

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

Objectives

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

Scope

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

The Misuse of Drugs (Safe Custody) Regulations 1973 (SI 1973 No. 798) apply to Schedule 2 CDs (except quinalbarbitone (secobarbital), some liquid formulations and the commonly used Schedule 3 CDs e.g. temazepam, flunitrazepam, diethylpropion and buprenorphine. All other S3 CDs such as tramadol, midazolam, phenobarbital, gabapentin and pregabalin and all S4 and S5 CDs are exempted for the Safe Custody Regulations.

Responsibilities

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

Process

Receipt and Supply

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

Storage of controlled drugs

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

- a. safe that has been certified to an appropriate CEN Grade (e.g. I to XIII) of BS/EN 1143-1
- b. A small safe that has been certified to Grades S1 or S2 of BS/EN 14450
- c. A cabinet that complies with the specifications set out in the Misuse of Drugs (Safe Custody) Regulations 1973.

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

Record Keeping

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

For S2 CDs received into stock

- a. Name and address of supplier e.g. wholesaler or Pharmacy
- b. Name of drug, including strength and formulation
- c. Quantity
- d. Date received/supplied
- e. A running total balance.

For S2 CDs supplied to patient

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

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

References

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