

Template Standard Operating Procedure For: Handling of Controlled Drugs in GP Practices

Name of Practice :	
Objectives	<ul style="list-style-type: none"> To ensure implementation of the regulations and guidance on safe and secure handling of controlled drugs
Scope	<ul style="list-style-type: none"> To cover all aspects of obtaining controlled drug stock, handling, responsibilities, prescribing, storage, access, stock checks and record keeping in Wirral GP practices This document is not intended to give clinical guidance on the prescribing of controlled drugs
Target Group (Staff who are authorised to follow standard operating procedure)	<ul style="list-style-type: none"> GPs and all practice staff who are involved in handling controlled drugs.
Cross reference related policies	<ul style="list-style-type: none"> PCT Wide policy: Safe Handling and Administration of Medicines Template Standard Operating Procedure for Safe Handling of Prescription Pads in GP Practices
Evidence to support procedure	<ul style="list-style-type: none"> Safer Management of Controlled Drugs: Changes to Requirements for Requisitions for the supply of schedule 1,2 and 3 Controlled Drugs <i>Department of Health January 2008</i> A guide to good practice in the management of controlled drugs in primary care (England) Third Edition <i>National Prescribing Centre December 2009</i> Safer Management of Controlled Drugs: Guidance on standard operating procedures for controlled drugs <i>Department of Health January 2007</i> Safer Practice Notice No 12: Ensuring Safer Practice with High Dose Ampoules of Diamorphine and Morphine <i>National Patient Safety Agency May 2006</i> The Safe and Secure Handling of Medicines: A Team Approach <i>Royal Pharmaceutical Society March 2005</i>

Procedure		
Activity	Rationale	Responsibility
1. Ordering Stock Controlled Drugs		
<ul style="list-style-type: none"> Practitioners must NOT use controlled drugs (CDs) dispensed for specific patients, to top up or replace their bags for home visits or practice stock. 	To comply with good practice. This is also a potential offence under the Theft Act 1968	Registered Doctor

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<ul style="list-style-type: none"> The supplier of CDs should provide a delivery note for the doctor or authorised messenger to sign The doctor or messenger must check the CDs supplied at the point of receipt, checking the drug name, form, strength, quantity, expiry date and that the CDs are in good condition then sign the delivery note for receipt of the CDs. 	<p>To comply with good practice</p> <p>It is the responsibility of the doctor to ensure that the correct item has been supplied</p>	<p>Nominated staff Member</p>
<ul style="list-style-type: none"> The doctor or messenger must then transport the controlled drugs directly to the GP practice. It is recommended that the CDs are transported in the boot of the car 	<p>To comply with good practice</p> <p>For maximum security</p>	<p>Nominated staff Member</p>
<p>3. Entering stock CDs into Practice Stock</p>		
<ul style="list-style-type: none"> On receipt of CDs into the practice, the CDs must be immediately recorded into the CD register, and placed in an appropriate locked cupboard. This task may be delegated, but the doctor retains full accountability for this process. It is recommended that the copy of the requisition and the delivery note are stapled together and kept for at least 5 years 	<p>To comply with legal requirements</p> <p>Legally copies of requisitions should be kept for a minimum of 2 years, however cases often come to court much later than the mandatory 2 years</p>	<p>Nominated staff Member or doctor</p>
<p>The CD register must:</p> <ul style="list-style-type: none"> Be bound (not loose leaved) Contain class sections for each individual drug Have the name of the drug specified at the top of each page Have entries in chronological order and made on the day of the transaction Have entries in ink 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 Be kept at the GP Practice Be kept for a minimum of two years after the date of the last entry, once complete A running balance of stock CDs should be maintained 	<p>Although there is provision in law for computer generated CD registers, the PCT is not aware that computer generated CD registers are in use at the present time in any Wirral GP Practices</p> <p>To ensure irregularities are identified as quickly as possible</p>	
<p>The following details must be recorded in the CD register:</p> <ul style="list-style-type: none"> The date on which the CD was received The name and address of the supplier, e.g. Name of Pharmacy 	<p>To comply with legal requirements and good practice</p>	

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<ul style="list-style-type: none"> • The quantity received • The name, form and strength of the CD • The serial number of the requisition <p>Two designated practitioners must verify the stock level and sign the CD register.</p>		
4. Storage of CDs		
<ul style="list-style-type: none"> • Practice stocks of CDs must be stored in a locked cabinet or safe that must be bolted to a solid wall or floor. • It is highly recommended that the cabinet or safe complies with The Misuse of Drugs Act Regulations 1973 (New CD Cabinets purchased should therefore be designed specifically for the purpose of storing CDs) • Access must be limited to Designated Practitioners who must be a registered nurse or doctor • Stocks of CDs should be kept to a minimum, • High strength opiates (e.g. 30mg or 100mg diamorphine) must not be stored alongside lower strength products. • CDs must be kept in the container issued by the supplying pharmacy or wholesaler • Naloxone injection must be available in all clinical locations where strong opiates are stored or administered • CD cabinets should not be used to store valuables, but should be used exclusively for the storage of CDs and related pharmaceuticals • The doctor or a delegated staff member must undertake a monthly stock check of CDs 	<p>To comply with legal requirements and good practice</p> <p>To reduce the risk of error and to comply with Safer Practice Notice No 12</p> <p>In the event of an emergency</p> <p>To check for out of date stock</p>	<p>Designated Practitioner who may be a doctor or a nurse</p>
5. Doctors' Bags		
<ul style="list-style-type: none"> • A doctor's bag is a locked bag or case, which is kept locked at all times, except when in immediate use. • The doctor in legal possession of this bag must retain the key, alternatively a digital combination lock may be used • The person responsible for the bag must have it under their direct control. Bags containing CDs should not be left in a locked vehicle overnight, or in a locked vehicle for long periods of time. • Stock held in the bag must be kept to a minimum • It is highly recommended that only one strength of each CD is kept in the bag. 	<p>To minimise risk of error</p>	<p>Registered Doctor</p>

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<ul style="list-style-type: none"> Oral preparations of CDs for home visits are not routinely considered essential. 		
<ul style="list-style-type: none"> When a bag for home visits is stored in the practice, it must be stored in a safe place away from patient areas in a locked room The doctor or a delegated staff member should undertake a monthly stock check of CDs held within each bag for home visits and to check for out of date stock A separate CD register should be kept for all the CD stock held within the bag. The CD register for the bag containing CDs should not be kept in or directly with the bag Restocking of a bag for a home visit from practice stock should be witnessed by another member of the practice staff, as the process should include the appropriate entries into the practice CD register 	<p>Each doctor is responsible for the receipt and supply of CDs from their bag In case of theft the register would provide a reference as to what had been stolen</p>	Registered Doctor
6. Security of Related Stationary		
<ul style="list-style-type: none"> All CD Related Stationary such as dedicated requisitions, Prescription Pads and CD registers must be kept locked away when not in immediate use. The keys to the CD cabinet must be kept personally by the senior practitioner when on duty, out of hours the keys must be kept locked away only accessible to authorised staff. 	<p>To ensure security of order forms.</p> <p>To enable staff to locate key to access cupboard</p>	Designated Practitioner who may be a doctor or a nurse
7. Disposal of Expired CD Stock		
<ul style="list-style-type: none"> When stock CDs become expired they should be clearly marked –“date expired” and segregated from other stock. The stock destruction must be witnessed by a PCT Prescribing Adviser (or Pharmaceutical Adviser) or another authorised person. The destruction must be performed by the GP, using appropriate CD destruction kits (DOOP Kits provided by the PCT at the time of destruction). The doctor and the authorised person must both sign the CD register. The denatured CDs should then be disposed of 	<p>To comply with legal requirements and good practice</p> <p>People authorised to witness destruction of stock CDs include PCT Prescribing Advisers who have been authorised to destroy CDs by the PCT Accountable</p>	Registered doctor in conjunction with a PCT Prescribing Adviser (or Pharmaceutical Adviser)

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with clinical waste for incineration.	Officer, Inspectors of the RPSGB and Police Constables	
8. Prescribing of Controlled Drugs		
<ul style="list-style-type: none"> • Dosages and frequencies for all controlled drugs must be written in full by the prescriber to aid correct administration. • Prescriptions for controlled drugs should not exceed 30 days supply except in justifiable exceptional circumstances. • If prescribing in excess of 30 days the reason should be noted in the patient's notes • Other than in extreme emergencies prescribers should not prescribe for themselves or anyone with whom they have a close personal or emotional relationship • All private prescriptions for schedule 2 and 3 CDs must be written on a prescription form FP10PCD. Access to a private CD prescription code is authorised by the PCT Medicines Management Team (Fax No/ -0151 643 5442 Tel No/ -0151 643 5319) There is a 3 week delay whilst prescriptions are ordered. 	<p>To comply with legal requirements and good practice To comply with Department of Health recommendations</p> <p>Pharmacists can not dispense Private CD prescriptions unless written on this form</p>	Registered Doctor
9. Administration of Controlled Drugs		
<ul style="list-style-type: none"> • If administering CDs from practice stock, a record must be made in the CD register, including the date, name of patient, drug /dose/ quantity /route • The register must be signed by the practitioner administering the CD and whenever possible, a witness, who should be a practice employee. • When administering from the doctor's bag in a patient's home, it may not be possible for the administration to be witnessed. • The information must also be recorded in the patient's record and specify the date, time, strength, presentation and form of administration, dose administered as well as name and occupation of the person administering it • A record of batch numbers and expiry dates are also recommended 	To comply with legal requirements and good practice	Designated practitioner who may be a doctor or a nurse
10. Advice to Patients and Carers		
<ul style="list-style-type: none"> • CD prescriptions must be presented to a pharmacy for dispensing as soon as possible 	Prescriptions for Schedule 2 and 3 CDs are only valid	Patient or Carer

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<ul style="list-style-type: none"> register correcting the discrepancy in the balance • When a discrepancy occurs, a record should be kept of the actions taken • If the loss cannot be solved satisfactorily the Local Security Management Specialist must also be informed • If any member of the GP practice has concerns regarding any aspect of CD management they must contact the Accountable Officer for CDs at the PCT • All clinical incidents involving CDs including near misses must also be reported to the PCT Accountable Officer for CDs 		
12. Staff Training		
<ul style="list-style-type: none"> • All members of the Practice who are involved with the prescribing or handling of CDs must be trained to do so and be aware of the contents of this SOP and abide by it. • All practitioners are responsible to keep up to date with practice through programmes of CPD 	To comply with good practice and legal requirements	GPs and all practice staff who are involved in handling Controlled Drugs.
13. Self-assessment and CDs Declaration Statement		
<ul style="list-style-type: none"> • Each GP Practice is required to complete an annual declaration as requested by the PCT Accountable Officer, relating to the prescribing, management, usage and handling of CDs 	This is a requirement of the Health Act 2006	Authorised person within GP Practice with responsibility for the management and use of CDs

Training	
Specialist competencies or qualifications	Appropriately trained in the SOP
Continuing education & training	Update on SOP when SOP is reviewed
Risk Assessments	Controlled drugs are drugs of potential abuse.

Organisation	NHS Wirral
GP Practice	

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Standard Operating Procedure Developed By	
Medicines Governance Pharmacist	Name: Lisa Knight Position: Medicines Governance Pharmacist <i>Signed copy held by Medicines Management</i> Signature: _____ Date: _____
Practice Lead	Name: _____ Position : _____ Signature: _____ Date: _____
Authorisation	
Lead Pharmacist	Name: Julia Simms Position: Head of Medicines Management, Wirral PCT Accountable Officer Wirral PCT <i>Signed copy held by Medicines Management</i> Signature: _____ Date: _____

Standard Operating Procedure (SOP) peer reviewed by:-	
Forum	Members of the Medicines Management Strategy Committee, NHS Wirral

Individual Authorisation

Practice employed staff named below based atGP Practice

I have read and understood the Standard Operating Procedure and agree to handle medicines in accordance with this procedure.

Name of Employee	Signature	Authorising Manager	Date

