctor's Bag</u>	8
	3.1 Storage and register requirements	8
	3.2 Security	8
	3.3 Stock levels	8
4	<u>CD Prescribing</u>	9
	4.1 Legal prescription writing requirements	9
	4.2 Good practice	9
	4.3 Validity and duration of prescriptions	10
	4.4 Transporting prescriptions for CDs	10
	4.5 Non-medical prescribers	10
	4.6 Emergency supplies of CDs to a patient	12
	4.7 Administration of CDs	12
	4.8 Private prescriptions	12
	4.9 Minor technical errors	12
	4.10 Electronic Prescription Service (EPS)	13
5	<u>Dispensing of CDs (Dispensing Doctors)</u>	14
	5.1 Legal requirements	14
	5.2 Good practice	14
	5.3 Collecting and delivering dispensed CDs	15
	5.4 Dispensing against instalment prescriptions	15
	5.5 Owing prescriptions for CDs	16
6	<u>CD Requisitions/ Obtaining CDs</u>	17
	6.1 Emergency supply to a practitioner	17
7	<u>Records and Record Keeping</u>	18
	7.1 Register requirements	18
	7.2 Details which MUST be included in the CD register	19
	7.3 Computerised registers	20
	7.4 Dealing with discrepancies	20
8	<u>CD Destruction</u>	21
	8.1 Expired practice Schedule 2 CDs	21
	8.2 CDs belonging to patients	21
9	<u>Clinical Governance</u>	23
	9.1 Standard Operating Procedures	23
	9.2 Risk Management	23
	9.3 Inspections and monitoring	23
	9.4 The NPSA safer practice notice (May 2006): Ensuring safer practice with high dose ampoules of diamorphine and	24

	morphine	
	9.5 The NPSA Rapid Response Report 'reducing dosing errors with opioid medicines'	24
	9.6 NHS England – Patient Safety Alert, Risk of distress and death from inappropriate doses of naloxone in patients on long term opioid/opiate treatment	25
	9.7 Travelling abroad with controlled drugs	25
10	References	26
	Appendix 1 - CD Regulations	27
	Appendix 2 – Classification Table	28
	Appendix 3 - Standard Operating Procedure Template	29
	Appendix 4 - Prescribing for substance misuse patients	32
	Appendix 5 - Travelling abroad with CDs	33

Authors

Medicines Optimisation Team NHS Nottingham & Nottinghamshire ICB

Contacts

Please contact a member of the ICB Medicines Optimisation Team if you have any general queries.

City PBP: nnicb-nn.medsopnottscity@nhs.net

Mid Notts PBP: nnicb-nn.medsopmidnotts@nhs.net

South Notts PBP: nnicb-nn.medsopsouthnotts@nhs.net

Disclaimer

This guidance has been produced by the Medicines Optimisation Team at NHS Nottingham & Nottinghamshire ICB 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.

1. INTRODUCTION

This document aims to give GP Practices guidance on regulatory and good practice systems for obtaining, storing, supplying, recording, monitoring and disposing of controlled drugs (CDs). It does not discuss the clinical choice or application of CDs and does not cover legislation relating to the Human Medicines Regulations 2012, which relates to all medicines.

Following the Shipman enquiry, legislative changes were brought into effect to improve the safe management of CDs. Amended regulations for the supervision of management and control of controlled drugs also came into force on the 1st April 2013 – ‘Controlled Drugs (Supervision of Management and Use) Regulations 2013’. These revised and updated the previous (2006) regulations and aligned them with the new structure of the NHS in England.

Further resources on comprehensive information about controlled drugs legal requirements and best practice are listed below

Gov.uk: [Controlled Drugs \(Supervision of management and use \) Regulations 2013](#)
National Institute for Health and Clinical Excellence (NICE): [Medicines and prescribing](#)
National Institute for Health and Clinical Excellence (NICE): [Controlled Drugs: safe use and management](#)
Care Quality Commission (CQC): [GP mythbuster 28: Management of controlled drugs](#)

An opioid learning module for prescribers is also available at www.mhra.gov.uk

A summary of legislation relating to CDs can be found in [Appendix 1](#).

1.1 Responsibilities of NHS England (NHSE)

NHS England is defined as both a responsible body and a designated body in the Regulations. As a designated body it must appoint a Controlled Drug Accountable Officer (CDAO). The CDAO for North Midlands (Derbyshire, Nottinghamshire, Shropshire and Staffordshire) is Samantha Travis

Contact Details

Email: Samantha.travis@nhs.net

Tel: 0113 8254717

Generic email: england.northmidlandscd@nhs.net

The CDAO is responsible for ensuring the safe and effective use and management of controlled drugs within local organisations. Each year NHS E will request GP practices to complete a self-assessment declaration form for the management of CDs. This form can be completed via the [CD online reporting tool](#).

Please report all incidents, near misses and concerns relating to CDs (including complaints) to the CDAO via the [CD online reporting tool](#)

CDAO's across the country will collate information concerning CD incidences and best practice to inform discussion at CD Local Intelligence Networks.

1.2 Responsibilities of Integrated Care Boards (ICBs)

ICBs are defined in legislation as responsible bodies. The ICB has a nominated CD lead, who will liaise with the CDAO on behalf of the organisation. For support on CD queries, contact your ICB Medicines Optimisation Team (details on page 3).

1.3 Responsibilities of the Care Quality Commission

The Care Quality Commission (CQC) has responsibility for making sure that health and social care providers and other regulators maintain a safe environment for the management of controlled drugs. The elements of this oversight role are underpinned by [Controlled Drugs \(Supervision and use\) Regulations 2013](#).

CQC produces an annual update on the [safer management of controlled drugs](#). This report looks at national trends in the prescribing of controlled drugs, issues found during inspections, and makes recommendations to drive improvement in the safer management of controlled drugs. It would be useful for the practice to read and consider implementation of any recommendations made by this document.

CQC has a [self-assessment tool](#) to assess CD governance. It is recommended that GP practices complete periodic self-assessment of CD governance using this tool to avoid any CD issues during CQC visits. For more information, see the [CQC website](#).

1.4 Responsibilities of GP Practice Staff

A Standard Operating Procedure (SOP) **MUST** be in place to cover assigning responsibilities regarding CDs. A template for a SOP is included as [Appendix 3](#).

One designated professional person, within the practice should be appointed as CD lead to hold overall accountability for the management of CDs, even if tasks are delegated to other members in the practice. Within a dispensing practice, the designated person should be a doctor with a good understanding of the CD requirements. A deputy should also be appointed to cover holidays, sickness etc. Please remember to review CD leads when staff leave.

All individuals working in GP practices, who are involved in CD supply, administration, storage, prescribing and destruction should ensure they have appropriate, timely and up-to-date knowledge of the processes involved in managing CDs. This can be achieved by having Standard Operating Procedures for different CD tasks and processes within the practice setting ([see section 9.1](#)), ensuring staff have read them along with appropriate training.

Practitioners and staff who work with CDs should demonstrate reflective learning by relevant inclusions in their CPD portfolio.

2. STORAGE OF CDs

This section covers legal and good practice issues for the storage of CDs. It does not cover any clinical or drug stability issues.

Practices should assess their need to store CDs on premises or in doctor's bags. Many practices have made a clinical decision to no longer hold CDs. However, the following section applies to practices that continue to store CDs.

SOPs **MUST** be in place to cover storage arrangements for CDs, particularly: who has access to CDs, where the CDs are stored and who is to be alerted if complications arise (see also [section 9: Clinical Governance](#)).

2.1 Drugs which require safe storage

- All Schedule 2 drugs (except quinalbarbitone (secobarbital))
- The following Schedule 3 drugs:
 - temazepam
 - buprenorphine
- Other drugs that are liable to misuse can be locked in the CD cabinet.
- Any expired stocks of the above drugs should still be stored in the CD cabinet in a separate area and labelled as such.
- Patient returns **should not** be accepted and should be signposted to a community pharmacy for safe disposal

Safe storage requirements apply regardless of how long the CDs will be stored in the practice.

Although the other schedule 3 and all schedule 4 and 5 CDs do not require safe storage, it is good practice to take extra precautions e.g. to store them out of sight of patients in the dispensary, if you are a dispensing practice.

2.2 CD Receptacle

CDs requiring safe storage should be:

- Kept in a locked, secure cabinet that is not portable and should not be identifiable as containing CDs. It is recommended that it should be a metal cabinet with protected hinges, fixed to a wall or floor of suitable thickness and material with rag-bolts, which are not accessible from outside the cabinet. It should be fitted with a robust multiple point locking mechanism or digital/combination lock. Other items such as keys, money, valuables and paperwork should not be stored with the CDs.
- In premises/area should be fitted with an alarm system.
- Kept in a separate container, away from other items, if stored within a safe (which should be attached to the wall and conform to regulations).
- Inside the CD cabinet it is good practice to separate strengths of the same medicine to minimise the risk of incorrect selection.
- Entered in the CD register which should be stored safely outside of and as near as possible to the CD cabinet but not easily identifiable as such.

2.3 Duties of the designated person within the GP practice

- Overall responsibility for access to the CDs.
- Be aware at all times of the number of sets of keys (or who has access codes for digital keypads) to CD receptacles and who holds them.
- Ensure the keys are always kept separate from the cabinet and are never accessible to unauthorised persons (including the code if a digital lock is used).
- Ensure the cabinet is only opened by themselves, or a designated / authorised person.
- Be responsible for maintenance of the practice CD register, and a regular check of accuracy of records.
- CD keys should be out of sight and locked away overnight.

2.4 Stock control

It is recommended that all practices have a robust system of stock control.

All practices should:

- Undertake suitable and weekly stock and date checks
- Record all stock movements and checks in the CD register and have a witness countersign the entry.
- Keep stock levels to a minimum and maintain a running balance after each stock movement.
- Investigate all discrepancies and document outcomes, including stock in doctors' bag.
- Report any unresolved discrepancies via the [CD online reporting tool](#)
- Expired stock should be destroyed as soon as possible fulfilling the legal requirements for destruction (see [Section 8: CD Destruction](#)). Out of date CDs should be clearly labelled as such and segregated from the rest of the CD stock until they can be destroyed.
- In dispensing practices, leave intact any tamper evident seals on packs of CDs and only break them when the pack is required for dispensing

3. DOCTOR'S BAG

3.1 Storage and register requirements

Each professional is responsible for CDs in their own possession. CDs in an individual doctor's possession should be kept in a locked box or bag (doctor's bag). This bag/box should be:

- Stored in a safe place away from patient areas
- Locked at all times, except when in immediate use
- Kept separate to the key (which must be retained by the person in lawful possession of the bag, or an individual authorised by them). A digital combination lock on the bag may be more practical and convenient.

A separate register should be kept for each bag. If the bag is stored in the practice CD receptacle or cabinet (i.e. it is not considered a specific doctor's personal stock) and only removed for patient visits, a separate register is not required. It is good practice to carry a small book in the bag to record any CD that is administered during a home visit. The information from the book should then be transferred to the practice CD register on returning to the practice.

3.2 Security

A vehicle e.g. car, van etc is not a suitable container for storing controlled drugs. It is recommended that a doctor's bag is not stored in a vehicle. However, on occasions where a locked doctor's bag is required to be kept in a vehicle, the bag must be kept out of sight and not left overnight or unattended for long periods of time. Any medicines transported in a vehicle should not be subjected to extremes of temperature.

3.3 Stock levels

Stock levels should be kept to a minimum. Each doctor is responsible for the receipt and supply of CDs from their own bag:

- Only one strength of each CD should normally be kept to minimise the risk of confusion, error and inappropriate administration
- Oral preparations of CDs would not normally be considered essential
- A suitable stock check should be carried out on a weekly basis
- Restocking of the bag and appropriate entries into the CD registers should be witnessed and countersigned

A doctor who does not normally work in the practice may bring their own CD stock with them. If they are required to administer a CD this should be replaced by the practices' own stock and should be recorded in the relevant registers.

It is recommended that naloxone injection is available in all clinical locations where diamorphine and morphine injections are stored or administered.



Caution is advised to practices/doctors holding Naloxone for administration in patients on long-term opioids/opiates. A National patient safety alert was released in November 2014 titled 'Risk of distress and death from inappropriate doses of naloxone in patients on long term opioid/opiate treatment'. See [NHS England website](#) to read the alert.

4. CD PRESCRIBING

Doctors, nurses and pharmacists (independent prescribers) may prescribe all Schedule 2 to 5 CDs to patients for organic disease within their remits of competency (see [Appendix 4](#) for prescribing in substance misuse).

CDs prescribed for an individual patient **MUST** be supplied to and used by that patient only. Any stock left over **MUST** be destroyed. Recycling of CD stock could be considered a potential offence under the Theft Act 1968 and might be seen as a means of obtaining CDs by deception.

4.1 Legal prescription writing requirements

All Schedule 2 & 3 prescriptions **MUST** contain the following information:

- The patients full name, address and age (if under 12 years old). An email address or PO Box is not acceptable. 'No fixed abode' is acceptable as an address for homeless people.
- The name and form of the drug, even if only one form exists
- The strength of the preparation, where appropriate
- The dose to be taken (as directed is **not** acceptable).
- The total quantity of the preparation, or the number of dosage units, to be written in both words and figures
- Address of the prescriber
- Indicate if the practitioner is a doctor, supplementary prescriber, etc.
- Must be indelible, signed by the prescriber and include the date when signed.

Prescriptions for Schedule 2 to 5 CDs can be computer generated. The prescription **MUST** be signed by hand by the prescriber. The date does not have to be handwritten. Any alterations should be signed by the prescriber.

Advanced electronic signatures can be accepted for schedule 2 and 3 controlled drugs where the Electronic Prescribing Service (EPS) is used (prescribers should regularly review patients clinical needs and quantity prescribed). See [section 4.10](#)

Schedule 2 and 3 CDs cannot be prescribed on the Repeat Dispensing Service (eRD). Further information on eRD can be found on [NHSBSA website](#)

See [appendix 4](#) for information on instalment prescriptions.

4.2 Good practice

Dosages and frequencies for all CDs should be written in full, to aid administration by nurses and carers (clarity is especially important for syringe drivers). Any space on the prescription form that has not been written on should be blanked off (e.g. by drawing a line through it) to reduce the opportunity for fraud.

The prescriber's full name, address, telephone number and the organisation in which they are working (normally pre-printed) should be included on the prescription. The profession of the prescriber and their registration number should also be added to the CD prescriptions they issue, to assist with any future audit.

If a handwritten prescription for a CD is issued, it should also be recorded on the patients' computer records.

It is inappropriate to prescribe (or administer from stock) a CD for personal use or to anyone with a close personal relationship to the prescriber e.g. family members, except in genuine emergencies. Each professional body has their own code of conduct / ethics which should be referred to and adhered to at all times.

4.3 Validity and duration of prescriptions

NHS and private prescriptions for Schedule 2, 3 and 4 CDs are valid for **28 DAYS** from the appropriate date on the prescription. Schedule 5 CD prescriptions are valid for 6 months from the date on the prescription.

The quantity of drug prescribed on each prescription should be appropriate for the clinical need of the patient. Careful consideration should be given to the quantities prescribed, both to anticipate requirements (e.g. over a weekend) and to reduce the amount of excess CDs stored in the patient's home.

Guidance has been given to make it clear that single prescriptions for CDs in schedules 2, 3 or 4 should normally be limited to a supply of **30 days**. Only in exceptional circumstances should the prescriber issue a prescription for a longer period 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 patients notes.

As with all prescriptions, CD prescriptions either blank or completed should be stored securely to prevent theft and misuse to fraudulently obtain controlled drugs. For more information on management and control of prescription forms visit the [NHS Counter Fraud Authority](#) website.

4.4 Transporting CD prescriptions

Prescription forms for Schedule 2 CDs should not routinely be sent to the patients' pharmacy via the postal system but should be collected from the surgery. It is good practice for patients to sign to say they have collected the CD prescription. A SOP should be developed if CD prescriptions have to be regularly transported by mail / taxi etc. which reflects a risk management assessment to reduce any likelihood of prescription diversion or going missing. If it is necessary to send a CD prescription by mail, recorded delivery should be used.

4.5 Non-Medical Prescribers

A range of non-medical healthcare professionals can prescribe medicines for patients as either Independent or Supplementary Prescribers.

Independent prescribers are practitioners responsible and accountable for the assessment of patients with previously undiagnosed or diagnosed conditions and for decisions about the clinical management required, including prescribing.

Supplementary prescribing is a partnership between an independent prescriber and a supplementary prescriber to implement an agreed Clinical Management Plan for an individual patient with that patient's agreement.

Nurse & Pharmacist Independent Prescribers

- Nurse and pharmacist Independent Prescribers can prescribe any medicine for any medical condition. This includes unlicensed medicines, subject to accepted clinical good practice.
- They are also able to prescribe, administer, and give directions for the administration of Schedule 2, 3, 4, and 5 Controlled Drugs. This extends to diamorphine hydrochloride, dipipanone, or cocaine for treating organic disease or injury, but not for treating addiction.
- Nurse and pharmacist Independent Prescribers must work within their own level of professional competence and expertise.

Community Practitioner Nurse Prescribers

Can only prescribe products and medicines which are specified in the 'Nurse Prescribers' Formulary for community practitioners'. No CDs are included in this formulary.

Supplementary Prescribers

Can prescribe any CD (except diamorphine, dipipanone and cocaine for substance misuse) as long as it is within the Clinical Management Plan specific to that patient and agreed between the doctor (independent prescriber), supplementary prescriber and the patient. Supplementary prescribers may be registered nurses, midwives, pharmacists, chiropractors, podiatrists, physiotherapists, radiographers or optometrists.

Further information can be found in the [BNF](#)

Patient Group Directions (PGDs)

A patient Group Direction (PGD) is a written direction relating to the supply and administration of a licensed prescription-only medicine by another healthcare professional. The following controlled drugs can be included in PGDs (for those professionals listed in the PGD legislation and not excluded from doing so):

- Schedule 2: Morphine and Diamorphine (only by registered nurses and pharmacists for the immediate necessary treatment of a sick or injured person. Not for treating addiction).
- Schedule 2: Ketamine
- Schedule 3: Midazolam
- Schedule 4: All drugs including benzodiazepines (except anabolic steroids and injectables used for treating addiction).
- Schedule 5: All drugs.

4.6 Emergency supplies of CDs to a patient

Requests for emergency supplies of Schedule 2 & 3 CDs for a specific patient without an existing prescription by an authorised prescriber, are **NOT** permitted, either at the request of the patient or a practitioner (except phenobarbital for the treatment of epilepsy - 5 day maximum supply).

4.7 Administration of CDs

On administering a CD from the doctor's bag or practice stock, a record **MUST** be made at the time in the appropriate CD register (see Section 6: Records and record keeping). The prescriber should record the issue or administration of a CD in the patient records as soon as possible and write an FP10 for submission and reimbursement by the practice to NHSBSA Prescription Services, endorsing the FP10 with the word "Administered" and the date.

A SOP should be in place to cover the preparation and administration of injections, including CDs.

4.8 Private prescriptions

- Private prescribers of Schedule 2 and 3 CDs **MUST** use the pink prescription pad (FP10 PCD). Private prescriptions on any other stationary (e.g. headed notepaper) are no longer allowed for Schedule 2 & 3 CDs.
- In order for NHS Prescription Services (NHSBSA) to monitor the issuing of Schedule 2 and 3 CDs, private prescribers are required to notify the CD Accountable Officer (by emailing England.northmidlandscd@nhs.net) to obtain a unique 6 digit prescribing code (assigned by the NHSBSA) before prescribing these drugs privately. This prescribing code is different to the NHS prescriber's identification code. Prescribers who work privately and for the NHS will therefore need to use 2 different codes.
- FP10 PCD prescription pads should be ordered via Primary Care Support England (PCSE).
- Private prescribers **MUST** comply with legal requirements for CDs.
- Schedule 2 & 3 CD private prescriptions cannot be repeatable for a specified number of times. However, it is possible to prescribe Schedule 4 & 5 CDs on a repeatable basis.

4.9 Minor technical errors

Pharmacists can supply Schedule 2 & 3 CDs against some prescriptions that have a minor technical error* but where the prescriber's intention is clear. The amendments must be indelible and clearly attributable to the pharmacist.

* Where a prescription for a schedule 2 or 3 controlled drug contains a minor typographical error or spelling mistake, or where either the words or figures (but not both) of the total quantity has been omitted, a pharmacist can amend the prescription indelibly so that it becomes compliant with legislation. Pharmacists cannot correct other amendments or omissions (e.g., missing date, incorrect dose, form or strength). These should be corrected by the original prescriber or, in an emergency, another prescriber authorised to prescribe controlled drugs. Amendments cannot be made by covering letter from the prescriber.

4.10 Electronic Prescription Service (EPS)

Following changes to home office legislation and NHS and Human Medicines Regulations controlled drugs (including schedule 2 and 3) can now be prescribed electronically.

Prescribers are reminded that face-to-face consultations are considered best practice when prescribing controlled drugs. Although the introduction of EPS may result in opportunities for remote consulting and prescribing, particularly in urgent and emergency care, this should be a last resort for controlled drugs, particularly without access to the primary care record or personal knowledge of the patient. SOPs should be updated to reflect the need to consider face-to-face consultations where controlled drugs are requested or systems put into place to check CD scripts before signing and sending electronically.

Benefits of prescribing controlled drugs through EPS include:

- Fewer patients with both paper and electronic prescriptions, making it easier for them as all their prescriptions are sent to their nominated pharmacy.
- Sending more prescriptions electronically will reduce the administrative burden on both GP practice and pharmacy staff
- Prescriptions will be sent securely and electronically and so can't be lost or misplaced
- Being able to see everything that has been prescribed helps pharmacists make the right decisions to safely and effectively dispense the right drugs for patients
- Patient safety is increased as errors are less likely.

Exclusions

- Oral liquid methadone – Because it isn't possible for all dispensing systems to endorse electronic prescriptions for oral liquid methadone with a packaged dose endorsement (PDn), a paper FP10 prescription will still need to be generated for this drug to allow the pharmacy to claim the correct fees.
- Instalment prescribing – EPS cannot be used for prescribing in instalments (FP10MDA prescribing)

5. DISPENSING OF CDs (Dispensing Doctors only)

It is lawful for a dispensing doctor to delegate the act of dispensing medicines for their patients to trained staff. However, accountability remains with the dispensing doctor and the practice and partners carry vicarious liability for errors made, or for any breach of the law.

A dispenser or other employee would **NOT** normally be expected to dispense a Schedule 2 or 3 CD without first checking the dispensed items with a doctor. The Dispensing Doctors Associations (DDA) Dispensing Guidance (2019) states that 'it is good practice for the doctor to check all prescriptions for CDs'.

SOPs should be in place for all aspects of the dispensing process and should include guidance for dispensers on CD prescriptions.

5.1 Legal requirements

Details of supplies of Schedule 2 CDs **MUST** be entered into the CD register no later than the day following the day of the supply. The date entered in the CD register **MUST** be the date of supply (i.e. the date the CD is given out) and **NOT** the date when it is assembled. The dispensing doctor **MUST** endorse prescriptions for Schedule 2 and 3 CDs with the date of supply to the patient.

A manufacturer's patient information leaflet **MUST** be supplied with all dispensed medicines.

Dispensing doctors **MUST** send the original copy of the private Schedule 2 and 3 CD Prescription to NHSBSA Prescription Services using the form [FP34 PCD](#) for data collection and audit purposes.

5.2 Good practice

If a CD has been assembled but is awaiting collection, details should not be entered in the CD register until after the CD has been collected. The assembled CD should be kept in the CD container until collected and it is good practice to keep the prescription attached to it.

Where possible a second person should check all the details of a CD being dispensed. Except in exceptional circumstances, the person prescribing the CD should not undertake the whole dispensing process.

All medicines, but especially CDs, should be dispensed in child resistant containers. Blister packs are usually considered to be child resistant. Verbal and written advice should be given on the safe and secure storage of CDs and the return of any unused CDs for destruction.

At the time of dispensing, packs of medicines should be opened (breaking the seal where necessary) to confirm the number of unit doses is the same as that stated on the container. Products should be dispensed in the original packs if possible. This further clarifies the strength dispensed and includes the patient information leaflet.

5.3 Collecting and delivering dispensed CDs

The person collecting a prescription for a schedule 2 or 3 CD should sign in the relevant box on the back of the prescription or EPS token and be asked for proof of identity (a legal requirement when collecting a schedule 2 CD). If dispensing in instalments, patients are not required to sign for each instalment. If evidence of identity is not shown the prescription may still be issued using professional discretion. Guidance for collecting this information and recording of it should be included within dispensary SOPs.

If schedule 2 CDs are collected by someone other than the patient, the name, identification and role of the person collecting the CD and their relationship with the patient should be established prior to any discussion about the prescription or supply of the medicine.

If a health care professional acting in his professional capacity on behalf of the patient collects the CD, the dispenser **MUST**

- Obtain the professional's name and address
- Request identification unless he is acquainted with that person

A supply may still be made if appropriate identification is not available.

CDs should not routinely be delivered to patients (e.g. by mail or taxi) unless it is part of an organised delivery service. SOPs should be in place if dispensed CDs or CD prescriptions are delivered to patients by any route. Healthcare professionals involved in the delivery of patient care should not routinely transport patients' own CDs to and from that patient's home. If it is essential, it is good practice to keep CDs out of view during transit.

If a taxi is sent by the patient to collect a CD it is recommended that the driver has a letter of authority from the patient. If the practice asks a taxi service to deliver, where possible the driver should return a delivery note signed by the patient to the practice to confirm delivery.

If sending CDs by mail, special delivery should be used to ensure the pathway is auditable.

5.4 Dispensing against instalment prescriptions

For instalment prescriptions of Schedule 2 CDs, it is recommended to complete register entries for each instalment at the time of supply. Waiting to complete entries at the end of the day may lead to omissions. The completion of instalment entries must not be done in advance of supply as this may lead to incorrect balances in the CD register.

Supply may be made in advance of the instalment due date if the pharmacy is closed on the instalment date providing the following wording is present on the prescription 'instalments due on closed days should be dispensed on a prior suitable day (see appendix 4 for more information).

The following also applies:

- Where appropriate, shared care arrangements for the prescribing and dispensing of CDs for substance misusers, should be developed.

- If an instalment prescription for a CD is presented, it should be stamped with the dispensing practice address at the time of the first dispensing in order to prevent the possibility of future misdirection.
- If methadone prescriptions are made up ahead of patients' collection, the dispensed medication should be stored in the CD container.
- If an instalment is made up and not collected, it can be returned to stock, provided it is labelled appropriately as stock (i.e. with batch number and expiry date). The patient's medication record should be amended and the prescription annotated to reflect the fact that the supply was not collected.
- Third party collection of CDs for patients being treated for addiction should only occur in exceptional circumstances. A letter of authenticity from the patient should be obtained on **every** occasion that the representative collects the prescription and the letter retained by the practice.

5.5 Owing prescriptions for CDs

If a 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. You may wish to annotate this entry as "part supply". A further entry must be made when the balance is supplied. You may wish to annotate "supply complete".

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. For example, if the patient has died.

Where the prescriber has written on the prescription that it must be supplied on a specific date, as in the case of instalment prescriptions, those instructions **MUST** be complied with. Where a prescription requires a specific quantity of CDs to be supplied on a specific date, the dispenser **MAY NOT** dispense a part of this quantity and then the rest at a later date. CD stock checks need to be carried out to ensure adequate supplies are held by the dispensary. However, the stock held in the dispensary, plus the balance remaining can be dispensed to the patient, as long as it is done during the same calendar day.

Dispensed item or owings for Schedule 2, 3, and 4 CDs cannot be supplied more than 28 days after the appropriate date on the prescription.

6. CD REQUISITIONS / OBTAINING CDs

A SOP **MUST** be in place to cover the ordering and receipt of CDs.

It is recommended that quantities of CDs within the GP practice are kept to a minimum, whilst ensuring that they are adequate to meet practice need.

If a GP is obtaining Schedule 2 or 3 CDs from another GP Practice or a pharmacy, a mandatory requisition form (FP10 CDF) **MUST** be used. Both parties **MUST** ensure that the correct entries are made in their respective CD registers within 24 hours. A requisition is not legally required before supplying or obtaining Schedule 4 or 5 CDs. All requisitions/orders for CDs should be retained for at least 2 years.

The [FP10 CDF requisition form](#) is available from the NHSBSA website.

- The form can either be handwritten in indelible ink or computer generated with a handwritten signature (sections B & C should be completed in full).
- The practice should keep a copy of the requisition form for their records.
- The requisition order should be taken to the pharmacy. It is not permitted to be faxed or electronically transmitted.
- If ordering from a wholesaler, the GP must provide the wholesaler with a requisition, as described above, on receipt of the CDs.

The person sent to collect the CD should carry a bearer's note, which is signed and dated by the prescriber, stating they are authorised to collect the CD. The person should also carry formal ID. The person receiving CDs should be authorised in writing in advance to do so by the doctor and should sign the supplier's delivery note on receipt of these CDs. All documentation, including bearer's notes should be kept for at least TWO years.

It is the responsibility of the designated person or appropriate GP, when receiving a supply of CDs, to ensure that the correct item/quantity is delivered and that all appropriate entries are made in the CD register within 24 hours.

GPs may obtain their own individual supplies e.g. for inclusion in a doctors bag or the practice may obtain a stock which is stored in the practice CD cabinet. Supplies may then be made from this stock to individual GPs. A record of the supply to individual GPs **MUST** be made in the practice register, though individual GPs do not need to supply a requisition to their own practice for this.

6.1 Emergency supply to a practitioner

Controlled drugs (CDs) in schedule 2 and 3 may not be supplied under the emergency supply provision, whether at the request of a patient or a prescriber, with the exception of phenobarbital for the treatment of epilepsy (5 day supply maximum).

7. RECORDS AND RECORD KEEPING

When Schedule 2 CDs are obtained or supplied the law requires that practitioners **MUST** make an entry in a CD register. Entries are not required in the register for Schedule 3 drugs but records (invoices etc.) **MUST** be kept for at least 2 years.

All healthcare professionals who hold personal CD stock (i.e. each individual doctor's bag) **MUST** keep their own register and are personally responsible for keeping this accurate and up-to-date (see Section 3: Doctor's Bag for further information).

7.1 Register requirements

The register **MUST** provide an audit trail for all CDs purchased by the practice:

- The register **MUST** be a bound book; designed for the purpose it is used. The register must not be a loose-leaf format or card index. Computerised registers may be used (see section 7.3).
- The register **MUST** contain individual sections for each drug and the name, form and strength of each drug specified at the top of the page. Separate pages should be used for each form and strength of a drug. Entries made in respect of drugs obtained or drugs supplied may be made on the same page or on separate pages on the register.
- Handwritten register entries **MUST** be in indelible ink. All entries **MUST** be made in chronological sequence and be made on the day or day after the transaction took place. There **MUST** be no crossing out, obliteration (e.g. Tippex) or alteration of entries. All errors should remain visible and corrections should be made in the form of footnotes or the erroneous entry should be bracketed and re-written. Changes should be initialled and dated.
- The register **MUST** be retained for a period of TWO years after the date of the last entry and must not be used for any other purpose. This applies even if transferring stock to a separate register or if the practice no longer holds CDs.
- The register **MUST** be kept at the premises to which it relates. Practices with more than one set of premises **MUST** keep a register at each premises to which it relates. The register should not be stored in the CD cupboard but should be stored safely close by.
- The register **MUST** be available for inspection at any time and not used for any other purpose.
- If GPs are taking individual stock from the practice stock e.g. for a doctor's bag, then they **MUST** keep an **individual register** to record receipts of drugs from the practice stock and issues / administration to patients.

Details of the administration of CDs should be recorded in the patient notes / computer records in addition to the practice register. Wherever possible, 2 members of staff should initial entries in the CD register. A running balance of CDs should be maintained, which is calculated and recorded after

each transaction and checked regularly (good practice is on a weekly basis).

7.2 Details which MUST be included in the CD register

For CDs received into stock

- Date supply obtained
- Name and address of the supplier (e.g. wholesaler or pharmacy)
- Quantity obtained
- Name, form and strength of the CD

For CDs taken out of stock (e.g. for administration to patients or transferred to practitioners e.g. a doctor's bag)

- Date supplied
- Name and address of the patient or practitioner supplied
- Details of authority to possess – prescriber or licence holder's details
- Quantity supplied
- The person collecting Schedule 2 CD (patient/patient's representative/healthcare professional) if appropriate and, if healthcare professional, name and address. Plus:
 - Was proof of identity requested of patient/patient's representative? (Yes/No)
 - Was proof of identity of person collecting provided? (Yes/No)

These 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 that will help guarantee the integrity and accuracy of the audit trail. It is good practice to record

- Running balances
- Prescriber identification number and/or the professional registration number of the prescriber
- The name and professional registration number of the healthcare professional supplying the CD

7.3 Computerised registers

Controlled Drug registers are allowed to be held on a computerised system. The Regulations require that entries in computerised registers must be attributable and capable of being audited and

- Safeguards should be incorporated in the software to ensure the author of each entry is identifiable.
- Entries cannot be altered at a later date.
- A log of all data entered is kept and can be recalled for audit purposes.

Electronic records should be retained for 2 years.

7.4 Dealing with discrepancies

CD stocks and records should be checked for accuracy regularly (ideally weekly to ensure discrepancies are picked up quickly). This check should be recorded in the register. Any discrepancies should be immediately investigated and outcomes recorded. A SOP **MUST** be in place to cover dealing with discrepancies. Once a discrepancy is resolved, a note should be made in the CD register and appropriate records kept.

If the source of the discrepancy cannot be identified during the stock check, then the CD Accountable Officer should be notified via the NHS England online [controlled drug reporting tool](#). A formal internal investigation should be undertaken. This process may include discussion with the relevant professional body. If this issue is still not resolved satisfactorily then the police should be informed.

8. CD DESTRUCTION

The legal requirements for destruction of CDs are different depending on the source of the supply. SOPs should be in place for maintaining a record of Schedule 2 CDs destroyed. All Schedule 2, 3 and 4 (part 1) must be destroyed /denatured before being placed into waste containers. In order to do this, a GP practice must obtain a T28 exemption from the Environment Agency to negate the need to obtain a licence to carry out this process. The T28 exemption is free of charge and lasts 3 years. More information can be found on the [gov.uk website](https://www.gov.uk).

8.1 Expired practice Schedule 2 CDs

Destruction **MUST** be witnessed by an authorised person i.e. a person who has been authorised by the Accountable Officer to witness CD destructions. Examples include ICB Medicines Optimisation Team.

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

CDs awaiting destruction should be stored in the CD cabinet. They should be segregated and clearly marked 'date expired' to prevent them being issued in error.

Details **MUST** be entered in the CD register when the drug is destroyed, including the name, form, strength, and quantity, the date of destruction and the signature of the authorised person who witnessed the destruction and the professional destroying it (i.e. two signatures)

If CDs kept in a doctor's bag expire, they should be returned to the central practice stock for future authorised destruction. If the practice does not hold central stock, then the CDs need to be destroyed directly from the bag, witnessed by an authorised individual (see above) and appropriate records made in the CD register.

Schedule 3 and 4 (part 1) controlled drugs **do not** require their destruction to be witnessed by an authorised witness but it is good practice to have another member of staff witness the destruction.

8.2 CDs belonging to patients

Non –dispensing GP Practices

CDs returned from patients / care homes should **NOT** be accepted back by GP practices. Patients or their representatives should be directed to a local community pharmacy. Community pharmacies are paid to accept unused patient returned medication as part of their contract.

If a GP finds CDs in a deceased patient's home and there are no relatives / carers to return them for destruction, then he may act as the patient's representative and return them to a community pharmacy.

Dispensing GP Practices

Dispensing practices may accept patient returns of CDs whether or not they have been supplied by their practice. Pharmacies can also accept patient returns.

Although unused medicines from care homes providing personal care (residential homes) may be accepted back to a dispensing practice, **NO** unused medicines should be accepted back from a care home providing nursing care (nursing home), including CDs (unless a licence and contract are in place). These homes usually have their own waste disposal provider arrangements, to dispose of unused medicines.

Packages of medicines returned to the practice should be inspected in the presence of the patient or their representative. CDs returned from patients **MUST NOT** be entered back into practice stock or re-issued to another patient. They **MUST** be destroyed.

CDs can be placed into waste containers only after the CD has been rendered irretrievable i.e. by denaturing. A specifically designed CD denaturing kit should be used which can then be disposed of through normal medicines waste.

Dispensing doctors and community pharmacists may legally destroy prescribed drugs returned by a patient or their representative without making a record and without a witness, however it is good practice to have a witness. It is recommended that a separate book is set up specifically for recording returned unused CDs to ensure that returned drugs do not get confused with active stock. The date, drug quantity, name, form and strength and the name of the person returning the CD should be recorded. The destruction should be witnessed by a doctor, recorded in the patient returns CD destruction register returned CD book and signed by both the person destroying the CD and the witnessing doctor.

9. CLINICAL GOVERNANCE

9.1 Standard Operating Procedures (SOPs)

A SOP is an unambiguous document, describing the responsibilities and the procedures, necessary to manage any set of processes safely and accountably.

SOPs are required in all premises where CDs are handled. They should cover all aspects of CD management – from ordering, receiving, storage, administration, guidance for dealing with incidents, disposal and record keeping. They should also highlight the accountabilities and roles of all members of the healthcare team. SOPs are one of the measures introduced that will help to ensure good practice throughout the health and social care system. It is important that SOPs are reviewed regularly to reflect current legislation and guidance.

GP practices need to have appropriate processes in place to agree and adopt SOPs for use. SOPs need to be agreed at a senior level on behalf of the organisation, usually in the case of General Practice, the Senior Partner.

A SOP template is included in [appendix 3](#).

Where a specific person is named in the SOP then the SOP will need to be changed if personnel change.

9.2 Risk management

Risk management systems should be used to help minimise risks in the management of CDs. Such systems should be written and readily accessible to all relevant practitioners and staff. They should include:

- Assessment of risks arising from managing CDs
- Procedures for training new staff members or locums in the management of CDs
- Identification of tasks which require the presence of a witness
- Handling of all records relating to CDs including requisitions, invoices, private and NHS prescriptions, transport and delivery notes and CD registers
- SOPs related to the dispensing of CDs within the practice (if applicable)
- SOPs for monitoring and recording stock reconciliation (e.g. in CD cabinets / doctor's bags) and action to be taken if a problem is identified
- SOPs for checking expiry dates and the process for dealing with expired CDs
- Recording of critical incidents, errors and near misses with CDs through local systems and the NPSA national reporting and learning system
- Procedures for reporting loss or suspected theft of CDs
- NHS complaint procedures
- How to report suspected cases of NHS fraud
- Signposting of where to locate the local policy and processes for raising concerns
- Who the local ICB contact is if they have a concerns regarding performance or practice of healthcare professionals, or their staff, involving CDs

9.3 Inspections and monitoring

All providers of NHS general practice and other health & social care providers must be registered with the Care Quality Commission (CQC) who are responsible for monitoring, inspecting and regulating these services. The CD Accountable Officer within NHS England – North Midlands also has a local responsibility to perform visits at those premises not subject to inspection by other regulatory bodies.

Medicine Optimisation pharmacists or clinical governance leads may also discuss CD issues with GP practices as part of their normal visits and use information from these visits to share good practice and to inform monitoring and inspection processes.

ICB Medicines optimisation teams monitor the prescribing of Schedule 2, 3 & 4 CDs through ePACT2 data and investigate any unusual prescribing patterns. If a GP is prescribing high doses of a CD for a patient, particularly where prolonged use is expected, it is good practice to report this to the ICB Medicines Optimisation team to aid the interpretation of this data.

9.4 The NPSA safer practice notice (May 2006): Ensuring safer practice with high dose ampoules of diamorphine and morphine

This safer practice notice recommends that practices have procedures in place for safely prescribing, labelling, supplying, storing, preparing and administering diamorphine and morphine injections. In particular:

- Risk assessing the strengths of diamorphine and morphine that are stocked in all locations, including doctor's bags.
- Separate storage locations e.g. shelf/box used for low strength and high strength products and adequately labelled and differentiated.
- Where possible a second person should provide an independent check to confirm the identity of the drug, strength etc. to help minimise the risk of errors.
- Recommend that naloxone injection is available in all clinical locations where diamorphine and morphine injections are stored or administered.

It is recommended that GP practices who hold or administer diamorphine and morphine ampoules read the [safer practice notice](#).

9.5 NPSA Rapid Response Report 'reducing dosing errors with opioid medicines' July 2008 NPSA/2008/RRR05

The NPSA received reports of five deaths and over 4,200 dose-related patient safety incidents concerning opioid medicines up to June 2008. This rapid response alert raises the issues relating to the incidents and that all prescribers, pharmacists and those administering opioid medicines have a responsibility to check that the intended dose is safe for the individual patient by:

- Confirming any recent opioid dose, formulation, frequency of administration and any other analgesic medicines prescribed for the patient.
- Ensure where a dose increase is intended, that the calculated dose is safe for the patient
- Ensure they are familiar with the following characteristics of that medicine and formulation: usual starting dose, frequency of administration, standard dosing increments, symptoms of overdose, common side effects

Prescribers are recommended to familiarise themselves with the [rapid response alert](#)

9.6 NHS England – Patient Safety Alert, Risk of distress and death from inappropriate doses of naloxone in patients on long term opioid/opiate treatment 20 November 2014 (NHS/PSA/W/2014/016)

This alert highlighted the risk of distress and death from inappropriate doses of naloxone. It highlighted that naloxone must be given with great caution to patients who have received long term opioid/opiate treatment or who are physically dependent on opioids/opiates.

It is recommended that those GP practices who hold or may administer naloxone read the [patient safety alert](#).

9.7 Travelling abroad with controlled drugs

The Home Office Drugs and firearms Licensing Unit issues licenses for persons travelling for longer than 3 months with CDs (schedules 2, 3 or 4 Part 1). For further information see [Appendix 5](#).

10. REFERENCES

[NICE Guideline NG46 – Controlled drugs: safe use and management April 2016](#)

[GP mythbuster 28: Management of Controlled Drugs \(CQC\)](#)

[NICE Medicines Practice Guideline MPG2: Patient Group Directions March 2017](#)

[Department of Health: Controlled Dugs \(Supervision of management and use\) Regulations 2013, Information about the regulations. February 2013.](#)

[Dispensing Doctors Association: Dispensing Guidelines 2019 8th Edition](#)

[National Patient Safety Agency: Safer Practice Notice No 12F \(25 May 2006\): Ensuring Safer Practice with high dose ampoules of diamorphine and morphine](#)

[National Patient Safety Agency: Rapid Response Alert Ref 10157 \(4 July 2008\): Reducing dosing errors with opioid medicines](#)

[NHS England – Patient Safety Alert, \(20th November 2014\) NHS/PSAW/2014/016 Risk of distress and death from inappropriate doses of naloxone in patients on long term opioid/opiate treatment](#)

[Home Office Circular 027/2015: Approved mandatory requisition form and Home Office approved wording Published 9 November 2015](#)

[The Misuse of Drugs \(amendment\) Regulations 2015](#)

[The National Health Service Regulations 2015 \(amendments to Primary Care Teams of Service relating to the Electronic Prescription Service\)](#)

[The Human Medicines \(Amendment\) Regulations 2015](#)

[Home Office Guidance: Security guidance for all existing or prospective Home Office controlled drug licensees Jan 2020](#)

[Who can supply or administer Controlled Drugs under the terms of a Patient Group Direction and under what circumstances \(Specialist Pharmacy Services\)](#)

Appendix 1

CD Regulations

Misuse of Drugs Act 1971 – Prohibits certain activities in relation to controlled drugs in particular their manufacturing, supply and possession and the penalties applicable to offences involving controlled drugs.

Misuse of Drugs (Safe Custody) Regulations 1973 – Details the storage and safe custody requirements for controlled drugs.

Misuse of Drug Regulations 2001 (and subsequent amendments) – Govern the possession and supply of the controlled drugs under the Misuse of Drugs Act 1971. Defines who is authorised to supply and possess controlled drugs while acting in their professional capacity. Also divides drugs into five schedules specifying the requirements for each.

Health Act 2006 – Introduced the concept of the ‘Accountable Officer’.

Controlled Drugs (Supervision of Management & Use) Regulations 2013 – Ensures good governance concerning the safe management and use of controlled drugs.

Appendix 2 Classification Table

		Schedule 2 CD POM CD2 in BNF	Schedule 3 CD No Reg POM CD3 in BNF	Schedule 4 (Part I) CD Benz POM CD4-1 in BNF	Schedule 4 (Part II) CD Anab POM CD4-2 in BNF	Schedule 5 CD Inv POM/P CD5 in BNF
Examples (list not exhaustive)		Dexamfetamine/Lisdexamfetamine Diamorphine Fentanyl Ketamine Methadone Methylphenidate Morphine Oxycodone Pethidine Quinalbarbitone (Secobarbital)	Barbiturates e.g. phenobarbital Buprenorphine Gabapentin Midazolam Pentazocin Pregabalin Temazepam Tramadol	Clonazepam Diazepam Lorazepam Nitrazepam Sativex (cannabinoid) Zaleplon Zolpidem Zopiclone	Somatropin Testosterone products	Co-codamol Codeine Co-dydramol Oral morphine 10mg/5ml Pholcodeine
Safe Custody (locked cabinet)		Yes Exemptions: quinalbarbitone	No Exemptions: Buprenorphine & Temazepam	No	No	No
CD Register Entry		Yes	No (but recommended for those stored in a CD cabinet)	No (except for Sativex)	No	No
Ordering (Requisition Required)		Yes (via FP10CDF)	Yes (via FP10CDF)	No	No	No
Prescription Requirements		Legal prescription writing requirements for CDs apply	Legal prescription writing requirements for CDs apply	Standard prescription writing requirements apply	Standard prescription writing requirements apply	Standard prescription writing requirements apply
Quantity in words & Figures		Yes	Yes	No	No	No
Validity of Prescription		28 Days	28 Days	28 Days	28 Days	6 months
Emergency Supply		No	No (Except phenobarbitone for treatment of epilepsy 5 days)	No	Yes 5 days max	Yes 5 days max
Destruction	Denature	Yes	Yes	Yes	No	No
	Stock	Authorised Witness Required	Internal Witness Recommended	Internal Witness Recommended	Internal Witness Recommended	Internal Witness Recommended
	Patient Returns (Dispensing Doctors)	Denature & Internal Witness Recommended	Denature & Internal Witness Recommended	Denature & Internal Witness Recommended	Place in green pharmaceutical waste bins	Place in green pharmaceutical waste bins

Appendix 3

Standard Operating Procedure Template for The Use of Controlled Drugs in Primary Care Practices
<p>Organisation/Area/Service within which the SOP applies: Detail which premises this SOP relates to.</p>
<p>Objectives / Purpose List the key objectives for the procedure</p> <p>For example</p> <ul style="list-style-type: none"> • To improve governance of controlled drugs within the organisation • To provide clarity and consistency for all staff handling controlled drugs • To define accountability and responsibilities and clarify where responsibility can be delegated • To ensure practice is in line with the regulatory frameworks • As a training tool for new and existing staff.
<p>Scope Detail where the SOP applies and which staff are required to work within it</p>
<p>Responsibilities Responsibilities of staff covered by this SOP</p>
<p>Related Guidelines and Standing Operational Procedures List related guidelines and procedures</p> <p>Other useful information such as what to do if circumstances change- cascade to staff</p>
<p>Review Period Usually two years or in the event of change in legislation, circumstances or significant events.</p>
<p>Validation process Author and contributors Date Written</p>
<p>Introduction Provide brief detail on development of SOP</p> <p>For Example Following the Shipman Inquiry, the Department of Health instigated a review of the current management of controlled drugs (CDs). As a result, several pieces of guidance have been issued to further strengthen the governance arrangements around the prescribing and use of controlled drugs. The guidance promotes the safe and effective use of all CDs and is underpinned by key legislation.</p> <p>All health and social care organisations are accountable for ensuring the safe management of CDs. These arrangements are intended to encourage good practice in the management of CDs as well as help to detect unusual or poor clinical practice or systems, criminal activity or risk to patients. The Government has introduced new monitoring and inspection arrangements for controlled drugs in the Health Act 2006. The Regulations also introduce standard operating procedures (SOPs) for the use and management of controlled drugs. These are one of the practical measures that will help to ensure good practice throughout the health and social care system.</p>

Process	Responsible Person
<p><u>Ordering Controlled Drugs</u> Include details of:</p> <ul style="list-style-type: none"> ○ Who is authorised to order CDs (inc. deputy) ○ What stationary is used & where is it kept ○ Process for ordering ○ Record keeping (below) <p><u>Receiving Controlled Drugs</u> Include details of:</p> <ul style="list-style-type: none"> ○ Who is authorised to receive CDs (inc. deputy) ○ Security of receipt ○ Record keeping (below) <p><u>Storage of controlled drugs</u> Include details of:</p> <ul style="list-style-type: none"> ○ Detail of suitable locked container ○ Location & authorised access controls inc. OOH ○ Process for stock control & checks (inc. frequency) ○ Staff involved in process ○ Other locations (e.g. doctors bags) <p><u>Record keeping</u> Include details of:</p> <ul style="list-style-type: none"> ○ How register entry is made ○ Location of register ○ Record of stock control & checks ○ Retention of records ○ Arrangement for controlled stationary <p><u>Transport of CDs or prescriptions/orders for CDs</u> Include details of:</p> <ul style="list-style-type: none"> ○ Authorisation & reasons for transfer ○ Who is authorised to authorise transfer of CDs (inc. deputy) ○ Process for transfer and audit trail ○ Storage and security during transfer (e.g. doctors bags) ○ Handing over to persons authorised to receive <p><u>Prescribing</u> Include details of:</p> <ul style="list-style-type: none"> ○ Who is authorised to prescribe (inc. Non-Medical Prescribers) ○ Prescription requirements ○ Process for private prescriptions <p><u>Assembly (Dispensing GP Practices)</u> Include details of:</p> <ul style="list-style-type: none"> ○ Who is authorised to assemble and check CDs ○ Dispensing process <p><u>Handing over prescription/ Supply of dispensed item</u> Include details of:</p> <ul style="list-style-type: none"> ○ Process for collection of CD prescriptions ○ Checking right patient ○ ID arrangements for person collecting ○ Record keeping 	

Process	Responsible Person
<p><u>Administration</u> Include details of:</p> <ul style="list-style-type: none"> ○ Who is authorised to administer ○ Process for assembly and administration ○ Documentation <p><u>Destruction</u> Include details of:</p> <ul style="list-style-type: none"> ○ Who is authorised to destroy CDs ○ Who is authorised to witness destruction ○ Process of notification ○ Process for segregation and destruction ○ Unused doses ○ Expired stock ○ Dealing with patient own / patient returned incl. illicit substances ○ Record keeping <p><u>Actions in event of discrepancies.</u> Include details of:</p> <ul style="list-style-type: none"> ○ Who to inform if discrepancy in stock/other event ○ Process for reconciliation when necessary ○ Incident recording ○ Review process 	
Training	Responsible Person
<p>Include details of:</p> <ul style="list-style-type: none"> ○ Induction training ○ Regular updates provided ○ Updates in event of changes 	
Audit	Responsible Person
<p>Include details of:</p> <ul style="list-style-type: none"> ○ By whom ○ Format ○ Frequency ○ Reporting route ○ Record management 	

References:

[Controlled Drugs – Safe Use & Management NICE NG46 \(2016\)](#)

Appendix 4

PRESCRIBING FOR SUBSTANCE MISUSE PATIENTS

Instalment prescribing for substance misusers for Schedule 2 CDs, buprenorphine or diazepam **MUST** be done on an FP10 (MDA) form, which **MUST NOT** be used for any other purpose (e.g. when the total quantity needs to be dispensed at one time, in this case the normal FP10 form must be used). FP10 (MDA) forms are only for NHS use and only one prescription charge will be levied regardless of the number of instalments.

EPS **cannot** be used for prescribing in instalments

If a CD prescription is to be dispensed in instalments then, along with the usual prescription writing requirements, the prescription **MUST** specify the following details:

- the number of instalments
- the intervals to be observed between instalments, including instructions for weekends / bank holidays
- the total quantity of CD that will provide treatment for a period not exceeding 14 days
- the quantity to be supplied in each instalment

The prescription **MUST** be dispensed on the date on which it is due unless this falls on a pharmacy closed day. The home office has approved specific wording which provides some flexibility for supply. These are:

1. Please dispense instalments due on pharmacy closed days on a prior suitable day
2. If an instalment's collection day has been missed, please still dispense the amount due for any remaining day(s) of that instalment
3. Consult the prescriber if 3 or more consecutive days of a prescription have been missed
4. Supervise consumption on collection days
5. Dispense daily doses in separate containers.

See [Home Office Circular 027/2015](#) for further information

Appendix 5

TRAVELLING ABROAD WITH CDs

Travellers must be able to provide proof that a medicine containing a controlled drug has been prescribed to them if:

- it contains a 'controlled drug' (schedule 2,3 and 4 (part 1))
- they have it on them when they are entering or leaving the UK

A letter from the prescriber should be obtained. The letter must include:

- Patient name
- Destination
- Dates of departure and return
- Details of the medicine – name/form/strength/dose/quantity
- the signature of the person who prescribed them

A personal licence may also be required if travelling for more than 3 months or carrying enough medicine to last longer than 3 months.

To obtain advice or apply for a licence contact - dflu.ie@homeoffice.gov.uk

The following advice should be given to patients wishing to travel abroad with CDs:

- Travellers should check with the individual country's Embassy well ahead of travel as regulations regarding CDs vary considerably.
- Patients should be advised to carry their medicines in their hand luggage with a covering letter from their GP (to prove the medicines are theirs) and the Home Office Licence if required.
- Medicines should be left in their original packaging with the pharmacy label intact
- If a person is staying outside their resident country for more than 3 months, they should be advised to register with a doctor in the country they are visiting in order to obtain further prescriptions
- Patients should check with the airline and airport prior to travel as security arrangements may change at any time; for example, restriction on volume of liquids.
- Patients should ensure that they apply for their licence at least 15 days before travelling (if required).

More information can be found at <https://www.gov.uk/travelling-controlled-drugs>