NHS FORTH VALLEY
Standard Operating Procedure for the Management of Controlled Drugs for Community Pharmacies

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Consultation and Change Record

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Standard Operation Procedure for the Management of Controlled Drugs for Community Pharmacies

1. Purpose.

The document ensures that all legal and professional requirements relating to the use of Controlled Drugs (CDs) are satisfied. There is a legal requirement for all areas of healthcare services that hold stocks of CDs to have Standard Operating Procedures (SOPs) in place. For full details see HDL (2007) 12 and CEL (2007) 14 (www.show.scot.nhs.uk/sehd)

2. Scope

Pharmacies can develop their own SOPs in line with the national guidance or may adopt this locally agreed SOP. This SOP is intended to provide advice on the minimum standards and does not preclude more stringent controls being in place. This SOP covers all aspects of Controlled Drugs Management.

3. References

Medicines, Ethics and Practice- A Guide for pharmacists and pharmacy technicians
HDL (2006) 27
HDL (2007) 12
CEL 14 (2007) 17 October 2007
CEL 16 (2007) 6 November 2007
CEL 21 (2007) 21 December 2007
Fitness to Practise and Legal Affairs Directorate Fact Sheet one- Controlled Drugs and Community Pharmacy – Royal Pharmaceutical Society of Great Britain

4. Definitions

Accountable Officer (AO) - A person nominated by NHS Forth Valley to be responsible for a range of measures relating to the monitoring of the safe use and management of Controlled Drugs in accordance with the Health Act 2006 and the Controlled Drugs Regulations. The Accountable Officer is Gail Caldwell. Pharmacy, Euro House, Wellgreen, Stirling FK8 2DJ, Tel 01786 431200

5. Safety Requirements

Any member of healthcare staff carrying out this procedure must be aware of the Health and Safety Regulations and of their own personal safety at all times.

6. Responsibilities

It is the responsibility of the pharmacist in charge to ensure that the SOP is followed.
It is the responsibility of those working to the procedures to highlight to the pharmacist in charge any deficiencies in the SOP.

7. Procedure

7.1 Obtaining CD stock

7.1.1 Orders for CDs are placed with pharmaceutical wholesalers.

7.1.2 Order quantities should be kept to a minimum based on previous and anticipated usage.

7.1.3 Those pharmacies contracted to provide specialist palliative care services should ensure that the current list of agreed stock is held at the correct level.

GOOD PRACTICE ADVICE/INFORMATION

- Records of ordered stock should be kept by the pharmacy for at least two years to meet the requirements of the Misuse of Drugs Regulations. Records may be kept either in the original form or in computerised form.

- The two year retention is considered a minimum. There may be other reasons, eg tax records, which require records to be retained for longer periods.

Name of Nominated Wholesalers for supplies:

Wholesaler Name And Address	Account Number	Phone Number

7.2 Receipt

7.2.1 Records of schedule 2 CDs must be kept in a Controlled Drugs register. See section 3 for record keeping requirements.

7.2.2 The recipient of the CDs should check the stock received to ensure that it matches with what was ordered and what was invoiced.

7.2.3 Where the manufacturer's tamper-evident seal remains intact, assume that the quantity in the pack is the same as that stated. Packs of medicines should be left sealed until needed.

7.2.4 Where there is a discrepancy, this should be brought to the immediate attention of the supplier. Stock should not be accepted unless there are exceptional circumstances preventing return. In this case records must be kept of receipt of stock and transfer back to the supplier at the next available opportunity.

7.2.5 The recipient of the CDs must sign any delivery note/electronic delivery receipt from the wholesaler that accompanies the CDs. The wholesaler may insist this is a pharmacist, otherwise it should be a member of staff authorised to handle CDs.

7.2.6 CDs must be stored appropriately within the CD cabinet as soon as possible after receipt.

7.2.7 The CD register must be updated as soon as possible with the receipt of new stock. This must be on the day of receipt or the following day at the latest.

GOOD PRACTICE ADVICE/INFORMATION

- The pharmacist in charge of the premises has overall responsibility for CDs while they are on duty.
- There should be a list of staff authorised by the pharmacist manager or superintendent pharmacist to receive and handle CDs and have access to safe storage facilities, eg. accredited checking technicians.
- All staff should be aware of who the authorised people are.
- There should always be at least one authorised person on duty. If that person is not a pharmacist, there must also be a registered pharmacist working in the premises before and transactions involving CDs can take place.

List of staff authorised to handle CDs and access safe storage facilities

Name	Role	Signature

7.3 Record Keeping

7.3.1 Records of all receipts and issues of schedule 2 CDs must be made in the CD register, at the time of issue or receipt or as soon as possible after the action. An entry must be made on the day of the transaction or the next day at the latest.

7.3.2 All the relevant sections of the entry must be completed.

7.3.3 CD registers must be available for review during inspections or destructions. Registers may be examined by the RPSGB during routine inspections. These are likely to be carried out every 2-3 years.

7.3.4 The CD register must:

a. Be bound (not loose-leaf) or a computerised system which is in accordance with best practice guidance.

b. Contain a separate section for each strength and formulation of drug, eg morphine 10mg injection, MST 10mg tablets, Sevredol 10mg tablets, with the name of the drug, brand, strength and formulation specified at the top of each page.

c. Have the entries in chronological order and made as soon as possible on the day of the transaction or the next day at the latest.

d. Have indelible entries, eg in ink, or in a computerised form in which every such entry is attributable and capable of being audited and is in accordance with best practice guidance endorsed by the Secretary of State under section 2 of the NHS Act 1977.

e. Not have cancellations, obliterations or alterations; corrections must be made by a signed and dated entry in the margin or at the bottom of the page.

f. Be kept at the premises to which it relates and be available for inspection at any time.

g. Be kept separate from CDs.

h. Not be used for any other purpose.

i. Be kept for two years after the last entry.

7.3.5 For schedule 2 CDs received into stock, the following details must be recorded:

a. The date on which the CD was received.

b. The name and address of the supplier, eg wholesaler, pharmacy.

c. The quantity received.

d. The name, form and strength of the CD.

7.3.6 For schedule 2 CDs supplied to patients (by prescription), or to practitioners (by requisition), the following details must be recorded:

a. The date on which the supply was made.

b. The name and address of the patient or practitioner receiving the CD.

c. Particulars of the authority of person who prescribed or ordered the CD.

d. The quantity supplied.

e. The name, form and strength in which the CD was supplied.

f. In the event of an owing, each supply should be recorded separately at the time of collection to produce an accurate audit trail.

7.3.7 For schedule 2 CDs supplied the following details must be recorded:

a. Whether the person who collected the drug was the patient, the patient's representative or a healthcare professional acting on behalf of the patient;

b. If the person who collected the drug was a healthcare professional acting on behalf of the patient, proof of identity should be requested and that person's name and practice address must be recorded.

c. If the person who collected the drug was the patient or their representative records should show whether evidence of identity was requested (annotated in the yes/no columns) and whether evidence of identity was provided by the person collecting the drug. See also 7.6- Collection and Delivery of Dispensed Medicines

7.3.8 When transferring balances of stock to new registers, this should include owings not yet collected and out of date stock which is awaiting destruction.

7.3.9 If a pharmacist becomes aware that a dispensing error has been made, the CD register should be amended to ensure the record shows what was actually dispensed and balances are corrected accordingly. Any medicines dispensed in error which are returned should be recorded as returns and retained pending any investigation.

7.3.10 Practitioners who manufacture or compound Schedule 3 or 4 CDs or import or export schedule 3 or 4 CDs, are required to keep records of this activity.

GOOD PRACTICE ADVICE/INFORMATION

- The use of running balances will become a legal requirement and is currently recommended as good practice. The first page of each section should contain an entry stating the opening balance. Further pages in the same section do not require specific entries for opening balance. Include out of date stock within the running total. The out of date stock total may be annotated in brackets alongside the full running stock total.

- The 2001 Regulations were amended in July 2006 to make clear that the record keeping requirements of the CD Regulations are a minimum and do not prevent inclusion of additional related information.

- ♦ All register entries should be made before the end of the shift period.
- ♦ A note should be included as to why identification was not requested from persons collecting a schedule 2 CD, eg patient known to pharmacy staff.
- ♦ A note should be included as to why evidence of identity was not provided by a patient or their representative on request, eg no identification available.
- ♦ The pharmacist may refuse to supply the CD if the identity or authority of the person collecting the script is unclear.
- ♦ It is good practice for a second person to witness receipt and destruction of patient returned CDs. See also Destruction of CD Stocks 7.11

7.4 Dispensing

7.4.1 CDs are Prescription Only Medicines but prescriptions for schedule 2, 3 or 4 CDs are valid only for 28 days from the date of issue or any stated start date.

7.4.2 Owings can only be supplied while the prescription is valid. Patient should be made aware of this restriction, by addition of an expiry date to the owings slip.

7.4.3 Where a prescription calls for instalments to be dispensed, such instalments can be supplied after the 28 day validity period has expired as long as the first instalment is dispensed within 28 days and the remainder of the script is dispensed in accordance with the written directions.

7.4.4 Refer to existing SOPs for dispensing, owings, labelling, counselling, use of compliance aids, dispensing and supervision of methadone and buprenorphine.

7.4.5 After dispensing, CDs should be stored appropriately in the CD cabinet while awaiting collection. Compliance aids which contain CDs subject to safe storage requirements must be stored in the CD cabinet before collection.

7.4.6 Pharmacists can make specific minor changes (minor technical error) to CD prescriptions where the prescriber's intentions are clear. If the error is a spelling mistake, a minor typographical error or the omission of either words or figures in the total quantity, the pharmacist can make the relevant change and dispense the prescription.

a. The pharmacist making the amendment must ensure the script is genuine, be sure they are supplying what the prescriber intended , amend the script clearly in ink and annotate to show who has made the amendment either by adding a signature or registration number.

7.4.7 Private prescriptions for schedule 2 or 3 CDs must be written on the standard PPCD1 form. Prescribers can obtain this from Primary Care Contractor Services (see Resources).

a. PPCD1 forms should be submitted to NHS NSS for processing with NHS prescriptions.

7.4.8 Emergency supplies from a pharmacist without a prescription (as defined in the Medicines Act) of Schedule 2 and 3 CDs, for a specific patient, are not permitted except for phenobarbital for the treatment of epilepsy.

7.4.9 Doctors and dentists may prescribe CDs in Schedules 2 to 5 for organic disease.

7.4.10 Community practitioner nurse prescribers may not prescribe CDs (June 2008).

7.4.11 Nurse independent prescribers can prescribe some CDs for specific conditions (June 2008).

7.4.12 Pharmacist independent prescribers cannot currently prescribe any CDs (June 2008).

7.4.13 Supplementary prescribers may prescribe any CD within the Clinical Management Plan specific to that patient and agreed between the independent prescriber, supplementary prescriber and the patient.

GOOD PRACTICE ADVICE/INFORMATION

- Copies of private scripts for schedule 2&3 CDs do not need to be kept for two years, but it may be useful to keep copies of schedule 3 CD scripts as there is no CD register record. Schedule 2 CDs need to be written through the CD register but good practice would advise to make a record in the private prescription record book. Schedule 3 must be written through the private prescription record book

7.5 Supply against requisitions

7.5.1 NHS requisitions by general medical practitioners must be made on GP10A stock order forms.

7.5.2 Private requisitions for schedule 2 and 3 CDs for human use should usually be made on the standard CDRF private requisition form. It is, however, legal to dispense requisitions written other than on the standard form as long as all legal requirements are met.

7.5.3 In all cases, community pharmacists must add their address to all requisitions received. The pharmacy stamp can be used as long as the full address is included and the information is clear and legible.

7.5.4 Community pharmacists must send GP10As, private requisitions CDRFs and any non-standard requisitions to NHS NSS with other prescriptions.

7.5.5 Community pharmacists must keep a copy of private requisitions (CDRF), for two years until the Miscellaneous Provisions are changed to cover private requisitions.

7.5.6 Requisitions should normally be supplied directly to the person who has signed the order. Where a third party presents to collect a schedule 2 or 3 CD on behalf of the recipient, they must possess a written statement signed and dated by the recipient stating that they are permitted to collect the drugs.

7.5.7 A full list of other persons who may legally requisition Controlled Drugs and the legal requirements of the requisition are included in Medicines, Ethics and Practice.

GOOD PRACTICE ADVICE/INFORMATION

♦ Supply against requisitions is considered to be wholesaler dealing. Where a wholesale transaction occurs, only whole packs should be supplied and the pharmacy should not label the medicines.

♦ For transfer of CD stock between community pharmacies, a written requisition should be obtained and submitted to NHS NSS as with other private CD requisitions. NHS NSS have made available a suitable form for pharmacies to use when supplying Controlled Drugs to other pharmacies.

♦ For UK registered ships in UK waters-

- The Maritime and Coastguard agency (MCGA) issued a Merchant Shipping Notice (MSN 1768), which lists the medical supplies to be carried by different classes of vessel.
- The Master/owner of the ship can requisition CDs in accordance with the regulations (a sample is included in MSN 1768). It is good practice for the requisition to be on headed paper. Note that private requisitions do not need to be on CDRF forms
- The RPSGB recommends that pharmacists presented with a shipping requisition for CDs should check the identity of the operator of the ship with Lloyds Registry
- The crew department of the operator will be able to identify the Master of the ship
- The RSPGB recommends that pharmacists should contact the MCGA to confirm that the requested drugs are appropriate for the category of ship
- Dispense appropriately and make relevant entries in the CD register
- Mark the requisition with the date of supply and name and address of the pharmacy
- Preserve and retain a copy of the requisition for 2 years from the date of supply
- Send the original requisition NHS NSS

♦ For Foreign Ships in British waters- see information in Medicines, Ethics and Practice

♦CDs from ships can be accepted by Community Pharmacies from ships.

- If accepting CDs for destruction, enter the full details into the CD register and provide a receipt
- Do not use for onward supply but segregate stock in the CD cabinet to await destruction by an Authorised Witness

7.6 Collection and delivery of dispensed medicines

7.6.1 The person collecting the medicine from the dispensing pharmacy should sign the back of the prescription form when collecting Schedule 2 or 3 CDs. See section 3.6 for details.

7.6.2 Where medicines are collected by someone other than the patient, no confidential information must be disclosed about the patient or their condition unless the patient has given specific permission for this.

7.6.3 Where any medicine, including CDs are delivered to patients' homes or to care homes it is necessary that an audit trail is maintained. Appropriate records must also be kept of any undelivered medicines returned to the pharmacy before another attempt at delivery is made.

7.6.4. The person delivering the medicine should sign the back of the prescription and the CD register should show the details of the person delivering the medicine.

7.6.5 A delivery record should be maintained which allows the patient or carer to sign for receipt of the medicines.

GOOD PRACTICE ADVICE/INFORMATION

- Where patients are not collecting their own medication, it may be appropriate to ask the patient to provide written authority to the person collecting on their behalf. This is advised when the CD, eg methadone or buprenorphine, is being prescribed as part of a harm reduction programme. The signature can be checked against the signature on the prescription. The pharmacist should retain this letter of authorisation in case of any dispute about supply.

- If access cannot be gained to a patient's home for delivery, the medicines must be brought back to the pharmacy and information left for the patient regarding collection or re-delivery. Medicines must not be pushed through a letterbox or left unattended. CDs can only be left with a neighbour if there is a prior arrangement to do so.

7.7 Storage

7.7.1 All CDs must be stored at the level of security specified within the Misuse of Drugs Act 1971, the Misuse of Drugs (Safe Custody) Regulations 1973 as amended, and the Misuse of Drugs Regulations 2001.

a. Schedule 2 drugs, eg diamorphine, fentanyl, methadone, morphine & oxycodone, and certain Schedule 3 drugs, ie buprenorphine, diethylpropion, flunitrazepam and temazepam, must be stored in an approved Controlled Drug cabinet.

b. Where storage facilities do not meet the requirements of the Misuse of Drugs Regulations, an exemption certificate must be obtained from Central Scotland Police to confirm that storage facilities are suitable.

7.7.2 Keys for CD storage facilities must themselves be securely stored under personal control of the pharmacist (see section 2). This arrangement must ensure that no unauthorised person is able to access them.

7.7.3 There must be a secure method of transferring keys to the control of the next pharmacist on duty when personal hand over is not possible. This might be via sealed and signed envelopes.

7.7.4 Prescription stationery should be stored securely in a locked cabinet at all times, except when supervised or in immediate use.

GOOD PRACTICE ADVICE/INFORMATION

- An approved CD cabinet is one which can be locked with a key or approved digilock and made of metal with hinges that cannot be accessed from outside the cabinet. It should be fixed to the wall or the floor with rag bolts that are not accessible from outside the cabinet.

- Schedule 3 (except buprenorphine, diethylpropion, flunitrazepam and temazepam), 4 and 5 drugs do not require storage in CD cabinets but any drugs liable to abuse which are held on the premises should be stored securely.

- Blank prescription forms must never be pre-signed or left unattended.

- The security of prescription stationery (NHS or private) is the responsibility of the practitioner. It is good practice to record the number of the next unused form at the end of the working day. This will help to identify quickly any lost or stolen forms.

7.8 Prescribing by community pharmacists

7.8.1 Pharmacist independent prescribers cannot currently prescribe any CDs.

7.8.2 Supplementary prescribers may prescribe any CD within the Clinical Management Plan specific to that patient and agreed between the independent prescriber, supplementary prescriber and the patient.

7.8.3 To meet legal requirements, the following details must be present on the prescription.

a. The name and address of the patient.

b. The form and strength of the preparation.

c. The total quantity or the number of dose units, in words and figures.

d. The dose.

e. The name, prescriber reference, address and signature of the prescriber.

f. Particulars to indicate the class of prescriber, eg doctor, dentist, nurse supplementary prescriber.

g. The date.

7.8.4 Prescriptions for schedule 2, 3 and 4 CDs are valid for 28 days from the date of issue or the indicated start date.

GOOD PRACTICE ADVICE/INFORMATION

- There should be separation of the dispensing and prescribing functions where possible.

- Pharmacist prescribers should not prescribe for themselves, family or friends.

- It is good clinical practice not to issue prescriptions for more than 30 days' supply. Prescribers who do issue scripts for longer periods should be able to justify this decision on the basis of clinical need with no detriment to patient safety.

- When prescribing opiate substitution treatment, it is good practice to add the name of the dispensing pharmacy and record this in the patient's notes.

- When prescribing opiate substitution treatment, it is good practice to add the start date into the body of the prescription.

- When prescribing opiate substitution treatment for daily dispensing, scripts must clearly indicate which doses should be supervised and which doses can be provided to the patient as take home doses for days that the pharmacy is closed. The wording below is approved by the Home Office to cover pharmacy closing: "Instalments due on days when the pharmacy is closed should be dispensed on the day immediately prior to closure".

- The dispensing pharmacist may query scripts which do not conform to best practice advice.

- NHS and private CD prescribing will be monitored through PRISMS.

7.9 Checks of stock holding

7.9.1 It will become a legal requirement to keep a running total of CD stocks held. It is therefore recommended as good practice to keep running balances now.

7.9.2 The RPSGB advise that the running balance should normally be checked with the physical amount of drug each week.

7.9.3 The responsible person should ensure that full stock checks are performed at least quarterly for all items even if no transactions have occurred in that time.

7.9.4 Old/completed CD registers should be kept for two years after the date of last entry and then can be shredded or disposed of in confidential waste.

GOOD PRACTICE ADVICE/INFORMATION

- It is good practice for any authorised person who makes a transaction involving CD stock to check the balance at that time.

- Depending on the volume of CDs dispensed, it might be necessary to reconcile the stock more often than the recommended once weekly.

- Packs of liquid preparations have a varying degree of overage. This overage can become part of pharmacy stock, provided appropriate records are made, ie it should be entered in the obtained section of the register. Discrepancies may also arise as a result of the measurement process or spillage. Where a pharmacist can be satisfied that any overage or loss of liquid preparations are a result of manufacturer's overage, measurement (manual or electronic) or spillage, a record should be made of this and the running balance corrected to take account of the overage or loss. Whenever possible, spillages should be witnessed and the record initialled by a second person.

- Full stock checks should be done in the presence of and countersigned by another member of dispensary staff. The procedure is as follows:

    - Confirm each order received since the previous check has been entered into the register and tick each line, check there are no pages missing.
    - Check each entry into the register is correct.
    - Check arithmetic for both receipt and use.
    - Go through the register and verify that each drug in the register is in the cupboard.
    - Verify identification of drugs and check expiry date.
    - Check the balance of each item is correct. Where the manufacturer's tamper-evident seal has been examined and remains intact, assume that the quantity in pack is the same as that stated.

  When you are satisfied that everything is correct, for each item write across the next line "date, drugs checked and correct, signature x 2, balance".
  When a CD register is complete and a CD check has been done, score across the front and endorse it with "date, register complete, signature". Any remaining blank pages should be scored through.

- During inspections the RPSGB will monitor processes for keeping running balances and ensure record keeping requirements are being complied with.

7.10 Dealing with discrepancies

7.10.1 If a pharmacy becomes aware of a CD discrepancy this must be fully investigated as soon as possible.

- Check arithmetic since last correct balance.
- Re-check CD holdings with second person (include date expired stock and exclude patient returns).
- Check other register sections of same drug class for erroneous entries.
- Check other holdings, eg dispensed medicines not yet collected.
- Sense-check register (correct pack sizes, patterns of entry for potential missing entries, and unusual quantities).
- Check orders have all been entered by checking delivery notes / invoices / stock orders for discrepancies.
- Check diary and contact all practitioners who have worked at the practice during the relevant period to verify any supplies made that have not been entered.

7.10.2 As each step is carried out and completed record date and initials on report form – see appendix A, and add details of any discoveries including details of how resolved and corrections made in CD register. If discrepancy can be resolved at any of the above steps, pharmacist to make a dated footnote in the CD register to reflect correction.

7.10.3 Discrepancies and any identified methods of resolution should be notified to the contractor / owner / area manager / superintendent pharmacist in accordance with local policy.

7.10.4 Any discrepancy which cannot be resolved should be notified to the Accountable Officer.

GOOD PRACTICE ADVICE/INFORMATION

- If considered appropriate eg concerns over professional standards or behaviour, any discrepancy which cannot be resolved should also be reported to the RPSGB.
- Where there is suspicion of any criminal activity Central Scotland Police should also be informed.

7.11 Destruction of CD Stocks

7.11.1 All CDs in schedule 2, 3 and 4 (part 1) must be rendered irretrievable (ie. By denaturing) before being placed into pharmaceutical waste containers. Pharmacists should use denaturing kits – these can be ordered from Primary Care Contractor Services tel 01786 434776

7.11.2 Schedule 2 CD stocks that are past their expiry date or are unsuitable for use for any other reason can only be destroyed in the presence of persons authorised by the Accountable Officer or Secretary of State. Such persons include RPSGB inspectors or NHS Forth Valley Controlled Drug Governance Inspectors or Authorised Witnesses. (Pharmacists that produce (ie manufacture or compound) Schedule 3 and Schedule 4 Controlled Drugs, or import or export Schedule 3 or 4 Controlled Drugs also require to have the destruction of these drugs witnessed by an Authorised Witness). When CDs (which require an Authorised Witness to witness their destruction) require destruction, the following procedure must be followed:

- Contact the Controlled Drug Governance Team on 01786 431200 to arrange an appropriate appointment. (Some multiples also have pharmacists who have been given authority to witness the destruction of CDs. These pharmacists will have a certificate of authorisation from one Scottish Health Board.)
- Store expired CDs appropriately but ensure they are segregated from normal stock and clearly marked so that they are not used for patients.
- Include this quantity in running balances and do not make alterations to the CD register until destruction has taken place.

7.11.3 Patient returned CDs can be destroyed without the presence of a witness authorised by the Accountable Officer see 7.12 below

7.11.4 Where schedule 2 CDs are returned, enter details of the name, form, strength and quantity of the drug in the CD returns register together with the date the drugs were returned, and where available, the name and address of the patient; role of the person returning the drugs (if not the patient); name and signature of the person who received the CDs.

7.11.5 Denatured / destroyed CDs should be disposed of appropriately with other medicine waste.

7.11.6 Do not accept expired CD stocks from GPs. In exceptional circumstances, GPs may return small quantities of unwanted CDs, previously dispensed to patients, on behalf of the patient. As good practice, sign any documentation requested by the GP regarding the return and treat the CD as a patient returned CD as in 7.12 below

GOOD PRACTICE ADVICE/INFORMATION

- Controlled Drug denaturing kits should be used for destruction. To order- contact Carol Droubay, Primary Care Contractor Services on 01786 434776
- The Authorised Witness will request that a competent member of staff, usually a healthcare professional, be present at the time of destruction and sign the register to verify the drug and quantity destroyed.
- The Authorised Witness will work to their own SOP for the destruction of schedule 2 CDs

7.12 Destruction of CD Patient Returns

7.12.1 Patient returned CDs must not be re-used as pharmacy stock and must be destroyed. All CDs in schedule 2, 3 and 4 (part 1) must be rendered irretrievable (ie. By denaturing). Pharmacists should use denaturing kits – these can be ordered from Primary Care Practitioner Services tel 01786 434776

7.12.2 Patient returned CDs should be destroyed as soon as possible after receipt to avoid stockpiling which constitutes a clinical and security risk.

7.12.3 Ensure that patient returned CDs (which require safe custody) are segregated from the other stock in the CD cabinet and clearly labelled as patient returns.

7.12.4 Patient returned schedule 2 CDs must be recorded. This should be in a separate book kept for this purpose, referred to as the CD returns register. See 7.12.6 below for information on destruction of CDs.

7.12.5 For schedule 2 CD patient returns, enter details of the name, form, strength and quantity of the drug in the CD returns register together with the date the drugs were returned, and where available, the name and address of the patient; role of the person returning the drugs (if not the patient); name and signature of the person who received the CDs and the date of destruction.

7.12.6 When destruction is completed, add details of name, position and signature of the person destroying the drugs and the witness; and the date of destruction to the CD returns register

7.12.7 Carry out the destruction of the drugs in the presence of a delegated member of staff. See below for procedure.

- Select the drug to be destroyed

- Ensure appropriate protective clothing is available and used e.g. gloves, mask, goggles and apron. Other equipment required- mortar and pestle and vessel for holding liquids

- Ensure adequate ventilation

- Choose appropriate size of Controlled Drug denaturing kit depending on the size and nature of the CDs to be destroyed.

- Depending on the formulation of the CD, the recommended destruction methods, as detailed in the table below, should be followed.

- Destroy products containing liquids towards the end of the process to minimise the Controlled Drug denaturing kit congealing prematurely.

- The instructions on the Controlled Drug denaturing kit should be followed- these will vary depending on the CD denaturing kit

- Some CD denaturing kits require the denaturing kit to be placed in the CD cupboard for 24 hours after destruction to allow the kit to solidify.

- Wash hands

- Place denaturing kit into pharmaceutical waste bin after the recommended time (as stated on the denaturing kit)

Formulation	**Method**
Tablet	Remove from blister strips and crush using mortar and pestle empty contents into Controlled Drug denaturing kit. Rinse out mortar and put washings into Controlled Drug denaturing kit.
Capsules	Open capsules and pour contents, and empty shell into Controlled Drug denaturing kit.
Patch	Remove from packaging, remove backing and fold patch over on itself. Put in Controlled Drug denaturing kit
Vial/ampoule	Reconstitute, if necessary, carefully shake contents into another vessel. Empty the contents of the vessel into the Controlled Drug denaturing kit. Rinse out vessel and add washings to CD denaturing kit. Put the vial/ampoule into the Controlled Drug denaturing kit.
Sachet	Open and pour into Controlled Drug denaturing kit. Put empty sachet into Controlled Drug denaturing kit
Liquid	Pour straight into Controlled Drug denaturing kit. **Thoroughly** wash out glassware and put the washings into the Controlled Drug denaturing kit. Put the empty bottle into the general rubbish or glass recycle.

GOOD PRACTICE ADVICE/INFORMATION

- Retain the record of the CD return from the patient for at least 7 years

7.13 Incidents

7.12.1 All incidents involving CDs should be recorded and investigated in line with existing procedures for clinical or medication incidents.

7.12.2 The Accountable Officer must be notified of the incident involving CDs as soon as possible, without compromising the steps needed to ensure patient safety.

7.12.3 The Accountable Officer must be notified of the outcome of all incidents involving CDs, any learning points identified and the actions taken to prevent recurrence.

7.12.4 Where there is suspicion of criminal activity, Central Scotland Police should be notified as well as the Accountable Officer.

7.12.5 Initial notification should be made to the Controlled Drugs Governance Team by telephone on 01786 431200.

GOOD PRACTICE ADVICE/INFORMATION

- Incidents include significant events, theft, breakage, unexplained discrepancies, dispensing errors.
- Concerns about patients and concerns about the practice of healthcare professionals should also be reported to the Accountable Officer who can undertake relevant investigations. This may include patients receiving duplicate quantities or professionals suffering from drug or alcohol abuse or prescribing for self or family.
- Concerns about the behaviour or practice of any pharmacist should also be reported to the RPSGB.
- Anonymous information may be used in educational material to share best practice and prevent recurrence.
- The standard NHS Forth Valley Controlled Drug incident reporting form is available as an appendix- see appendix B or an electronic version may be downloaded from the intranet http://intranet.fv.scot.nhs.uk/home/Depts/PrimaryPharmacy/AccountableOfficer.asp
- The authorised witness will request that a competent member of staff, usually a healthcare professional, be present at the time of destruction and sign the register to verify the drug and quantity destroyed.

7.14. Resources

- NHS Forth Valley Controlled Drug Governance Team 01786 431200.

- Palliative Care Pharmacist: Anne Davenport, Strathcarron Hospice 01324 826 222, Radiopager 07699716135

- NHS Forth Valley Specialist Pharmacist in Substance Misuse, Jean Logan 01786 434762

- Registers which comply with the legislation are available from:

    - The National Pharmaceutical Association 01727 858687 produce CD registers and patient returns books.

    - Surelines Pharmaceutical Service Ltd 01604 859000

    - Jordan Woodrows Ltd 0151 933 5000.

- Practitioners should report a suspected loss or theft of any prescription stationery to NHS Forth Valley Primary Care Contractor Services on 01786 434776 as soon as the loss/theft is discovered. They should report the approximate number of prescription or requisition forms lost or stolen, their serial numbers and where and when they were lost or stolen.

- Controlled Drug denaturing kits can be purchased from wholesalers or the NPA, or obtained free of charge from Primary Care Contractor Services, 01786 434776.

- CDRF forms for community pharmacists to use in stock transfer are available from: NHS NSS Practitioner Services, 3 Bain Square, Kirkton Campus, Livingston, EH54 7DQ (Tel: 01506-705-100).

- More information on private prescribing of CDs including access to application forms is available at http://showcc.nhsscotland.com/shsv53_STAGE/information-and-statistics.jsp?pContentID=3885&p_applic=CCC&p_service=Content.show&

- RPSGB (www.rpsgb.org.uk):

    - Russell Liddell, RPSGB Inspector

    - Raising Concerns http://www.rpsgb.org.uk/pdfs/raisingconcernsguid.pdf

8. Monitoring and Reporting

Monitoring- Routine monitoring will be undertaken by the Accountable Officer.
NHS Forth Valley will undertake a review of this Standard Operating Procedure every 2 years or if an incident demonstrates a deficiency within the procedure or if there is a change in legislation or best practice or when a person named in the SOP leaves.

Reporting- Any pharmacist must report any deficiencies within the Standard Operating Procedure to the Accountable Officer.
The Accountable Officer can be contacted on 01786 431200

9. Records

This SOP gives rise to the following records:
Entries in the Controlled Drug register and prescription book
Copies of private requisitions (CDRF)

10. Attachments

Appendix A- CD Action to resolve discrepancies
Appendix B- Controlled Drugs: Issue for Investigation form
Appendix C- Record of names of employees who have read and understood Standard Operating Procedure

Appendix A

CD- Action to Resolve Discrepancies

Action to Resolve Discrepancies	Person responsible	Date
Check arithmetic since last correct balance.		
Re-check CD cupboard with second person (remember to include date expired stock and CDs dispensed but not yet given to patient; and exclude patient returns which may have become mixed with stock).	1. 2.	
Check other register sections of same drug class for erroneous entries.		
Check other holdings, eg additional CD cabinet for stock		
Sense-check register (correct pack sizes, patterns of entry for potential missing entries, and unusual quantities).		
Check orders have all been entered.		
Check all supplies have been entered		
Contact made with pharmacists who have worked at the pharmacy during the relevant period. (Include details of all names and contact dates under notes.)		
AO notified?		
Amendments made to register?		
NOTES:		

Controlled Drugs: Issue for Investigation
Reference Number:

1. NAME OF PERSON RAISING ISSUE

Name		Job Title	
Telephone		E mail	
Person notified of issue		Date issue raised	

2. GENERAL

Premises where issue identified *NB Community pharmacy inspection is carried out by RPSGB*	GP practice		GP out of hours centre	
	Hospital ward		Hospital theatre	
	Hospital pharmacy		Hospital other (specify)	
	Dental practice		Addiction clinic	
	Community outpatient clinic		Prison	
	Care home		Community pharmacy	
	AO network			
	Other (specify)			
Premises name				
Address				
Telephone number				
E mail address				

3. DESCRIPTION OF ISSUE

Type of issue (indicate as appropriate)	Prescribing error	
	Administration error	
	Suspected inappropriate prescribing	
	Inappropriate destruction	
	Dispensing / supply error	
	CD register discrepancy	
	Suspected inappropriate supply / dispensing	
	Unexplained loss	
	Other (specify)	
Description of issue / concern		
Details of prescriber		

Details of dispenser / supplier	
Details of person administering	
Details of patient (No patient identifiable information)	

4a. ACTION TAKEN (Please complete separate section for each action)

For Controlled Drugs Governance Team use only

Person investigating: Name		Job Title	
Action taken		Date	
Outcome		Date	

4b. ACTION TAKEN

Person investigating: Name		Job Title	
Action taken		Date	
Outcome		Date	

5. FINAL OUTCOME

For Controlled Drugs Governance Team use only

No evidence found to merit further action		Update to local SOPs	
Update to NHS Forth Valley SOPs		Communication to practitioners	
NHS Forth Valley Disciplinary proceedings		Referral to NHS Counter Fraud	
Referral to Professional Reference Committee (specify)		Referral to Professional Regulatory Body (specify)	
Referral to police		Referral to Area Dug and Therapeutics Committee	
Referral to clinical incident reporting procedures		Referral to other (specify)	
Referral to employer			

6. RECOMMENDATIONS

For Controlled Drugs Governance Team use only

1.

7. ACTIONS

For Controlled Drugs Governance Team use only

1.

8. PERSONNEL INVOLVED

For Controlled Drugs Governance Team use only

Name, Job Title	Role

9. SUMMARY OF DOCUMENTS RELATING TO INVESTIGATION

For Controlled Drugs Governance Team use only

Number	Description	Date

APPENDIX C

Record of names of employees who have read and understood Standard Operating Procedure for the Management of Controlled Drugs for Community Pharmacies

I have read and confirm that I have understood the above named Standard Operating Procedure. I confirm that I have the necessary competency and training.

Name of Professional/ Individual	Job Title	Signature	Date