

Devon Primary Care Trust

Controlled Drugs Guidance for Primary Care

FINAL VERSION 1.2

Purpose of this document

Following a number of recent changes to Controlled Drugs / Misuse of Drugs Regulations, the PCT Medicines Management Team has produced guidance for primary care practitioners. This guidance has been developed in consultation with general practitioners, general dental practitioners and pharmacists, as a self assessment tool.

The guidance can also be used to review current practice, prior to QOF Medicines Management Action 3 (Controlled Drugs Assessment), which will be sent to general practices in January 2009.

Review Date: October 2010

Version History

Version	Date Issued	Brief Summary of Change	Owner's Name
0.1	September 2008	First draft	Stephen Murphy
0.2	07/10/2008	Second draft – comments added from Local Counter Fraud Specialist	Stephen Murphy
0.3	8/10/08	Third draft – document updated, following comments from Devon PCT Prescribing Task Group	Stephen Murphy
1.0	28/10/08	Final version	Stephen Murphy
1.1	17/11/08	Document updated, following feedback from AO network (witnessed destruction of broken vials)	Stephen Murphy
1.2	02/12/08	Updated following feedback from practices (clarification of repeat prescriptions, and requisitioning from wholesalers)	Stephen Murphy

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CONTROLLED DRUGS GUIDANCE

Recent Changes to Legal Framework

Some early changes in the legislation governing controlled drugs were implemented by amendments to the Misuse of Drugs Regulations that came into force on 14th November 2005¹. The principal changes allowed:

- All details on prescriptions for controlled drugs except the signature to be computer generated.
- Computerisation of controlled drugs registers for drugs listed in Schedules 1 and 2.
- Extension of the list of controlled drugs which nurse independent prescribers may prescribe for certain medical conditions following changes to the Prescription Only Medicines (Human Use) Order effective from 1st May 2006.
- Amendment of the list of allowable drug paraphernalia to include ascorbic acid.

Further changes have taken place following amendments to the Misuse of Drugs Regulations that came into force on 7th July 2006². These include:

- Introduction of special forms (FP10PCD) for any private prescription of Schedule³ 2 & 3 controlled drugs dispensed by community pharmacists. Records of these prescriptions will be held on a central database so that they can be monitored by local primary care trusts (PCTs).
- Modified arrangements for the dispensing of NHS prescriptions for Schedule 2 & 3 controlled drugs, including a new requirement for patients or other people collecting medicines on their behalf to sign for them.
- Validity of any prescription for Schedule 2, 3 & 4 controlled drugs to be restricted to 28 days.
- Introduction of requirement that all healthcare providers holding stocks of controlled drugs should have and comply with the terms of an agreed Standard Operating Procedure (SOP).
- Strong recommendation that the maximum quantity is limited to 30 days for prescriptions of Schedule 2, 3 & 4 controlled drugs.
- Re-emphasis of professional guidance that doctors should prescribe controlled drugs for themselves or family members only in exceptional circumstances.
- Standardised requisition forms (FP10CDF) are now available for ordering Schedule 2 and 3 controlled drugs. These forms should be used at all times as a matter of good practice unless, there are exceptional circumstances; FP10CDF forms are not available; or where requisitions are made from pharmaceutical wholesalers or manufacturers.

SYSTEMS FOR THE SAFE AND SECURE HANDLING OF CONTROLLED DRUGS

This guidance will address the following points regarding controlled drugs: obtaining / requisitioning, record keeping, storage / safe custody, and destruction.

1. Requisitions for Controlled Drugs

In order for a wholesaler or pharmacy to supply a Schedule 2 or 3 controlled drug to a practitioner (doctor or dentist) for stock or for practice use, the practitioner must furnish a written requisition to that supplier. Prescriptions and requisitions are not interchangeable. A prescription specifies the individual that can be in receipt of, and use the medicine on the prescription; a requisition is an order for stock or practice use, and a clear distinction must be made between the two. Prescriptions must not be used to replenish practice stock or GPs 'bags' even if the stock was used for the patient initially. The use of prescriptions in this way could be considered an offence under the Theft Act 1968 and may also be considered as a means in which to obtain controlled drugs by deception.⁴

Prescribers will need to complete a Devon PCT application form for approval by the PCT Accountable Officer before an initial supply of standardised requisition forms (FP10CDF) can be authorised. Details of applications will be recorded on a PCT database and analysed on a regular basis to identify trends which will be shared with the Controlled Drugs In House Management Group. Further requests are then supplied via the PCT approved representative and are monitored on a quarterly basis by the PCT Medicines Management Team. Prescribers who do not have a prescriber code and wish to requisition controlled drugs will need to apply for a private prescriber code, to enter onto the requisition.

Requisitions for controlled drugs are defined as 'wholesale supply' according to The Medicines Act 1968⁵. As such pharmacies can only supply whole packs against a requisition not individual units.

Requisitions for Schedule 2 and 3 controlled drugs should be on the standardised FP10CDF forms available from the PCT Accountable Officer. These forms should be used at all times as a matter of good practice unless, there are exceptional circumstances; FP10CDF forms are not available; or where requisitions are made from pharmaceutical wholesalers or manufacturers.

Requisitions do not have to be in the recipient's own handwriting but must:

- be signed by the recipient (computer generated signatures are not permitted)
- state the recipient's name
- state the recipient's address
- state the recipient's profession or occupation
- state the recipient's individual prescriber code
- specify the total quantity of the drug
- specify the purpose for which the drug is required

Ideally, requisitions for all controlled drugs should be made as a stock requisition for the central controlled drug cabinet not for individual GPs bags. The GPs bags can then be stocked from this central store with the relevant paperwork completed in the corresponding controlled drugs registers, (i.e. one register for each GP bag plus a central stock register). Having a central controlled drugs cabinet/register and supplying to GPs bags from this central store, removes the necessity for all GPs at a practice to individually order controlled drugs from (various) suppliers, and having to store patient returned and out of date controlled drugs in their bags. As pharmacies

can now only supply whole packs and not individual units of drugs on requisitions, having a central store will also keep stock of controlled drugs in GPs bags to a minimum.

2. Controlled Drugs Registers

Controlled drugs registers must be kept for all Schedule 1 (except Sativex®) and 2 controlled drugs received or supplied.

Controlled drugs registers must comply with the following points:

- Entries must be in chronological sequence.
- Must be a computerised form or a bound book ideally with numbered pages; it must not be a loose-leaf book or card index.
- A separate register or separate part of the register must be used for each class of drugs.
- In each separate register or separate part of the register used for each class of drug, a separate page must be used for each strength and form of that drug.
- The class of the drug, its strength and form must be specified at the head of each page.
- Entries must be made on the day of the transaction or on the next following day.
- Have no cancellations, obliteration or alteration; corrections must be dated and signed by marginal notes or footnotes.
- Entries must be in ink or otherwise indelible, or shall be in a computerised form.
- Computerised forms must ensure every entry is attributable and capable of being audited.
- The register must be kept at the premises to which it is related and a separate register must be kept for each premise storing controlled drugs. Where the register is in computerised form, it must be accessible from those premises.
- Particulars of stocks, receipts and supplies must be furnished on request.
- Paper registers must be kept for two years from the last date of entry and electronic registers for eleven years⁶.
- Records must be kept in their original form or copied and kept in a computerised form.
- Not be used for any other purpose.
- Not be kept inside the controlled drugs cabinet.

At present it is not a legal requirement but good practice for controlled drugs registers to contain a running balance of stock. In the future this will become a mandatory requirement.

Example of an entry into the Controlled Drugs register:

Class of Drug: Diamorphine Strength: 10mg Form: Ampoules

Date supply received or date supplied	Received		Supply						Balance
	Name and Address from whom received	Quantity received	Name and Address of Person or firm supplied	Details of authority to possess-prescriber or licence holders details	Person collecting Schedule 2 Controlled Drugs (patient / patient's representative or healthcare professional) If healthcare professional, name and address.	Was proof of identity of patient / patient's representative requested? Y/N	Was proof of identity of person collecting provided? Y/N	Quantity Supplied	
01.02.2008	Unichem plc, Marsh Barton, Exeter	10							10
03.02.2008			A.N. Other, 12 Sun Lane,	Dr Smith, FP10	Mrs A.N. Other	Y	Y	5	5

			Anytown						
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Electronic controlled drugs registers must be capable of printing or displaying the name, form and strength of the drug in such a way that the details appear at the top of each display or printout. In addition to the above guidance electronic registers must also:

- Only be kept in computerised form if safeguards are incorporated into the software ensuring:
 - a) the author of each entry is identifiable
 - b) entries cannot be altered at a later date
 - c) a log of all data entered is kept and can be recalled for audit purposes
- Have access control systems in place to minimise the risk of unauthorised or unnecessary access to the data
- Allow adequate backups to be made

Controlled drugs registers can be ordered from (amongst others);

- a) The National Pharmaceutical Association on 01727 858687 ext 3469, or
- b) Jordan Woodrows on 01519 335000
- c) p.travis@virgin.net (controlled drugs registers for GPs bags.)

3. Safe Custody of Controlled Drugs

The Misuse of Drugs Act 1971 and subsequent Regulations (Safe Custody) 1973 and 1985 require all Schedule 1, 2 (except quinalbarbitone (secobarbital)) and the following Schedule 3 controlled drugs, temazepam, diethylpropion, buprenorphine and flunitrazepam to be kept according to safe custody requirements. This requirement applies equally to patient returned and out-of-date controlled drugs, which until such time that they can be denatured and rendered irretrievable (see Destruction of Controlled Drugs, below) must be kept in the controlled drugs cabinet.

Controlled Drugs Stored on Surgery Premises

- Must be stored under lock and key in a safe/cabinet which either meets or exceeds the requirements of The Misuse of Drugs (Safe Custody) Regulations 1973.
- The safe/cabinet should preferably be made of steel, with suitable hinges, fixed to a wall or floor with rag bolts (which should not be accessible from outside the cabinet).
- The safe/cabinet should be within a cupboard or some other position to avoid easy detection by intruders.
- The room containing the safe/cabinet should be lockable and tidy around the safe/cabinet area to avoid drugs being misplaced.
- Walls of the room in which the safe/cabinet is kept should be constructed to a suitable thickness using suitable materials.
- Stock should be kept to a minimum and nothing should be displayed outside to indicate that controlled drugs are kept within the safe/cabinet.
- The safe/cabinet should not be used to store anything else other than controlled drugs so to prevent unnecessary/unauthorised access and to keep the number of keys available to open the cabinet to a minimum.

Controlled Drugs Stored in GPs bags

- A GP's bag/box, once locked is regarded as a suitable 'locked receptacle' in which to store or transport controlled drugs although a locked car is not (RAO v WYLES 1949).
- The GP's bag should be stored securely in the practice when not in use. This will vary in each particular practice but access to GPs bags must be restricted. The general public must not be able to gain access to areas where GPs bags are stored nor be left unsupervised with a GP's bag.
- When in transit a GP's bag should be kept out of sight.
- A GP's bag should never be left unattended.
- A GP's bag should not be left in a vehicle overnight or left in a vehicle unattended for long periods of time. N.B. The temperature stability of drugs within the GPs bag should also be taken into consideration when the bag is left in a locked vehicle.

A locked car/boot of a car, does NOT satisfy the safe custody requirements laid down by the Home Office and should not be used to transport controlled drugs. However, a locked GP's bag in a car does satisfy the safe custody regulations. It is the individual GP's responsibility to ensure safe storage of controlled drugs in their doctor's bag.

Practices may wish to consider putting systems in place to allow locums and/or trainee registrars to have access to emergency drugs, to include controlled drugs, which would take the form of a doctor's bag. Clear lines of responsibility and accountability for the safe custody of such drugs should be defined in practice procedures and be included in Standard Operating Procedures.

4. Destruction of Controlled Drugs.

A clear distinction must be made between obsolete, expired and unwanted stock controlled drugs and patient-returned controlled drugs, as the requirements for the destruction of these two classes are markedly different. Obsolete, expired and unwanted stock will be recorded in the controlled drug register as still in stock having not left the premises; therefore any destruction must be witnessed by an 'authorised person' (Appendix 1) and the register annotated accordingly. This differs to patient-returned controlled drugs as these will have been entered into a controlled drug register as leaving the premises when they were dispensed, the audit trail stops here. Hence any patient-returned controlled drugs can therefore be destroyed without the need of an authorised person to be present, although a separate register for recording their destruction must be kept.

Obsolete, Expired and Unwanted Stock CDs

- Obsolete, expired and unwanted stock controlled drugs must be kept according to safe custody requirements in the controlled drugs cabinet. However, they must be clearly segregated from stock controlled drugs in order to minimise the risk of errors and inadvertent use / supply to patients.
- Obsolete, expired and unwanted stock controlled drugs must only be destroyed in the presence of a person authorised as a witness by the Secretary of State, Home Secretary or PCT Accountable Officer either personally or as a member of a class (Appendix 1).
- Any stock controlled drug which becomes unusable or unwanted due to accidental breakage or spoiling of its container must still be kept according to safe custody requirements in the controlled drugs cabinet, and destroyed in the presence of an authorised witness.
- A person authorised as a witness must not witness the destruction of controlled drugs that have been supplied by them or to them; the segregation of roles must be clear in this respect.

- The name of the drug, its form and strength, the date of destruction and the quantity destroyed must be entered in the controlled drugs register and signed by the authorised person in whose presence the drug is destroyed.

Example of stock destruction entry in the Controlled Drug register:

Class of Drug: Diamorphine

Strength: 10mg

Form: Ampoules

Date supply received or date supplied	Received		Supply						Balance
	Name and Address from whom received	Quantity received	Name and Address of Person or firm supplied	Details of authority to possess - prescriber or licence holders details	Person collecting Schedule 2 Controlled Drugs (patient / patient's representative or healthcare professional) If healthcare professional, name and address.	Was proof of identity of patient / patient's representative requested? Y/N	Was proof of identity of person collecting provided? Y/N	Quantity Supplied	
02.03.2008	Unichem plc, Marsh Barton, Exeter	5							10
04.03.2008			Destroyed	Dr Smith	Signature of Authorised Person and GP			5 Destroyed	5

Patient-returned Controlled Drugs

- Patients or their representatives who wish to return controlled drugs should be encouraged to return them to their community pharmacist. If this cannot be done then they can be returned to the practice but a record must be made of their return.
- Although not a legal requirement under the Misuse of Drugs Regulations 2001, the recording of patient-returned controlled drugs specified in Schedule 2 is required under the Controlled Drugs Regulations 2006. The 2006 regulations require Standard Operating Procedures (SOPs) to be in place for maintaining a record of Schedule 2 controlled drugs returned by patients.
- A record of the return and destruction must be made in a bound book (not the controlled drug register) specifically for that purpose.
- It is recommended by the Royal Pharmaceutical Society to keep records for at least seven years.⁶
- The following details should be recorded:
 - The date of return of the controlled drugs
 - The name of the controlled drug
 - Quantity of the controlled drug
 - Strength of the controlled drug
 - Form of the controlled drug
 - The role of the person who returned the controlled drugs (if known)
 - The name and signature of the person who received the controlled drugs
 - The patients name and address (if known)
 - The date of destruction
 - The names, positions and signatures of:
 - The person destroying the controlled drugs, and
 - The person witnessing the destruction

- Ideally patient-returned controlled drugs should be destroyed immediately to minimise security risk and prevent storage problems. If this cannot be achieved they must be kept according to safe custody requirements, in the controlled drugs cabinet. However they must be clearly segregated from stock controlled drugs in order to minimise the risk of errors and inadvertent use / supply to patients.
- Patient-returned controlled drugs must not be returned to stock.

The following points apply to patient-returned and obsolete, unwanted and expired controlled drugs:

- All controlled drugs destroyed must be disposed of in a safe and appropriate manner ie in the relevant waste containers which are then generally sent away for incineration.
- Controlled drugs must not be disposed of in the sewerage system.
- All controlled drugs must be rendered irretrievable (by denaturing) before being placed into waste containers. Denaturing kits can be ordered from the following suppliers:
 - a) National Pharmaceutical Association 01727 858687 ext 3469
 - b) Cliniserve 01243 782288
 - c) Denward Manufacturing Ltd 01245 492986
- Other forms of denaturing controlled drugs such as mixing with cat litter are no longer recommended and must not be used as this is classed as waste treatment by the Environment Agency for which a licence is needed.

See Appendix 2 for guidance on the denaturing of controlled drugs, issued by the Royal Pharmaceutical Society of Great Britain.

5. Dealing with Discrepancies Relating to Controlled Drugs

Any discrepancies identified must be dealt with promptly (within 24 hours) and correctly. An investigation must be carried out to identify the cause of the discrepancy, initially at practice level. If the discrepancy is still unresolved then an incident report must be filed to the PCT Patient Safety and Quality Manager. The PCT Accountable Officer must also be informed. A screening panel will be called if required or the police may be contacted if theft is suspected.

If the Accountable Officer has reason to suspect an offence of fraud has been committed against the Trust, the Director of Finance or the Local Counter Fraud Specialist will be notified in accordance with the Trust Counter Fraud Policy.

At Practice level:

- An audit of all controlled drugs registers (central register and individual GP registers) must be completed to ensure that there has not been a bookkeeping error. These can be cross referenced to identify the source of the discrepancy.
- Stock checks of both the central controlled drugs cabinet and GPs bags must be completed.
- If the course of the discrepancy cannot be identified then an incident report should be filled to the PCT.

6. Standard Operating Procedures for Controlled Drugs

A Standard Operating Procedure specifies in writing what should be done, when, where, and by whom. Having Standard Operating Procedures in place assures quality and consistency and ensures good practice at all times. A Standard Operating Procedure clarifies job roles and is a useful aid to the audit process. All healthcare providers who hold a stock of controlled drugs on their premises must have up-to-date standard operating procedures in place that cover the following ⁶:

- a) Who has access to the controlled drugs cabinet / keys
- b) Where the controlled drugs are stored
- c) Security in relation to the storage and transport of controlled drugs
- d) Disposal and destruction of controlled drugs
- e) Who is to be alerted if complications arise (e.g. discrepancies)
- f) Record keeping, including:
 - i. Maintaining relevant controlled drugs registers under misuse of drugs legislation, and
 - ii. Maintaining a record of controlled drugs specified in schedule 2 of the misuse of drugs regulations 2001 that have been returned by patients

Devon PCT has developed template Standard Operating Procedures (Appendix 4) to be adapted and implemented in practice where Standard Operating Procedures covering the above are not yet in place:-

1. Requisitioning controlled drugs / obtaining standardised requisition forms
2. Safe custody of controlled drugs
3. Record keeping for controlled drugs
4. Disposal of stock and patient returned controlled drugs
5. Prescribing requirements for controlled drugs
6. Discrepancies relating to controlled drugs

APPENDIX 1

Persons Currently Authorised to Witness the Destruction of Controlled Drugs

The Misuse of Drugs Regulations 2001⁷ Regulation 27 enables the Secretary of State for Health and the Home Secretary to specify groups of people who are authorised to witness the destruction of stock.

The Secretary of State for Health currently authorises the following groups in England:

- Chief Dental Officer of the Department of Health or a Senior Dental Officer to whom authority has been delegated
- Supervisors of Midwives appointed by the Local Supervising Authority
- Senior officers in an NHS Trust who report directly to the Trust Chief Executive and who have responsibility for health and safety, security or risk management matters in the Trust
- Chief Executives of NHS Trusts
- A Primary Care Trust Chief Pharmacist or Pharmaceutical/Prescribing Adviser who reports directly to the Chief Executive or to a Director of the Primary Care Trust
- A Registered Medical Practitioner who has been appointed to the Primary Care Trust Professional Executive Committee or equivalent
- The Primary Care Trust Board Executive member with responsibility for Clinical Governance or Risk Management
- Medical Director of a Primary Care Trust

The Home Secretary also authorises:

- Inspectors of the Royal Pharmaceutical Society of Great Britain
- Inspectors of the Home Office Drugs Branch
- Police constables

The PCT Accountable Officer is able to authorise a person or class of persons to be an authorised witness. The Accountable Officer for Devon PCT has authorised members of the prescribing team to witness the destruction of controlled drugs. Please contact the Medicines Management Team if an authorised person is required to visit the practice/pharmacy. (N.B. most community pharmacy multiples have their own process in place via host PCTs.)

APPENDIX 2

Denaturing of Controlled Drugs

All controlled drugs in Schedule 2, 3 and 4 (Part I) must be rendered irretrievable (ie by being denatured) before being placed into waste containers. Different forms of controlled drugs should be denatured according to the following procedures:

- Solid Dose formulations should be removed from their outer packaging and any blister packaging. Ideally capsules should be opened and the contents placed into the denaturing kit; tablets should be ground or crushed and the resulting powder added to the denaturing kit.
- Controlled drug liquids should be added to the controlled drug denaturing kit and mixed.
- Fentanyl and buprenorphine patches should have the backing removed and the patch folded over onto itself and placed in the controlled drug denaturing kit or medicines waste bin.
- Ampoules should be opened and the liquid poured into the controlled drugs denaturing kit. An ampoule that contains powder can have water added to it to dissolve the powder and the resulting mixture poured into the controlled drug denaturing kit.
- Aerosol Formulations should be expelled into water and the resultant liquid disposed of as a liquid formulation.

Once the controlled drug has been added to the kit follow the manufacturer's instructions (which normally involve adding water and shaking) on how to render the controlled drug irretrievable.

Taken from: Medicines, ethics and practice, July 2008, The Royal Pharmaceutical Society of Great Britain.

APPENDIX 3

List of Commonly Prescribed Schedule 2, 3 and 4(Part I) Controlled Drugs

The following list is not comprehensive but includes the most commonly prescribed controlled drugs encountered in Primary Care. Please refer to the links at the bottom of this page if the drug is not listed here.

Schedule 2	Schedule 3	Schedule 4(Part I)
Cocaine	Amobarbital	Bromazepam
Codeine 60mg/1ml solution for injection	Amytal	Chlordiazepoxide
Codeine Phosphate powder	Buprenorphine	Clobazam
Dexamphetamine	Diethylpropion	Clonazepam
Diamorphine	Equagesic	Diazepam
Dihydrocodeine injection	Flunitrazepam	Flurazepam
Dipipanone	Meprobamate	Ketamine
Fentanyl	Pentazocine	Loprazolam
Hydromorphone	Phenobarbital	Lorazepam
Methadone	Phentermine	Lormetazepam
Methylphenidate	Temazepam	Nitrazepam
Morphine ²		Oxazepam
Oramorph conc. oral solution		Oxazolam
Oxycodone		Zolpidem
Pethidine		
Secobarbital		

Links:

1. http://www.psn.org.uk/pages/controlled_drugs_information.html
2. <http://drugs.homeoffice.gov.uk/publication-search/drug-licences/controlled-drug-list-jan-2008?view=Binary>

APPENDIX 4

The following Standard Operating Procedures can be adapted and implemented in practice where Standard Operating Procedures are not yet in place.

Standard Operating Procedure: Dealing with Discrepancies relating to Schedule 2 and named Schedule 3* Controlled Drugs at **INSERT NAME OF PRACTICE.**

Objective

To ensure that any discrepancies relating to controlled drugs at **INSERT NAME OF PRACTICE** are dealt with promptly and correctly. These include:

- Stock received against a requisition
- Registered stock and actual stock following a stock take
- Stock received which is deemed unfit for use
- Stock supplied/administered to patients

Discrepancy between stock requisitioned and that received from supplier

Process

- **INSERT NAME OF APOINTED PERSON** to contact the supplier as soon as possible to inform them of the discrepancy.
- **INSERT NAME OF APOINTED PERSON** to make an entry into the received section of the relevant controlled drugs register stating the quantity obtained (not what was requested).
- If the stock needs to be returned to the supplier arrange for them to collect ensuring they will have the appropriate paperwork to legally enable them to take the controlled drug away.
- **INSERT NAME OF APPOINTED PERSON** to make an entry into the 'supplied' section of the relevant controlled drugs register when the stock is returned to the supplier.
- If the discrepancy cannot be rectified with the supplier then **INSERT NAME OF SENIOR PARTNER** should be informed. An incident report should be filed following **INSERT NAME OF PRACTICE** procedure. The PCT Authorised Officer must be informed, who will investigate the discrepancy. If criminal activity is suspected the police will be informed.

Discrepancy of registered stock and actual stock

Process

- **INSERT NAME OF APPOINTED PERSON** to check back through the relevant entries in the controlled drug register and ensure that there has not been a book-keeping error.
- **INSERT NAME OF APPOINTED PERSON** to check back through the individual GPs controlled drug registers, invoices from suppliers and copies of requisitions. Cross reference these to the central controlled drugs register to look for the source of the discrepancy.
- If the discrepancy can be identified make a signed and dated amendment into the relevant controlled drugs register(s).
- If the discrepancy cannot be identified **INSERT NAME OF SENIOR PARTNER** should be informed. An incident report should be filed following **INSERT NAME OF PRACTICE** procedure. The PCT Authorised Officer must be informed, who will investigate the discrepancy. If criminal activity is suspected the police will be informed.

Stock received which is deemed unfit for use

Process

- **INSERT NAME OF APPOINTED PERSON** to make an entry into the relevant section of the controlled drugs register.
- Store the unfit stock in the controlled drugs cabinet but clearly labelled and segregated from other stock.
- Inform the supplier that the stock received is unfit for use giving a reason why.
- Arrange for the supplier to pick up the unfit stock ensuring they will have the appropriate legal documentation to do so.
- When the stock is collected by the supplier **INSERT NAME OF APPOINTED PERSON** will make an entry into the supplied section of the relevant controlled drugs register.

Stock supplied/administered to patients

Process

- **INSERT NAME OF APPOINTED PERSON** to check through prescriptions and administration records to see what was intended to be given to the patient.
- **INSERT NAME OF APPOINTED PERSON** to check through the relevant controlled drug register to see what was recorded as being given to the patient.
- **INSERT NAME OF APPOINTED PERSON** to carry out a stock check to ascertain how much was actually given to the patient.
- Depending on the course of the discrepancy **INSERT NAME OF APPOINTED PERSON** to make a signed and dated amendment to the controlled drugs register; and/or supply the correct amount/collect the excess supplied to the patient. A report must be filed according to practice incident procedures.
- If any discrepancies cannot be resolved an incident report must be filed according to **INSERT NAME OF PRACTICE** procedure. **INSERT NAME OF APPOINTED PERSON** must inform the PCT Accountable Officer (Joy Davey) to report the discrepancy.

Responsibility

INSERT NAME OF APPOINTED PERSON has overall responsibility and accountability for all aspects relating to controlled drugs at **INSERT NAME OF PRACTICE**.

* The named Schedule 3 controlled drugs are: Temazepam, diethylpropion, buprenorphine and flunitrazepam.

INSERT NAME OF PRACTICE Standard Operating Procedure for Disposal of Schedule 2, 3 and 4(Part I) Controlled Drugs from Practice Stock (Including 'GPs bag.')

Objective

To ensure all legal requirements and current Home Office advice is met when obsolete, expired or unwanted Schedule 2, 3 and 4(Part I) controlled drugs are disposed of at **INSERT NAME OF PRACTICE**.

Process

- Any Schedule 2 controlled drugs (see Appendix 3) from practice stock which are obsolete, expired or unwanted **MUST NOT** be destroyed by any person at **INSERT NAME OF PRACTICE** unless an Authorised Person (see Appendix 1) is present to witness their destruction. This includes all stock which becomes unusable or unwanted due to accidental breakage or spoiling of its container.
- All Schedule 3 or 4(Part I) (see Appendix 3) controlled drugs from practice stock which are obsolete, expired or unwanted can be destroyed at **INSERT NAME OF PRACTICE** by **INSERT THE NAMES OF STAFF PERMITTED TO DESTROY CONTROLLED DRUG STOCK** WITHOUT the need for an Authorised Person to be present. However they must still be rendered irretrievable by denaturing before disposal. (Appendix 2).
- **INSERT NAME OF APPOINTED PERSON** is responsible for ensuring a controlled drugs denaturing kit is in stock prior to arranging for an Authorised Person to visit **INSERT NAME OF PRACTICE**.
- Other than themselves **INSERT NAME OF APPOINTED PERSON** also authorises **INSERT NAMES OF STAFF PERMITTED** to destroy any obsolete, expired or unwanted Schedule 2 controlled drug(s) from practice stock when **IN THE PRESENCE OF** an Authorised Person.
- See Appendix 2 for details on how to denature controlled drugs.
- **INSERT NAME OF APPOINTED PERSON** or **INSERT NAMES OF STAFF PERMITTED** must make an entry into the relevant section of the controlled drugs register immediately after destruction of all Schedule 2 controlled drugs detailing:
 1. The Date the Schedule 2 controlled drug was destroyed
 2. The Name of the person who destroyed the controlled drug
 3. The Name of the Authorised Person who witnessed the destruction
 4. Signatures of both the person who destroyed the controlled drug and the Authorised Person.
 5. The Quantity of drug destroyed
 6. The stock balance after destruction.
- The destruction of Schedule 3 and 4(Part I) controlled drugs does not need to be recorded.
- The resulting waste can be added to other obsolete, expired or unwanted stock waiting for collection (as the controlled drugs in it are rendered irretrievable after mixing in the controlled drugs denaturing kit).

Responsibility

INSERT NAME OF APPOINTED PERSON has overall responsibility and accountability for all aspects relating to controlled drugs at **INSERT NAME OF PRACTICE** and authorises **INSERT NAME(S) OF STAFF** to act on their behalf.

Other

A person authorised as a witness must not witness the destruction of controlled drugs that have been supplied by them or to them, the segregation of roles must be clear in this respect. All

obsolete, expired or unwanted stock must be stored segregated from other stock, clearly labelled, according to safe custody requirements until denatured.

INSERT NAME OF PRACTICE Standard Operating Procedure for Disposal of Schedule 2, 3 and 4(Part I) Controlled Drugs Returned to INSERT NAME OF PRACTICE.

Objective

To ensure all legal requirements and current Home Office advice is met when patient returned Schedule 2, 3 and 4(Part I) controlled drugs are disposed of at **INSERT NAME OF PRACTICE**.

Legal Framework

Although recording of patient-returned controlled drugs is not a current legal requirement according to the Misuse of Drugs Regulations 2001, as amended, The Controlled Drugs (Supervision of Management and Use) Regulations 2006 require Standard Operating Procedures to be in place for maintaining a record of the controlled drugs specified in Schedule 2 that have been returned by patients.¹

Process

- Patients or their representatives who wish to return controlled drugs to **INSERT NAME OF PRACTICE** should be encouraged to return them to their community pharmacist.
- All Schedule 2, 3 and 4(Part I) controlled drugs returned to **INSERT NAME OF PRACTICE** can be destroyed by **INSERT NAME OF STAFF MEMBER(S) PERMITTED TO DESTROY CONTROLLED DRUGS** under the supervision of **INSERT NAME OF APPOINTED PERSON** without the need for an Authorised Person to be present. However they must still be rendered irretrievable by denaturing before being taken away.
- Any Patient returned controlled drugs that **INSERT NAME OF PRACTICE** receives should be destroyed as soon as possible to reduce security risks and avoid storage problems.
- **INSERT NAME OF APPOINTED PERSON** must make a record of the return and destruction of all Schedule 2 controlled drugs in a separate bound book (but NOT the controlled drugs register) detailing:
 - g) The date of return of the controlled drugs
 - h) The name of the controlled drug
 - i) Quantity of the controlled drug
 - j) Strength of the controlled drug
 - k) Form of the controlled drug
 - l) The role of the person who returned the controlled drug(s) (if known)
 - m) The name and signature of the person who received the controlled drug(s)
 - n) The patients name and address (if known)
 - o) The date of destruction
 - p) The names, positions and signatures of;
 - i. The person destroying the controlled drugs; and
 - ii. The person witnessing the destruction
- See Appendix 2 for details on how to denature controlled drugs.
- The destruction of Schedule 3 and 4(Part I) controlled drugs does not need to be recorded.
- The resulting waste can be added to other drug waste waiting for collection (as the controlled drugs in it are rendered irretrievable after mixing in the controlled drugs denaturing kit).

Responsibility

INSERT NAME OF APPOINTED PERSON has overall responsibility and accountability for all aspects relating to controlled drugs at **INSERT NAME OF PRACTICE** and authorises **INSERT NAME(S) OF STAFF** to act on their behalf.

Other

It is recommended by the Royal Pharmaceutical Society to keep records of the receipt and destruction of patient returned Schedule 2 controlled drugs for at least seven years.¹ Patient returned controlled drugs must never be returned to stock. If patient returned controlled drugs can not be destroyed immediately upon receipt they must be stored segregated from other stock, clearly labelled, according to safe custody requirements.

Ref:

1. The Royal Pharmaceutical Society, Medicines ethics and practice, July 2008

Standard Operating Procedure: The Prescribing of Schedule 2 and 3 Controlled Drugs at **INSERT NAME OF PRACTICE**.

Objective.

To ensure all prescriptions for Schedule 2 and 3 controlled drugs (with the exception of temazepam), prescribed at **INSERT NAME OF PRACTICE** meet all legal requirements.

Process.

It is unlawful to prescribe or dispense a Schedule 2 or 3 controlled drug (except Temazepam) unless it complies with the following requirements:

The prescription must:

- Be written so as to be indelible.
- Be signed by the person issuing it (this must be handwritten).
- Be dated (prescriptions for all Schedule 2 and 3 controlled drugs, including temazepam, are only valid for 28 days after the date on the prescription).
- Specify the name and address of the person for whose treatment it is issued.
- Specify the prescriber's name and address (which must be in the UK).
- For private prescriptions (including temazepam and midazolam) be on a standardised form (FP10PCD), and include the private prescriber's identification number.
- Specify the dose to be taken; 'as directed' or 'when required' is not acceptable
- Specify the form and where appropriate the strength of the preparation.
- Specify the total quantity **IN BOTH WORDS AND FIGURES** of controlled drug to be supplied.
- Have written on it 'for dental treatment only' if issued by a dentist.
- If instalments are intended, the dose **AND** the instalment amount must be specified on the prescription.

Responsibility.

Each prescriber is responsible for issuing and meeting the controlled drugs prescription requirements. **INSERT NAME OF APPOINTED PERSON** to contact the PCT Accountable Officers PA to order the standardised private prescription forms (FP10PCD).

Other.

- All Schedule 4 and 5 controlled drugs are exempt from these specific prescription requirements but must still comply with general prescribing requirements.
- Prescriptions for Schedule 4 (Parts I & II) controlled drugs are only valid for 28 days after the date of issue; prescriptions for Schedule 5 controlled drugs are valid for six months after the date of issue.
- Repeat prescriptions* are not permitted for controlled drugs in Schedules 2 or 3, but are permitted for Schedules 4 (Part I & II) and 5.
- Repeat prescriptions* for Schedule 4 controlled drugs must have the first supply made within 28 days of the date of issue, or the appropriate date specified by the prescriber as a valid period for that drug. An NHS repeatable prescription for a Schedule 4 controlled drug is valid for 12 months.
- Repeat prescriptions* for Schedule 5 controlled drugs must have the first supply made within six months of the date of issue.
- The Department of Health has strongly advised that the quantity of Schedule 2, 3 and 4 controlled drugs prescribed be limited to 30 days supply.

*Refers to repeat prescriptions issued under the NHS Repeat Dispensing Service, and all private prescriptions. It does not mean that patients can't have a 'repeat' of previously prescribed medication from their history.

Standard Operating Procedure for the Recording of Schedule 2 Controlled Drugs at **INSERT NAME OF PRACTICE.**

Legal Framework.

Regulations 19, 20 and Schedule 6 of the Misuse of Drugs Regulations 2001 as amended, specify the format and requirements for controlled drugs registers.

Objective.

To ensure all Legal requirements relating to record making, are met when Schedule 2 controlled drugs are received, supplied or transferred between safe storage (including GPs bags) at **INSERT NAME OF PRACTICE.**

The Process.

- **INSERT NAME OF PRACTICE** must keep a controlled drugs register for all Schedule 2 controlled drugs complying to the following requirements:
 1. Entries must be in chronological sequence.
 2. Must be a computerised form or a bound book ideally with numbered pages; it must not be a loose-leaf book or card index.
 3. A separate register or separate part of the register must be used for each class of drugs.
 4. In each separate register or separate part of the register used for each class of drug, a separate page must be used for each strength and form of that drug.
 5. The class of the drug, its strength and form must be specified at the head of each page.
 6. Entries must be made on the day of the transaction or on the next following day.
 7. Have no cancellation, obliteration or alteration; corrections must be dated and signed by marginal notes or footnotes.
 8. Entries must be in ink or otherwise indelible, or shall be in a computerised form.
 9. Computerised forms must ensure every entry is attributable and capable of being audited.
 10. The register must be kept at the premises to which it is related and a separate register must be kept for each premise storing controlled drugs. Where the register is in computerised form, it must be accessible from those premises.
 11. Particulars of stocks, receipts and supplies must be furnished on request
 12. Paper registers must be kept for two years from the last date of entry and electronic registers for eleven.
 13. Records must be kept in their original form or copied and kept in a computerised form.
 14. Not be used for any other purpose.
 15. Not be kept inside the controlled drugs cabinet.

- Each area storing controlled drugs must have its own controlled drugs register, this includes GPs bags.
- **INSERT NAME OF APPOINTED PERSON** will check the stock received against a copy of the requisition when stock arrives at **INSERT NAME OF PRACTICE.**
- If the stock received is correct then **INSERT NAME OF APPOINTED PERSON** will make the appropriate entry into the received section of the controlled drugs register.
- If the stock received is not that which was ordered, or is damaged, follow the Standard Operating Procedure for dealing with Discrepancies.
- Every time a Controlled Drug is supplied, received or transferred between safe custody at **INSERT NAME OF PRACTICE** an entry must be made in the relevant section(s) of the controlled drugs register(s) specifying:

1. The date of transaction
 2. The name and address from who received, or the name and address of person supplied or administered.
 3. The quantity received or supplied/administered.
 4. Details of the authority to possess (prescriber details) if supplying.
 5. The name of the person collecting/administered the controlled drug. If the person collecting the controlled drug is a healthcare professional then their address must also be recorded.
 6. A record of whether proof of identity was requested and provided if supplying and the person collecting is not known.
 7. The running balance of the drug remaining.
- Transfers between GPs bags and a central controlled drugs cabinet would necessitate two entries, one into the central controlled drugs register and one into the individual GPs bag register.
 - Individual GPs will take a stock check of controlled drugs in their bags and check this balances with their individual controlled drugs register every **INSERT TIME FRAME**. Follow the Standard Operating Procedure for dealing with discrepancies if the two do not correlate.
 - **INSERT NAME OF APPOINTED PERSON** will take a stock check of controlled drugs in the cabinet and check this balances with the central controlled drugs register every **INSERT TIME FRAME**. The stock check will be witnessed and signed by **INSERT NAME OF PRACTICE PARTNER**. Follow the Standard Operating Procedure for dealing with discrepancies if the two do not correlate.

Responsibility.

INSERT NAME OF APPOINTED PERSON has overall responsibility and accountability for all aspects relating to controlled drugs at **INSERT NAME OF PRACTICE**. This includes making entries into the appropriate section(s) of the controlled drugs register when stock is received or supplied to/from the central controlled drugs cabinet. Individual GPs are responsible for the recording of stock into and out of their own 'bags'.

Other.

Records must be made of all Schedule 2 controlled drugs returned by patients or patient's representatives to the practice; or stock which has been destroyed in the presence of an Authorised Person. For details see;

- 'Standard Operating Procedure for Disposal of Schedule 2, 3 and 4(Part I) Controlled Drugs Returned to **INSERT NAME OF PRACTICE**', and;
- 'Standard Operating Procedure for Disposal of Schedule 2, 3 and 4(Part I) Controlled Drugs from Practice Stock (Including 'GPs bag.')'.

Standard Operating Procedure: Requisitioning of Schedule 2 and 3 Controlled Drugs for **INSERT NAME OF PRACTICE**.

Objective

To ensure all legal requirements are met when a requisition is submitted to **INSERT NAME OF PHARMACY AND/OR WHOLESALER(S)**, to order stock of Schedule 2 and 3 controlled drugs for the central controlled drugs cabinet or GPs 'bags'.

Process

- Requisitions for Schedule 2 and 3 controlled drugs should be on the standardised FP10CDF forms available from the PCT Accountable Officer (Joy Davey). These forms should be used at all times as a matter of good practice unless, there are exceptional circumstances; FP10CDF forms are not available; or where requisitions are made from pharmaceutical wholesalers or manufacturers.
- **INSERT NAME OF APPOINTED PERSON** to order FP10CDF requisition forms from the PCT Accountable Officer before stock levels of Schedule 2 & 3 controlled drugs run low. Stock levels should be kept to a minimum but enough to meet clinical need.
- **INSERT NAME OF APPOINTED PERSON** to assess stock levels and inform practice practitioner to write a requisition when necessary.
- The requisition must:
 1. In Part B – State the name; form; strength; and quantity of drug to be ordered. Have the practitioner's signature in indelible ink at the bottom.
 2. In Part C – State the name; occupation/professional qualification; individual or organisation code; and address of the practitioner.
 3. In Part D – State the purpose for which the controlled drug is required.
- A copy of the requisition should be taken and filed for audit purposes.

Responsibility

INSERT NAME OF APPOINTED PERSON must ensure that there is sufficient but not excessive stock of controlled drugs at **INSERT NAME OF PRACTICE**. Individual practitioners signing the requisition must ensure all details are correct. Only qualified healthcare professionals that are members of a class specified in the Misuse of Drugs Regulations 2001 are permitted to sign the requisition.

Other

A messenger sent by the practitioner to collect the controlled drug on the practitioners behalf, may only be supplied with the controlled drug if they produce to the supplier a statement in writing given by the practitioner to the effect that the messenger is empowered to receive the drug on their behalf.

INSERT NAME OF PRACTICE

Safe Custody (Storage) of Schedule 2 and 3 Controlled Drugs

The Misuse of Drugs Act (MDA) 1971 and subsequent Regulations laid down the rules for safe custody of controlled drugs (CDs). All Schedule 2 and the following Schedule 3 CDs, temazepam, diethylpropion, buprenorphine and flunitrazepam must be stored according to safe custody requirements.

Objectives

- To ensure all Schedule 2 and the named schedule 3 CDs are kept in accordance with the Safe Custody Regulations.
- **INSERT NAME OF PRACTICE** does not pass returned CDs to another party e.g. a pharmacist for destruction.
- Stock levels of CD's are regularly monitored and expiry dates checked by **INSERT NAME OF APPOINTED PERSON**.
- All out of date CD's are segregated awaiting destruction by an authorised person. See Appendix 1.
- Access to the controlled drugs cabinet is restricted.

Storage of Practice CDs Stock

The Process

- **INSERT NAME OF APPOINTED PERSON** is responsible for the correct storage of all Schedule 2, and the named Schedule 3 CDs, in the practice central CDs cabinet and takes overall responsibility for the keys/codes to the cabinet.
- CDs should be stored in a locked, secure container that is not portable (bolted to the wall/floor).
- Ensure that the room containing the CD cabinet is lockable.
- Keep the area around the cabinet tidy to avoid drugs being misplaced.
- Do not display anything outside to indicate that CDs are kept within the cabinet.
- Keep the stock in the CD cabinet at a minimum.
- Do not keep anything other than controlled drugs in the CD cabinet.
- Keep the CD register in a safe place but not in the CD cabinet. **INSERT PLACE OF CD REGISTER STORAGE**.
- The keys should always be kept separate from the cabinet/safe and should never be accessible to unauthorised persons.
- The use of several sets of keys for the CD cabinet/safe should be avoided. However, if there is more than one set available strict controls on who is in possession of these keys should be implemented by **INSERT NAME OF APPOINTED PERSON**.
- The number of sets of keys to the cabinet/safe, and who is in possession of them, or who has access codes for digital key pads, must be known at all times by **INSERT NAME OF APPOINTED PERSON**.
- An emergency spare set of keys to the CD cabinet/safe should be available. These should not be stored with the normal set of keys. Access to these should also be restricted.
- Only the following people listed will be allowed access to the CD cabinet/safe. **SPECIFY THE NAMES OF ALL KEY HOLDERS HERE**.
- **INSERT NAME OF APPOINTED PERSON** remains ultimately accountable for the management of CDs.
- Clearly segregate the CD cupboard into
 - a. Stock
 - b. Out of date stock
 - c. Patient returned stock (if unavoidable)
- Date check the central stock every **INSERT TIME FRAME e.g. 3 MONTHLY AND/OR EACH TIME THE CD IS RECEIVED/SUPPLIED** by **INSERT NAME OF APPOINTED PERSON**

- Where patient returns are brought into **INSERT NAME OF PRACTICE** ask the **patients (or their representatives) to return their unwanted medicines to the local community pharmacist for destruction.** Do **not** pass returned CDs to another party e.g. a pharmacist for destruction.
- Keep all out of date stock segregated from all other stock awaiting destruction by an authorised person.

Storage of CDs in a 'doctor's bag'

The Process

General

- Keep the keys to the doctor's bag separate at all times. The bag should ideally consist of a combination lock as it negates the need for keys.
- Keep the stock in the doctors' bag to a minimum.
- Ensure that stock is date checked every **INSERT TIME FRAME e.g. MONTHLY AND/OR EACH TIME THE CD IS RECEIVED/SUPPLIED** by **INSERT NAME OF APPOINTED PERSON.**
- Keep only one strength of each CD in the doctor's bag in order to minimise the risk or error, confusion and inappropriate administration.
- Review stock levels every **INSERT TIME FRAME** to ensure stock is kept to a minimum but effective level.

When in the practice

- When a doctors' bag containing CDs is in the practice, store the bag and CD register separately to avoid the possibility of the bag and the register being stolen.
- Keep a separate CD register for the CD stock held in each doctor's bag and for each doctor in the practice.
- The GPs bag should be stored securely in the practice when not in use. This will vary in each particular practice but access to GPs bags must be restricted. The general public must not be able to gain access to areas where GPs bags are stored nor be left unsupervised with a GPs bag.

When in transit

- Keep all CDs in the possession of an authorised person, in a locked bag whilst in transit.
- If the doctor's bag is left unattended at any time in a car, the bag and the car must be locked, and the bag kept out of sight.

Responsibility

If **INSERT NAME OF APPOINTED PERSON** is unable to carry out the above duties then **INSERT NAME OF SECOND APPOINTED PERSON** will carry out the above. Individual GPs are responsible for the controlled drugs kept in their bags and must ensure that their bag is stored safely at all times.

Good practice

CD cabinet should only be for safe storage of CDs and not for anything else. This ensures that the number of people gaining access to the cabinet and the number of keys that are available to open the cabinet is kept to a minimum. Ideally the cabinet should be in a position to avoid easy detection by intruders.

Restocking of a doctor's bag from practice stock, should be witnessed by another member of staff, and the appropriate entries countersigned in the practice stock CD register.

References:

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2. <http://www.knowledgenetwork.gov.uk/HO/circular.nsf/79755433dd36a66980256d4f004d1514/2462fd7b73736929802571dc0048efe5?OpenDocument>
3. www.homeoffice.gov.uk/documents/cdlist.pdf?view=Binary
4. A guide to good practice in the management of controlled drugs in primary care (England)', 2nd edition; National Prescribing Centre; February 2007.
5. <http://www.rpsgb.org.uk/pdfs/factsheet1.pdf>
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7. <http://www.opsi.gov.uk/si/si2001/20013998.htm>