

STANDARD OPERATING PROCEDURE	MANAGEMENT OF CONTROLLED DRUGS
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Version Control

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1. CONTROLLED DRUG STATIONARY

- 1.1 CD stationary includes the requisition book and registers (Stock and Patient's Own). All should be kept locked in a cupboard or drawer when not in use.
- 1.2 A record must be kept of the supply of controlled stationary in Pharmacy which must include the following:
 - 1.2.1 Date.
 - 1.2.2 Ward/department.
 - 1.2.3 Name of person ordering the stationary.
 - 1.2.4 Type of stationary supplied.
 - 1.2.5 Quantity supplied.
 - 1.2.6 Signature of pharmacy staff supplying and ward staff receiving the item.
- 1.3 Loss or theft of any controlled stationary should be reported as soon as possible via Datix Web. The Chief Pharmacist will be notified automatically on submission of incident report.
- 1.4 Only one CD requisition book per ward or department should normally be in use.
- 1.5 Completed ward requisition books must be retained on the ward or in the department for a minimum of 7 years after the last entry.

2. ORDERING OF CONTROLLED DRUGS

- 2.1 Stock controlled drugs can only be ordered from the Pharmacy department by submitting a requisition in the official CD order book.
- 2.2 The ward/ departmental manager/delegated individual of the ward or department must sign the requisition for CD's (a copy of the signature is logged in the pharmacy department).
- 2.3 The ward/ departmental manager/delegated individual must regularly supply the Pharmacy department with an updated list of authorised signatories for their area.
- 2.4 New members of staff who wish to order CDs must be verified the relevant Ward/Department Manager. They must provide pharmacy with a copy of the signature sheet for the pharmacy records. Blank signature list sheets can be obtained from pharmacy for new members of staff.
- 2.5 All requisitions for CD's must comply with legislation and contain:
 - 2.5.1 Ward or department name (white and pink copies).
 - 2.5.2 Name, form, strength, ampoule size (if more than one) of available CD (white and pink copies).
 - 2.5.3 Total quantity to be dispensed (white and pink copies).
 - 2.5.4 Signature and printed name of the ward/ departmental manager/delegated individual (white and pink copies).
 - 2.5.5 Signature of person issuing the CD from pharmacy (white and pink copies.)
 - 2.5.6 Signature of the person checking the CD from pharmacy (white and pink copies.)
 - 2.5.7 Signature of person accepting the CD for delivery (white and pink copies.)
 - 2.5.8 Date (white and pink copies).
 - 2.5.9 Signature for receipt of CDs at ward or department (pink copy).
 - 2.5.10 Signature and page number of entry in CD Register (pink copy).

3 SUPPLY OF CONTROLLED DRUGS

- 3.1 The member of pharmacy staff dispensing CD's must do so in accordance with Pharmacy standard operating procedures for dispensing and checking controlled drugs.
- 3.2 Supply must only be made once the dispenser is satisfied that the requester is authorised to requisition CD's – their signature must be verified prior to dispensing.

4 TRANSPORT

- 4.1 All CD's must be transported in accordance with Home Office Guidance 'Guidance for the Safe Storage of CDs and drug precursors in transit' 2016.
- 4.2 Pharmacy staff are responsible for ensuring that CD tins and red CD transit bags are only issued to authorised personnel with a valid ID badge.
- 4.3 The delivery person must only hand over the CD tin to a registered nurse, midwife or ODP and obtain a signature at the time of delivery.

5 RECEIPT OF CONTROLLED DRUGS AND RECORD KEEPING

On receipt of a CD a Registered Nurse, Midwife or ODP must:

- 5.1 Open the tin/transit bag and verify the contents match the requisition.
- 5.2 Sign the "received by" section of the order book to accept onto the ward and log the serial number into the CD register .
- 5.3 Report any discrepancies to pharmacy immediately.
- 5.4 On receiving the CD the ward/departmental manager/delegated individual must complete an entry on the appropriate page of the CD register and the balance checked.
- 5.5 The medicines must be locked away immediately as per Section 6.
- 5.6 All details of receipt of CDs must be entered in the ward/department register.
- 5.7 Legally the records must be kept from 2 years from the date of receipt but as order books and registers may also contain details of destruction they should be stored for 7 years.

6 STORAGE

- 6.1 The ward/departmental manager/delegated individual of the ward or department during the times they are in charge is responsible for the stock of medicines held in the ward or department and for ensuring stocks of CDs corresponds with the details shown in the register.
- 6.2 Keys must be available only to authorised members of staff. The controlled drugs keys must be kept on a key-ring separate from all other keys. There must be arrangements for keeping the keys secure this is particularly important for areas such as the day surgery unit and wards that are not operational at all times.
- 6.3 The presence of all keys must be verified at the end of each shift and recorded on a handover log maintained by the ward/department manager (Appendix 1.)
- 6.4 Patients Own CDs must not be stored in their bedside lockers.

6.5 Within the trust all schedule 2 and 3 Controlled Drugs and some schedule 4 Controlled Drugs are subject to safe storage requirements in CD cupboards. As this list is subject to change pharmacy will provide this information to wards and departments (Appendix 2.)

6.6 Controlled Drugs Cupboards must: -

6.6.1 Be reserved solely for the storage of CDs.

6.6.2 Be secured to an internal wall.

6.6.3 Be made of metal.

6.6.4 Have a lock which is different from any other lock in the hospital.

6.7 Regulations apply equally to CD's requiring refrigeration.

7. OUT OF PHARMACY HOURS

7.1 Controlled Drug stocks must not be transferred between wards/departments.

7.2 If necessary for the urgent treatment, another ward may dispense a single dose of a CD for a specific patient, against a valid prescription (this may be on HIS or paper.)

7.3 The ward/ departmental manager/delegated individual from the ward/department requiring the medicine must take go to the ward/department that has stock. Two authorised staff (one from the donating ward and one from the receiving ward) check the prescription on HIS or the prescription chart to confirm the prescription details. A single dose must then be dispensed and the entry into the donating ward CD register made by the member of staff from that ward witnessed by the member of staff from the receiving ward.

7.4 Both members of staff return together to the receiving ward with the single dose of the controlled drug where together they make an entry in the receiving ward register with full details and "received from x ward out of hours" – the running balance is increased by the amount borrowed from the other ward/department

7.5 Two authorised staff (from the ward/department that the patient is on) sign the medication out of the receiving ward CD Register to the patient receiving it in the normal manner

7.6 Both witness administration and sign the eMAR on the HIS system or the prescription chart in areas where HIS is not in use.

8. CHECKING OF STOCKS AND BALANCES

8.1 The stock balances of all controlled drugs (including patients own controlled drugs) entered in the register must be checked every 24 hours. There is no requirement to open packs with tamper evident seals for stock checking purposes.

8.2 This will be recorded on the daily check form provided by the Pharmacy Department.

8.3 Two Registered Practitioners perform this check.

8.4 Stock balances of individual preparations must be checked before administration with the exception of liquids (Section 8.5).

8.5 During the daily balance checks, CD liquids should be visually inspected, not measured. If the balance is suspected to be significantly different to the recorded balance then it should be measured and verified by two members of staff. In addition the balance should be

measured whenever a new bottle is opened and at the monthly CD audit by the pharmacist and a witness.

- 8.6 If the balance of a liquid CD is more than 5% of the original volume out then a Datix Incident Report must be completed and the ward pharmacist notified.

9. PATIENTS OWN CONTROLLED DRUGS

- 9.1 If any patient's own CDs are to be used the CD must be assessed according to the "patient's own medicines" assessment criteria and only medicines that comply can be used. If the CD isn't to be used while inpatient then it should ideally be sent home.
- 9.2 Any CD being used must be recorded in a Patient's Own CD register and stored in the ward CD cupboard –the must be clearly marked and kept separate from the ward stock. Where space permits this is ideally in a separate patient's own CD cupboard.
- 9.3 Patients own CDs must never be used to treat other patients.
- 9.4 If the patient's own CD is deemed unfit for use, then patient consent is required prior to destruction. The pharmacist will check for Patient's own CDs requiring destruction each week and will destroy them on the ward with a witness who may be a nurse, pharmacist, medicines management technician or pre-registration pharmacist.
- 9.5 If a patient transfers to another ward it is the responsibility of the practitioner in charge of the transfer to ensure the patient's own CD's are transferred by signing out of the transferring wards book and into the receiving wards book, both events must be witnessed by a second trained member of nursing staff or a pharmacist.
- 9.6 Patients own CDs, which are required for discharge will be prescribed and returned to the patient. An entry will be made in the CD register and signed by two ward/ departmental managers/delegated individuals.
- 9.7 If the full medicines reconciliation takes place on a ward other than the admission ward and it is discovered that the patient's PODs contain CDs they must be entered into the POD register and stored in the CD cupboard at once.

10 ARCHIVING OF CONTROLLED DRUGS RECORDS

- 10.1 The time period for archiving CD documentation is 7 years for all requisitions, registers, order books, external orders, delivery notes and destruction records. This is due to the fact that it is very difficult to ensure that such records don't have destruction records in them.
- 10.2 Prescriptions for controlled drugs must be kept for 30 years, this may be in a paper or secure electronic format. Within the Trust the pharmacy department ensures that this is maintained via an external records management provider.

11. MONITORING

- 11.1 The Pharmacy Department audits all areas where CDs are stored on a monthly basis to ensure that these procedures are being adhered to.
- 11.2 The audit is conducted by a pharmacist not attached to the area being audited with a second member of staff that should usually be the ward manager of the ward/department.
- 11.3 If the ward manager is unavailable then the second member of staff can be another trained nurse, pharmacist, medicines management technician or pre-registration pharmacist.

12 HUMAN RIGHTS ACT

Implications of the Human Rights Act have been taken into account in the formulation of this document and they have where appropriate been fully reflected in its wording.

13 ACCESSIBILITY STATEMENT

This document can be made available in a range of alternative formats e.g. large print, Braille and audio CD.

For more details please contact the HR Department on 01942 77 3766 or email equalityanddiversity@wwl.nhs.uk.

APPENDIX ONE: SCHEDULES OF CDs WWL	Schedule ONE	Schedule TWO	Schedule THREE	Schedule FOUR Part 1	Schedule FOUR Part 2	Schedule FIVE
Examples of controlled drug	Drugs belonging to this schedule are thought to have no therapeutic value and therefore cannot be lawfully possessed or prescribed. These include LSD & MDMA (ecstasy)	Diamorphine Morphine Fentanyl Remifentanyl Pethidine Cocaine Codeine Inj Methylphenidate Methadone Oxycodone Sodium Oxybate	Buprenorphine Meprobamate Midazolam Phentermine Temazepam Tramadol Phenobarbitone	<u>Stored & Registered in WWL Trust</u> Zolpidem Zopiclone Diazepam – Oral form only Zaleplon Ketamine Chlordiazepoxide Clobazam Lorazepam Loprazolam Lormetazepam Nitrazepam Oxazepam Alprazolam	Androgenic and anabolic steroids Chorionic gonadotrophin (HCG) Non-human chorionic gonadotrophin Somatotropin	Codeine Lomotil Dihydrocodeine Oramorph 10mg/5mL Pavacol-D
Legal Discharge or OPD Prescription Handwriting Requirement	N/A	YES	YES	NO	NO	NO
Legal Storage Requirement	N/A	YES	NO	NO	NO	NO
Legal Register Requirement	N/A	YES	NO	NO	NO	NO
		WWL pharmacy securely stores & registers <u>all</u> schedule 2 & 3 CDs. WWL pharmacy securely stores & registers <u>some</u> schedule 4 part 1 CDs				

Appendix Two:

Key exchange signature sheet

DATE	SHIFT/TIME	KEYS FROM	KEYS TO