

# Guidance for Developing a Controlled Drugs\* Standard Operating Procedure (SOP) for Prescribers in Primary Care

*\*This guidance applies to all schedules of controlled drugs*

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## Introduction

As a result of the Shipman Review, the governance of controlled drugs was reviewed and additional pieces of legislation enacted to provide greater assurance in the management of controlled drugs.

Most recently the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 came into operation in October 2009.

The regulations require that appropriate arrangements are in place for securing the safe management and use of controlled drugs. This applies to ALL controlled drugs, and not just schedules 2 and 3. A robust system and audit trail should therefore be in place for all stages in the handling of Controlled Drugs (CDs) in primary care and all family practitioners that use controlled drugs as part of their practice must have in place adequate and up to date standard operating procedures. The Regulations specify that the standard operating procedures shall, in particular, cover the following matters—

- (a) Who has access to the controlled drugs;
- (b) Where the controlled drugs are stored;
- (c) Security in relation to the storage and transportation of controlled drugs as required by misuse of drugs legislation;
- (d) Disposal and destruction of controlled drugs;
- (e) Who is to be alerted if complications arise; and
- (f) Record keeping, including—
  - (i) Maintaining relevant controlled drugs registers under misuse of drugs legislation, and
  - (ii) Maintaining a record of the controlled drugs specified in Schedule 2 to the Misuse of Drugs Regulations (Northern Ireland) 2002(a) (specified controlled drugs to which certain provisions of the Regulations apply) that have been returned by patients.

**It is the aim of this document to provide guidance to GP practices on the processes they should consider when developing their own standard operating procedure (SOP). One SOP should be developed for each practice/organisation and this should be signed up to by all GPs and prescribers within the practice. A suggested sign-off sheet is included in Appendix 1. It is the responsibility of the practice/organisation to ensure that all practice staff, including locums are made aware of the practice's SOP.**

**Please note:** Every effort has been made to ensure that the information provided in this document is accurate and up-to-date. However, the legal and regulatory framework governing CDs may change and readers should always check that they are referring to the most up-to-date version of this guide, as well as cross-checking with other recognised sources of information and relevant professional representative bodies.

For further details on legal and best-practice requirements for managing controlled drugs, please refer to:

- 'Safer Management of Controlled Drugs *A guide to good practice in primary care (Northern Ireland) August 2010*' <http://www.dhsspsni.gov.uk/print/safer-management-of-controlled-drugs-2010.pdf>
- BNF Guidance on Prescribing Section 8 Controlled drugs & drug dependence.

## HSCB role and responsibilities

The Regulations place additional responsibilities on the HSCB to:

- Assure the quality of their CD management systems as an integral part of their governance processes, with external inspection, where appropriate, as an additional safeguard.
- Work with other agencies in a local network along with the Police Service and regulatory bodies to share intelligence
- Be accountable for ensuring the safe management of controlled drugs
- Be accountable for the monitoring of all aspects of the use and management of controlled drugs by all healthcare professionals who they employ or with whom they contract.

Under the Regulations, each designated body is required to appoint an Accountable Officer. For the HSCB, the post of Assistant Director, Integrated Care, Head of Pharmacy and Medicines Management has been designated as the Accountable Officer (AO). The appointment and the role and responsibilities of the AO will support the fulfillment of the statutory obligations of the HSCB. The HSCB Accountable Officer reports to the Director of Integrated Care and is accountable to the HSCB Board for this function.

## Scope

This guidance covers all aspects of the handling of Controlled Drugs (CDs). It includes information on the following:

- |   |  |
|---|--|
| 1. Obtaining CD stock for GP bags       | 10. Destruction  |
| 2. Receipt of CDs                       | 11. Incidents  |
| 3. Record keeping                       | 12. Self-assessment declaration                                |
| 4. Collecting CDs on behalf of patients | 13. Monitoring and auditing of prescribing data                |
| 5. Storage                              | 14. Management of CDs from GPs whose prescribing rights change |
| 6. Prescribing                          | 15. Additional Guidance for Dispensing Doctors                 |
| 7. Administration                       | 16. Additional Guidance for Out-of-Hours organisations         |
| 8. Checks of stock holding              |  |
| 9. Dealing with discrepancies           |  |

There are 5 schedules of CDs and different schedules are subject to different legal requirements. A summary of the key legal requirements for each of the controlled drugs' schedules is included in Appendix 2 and this should be referred to when developing each section of the SOP.

The management of CDs by GPs should be considered in the context of the following statement from DHSSPSNI, regarding the issue of holding central CD supply within a practice:

*'All health care professionals who hold personal CDs stock must keep their own CD register for any Schedule 2 CDs that they possess, administer or supply, and they are personally responsible for keeping this accurate and up-to-date. This will provide a clear and identifiable audit trail. GPs should not share controlled drugs stock or share a central controlled drugs register as there would be concerns about the legality of possession, onward supply and audit.'*

## **Section 1:           Obtaining CD stock**

### **1.1   Orders**

- a. GPs must obtain CDs for stock using their own HS21S stock order forms. Locums, trainees and other GPs without their own cipher number may also need to obtain CD stock via practices that they work in and similarly, this stock should be obtained using a HS21S stock order form. Authorisation for this should be given by the GP whose name appears on the HS21S form. The form should be signed by the locum, trainee or other GP for whom the stock is intended and their CD register updated accordingly upon receipt of the stock. Each practice should have their own documented process for this, including a requirement for the locum to produce the relevant page from their CD register before the stock prescription is issued. The practice retains the bottom copy of this triplicate form and the top two copies are sent to the pharmacy.
- b. Stock orders must not be faxed or electronically transmitted.
- c. Records of stock ordered must be kept in the practice for at least 2 years
- d. Each GP should prepare and must sign their own orders. Stock should NOT be ordered by one GP on behalf of all partners and then divided up.
- e. Stock requisitions can be either computer generated or handwritten but the signature must be handwritten in ink. The requisitions should include the name, address, profession and signature of the recipient, the purpose for which the drug is supplied and the total quantity of the drug to be supplied (this does not have to be written in words and figures). Orders placed with community pharmacies should be for complete original packs eg it is not acceptable to order single ampoules<sup>1</sup>.
- f. Orders should be kept to a minimum based on previous and anticipated usage. See section 8 for checks on stock holding.
- g. If patients are being seen privately, private orders for CDs must be obtained using a signed requisition which must be written to comply with the legal requirements outlined above.
- h. GPs should order CDs from one community pharmacy.

### **1.2   Medicines Stocked**

- a. CDs stocked should only be those required for immediate patient care. There should be no dispensing of stock CDs to patients in non emergency situations.
- b. Consider the range, strength and quantity of medicines stocked:
  - Normally only one strength of each CD should be kept in a doctor's bag to minimise the risk of confusion, error and inappropriate administration

*i. HSCB letter 1/11/11: Stock requisitions – Complete Packs*

- Lower strengths of morphine and diamorphine (5mg and 10mg) are generally required for acute care. There have been reports of deaths and harm due to the administration of high dose (30mg or greater) diamorphine or morphine to patients who had not previously received opioids.
- Naloxone should be kept for reversal of opioid overdose
- It is likely that only injectable Schedule 2 and 3 CDs will be needed in GP bags as oral Schedule 2 and 3 controlled drug preparations would not routinely be considered essential items to be carried in a doctor's bag.

## Section 2: Receipt of CDs

- a. GPs should order and collect their own CDs in person. Use of messengers should be avoided; practice staff should not be involved in accepting stock into the practice and verifying the order.
- b. In exceptional cases where a messenger is used to collect Schedule 2 and 3 CDs on behalf of a GP, the messenger must produce to the supplier a statement in writing signed by the recipient indicating that he/she is empowered to receive the drugs. The messenger must deliver the CDs directly to the GP who has placed the order; the supply must not be delivered to a third party.
- c. For Schedule 2 CDs, a GP should bring their CD register to the pharmacy when they collect their CD stock and make the necessary entry as they receive the CDs.
  - A check should be made of the quantity, form and strength of the CD, with the community pharmacist asked to sign the register as a witness
  - The CD register must be updated with the receipt of new stock (See section 3).
- d. If a GP operates from more than one set of premises and maintains a stock of Schedule 2 drugs on both premises, e.g. in a CD cabinet, they must keep a separate register at, and for, each of the premises. However if a GP operates from more than one set of premises but keeps their entire stock that relates to both premises together in a single locked bag, then only one CD register to cover the full stock is required.
- e. CDs must be stored appropriately immediately on receipt. (See section 5).

## **Section 3: Record Keeping for CDs – CD Registers**

All health care professionals who hold personal CD stock must keep their own CD register for any Schedule 2 CDs that they possess, administer or supply, and they are personally responsible for keeping this accurate and up-to-date.

### **3.1 Format of the register**

- a. The CD register must be in the form of a bound book (not loose-leaved).
- b. The headings of the CD Register **MUST** comply with current regulations and must have the appropriate number of columns which include columns for recording proof of identity.

In respect of entries made for drugs obtained -

- i. Date supply received
- ii. Name and address from whom received
- iii. Quantity received

In respect of entries made for drugs supplied -

- i. Date supplied
- ii. Name/address of person or firm supplied
- iii. Details of authority to possess (the prescriber's / or licensed holder's details)
- iv. Quantity supplied
- v. Role of person collecting Schedule 2 CDs (patient/patient's representative/healthcare professional) and if a healthcare professional, name and address. If the healthcare professional is unknown to the supplier proof of identification must be requested and recorded as per (vii) (see below).
- vi. Was proof of identity requested of patient/ patient's representative? (Yes/No)
- vii. Was proof of identity of person collecting provided? (Yes/No)

- c. These record keeping requirements are a minimum and do not prevent inclusion of additional relevant information.

### **3.2 Register entries**

- a. A separate page must be used in respect of each strength and form of the drug and the head of each such page must specify the class of drug, its form and its strength e.g. morphine injection 10mg.
- b. Entries in respect of drugs obtained and drugs supplied may be made on the same page or separate pages of the register. Entries on the same page will facilitate the maintenance of 'running balances'. The maintenance of running balances is good practice but not currently a legal requirement (see section 8).

- c. All the relevant sections of the entry must be completed.
- d. Records of all receipts and issues of Schedule 2 CDs must be made in the CD register. Entries must be made in chronological order and on the day of transaction, or if that is not reasonably practicable, on the next day.
- e. Where part ampoules are used, the register must contain details of the quantity administered and the quantity destroyed. (See section 10 for destruction of CDs)
- f. For patients prescribed CDs on standard HS21 forms or private prescription (PCD1s), entries into the CD register are not needed but appropriate clinical records should be completed on the clinical system.

### **3.3 Register storage & destruction**

- a. CD registers should be kept separate from CD stock so that records are not lost in the case of theft or loss but also be accessible to ensure proper record keeping.
- b. Old/completed CD registers must be kept for two years after the date of last entry and then can be disposed of in confidential waste.
- c. CD registers must be available for review during inspections or destructions.

## **Section 4: Collecting CDs on behalf of patients**

- a. Health care professionals generally should not collect CDs from dispensed prescriptions to deliver to patients.
- b. If the healthcare professional is collecting a Schedule 2 CD, the pharmacist must obtain their name and address and, unless he is acquainted with that person, request evidence of that person's identity such as proof of membership of their professional organisation e.g. GMC registration card.

## Section 5: Storage of CDs

- a. It is good practice to store all medicines securely, not just CDs.
- b. All schedule 2 drugs and certain schedule 3 drugs e.g. buprenorphine, diethylpropion, flunitrazepam and temazepam must be stored in line with legislation in either a CD safe/cabinet or a lockable doctor's bag.
- c. The person in lawful possession of this bag/cabinet or an individual authorised by them must always retain the keys.
- d. Patients' own CDs should not be stored by the GP or practice.
- e. It is good practice for the doctor or delegated member of staff to undertake a regular stock check of CDs held. A running balance of Schedule 2 CDs should also be kept. These processes also provide a good opportunity to check for any out-of-date (or short dated) stock. See section 8.
- f. Medicines should usually be stored in their original or dispensed containers. Where this is not practical extra care should be taken to prevent selection of the wrong product.

### 5.1 Doctor's Bag

- a. A suitable storage receptacle is the "doctor's bag" which is a locked bag, box or case for home visits or use away from the surgery. Each practitioner is responsible for their own bag.
- b. A locked doctor's bag is regarded as a suitable receptacle for storing CDs, but an unlocked bag in a locked car is not.
- c. Doctors' bags must be locked at all times apart from when in use.
- d. Doctors' bags should be stored in a safe manner when not in use to prevent unauthorised access, i.e. not left unattended in an unlocked consulting room or left in a vehicle for prolonged periods or overnight. If a bag is left unattended at any time in a car it should be locked and kept out of sight. The car should be locked and any security system activated.
- e. A digital combination lock is often the most practical and convenient solution and avoids problems with keys.
- f. External temperatures may have a significant effect on the stability of medicines and suitable precautions should be taken to protect them from extremes of temperatures.

### 5.2 Patients' Homes

There are no storage requirements for dispensed CDs in patients' homes, however it is good practice that patients are advised of the importance of safe and secure

storage of all drugs, and in particular CDs, in their own homes. In circumstances where a risk is identified, patients should be advised regarding the use of lockable secured receptacles with appropriate arrangements for access to keys.

## **Section 6: Prescribing of CDs**

- a. An up-to-date list of who can prescribe CDs in the practice should be kept and be available for audit purposes.
- b. Controlled drugs should always be prescribed with caution and only where clinically indicated. Where necessary doses should be titrated appropriately and to the minimum effective dose. Patients should be consulted fully in their use including potential side-effects; this should be recorded in the patient's notes.
- c. It is good practice that all patients receiving prescriptions for CDs are reviewed regularly and this is documented in the patient's notes.
- d. Consideration should be given before adding a CD to repeat prescribing records.

### **6.1. Prescription Requirements**

- a. All prescriptions, including those for all schedules of CDs, must be written so that they are indelible and may be handwritten, typed or computer generated. Only the signature must be in the prescriber's own handwriting.
- b. Computer systems should be used, wherever feasible, to generate a CD prescription as this provides an additional method to record and audit the prescribing. If a prescriber makes a domiciliary visit, and a prescription for a CD is issued, it is good practice to make a note of this in the prescribing section of the patient's computer record as soon as possible after the event.
- c. Where it is necessary to handwrite a prescription for a CD, this should be done by the prescriber.
- d. If a private prescription is to be written for a patient requiring a Schedule 2 or 3 CD, a PCD1 form must be used (see section 6.10). These are available upon request from the BSO.
- e. The Misuse of Drugs Regulations 2002 state that a prescription for Schedule 2 and 3 CDs (with the exception of temazepam and preparations containing it) must contain the following details:
  - The patient's full name, address and, where appropriate, age. (*NOTE: 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 (if more than one strength exists)
  - The dose to be taken. (*NOTE: the instruction 'one as directed' constitutes a dose but 'as directed' does not (see BNF). Dosages and frequencies for all CDs should normally be presented in full by the prescriber, to aid administration by nurses and carers.*)
  - Either
    - The total quantity of the preparation in both words and figures of the preparation or the number in both words and figures of dosage units to be supplied
    - Or
    - In any other case, the total quantity in both words and figures of the controlled drug to be supplied. *NOTE: The Home Office advises that quantities of liquid preparations, such as methadone oral solution, should be written in millilitres.*
- f. If supply is intended to start later than the date of the prescription, this should be clearly written on the prescription. The address of the prescriber must be stated on the prescription and must be within the UK. (NB: the UK does NOT include the Channel Islands or the Isle of Man).
- g. Prescriptions for temazepam and for Schedule 4 and 5 CDs are exempt from the specific prescription requirements of the Misuse of Drugs Regulations 2002. However, they must still comply with the general prescription requirements as specified under the Medicines Act.
- h. 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.

## 6.2 Validity of NHS and private prescriptions (PCD1s)

- a. The validity period of NHS and private prescriptions (PCD1s) for Schedule 1, 2, 3 and 4 CDs is restricted to 28 days from the date of issue or the indicated start date.
- b. In the case of a prescription which directs that specified instalments of the total amount may be supplied at stated intervals, the first instalment must be supplied no later than 28 days after the 'appropriate date'. However, if the prescription specifies a start date, the prescription can only be dispensed in accordance with the prescriber's directions.

## 6.3 Technical errors on a prescription

Alterations are best avoided but if any are made, they should be clear and unambiguous. Best practice would suggest that if an error is made, the prescriber should cross out, sign and date the error and then write the correct information. In addition the computer records should also be amended.

## 6.4 Quantity supplied on prescription

Although not a legal requirement, there is a strong recommendation that prescriptions for Schedule 2, 3 and 4 CDs are limited to a quantity necessary for up to 30 days clinical need. In exceptional circumstances, where the prescriber believes a supply of more than 30 days medication is clinically indicated and would not pose an unacceptable threat to patient safety, the prescriber:

- Should make a note of the reasons for this in the patient's notes
- Be ready to justify his / her decision if required.

## 6.5 Prescribing for Substance Misusers

- a. Substance misusers may be managed by specialist addiction clinics or by their GP, usually under the terms of a Local Enhanced Service (LES). GPs can prescribe opiate substitution treatment (Methadone 1mg/1ml, buprenorphine sublingual, Suboxone®, dihydrocodeine) on a HS21.
- b. Practices providing such a service under a LES should specify this in their SOP. However only medical practitioners who hold a special licence issued by the DHSSPS may prescribe, administer or supply diamorphine, dipipanone or cocaine in the treatment of drug addiction. (*NOTE: GPs do not require such a licence for prescribing these drugs for patients, including addicts for relieving pain from organic disease or injury.*)
- c. GPs can prescribe instalment prescriptions using a HS21 form. To be legally valid, an instalment prescription for a Schedule 2 or 3 CD (except temazepam) must include the following:
  - The signature of the appropriate practitioner issuing the prescription
  - The date
  - The address of the appropriate practitioner issuing the prescription
  - The dose to be taken ('as directed' is not acceptable, but 'one as directed' is acceptable)
  - The form of the preparation (e.g. mixture /tablets /capsules/ ampoules)
  - The strength of the preparation (if more than one strength is available). In the case of methadone, there is more than one strength available, therefore this must be specified on the prescription
  - The total quantity of the preparation in words and figures. This must be in dosage units (that is ml for a liquid, or number of tablets, capsules, ampoules and not the total mg of the drug)
  - The name and address of the patient
  - The instalment amount and the intervals to be observed:
    1. The number of instalments
    2. The intervals to be observed between instalments; (these intervals should take into account weekends and bank holidays, as the directions for instalments are binding).
    3. Order only such quantity of the drug as will provide treatment for a period not exceeding 14 days

4. The quantity to be supplied in each instalment.

Points 1, 2 and 3 are required by The Health and Personal Social Services (General Medical Services Contract) Regulations (Northern Ireland) 2004. Points 2 and 4 are required under the MDR, Regulation 15.

- d. The start date should also be added to the body of the prescription. It is good practice for the duration of the instalments to be set out on the prescription, e.g. dispense daily for five days starting on x date. Prescriptions should also clearly state which doses are to be supervised and which doses can be provided to the patient to take home.
- e. Where such a service is not provided by the practice the SOP must take account of situations where substance misusers present for treatment outside of the opening hours of the specialist addiction clinic.

## 6.6 Notification of Addicts

- a. The Misuse of Drugs (Notification of and Supply to Addicts) (Northern Ireland) Regulations 1973 require any doctor to notify the Chief Medical Officer (CMO) of the DHSSPS in writing within 7 days (even if the patient has been referred to specialist addiction services), if they attend (they do not have to prescribe to notify) a patient who he considers to be, or has reasonable grounds to suspect is, currently addicted to any of the following CDs:

- Cocaine
- Methadone (Physeptone)
- Dextromoramide (Palfium)
- Morphine
- Diamorphine (Heroin)
- Opium
- Dipipanone (Constituent of Diconal)
- Oxycodone
- Hydrocodone
- Pethidine
- Hydromorphone
- Phenazocine
- Levorphanol
- Piritramide

The list of notifiable drugs does not include Subutex/Suboxone and hence there is no requirement to notify the DHSSPS of patients who are stable on these drugs and not abusing any notifiable drugs to the best of the practice's knowledge.

### b. The following information must be supplied:

- Name
- Address
- Gender
- Date of Birth
- Health Service Number of patient (if known)
- Date of attendance
- Name of the drug, or drugs, concerned.

- c. Although notification does not imply that a prescription for a CD has been, or will be given by the doctor, where this is the case full details should be supplied.
- d. The above regulations require addiction cases to be re-notified annually. Practices may find it helpful to read code patients who are addicted to the above drugs for the purposes of facilitating annual re-notification of such patients to the DHSSPS
- e. All notifications should be addressed to:

Dr Ian McMaster  
Medical Officer  
C3.15 Castle Buildings  
Belfast  
BT4 3SQ  
Tel: (028) 90522421

- f. Patient consent for release of this information to the DHSSPS is not required as the requirement to make such notifications is a statutory requirement. In line with legislation, this information will be held at DHSSPS and registered under The Data Protection Act is for statistical and research purposes only and access is restricted to departmental staff requiring it to carry out their respective duties.
- g. No notification is required if the medication is being prescribed for a physical/organic reason. However if the patient was commenced on a notifiable drug for an organic reason and this has improved and the patient no longer requires the medication, then continuing it is essentially due to the patient's dependence and should be notified.
- h. The DHSSPS have advised that where a practice has failed to report such patients to the DHSSPS in the past that, unless they have presented in the last few weeks, practitioners should concentrate on notifications for newly presenting patients and not attempt to retrospectively report.

## **6.7 Repeat Dispensing**

- a. Repeat dispensing is the process by which patients can obtain supplies of their repeat medicines over a defined period from a pharmacy of their choice, without the need to contact their GP practice on each occasion a new supply is needed. Schedule 4 and 5 CDs may be ordered on prescriptions issued under the repeat dispensing scheme. For Schedule 4 CDs, the first prescription must be dispensed within 28 days.
- b. Schedule 2 and 3 CDs should not be prescribed as part of a repeat dispensing service. Whilst the Misuse of Drugs Regulations does not explicitly forbid the repeat dispensing of Schedule 2 and 3 CDs, guidance

from the Home Office is that, because it is not explicitly permitted, the repeat dispensing of such drugs is not allowed under the regulations.

### **6.8 Emergency supplies**

Emergency supplies (as provided for in the Medicines Act) of Schedule 2 and 3 CDs, for a specific patient, are not permitted either at the request of the patient or a practitioner. The only exception to this rule is phenobarbital for the treatment of epilepsy or in the event of a national pandemic where emergency supply of CDs may be allowed in specific circumstances.

### **6.9 Prescribing for self and family**

Practitioners should not prescribe CDs or any other drugs for themselves, their family or friends except in an emergency.

### **6.10 Private prescribing**

The term 'private prescribing' is used to describe the situation when a private prescription is written, either by NHS or non-NHS practitioners, in either NHS or non-NHS settings

- a. Normally, private prescriptions can allow a prescriber to request that the prescription is repeatable\* for a specified number of times. However, this is not permitted for Schedule 2 and 3 CDs. It is possible to prescribe Schedule 4 and 5 CDs on a repeat basis, both privately and under NHS repeat dispensing arrangements.

*\*The repeat method is where a private prescription is written for a specified quantity of drugs and the prescriber endorses the prescription with the number of times the prescription should be repeated. The pharmacist is then able to make the specified number of dispensing transactions from that prescription.*

- b. All private prescriptions for human use of Schedule 2 and 3 CDs (including temazepam) must be written on a standard prescription form (ie PCD1. To obtain a stock of PCD1 forms, an application form must be completed and returned to the BSO) which must include the private prescriber's unique identification number (cipher number).
- c. Private prescribers should indicate on the prescription when prescribing for non-UK resident.
- d. It should be noted that if a patient is receiving a CD on prescription (either on the NHS or privately) and then receives a second CD from another prescriber without informing both prescribers that he is receiving a CD from another prescriber, then an offence is being committed by the patient.

## **Section 7: Administration of CDs**

### **7.1. Authorisation to administer CDs**

- a. A doctor or a dentist is authorised to administer to a patient any drug specified in Schedule 2, 3 or 4.
- b. Any person other than a doctor or a dentist is authorised to administer to a patient, in accordance with the directions of a doctor or dentist, any drug specified in Schedule 2, 3 or 4.
- c. A valid authorisation must be in place for the administration of a CD to a patient e.g. a prescription, entry in patient notes.
- d. Where possible, the person who prescribes the CDs should not also personally undertake any of the following tasks: preparation, dispensing, transportation and administration of the CDs.

### **7.2. Administration of CDs**

- a. Prior to administration a check should be made to ensure:
  - the correct drug is to be given (the name, strength and form is the same as on the authorisation to administer)
  - the identity of the patient
  - the drug is suitable for use (correctly labelled, in date and in good condition)
  - the dosage is appropriate
- b. The health professional administering the CD must understand the prescription and have knowledge of the common indications, side effects, dosages and compatibilities of the CDs prescribed.
- c. It is good practice to ensure that wherever possible another appropriate and competent individual witnesses the administration. There will be occasions, such as the initial treatment of acute myocardial infarction, where this separation of tasks is not possible. Whenever this is the case, it is important that accurate records be kept.
- d. Record keeping:
  - Administration should be recorded in the relevant section of the patient's clinical notes. This record should specify the date, time, strength, presentation and form of administration, dose administered as well as the name and occupation of the person administering it.
  - Entries for schedule 2 CDs administered from stock must be made in the CD register.
- e. Preparation

Practices should have processes in place to ensure safe medication practice for the preparation and administration of injections, including CDs. Any such processes should include references to information on the following:

  - Drug compatibility when mixing two or more medicines in a syringe

- Correct labelling of prepared medicines, including an expiry date
  - Single-checking, versus double-checking with another practitioner or carer
  - Safe administration of bolus doses
  - Programming and safe use of syringe-driver pumps
  - Warnings about the danger of confusing different strengths and types of CDs during preparation and administration.
- f. On occasion, health professionals may be required to administer a drug so that there is some drug left (e.g. a part ampoule). See section 10.1 for guidance on disposal.
- g. Administration Errors  
See section 11.

## **Section 8: Checks of CD stock holding**

- a. External review will be undertaken by the HSCB officers during routine inspections.
- b. A running balance of Schedule 2 CD stock should be kept in the CD registers as a matter of good practice to ensure irregularities are identified as quickly as possible.
- c. An additional column may be made in the current CD register to incorporate running balances.
- d. It is recommended that the running balance of drug remaining should be calculated and recorded after each transaction and balances should be checked with the physical amount of stock at regular intervals. It is recommended as best practice that such checks should be initialled and dated to provide a verifiable audit trail.
- e. The task of reconciling stock should be undertaken by the GP. It can be delegated to an appropriately trained member of staff however, accountability for maintaining the running balance of CD stock and dealing with any discrepancies remains with this GP and not with the person to whom they may delegate day-to-day responsibility under the practice CD SOP.
- f. Balance checks should be done in the presence of, and countersigned by, another appropriately trained member of staff.
- g. Balance checks should include checking the expiry date of stock.

## Section 9: Dealing with discrepancies in controlled drugs' balance

a. All discrepancies should be investigated as soon as is practically possible.

Common sources of error include:

- Supplies not entered.
- Running balance incorrectly calculated
- Not all stock counted during the review (out of date stock)
- Including patient returns

Hence the first course of action should be to:

- Check the arithmetic since last correct balance
  - Recheck stock with second person (remember to include date expired stock and exclude patient returns which may have become mixed with stock).
  - Check other register sections of same drug class for erroneous entries.
  - Check that all stock received has been entered against copies of stock orders placed
  - Check with community pharmacy from whom stock is normally received.
- b. Once resolved, a dated footnote must be made in the CD register correcting the discrepancy in the balance by a GP. Appropriate records should be kept of the action taken when discrepancies arise. An example record template is shown below.
- c. If the source of the discrepancy cannot be identified during the stock check, contact the Accountable Officer via your HSCB Medicines Management Adviser and undertake a formal internal investigation. This process may include discussion with the relevant professional body, external inspectors and/or the Police.

### Example template record of action to resolve discrepancies

Action to resolve discrepancies	Actioned By	Date	NOTES
Check the arithmetic since last correct balance			
Recheck stock with second person			
Check other register sections of same drug class for erroneous entries			
Check stock orders have all been entered.			
Discrepancy resolved Y/N			
Amendments made to register			
Accountable Officer notified Y/N			

## **Section 10: Destruction of CDs**

### **10.1 Unused portions e.g. ampoules, syringe driver**

All CD waste arising from unused portions of e.g. ampoules or syringe drivers must be rendered irretrievable and unusable before disposal of the ampoule or syringe. This applies to CDs that are used in a GP practice setting, in care homes or in patients' own homes.

### **10.2 Out-of-date stock**

- a. If Schedule 2 CDs kept in the doctor's bag expire, the GP cannot destroy them him/her self but instead, they must be returned as soon as possible to a community pharmacy for destruction. It is good practice to follow this process for all out-of-date CD stocks.
- b. During the time between expiring and being returned to the community pharmacy, they should be stored in a safe place, e.g. in the doctor's bag. They should be segregated and clearly marked as "date expired" stock to prevent them being issued or administered to patients in error.
- c. For Schedule 2 CDs, the quantity should be included in the running balance of the GP's CD register until returned to the community pharmacy, at which point a record must be made in the doctor's CD register of the transfer of the stock to the community pharmacy. The GP may request the community pharmacist to indicate that he has received these by signing the GPs register.

### **10.3 Patients' own CD medication**

These CDs are the property of the patient, even after death. The patient or their representative should be encouraged to return the unused medication to a community pharmacy for destruction. However if it is judged by the prescriber that there may be a risk associated with leaving the medication, or there is no-one else who can take the medicine to the community pharmacy, the GP may decide to remove the medication themselves and bring it to a community pharmacy for destruction as soon as possible.

**Under these exceptional circumstances, the following guidance should be adhered to:**

- a. The following details must be recorded:
  - The name, strength and quantity of the drug
  - The name of the doctor accepting the drug
  - The name of the patient
  - The name and address of the person returning the drug if appropriate.
- b. Patients' CDs accepted for return to the community pharmacist must be stored safely in the doctor's bag, separated from the GP's own supply of CDs and clearly marked as "patient's CDs for destruction".

- c. A record should be made in the doctor's CD register of the transfer of the stock to the community pharmacy; this should be witnessed and countersigned where possible (eg by a carer). The GP should request the community pharmacist to indicate that he has received these by countersigning the GP record. The back page of the GP CD register may be used to record these details.
- d. Details of the return should be recorded in the patient's clinical notes and this record countersigned by the pharmacist to whom they have delivered the medication for destruction

Medicines returned from patient stocks **MUST NOT** be reissued or used to treat other patients.

## **Section 11: Management of Incidents involving CDs**

- a. All incidents involving CDs must be recorded and investigated in line with existing procedures for reporting and managing clinical or medication incidents. This includes events such as significant prescribing events, theft, breakage or unexplained discrepancies.
- b. The Accountable Officer (AO) for the Board must be notified via the HSCB Medicines Management Adviser of the incident as soon as possible, without compromising the steps needed to ensure patient safety.
- c. The AO must also be notified of the outcome of all incidents involving CDs, any learning points identified and the actions taken to prevent recurrence. Anonymised information may be used in educational material to share best practice and prevent recurrence.
- d. Where there is suspicion or evidence of criminal activity, the local police must be advised.

## **Section 12: Self-assessment declaration**

As part of the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009, the AO has powers to request a declaration and a self-assessment which states:

- Whether the healthcare provider uses CDs as part of the services provided
- How the healthcare provider manages and uses CDs

Individual GP practices and OOHs organisations are required to complete this upon receipt from the Board's AO.

## **Section 13: Monitoring and auditing of prescribing data**

- a. The AO is required to ensure systems are in place for monitoring and auditing the management and use of CDs by practitioners.

To facilitate this:

- Data on CD prescribing is available in the practice's quarterly COMPASS report. A system should be in place in the practice to ensure monitoring and follow-up of the information contained in this report.
- A number of review tools are available from the Board to facilitate more in-depth review of the prescribing of specific CDs e.g. fentanyl patches.

- b. HSCB staff may contact the practice requesting further details about the CD prescribing for individual patients or drugs. Practices should ensure that there are systems in place to respond quickly to these queries and take on board any recommendations made as a result of these queries and consider an audit of their processes around the management of CDs.

## **Section 14: Management of CDs by GPs whose prescribing rights change**

If the prescribing rights of a GP change for some reason, such that they are no longer permitted to prescribe these drugs, the GP in question should make contact with the Medicines Regulatory Group at the DHSSPSNI and make arrangements for the destruction of the drugs in his stock.

## **Section 15: Additional Guidance for Dispensing Doctors\***

It is lawful for a dispensing doctor to delegate the act of dispensing medicines for their patients to employed staff. However accountability remains with the dispensing doctor. The practice (and partners) carries vicarious liability for errors made, or for any breach of the law. A dispenser or other dispensing doctor employee would not normally be expected to dispense a controlled drug without first checking the dispensed items with a doctor. The Dispensing Doctor's Association's Guidelines for dispensing doctors state that 'the doctor should check all prescriptions for controlled drugs'.

Further guidance on managing the use of controlled drugs by dispensing doctors is available from the Dispensing Doctor's Association.

([www.dispensingdoctor.org](http://www.dispensingdoctor.org)).

## **Section 16: Additional Guidance for Out-of-Hours organisations\***

In general, controlled drugs are not included in the formulary of Out of Hours centres. Where a doctor working in the out-of-hours service is a GP principal or employed by a GP practice he/she will order drugs for their bag (including controlled drugs) using his/her own stock order pads. Where a GP e.g. a locum, does not have access to stock order forms, the practitioner may order controlled drugs using the relevant Out-

of-Hours service stock order forms. This should be via the Medical Manager for the Out-of-Hours centre most frequently worked in. Each OOHs organisation should have their own documented processes for this, including a requirement for the locum to produce the relevant page from their CD register before the stock order is issued. The stock order should be signed by the locum and the stock entered into the locum's CD register upon receipt.

A palliative care network has been set up by the Board to facilitate the supply of controlled drugs to individual patients, where necessary, outside normal working hours. Each Out of Hours centre should ensure that they have up-to-date details of their local network.

Out of Hours services should agree arrangements for drug misusers who contact the Out of Hours service requesting a prescription for an opiate substitute, such as methadone or buprenorphine. In such circumstances, it is generally inappropriate and potentially dangerous to commence prescribing an opiate substitute drug or to replace a lost, stolen or broken bottle or supply. A local SOP should be produced, in liaison with local specialist prescribers, as to how Out of Hours services should respond to ensure a consistent and fair treatment of patients.

Further guidance on the management of CDs in OOHs is available in the Regional GP OOHs guidance manual at <http://gpooh.hpssweb.n-i.nhs.uk/regional/index.html>

**\*Further information pertinent to both Dispensing Doctors and Out of Hours services can be found within this document (eg Ordering, recording and storage of controlled drugs) and within 'Safer Management of Controlled Drugs A guide to good practice in primary care (Northern Ireland) August 2010' <http://www.dhsspsni.gov.uk/print/safer-management-of-controlled-drugs-2010.pdf>**

**Appendix 1**

**Practice No** \_\_\_\_\_

**Practice Name** \_\_\_\_\_

This Standard Operating Procedure (SOP) has been developed for use in this practice to ensure the safe management and use of controlled drugs. It has been shared and agreed with all GPs and prescribers within the practice/organisation. These professionals will be notified of any change to this SOP as necessary.

<b>Prescriber Name</b>	<b>Signature</b>	<b>Date</b>

## Appendix 2

### Summary of the Legal Requirements for Prescribing Controlled Drugs

	Schedule <sup>1</sup>	2	3	4 I	4 II	5
Designation		CD	CD No Reg	CD Benz	CD Anab	CD Inv
Obtained only on prescription (see emergency supply)		Yes	Yes	Yes	Yes	No
Must be stored locked away and secure		Yes <sup>2</sup>	No <sup>4</sup>	No	No	No
Prescription requirements <sup>3</sup>		Yes	Yes <sup>5</sup>	No	No	No
Emergency supplies to patients are permitted		No	No <sup>6</sup>	Yes <sup>9</sup>	Yes <sup>9</sup>	Yes <sup>9</sup>
Repeatable prescriptions permitted		No	No	Yes	Yes	Yes
Prescription valid for:		28days <sup>8</sup>	28 days <sup>8</sup>	28 days <sup>8</sup>	28 days <sup>8</sup>	6m (if POM)
Prescription supply limited to 30 days as good practice		Yes	Yes	Yes	Yes	No
Private CD prescriptions to be written on Standardised form with unique prescriber identifier		Yes	Yes	No	No	No
Private CD prescription form to be sent to BSO		Yes	Yes	N/A	N/A	N/A
Can be prescribed by nurse independent prescriber		Yes <sup>7</sup>	Yes <sup>7</sup>	Yes <sup>7</sup>	No	Yes <sup>7</sup>
Can be prescribed by a nurse and pharmacist supplementary prescriber under a clinical management plan		Yes	Yes	Yes	Yes	Yes
CD register for stocks and supplies to be maintained		Yes	No	No	No	No
Destruction only under authorised witness		Yes	No	No	No	No

1. Schedule 2 (S2, CD) Strong opiates (eg morphine, diamorphine, fentanyl), major stimulants (e.g. amphetamines) and quinalbarbitone

Schedule 3 (S3, CD No Register) Minor stimulants (e.g. benzphetamine), temazepam, flunitrazepam, diethylpropion, buprenorphine and other drugs

Schedule 4 (S4, CD Benz (Part I) and CD Anab (Part II)) Benzodiazepines not in schedule 3, zolpidem, gammahydroxybutyrate (GHB), anabolic steroids, androgenic steroids, clenbuterol and growth hormones

Schedule 5 (S5, CD Inv.) Low strength opiate preparations

2. Except secobarbital

3. Written so as to be indelible, e.g. handwritten in ink, typed or computer generated:

- The patient's full name, address and, where appropriate, age. An email address or PO Box is not acceptable. 'No fixed abode' is an acceptable address for homeless people

- The name and form of the drug, even if only one form exists
  - The strength of the preparation (if more than one strength exists)
  - The dose to be taken
  - The total quantity of the preparation, or the number of dose units, to be supplied in both words and figures
  - Signed by the prescriber with their usual signature (this must be handwritten) and dated (the date does not have to be handwritten)
4. Except for temazepam, buprenorphine, flunitrazepam and diethylpropion
  5. Except temazepam
  6. Except phenobarbitone for epilepsy
  7. Restricted to diamorphine, morphine, buprenorphine transdermal, fentanyl transdermal and oxycodone in palliative care; diazepam, lorazepam and midazolam for palliative care and tonic-clonic seizures; morphine and diamorphine for pain relief in MI/trauma/post-op; chlordiazepoxide and diazepam for treating alcohol withdrawal symptoms; codeine phosphate, dihydrocodeine tartrate and co-phenotrope.
  8. From the appropriate date. In the event that the prescriber intends that the prescription is not to be supplied before a certain date then, in addition to recording the date on which the prescription was signed, he must also indicate the date before which it must not be supplied. This date is referred to as the 'appropriate date' within the MDR.
  9. Up to a quantity sufficient for 5 days treatment