POLICY FOR THE MANAGEMENT OF CONTROLLED DRUGS

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Approved by: Medicines Management Group

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Version Number	Change Details	Date
21.0	CD (and supporting SOPs) and the main medicines policy have been updated to provide clarity on transfer of CDs between wards in situations when a supply is not made directly from pharmacy. This will normally be in exceptional circumstances in an out of hours situation.	January 21
21.01	Full review of CD Policy	07/10/21
21.02	Interim review of CD policy. 1. The policy has been updated to incorporate the key elements of the CD framework providing all the information in one document. 2. The destruction of controlled drugs section has been updated to further clarify the situations in which an Authorised Witness is required. 3. Role of the CD Service Group lead 4. New section on monitoring and assurance by the service groups.	13/05/22
21.03	Review of Policy Addition regarding approval of appropriately trained HCSW to undertake 2nd checker function during CD administration in HMP Swansea	3/10/22

N.B. Where the term 'Service Group' is used, this refers to the four Health Board Service Groups.

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SECTION ONE

1 INTRODUCTION

1.1 Policy Statement

This policy focusses on the management of Controlled Drugs (CDs) specifically and should be considered supplementary to the wider SBU Health Board Medicines Policy (1 (wales.nhs.uk)).

Controlled drugs (CDs) defined in this document are those substances contained within Schedules 1, 2, 3, 4 and 5 of the Misuse of Drugs Act 1971. The Health Board, however, has extended this term to include other substances that are open to abuse, or are high risk medicines or 'controlled' for other reasons.

1.2 Purpose

Provide guidance to all Health Board staff on the procedures relating to the safe and secure handling, and storage of controlled drugs to ensure that:

- staff are clear on the standards that are expected of them in relation to the handling and storage of controlled drugs
- patients, carers, staff and visitors are not put at risk as a result of the incorrect handling of controlled drug medicines
- all legislation and guidance is adhered to with respect to controlled drugs
- risks associated with the incorrect handling and storage of controlled drugs are reduced to a minimum

1.3 Licensing of Controlled Drug activity

The Service Group is responsible for ensuring CD activity is in compliance with Medicines and Healthcare Regulatory Agency (MHRA) and Home Office licensing requirements.

Aims and Objectives of this Policy are to ensure the Health Board is compliant with:

- The Home Office requirements with regards to controlled drugs licencing
- The MHRA requirements to hold a WDL

The 'Policy to determine the requirement for Home Office Controlled Drug Licenses' may be found here for more information: (162 Policy for CD Licences - FINAL.docx.pdf (wales.nhs.uk))

1.4 Standard Operating Procedures (SOPs)

SOPs are designed to ensure that CD's are readily available for use by medical/nursing staff when clinically required by patients in the Health Board. They also aim to improve & clarify the governance of local arrangements for the safe management of CD's.

Service Groups must have Standard Operating Procedures (SOPs) in place covering all aspects of Controlled Drug management. As a minimum, these must cover:

- Who has access to the CDs
- Where the CDs are stored
- Security in relation to the storage and transportation of CDs (as required by the misuse of drugs legislation)
- Disposal and destruction of CDs
- Who is to be alerted if issues arise (may include but is not limited to issues such as missing CDs, storage issues etc)
- Record keeping, including maintaining relevant CD registers (as per misuse of drugs legislation) and maintaining a record of schedule 2 CDs that have been returned by patients (where applicable).

All Controlled Drug related SOPs must be approved by the SBU Health Board Policies Group. A list of approved SOPs can be found here: Clinical Online Information Network | CID398a Standard Operating Procedures to Support the Policy for the Management of Controlled Drugs (wales.nhs.uk) . Service Groups are responsible for ensuring that sufficient SOPs are in place to cover CD activity and that these CD SOPs remain relevant and fit for purpose through periodic review (including following any learning from incident reviews). The Service Group will work with pharmacy colleagues to address any gaps in policy or any amendments required to existing SOPs prior to seeking approval from the SBU Health Board Policies Group.

Where the Service Group has made contractual arrangements with others to provide services on behalf of the Health Board, written assurance must be received that they have SOPs in place to cover all aspects of CD management that ensure compliance with all relevant CD legislation that include the above minimum requirements. Confirmation must also be received that these SOPs are reviewed periodically to ensure they remain relevant and fit for purpose.

1.5 Monitoring and assurance (including audit)

The Service Group must ensure appropriate arrangements are in place to monitor and audit the management and use of CDs by all staff involved in the management of CDs (not limited to healthcare professionals – including porters, delivery drivers etc.).

Service Groups must audit the management of CDs at appropriate intervals. A pharmacy registrant should undertake these audits in conjunction with an appropriate registrant from the area being audited. Results of such audits are collated into a dashboard and must be reviewed by a multidisciplinary team at an appropriately senior level within the Service Group. Any actions identified as a result of the audits must be undertaken in timely manner.

- Appendix 3.7 contains an approved CD audit for wards and other departments managing CDs. An electronic form to complete the audit can be found here: https://forms.office.com/r/UYK7LraGgp
- Appendix 3.8 contains an approved CD audit for theatre areas. An electronic form to complete the audit can be found here: https://forms.office.com/r/fa4iApL79U
- Appendix 3.10 contains an approved CD audit for GPOOH.

It is the responsibility of Service Groups to ensure these audits remain relevant and fit for purpose through periodic review (including following any learning from incident reviews). The Service Group will work with pharmacy colleagues to address any amendments required to existing audits or need for additional audit templates for specific areas prior to seeking approval from the SBU Health Board Policies Group.

Service Groups must also work in conjunction with pharmacy to monitor and analyse CD use at appropriate intervals to ensure ongoing safe and appropriate use. As a minimum this must include review of the 'Drugs Liable to Misuse Dashboard.'

Both the, 'CD Audit,' and 'Drugs liable to misuse,' dashboards are available here: Controlled Drugs (sharepoint.com)

Where the Service Group has made contractual arrangements with others to provide services on behalf of the health board, monitoring/audit will be required relevant to the nature of CD management undertaken.

The Service Group can, where required, add additional controls around storage and/or recording of specific CDs (over and above what is required by Health Board CD policy). Any additional controls must be agreed by a multidisciplinary team at an appropriately senior level within the Service Group. Such controls must be regularly reviewed for ongoing appropriateness. Appendix 6 contains a template log of additional controls for use by Service Groups.

1.6 Training

The Service Group must ensure that everyone involved in the management of CDs (not limited to healthcare professionals – including porters, delivery drivers etc.) receives appropriate training to enable them to carry out their responsibilities. This includes as a minimum:

- Ensuring appropriate training on policy and local Standard Operating Procedures (SOPs) for controlled drug management at induction and as continuous learning, in particular when such documents are reviewed/updated.
- Ensuring staff clearly understand their responsibility to, and how to report CD related incidents and concerns as well as how they can contact the CDAO if required.
- Ensure staff clearly understand the need to adhere to policy and professional standards to protect their patients, themselves and the general public. Ensure staff are aware of the serious consequences of not doing this.

1.7 The Controlled Drug Accountable Officer (CDAO)

The Controlled Drugs (Supervision of Management and Use)(Wales) Regulations 2008 state that as a 'Designated Body', SBU Health Board must have a CDAO. Further details of the appointment and removal process can be found here: The Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008 (legislation.gov.uk).

The CDAO for SBU Health Board can be contacted at sbu.cdao@wales.nhs.uk or via telephone on 01792 704068.

1.8 Roles and Responsibilities

1 8.1 The Controlled Drug Accountable Officer (CDAO) for SBU Health Board

The CDAO must ensure that there are appropriate arrangements in place for securing the safe management and use of CDs both within the Health Board and where a body or person is acting on behalf of, or providing services under arrangements made with the Health Board. Further details on the role and responsibilities of the CDAO can be found here: The Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008 (legislation.gov.uk)

1.8.2 Service Groups

Service Groups are responsible for ensuring robust arrangements are in place for securing the safe management and use of CDs and that these arrangements (including compliance with statutory requirements and relevant policy) are effective. This responsibility extends to staff and locations managed directly by the Service Group (including hosted services) as well as those acting on behalf of, or providing services (paid or unpaid) for the Health Board under arrangements made with the Service Group.

As part of this, Service Groups are responsible for ensuring that staff are eligible to carry out the tasks required of them in the prescribing, administration and management of controlled drugs.

Service Groups must ensure that CD governance maintains a sufficiently high priority and visibility at a senior management/clinician level. As a minimum this must include

the addition of CD governance matters as a standing discussion agenda item on the Service Group Quality & Safety Committee.

1.8.2.1 Service Group Controlled Drug Lead

The Service Group must appoint a CD Lead who must hold a senior post within the Service Group. The Service Group must notify the CDAO of any changes to the Service Group CD Lead. The CD Lead is responsible for ensuring that the Service Group discharges their responsibilities outlined in section 1.5.2 of this policy.

The CD lead will meet with the CDAO every 6 months to review CD governance in the Service Group.

Where management of CDs falls below what is expected the Service Group CD Lead will ensure high quality action plans are put in place and executed in a timely manner.

The CD lead will take a proactive approach to improving CD governance within the Service Group including ensuring that learning from 'near misses' is used effectively to help prevent future incidents.
The Service Group CD Lead is responsible for alerting the CDAO by exception to any serious or sensitive incidents, complaints, concerns or suspicions relating to CD management.

1 8.3 Ward/Departmental Managers

Ward/Departmental Managers are responsible for ensuring: -

- There are local approved procedures (SOPs) for the storage, handling and security of controlled drugs available in their designated area and that these SOPs are followed.
- Pharmacy are informed of any problems in implementation of these local procedures.
- The written procedure for the holding and handover of controlled drug keys between staff at shift changes is adhered to.
- All staff have been trained on the handling and storage of controlled drugs.
- An adequate system is in place for ordering controlled drugs and that appropriate stock levels are maintained.

1.8.4 Nurse/Midwife/ODP in charge

The nurse/midwife/ODP in charge is responsible for all controlled drugs whilst in charge of that ward/department. They are responsible for ensuring pharmacy is informed and an incident report form completed in the event of discrepancies or apparent loss. To include that duty balance checks are completed. The registrant in charge is legally responsible for the security of medicines in their area and must know the location of CD keys at all times.

1.8.5 Ward/Departmental staff

Ward/Departmental staff have a responsibility to: -

- Adhere to the CD policy and procedures for the storage and handling of controlled drugs.
- Ensure that the security of controlled drugs and their own local procedures concerning controlled drugs are being followed.
- Ensure controlled drug cupboard keys are held by and/or passed to suitably qualified staff. Suitable quality staff include registered nurses, midwives, ODP, radiographer senior 1 and registered dental therapists, nurses and hygienists.
- Report all incidents involving controlled drugs to the nurse/midwife in charge and complete an incident report form.

1.8.6 Pharmacy

Pharmacy staff are responsible for: -

- Providing information and advice to Health Board personnel on the handling and storage of controlled drugs used within the Health Board.
- Assisting where appropriate in formulating local procedures at ward/departmental /directorate level.
- Undertaking checks on wards/departments with appropriate ward/department Managers and audits on the safe handling and storage of controlled drugs every 3-6 months.
- Ensuring that the laws relating to the safe and secure handling and storage of controlled drugs are complied with.
- Removing any controlled drugs, no longer required from that ward/department

- Assisting with the training on the storage and handling of controlled drugs to Health Board personnel.

1.8.7 Operating Department Practitioners (ODPs)

Operating Department Practitioners (ODPs) as registered with the Health Professions Council are legally entitled to order, possess and supply CDs for administration to patients in accordance with the directions of a doctor, dentist and supplementary or independent prescribers in the department within which they work. Responsibility stays with the senior registered practitioner in charge even if they are not the theatre manager.

1.8.8 Community Nursing Staff & Individual Members of Staff

All members of staff involved in delivery of the service relating to controlled drugs must keep up to date with this Policy and the relevant associated procedures.

1.8.9 Medical Staff

Medical staff have a responsibility to: -

- Prescribe in accordance with the CD legislation.
- Adhere to the CD policy and procedures for the storage and handling of controlled drugs.
- Ensure that the security of controlled drugs and their own local procedures concerning controlled drugs are being followed.
- Report all incidents involving controlled drugs to the nurse/midwife/ODP in charge and complete an incident report form.

1.9 Controlled Drug related incidents, complaints and concerns

Intelligence received from incidents, complaints and concerns provide an important part of ensuring safe an effective CD governance. The Service Group must ensure that such intelligence is captured, reviewed and acted upon appropriately and in a timely manner. Individual incidents, complaints and concerns should not be solely managed in isolation, but rather, in addition to individual management, each must be seen in a wider context with active observation for wider trends and themes.

It is important that Service Groups ensure that any learning gained is shared appropriately both within the Service Group and across the wider Health Board including via Quality & Safety forums.

Service Groups must ensure that any CD related incidents, complaints or concerns of a serious nature (involving patient harm, loss of a significant amount of CDs, Police involvement, staff suspensions etc) together with any significant themes/trends in CD incidents are communicated to the CDAO as soon as is practical.

It would be expected that the above forms the basis of ongoing discussions and subsequent action plans between the Service Group CD Lead and the Controlled Drug Accountable Officer during their 6 monthly meetings.

1.10 Controlled Drug related risks

The Service Group must ensure that any ongoing risks to the safe management and use of CDs are recorded on the appropriate Risk Register, reviewed regularly and reported to the CDAO.

1.11 Prescribing of Controlled Drugs

1.11.1 Inpatient

(i) Controlled Drugs must be prescribed in accordance with the Health Board policy for the prescribing of medicines as described in the Medicines Policy – (Policy on Prescribing, Supply, Ordering, Storage, Security, Administration and Disposal of Medicines).

(ii) Controlled drugs for inpatients can be prescribed and administered using the inpatient medication chart without the need for full prescription requirements expected for an outpatient/discharge prescription.

1.11.2 Outpatient

(i) Outpatient Prescriptions for Controlled Drugs are valid for 28 days from either the date of prescribing or a “valid from” date specified by the prescriber on the prescription.

(ii) Outpatient Prescriptions must contain all the required information in accordance with the Misuse of Drugs Regulations (as specified in the current

BNF). Prescriptions with minor technical errors may be amended and recorded by the dispensing pharmacist (e.g. if one of the requirements for words and figures has not been included).

(iii) Prescriptions must be on official Health Board prescription stationery and in indelible ink – carbon copies/faxes for out-patient or discharge medication for schedule 2 and 3 controlled drugs are not acceptable for dispensing (schedule 4 and 5 may be supplied from a fax/carbon copy prescription). Alternative forms of technology such as e-mail/scanned copies should be employed in preference to faxing where possible. For peripheral units without a pharmacy, faxed/carbon copy prescriptions may be accepted by pharmacy to enable assembly of the prescription in advance, however, the original copy **must** be received before the final release of the prescription.

1.11.3 Addressograph labels.

Pre-printed addressograph labels **are not normally** recommended. Where they are used they should be tamper-evident (i.e. it is obvious if an attempt has been made to remove them). If a sticky label is, used prescribers should also sign the sticky label or at least start their signature on the sticky label. This is a further safe guard to ensure sticky labels are not tampered with or another sticky label is not placed on top of the one that the prescriber signed for.

1.11.4 Prescribers

Independent pharmacist prescribers and independent nurse prescribers are enabled to prescribe, administer and give directions for the administration of schedule 2, 3, 4 and 5 controlled drugs. Neither independent pharmacist or nurse prescribers will be able to prescribe diamorphine, dipipanone or cocaine for treating addiction but may prescribe these items for treating organic disease or injury.

Paramedics:

- Morphine by oral administration
- Codeine by parenteral and oral administration
- Midazolam by parenteral administration
- Lorazepam
- Diazepam

Physiotherapist independent prescribers are able to prescribe the following controlled drugs for the treatment of organic disease or injury:

- Diazepam by oral administration
- Dihydrocodeine by oral administration
- Fentanyl by transdermal administration
- Lorazepam by oral administration
- Morphine by oral administration or by injection
- Oxycodone by oral administration
- Temazepam by oral administration

Chiropodist/podiatrist independent prescribers are able to prescribe the following controlled drugs for the treatment of organic disease or injury:

- Diazepam by oral administration
- Dihydrocodeine by oral administration
- Lorazepam by oral administration
- Temazepam by oral administration
- **Compounding (mixing)** – Changes will mean that any person acting in accordance with the written directions of a pharmacist independent prescriber, nurse independent prescribers, doctor, dentist, or supplementary prescriber (working in accordance with a clinical management plan), will be able compound schedule 2, 3, 4 or 5 controlled drugs.

Prescribers must not prescribe / administer controlled drugs for themselves, close family or friends except in exceptional circumstances. This should be discussed with the senior pharmacist on duty in the dispensary at the time of prescribing. The senior pharmacist on duty may refer the case to the Accountable Officer or Medical Director and is empowered to refuse to make a supply if they have professional concerns about so doing.

1.11.5 Specimen Signatures

Specimen signatures must be obtained by medical staffing on appointment of medical staff and be available for cross checking. These should be forwarded to the relevant pharmacy department who will maintain a copy for checking purposes. Non-medical prescribers' details will be retained in the Non-Medical Prescribers Register, which can be found on the Health Board website.

1.11.6 Prescribing for Drug Addicts

(i) No doctor may administer or authorise the supply of Cocaine, Diamorphine or Dipipanone to registered addicts, except for the purpose of treating organic disease or injury, unless licensed to do so by the Secretary of State.

(ii) If a newly admitted patient states that he/she is an addict on medication for their addiction, then the medication and dosage must be confirmed with a third party.

(iii) The third party must be either of the following:

- Patient's G.P.
- Patient's community pharmacist
- Or a member of the Drug Addiction Team

NB: within the SBUHB, this could be CDAT, PSALT or Dyfodol /Kaleidoscope; or within the Hywel DdaUHB area, this could be CDAT.
If out of area, it is important to confirm identity as part of a treatment team.

(iv) Key stakeholders in the care of the patient in the community (including whoever supplies their medication in the community) must also be informed of their **admission** by the ward nurse/midwife, so that they are aware not to dispense any more medication until informed by the hospital.

(v) The ward nurse/midwife must ensure that key stakeholders in the care of the patient in the community (including whoever supplies their medication in the community) are made aware when the patient is **discharged** (including relevant information regarding any medication changes and when they had their last dose etc.) to ensure there are no gaps in provision of care.

(vi) Whoever supplies their medication in the community must also be informed of their admission by the ward nurse/midwife, so that they are aware not to dispense any more medication until informed by the hospital.

(vii) It is an offence for a prescriber to issue an incomplete Outpatient or Discharge prescription and a pharmacist is not permitted by law, to dispense prescriptions for controlled drugs unless all the required information is detailed in the prescription. Failure to comply with the legislation concerning the writing of prescriptions will result in inconvenience to patients and delays in supplying the necessary medicines.

1.12 Authorisation for Non-Medical Prescribers and Administration/Supply under a Patient Group Directive

1.12.1 Non Prescribers

(i) Schedule 2 Controlled Drug

- Subject to robust governance, monitoring and training arrangements being in place, a PGD can be used for the supply and/or administration of diamorphine and morphine by nurses/midwives, pharmacists and paramedics for the immediate and necessary treatment of a sick or injured person (except for treatment of addiction).

Midazolam, Schedule 4 (CD benz POM) & 5 Controlled Drugs

- Subject to robust governance, monitoring and training arrangements being in place, these can be supplied and / or administered by any of the registered health professionals authorised to work under a PGD. This excludes anabolic steroids and the treatment of addiction.

1.12.2 Supplementary Non-Medical Prescribers

(i) Supplementary nurse and pharmacist prescribers can supply, prescribe, and administer or direct any person to administer the following:
Any CD as long as it is within the **Clinical Management Plan** specific to that patient and agreed between the designated supervisory medical practitioner (DSMP), the supplementary prescriber and the patient.

(ii) Chiropodists, podiatrists, physiotherapists, radiographers and optometrists who are supplementary prescribers are NOT able to prescribe CD's.

1.12.3 Patient Group Directions

The following CDs can be supplied or administered under Patient Group Directions (PGDs):

- Registered nurses, pharmacists, paramedics, midwives, ophthalmic opticians, chiropodists, orthoptists, physiotherapists, radiographers, occupational therapists, health visitors, dieticians, speech and language therapists and orthostists or prosthetists can supply and administer any drug listed in Schedule 4 of the Regulations except anabolic steroids and injectable formulations for the purpose of treating a person who is addicted to a drug. They can also supply and administer any drug listed in schedule 5 of the regulations.

- Whenever a supply or administration is made under a PGD or PSD supported by a care plan, a record must be made in the patients' notes, signed and dated by the person operating under the PGD/PSD (where an inpatient medication chart is not being used).

1.13 Midwives

Midwives can possess in their own right and administer parenterally, without a prescription, diamorphine, morphine, pethidine and pentazocine provided it is in the course of their professional midwifery practice. A midwife's records related to administration of medicines should be regularly audited by their named supervisor of midwives.

Further details can be found in section 7, SOP CDCOM1 & CDCOM2 – Community Nurses and Midwives management of controlled drugs.

1.14 Private Prescriptions

Private Prescriptions for controlled drugs to be dispensed by community pharmacists must be written on WP10 PCD or WP10 PCDSS. Prescriptions available fromNHS Shared Services Partnership.

1.15 Ordering of Controlled Drugs

1.15.1 Ordering

Controlled drugs must be ordered for ward stock using the official controlled drug order book for that ward/department. If clinical areas have more than one CD cabinet, there should be separate order books and registers. The order book must be kept in a locked place, and if missing the most senior nurse/midwife/ODP in charge must inform the appropriate departmental nursing manager, pharmacy and complete an incident form. All sections of the order book must be completed.

1.15.2 Who can order?

Only authorised registrants for example nurses, midwives, pharmacists, pharmacy technicians or ODPs can order controlled drugs for ward/theatre stock – authorisation is by the person in charge of the ward, clinic or theatre manager. The controlled drug requisition book must be completed, signed and sent to pharmacy.

1.15.3 Controlled Drug Stock

(i) Each ward/department should have a list of controlled drugs usually held as stock. This list should be agreed by the pharmacist/technician controlling stocks of medicines in that area and the registered nurse/midwife in charge. This list should be reviewed during the periodic CD inspection carried out by the pharmacist.

(ii) Controlled drugs ordered for ward/departmental stock can only be used to administer to patients on that ward against the inpatient prescription chart signed by an authorised prescriber

(iii) Ward stocks **must not** be issued to patients by ward staff for the purpose of taking home on discharge.

1.15.4 Out of hours' supply

The out-of-hours supply of a dose to another ward/clinical area should be authorised by the on-call pharmacist. The audit trail and record keeping must follow the guidance in the SOP – Administration of Controlled Drugs (SOP CDW4 and CDT4).

CDs should never be obtained from other Wards/ Departments during normal Pharmacy opening hours. If the request is very urgent the dispensary should be contacted and asked to prioritize and expedite the supply of the order needed.

Out of hours the on call pharmacist must be contacted and arrangements for supply agreed. This usually involves the pharmacist attendance on site to supply from pharmacy.

In exceptional circumstances when the medication is required urgently and the Pharmacy Department is closed, CDs sufficient for a **single dose** only may be obtained from another ward including PCAs or epidurals.

To obtain a CD from another ward, the on-call pharmacist should be contacted for advice and authorize the transaction.

The nurse requesting the supply should go to the ward where the required drug is held, taking the patient's drug chart to demonstrate the need for the supply.

The procedure specified in the controlled drug policy for administering and witnessing the administration of CDs must be followed. This means that the nurse from the ward where the drug is obtained **will accompany** the requesting nurse to the ward where the patient is to witness the administration.

The CD supplied is entered into the **supplying ward CD register**, this register then accompanies the nurse supplying the CD to the ward where it is required. Following administration, the nurse from supplying and receiving ward will sign the given by, witnessed by boxes of the CD register.
The **receiving ward** must then make an entry into their CD register against the name of the controlled drug – this should state the CD was administered from CD stock on ward x and both registrants involved should sign the entry and print their names. There will be no stock adjustment as the entry is to provide a cross reference of the process for audit purposes.

It is **NOT** permitted to transfer ward stock CDs from one Ward/ Department's CD cupboard, and Ward CD Record Book, to another. This would be seen as the nurse supplying a stock of a CD and would therefore be illegal

If there is any doubt as to the circumstances or the intention of the requesting nurse at any stage, this must be referred to the matron and pharmacy site manager, without hesitation.

1.16 Dispensing, Collection and transport of Controlled Drugs

1.16.1 Dispensing

There is an internal procedure for the dispensing of Controlled Drugs within the pharmacy department see the Standing Order Procedures - CDD2 and CDD9.

1.16.2 Collection and transport

(i) The identity of the staff/relative or patient representative collecting a CD for an individual patient from the Pharmacy must be recorded in the appropriate register in pharmacy department

(ii) Controlled drugs for ward stock may be delivered by pharmacy staff/porters or collected by ward staff. Both qualified and non-qualified staff can collect controlled drugs for ward stock provided they are official Health Board

employees with a full permanent Health Board identity badge on display when collecting the drugs. Staff delivering controlled drugs to an area must identify the key holder immediately.

(iii) Method of checking controlled drugs on collection from pharmacy is detailed in SOP: CDW 3 Procedure for the receipt of controlled drugs on wards and CDT3 – Procedure for the receipt of controlled drugs in Theatres. The person who accepts the CDs for transit should sign for receipt. This may be on the duplicate requisition or may be in a separate book or form for TTOs'.

NB Controlled drugs must not be transported in pneumatic tubes.

(iv) Transport of Controlled Drugs within and outside the Health Board must be by Health Board staff or by contractors that have a service level contract in place that includes authorisation to transport medication.

The Contractor does not need to obtain a Home Office licence for the transport of controlled drugs as this is exempt in the regulations.

Drivers must provide the issuing pharmacy with:

- An appropriate form of ID
- The transaction must be recorded in the transport log
- The log must be signed by the pharmacy staff and the delivery driver
- Pharmacy staff must ensure that completed controlled drug requisitions are received from the ward of department requesting the controlled drug

1.17 Receipt / Storage of Controlled Drugs on Wards and Theatres, and entry in the CD Register

(i) Each item must be signed for receiving by an authorised receiver.

(ii) The drugs once on the ward become the ultimate responsibility of the registered practitioner in charge of the ward at that time.

(iii) The top white copy of the CD order must then be returned to pharmacy

(iv) The drugs must then immediately be entered into the controlled drug register and the entry and balance checked and countersigned by a second authorised member of staff.

(v) Entries must be in ink (or otherwise indelible) and in chronological order.

(vi) Any CDs required to be stored in a CD cupboard must be secured in this way immediately.

1.17.1 Balance & checks of Controlled Drugs on Wards and Theatres

(i) Balance checks must be carried out at least once every 24 hours by authorised staff and the check documented and signed by both staff.

(ii) The balance check event must be recorded in the appropriate section of the Controlled Drug Register.

(iii) This is the responsibility of the ward senior registered practitioner in charge although this responsibility may be delegated.

(iv) Discrepancies should be reported immediately to the senior registered practitioner in charge of the ward who will then inform the Site Senior Manager and pharmacy. A Datix incident form must also be completed.

(v) Reconciliation of register balances against CD cupboard stock, and a sample of entries made against corresponding CD requisitions will be carried out periodically every **three to six months by pharmacy staff.** This is a joint responsibility between the ward/department manager and the pharmacist undertaking the check. Each controlled drug page must be signed by both parties that the content and balance are correct.

(vi) Additionally, a Senior Nurse/Midwife/ODP should undertake a **three to six months check of controlled drugs** by annotating the relevant page for each section of the CD register, to ensure that daily 24 hour checks have been carried out and that entries are consistent with policy.

1.18 Controlled Drug Cupboard & Keys

1.18.1 Controlled Drug Cupboard

The Service Group is responsible for ensuring that CD cupboards are in good working order.

(i) The controlled drug cupboard must be used for the storage of controlled drugs only and not for any other medication or items.

(ii) Controlled Drug cupboards or cabinets should conform to British Standard reference BS2881 or otherwise be approved by the Pharmacy Department.

(iii) In areas where higher security may be required, a security cabinet that has been evaluated against the SOLD SECURE standard SS304 (www.soldsecure.com) should be used.

(iv) No duplicate keys for controlled drugs must be kept in the clinical areas, any duplicates must be sent to pharmacy for destruction.

1.18.2 Key Management

The controlled drug cupboard must be kept locked when not in use and the key must not be common to any other key in the hospital.

The appointed practitioner (registered nurse/midwife, operating department practitioner, or other qualified person in charge of the ward/department) for each shift is responsible for controlling access to the controlled drug cupboard during that shift. The keys must be kept on the person of the appointed practitioner in charge. Staff requiring access to the controlled drug cupboard must return the keys to the Appointed Practitioner in charge when they have finished with the keys.
Key-holding may be delegated to other suitably-trained designated practitioners but the legal responsibility rests with the Appointed Practitioner in charge.

The CD key(s) must be held **separately** from the other medicine keys on a separate key ring.

At the end of each shift the Appointed Practitioner in Charge for the shift is responsible for handing the controlled drug keys over to the incoming Appointed Practitioner in charge.

Healthcare assistants, nursing or midwifery Students and auxiliary staff **are not** authorised to carry any keys for drug storage cupboards.
Pharmacists and pharmacy technicians are authorised to borrow controlled drug keys from designated Practitioners for a specific task, provided that the keys remain in the clinical area and are returned immediately after the completion of the task.
Pharmacists and pharmacy technicians must ensure they notify their presence to the Appointed Practitioner in charge.

If the CD keys **cannot be found**, every effort must be made to retrieve these as speedily as possible e.g. confirm that a staff member has the keys and to retrieve them as soon as possible. If there are doubts about the security of controlled drugs in the interim, the locks should be changed at the discretion of the

Appointed Practitioner in Charge using the HB incident reporting process. A HB incident form (Datix) must be completed.

When locks are changed or new cupboard are installed estates must provide all copies of keys to the practitioner in charge. The practitioner in charge must handover duplicate keys in person to pharmacy who will store securely or arrange for destruction. Where duplicate keys are stored, the duplicate key(s) must only be issued in an emergency in order to access the CD cupboard for patient care. No other sets of CD keys are permitted. If the location of the missing key is not established by the end of the appropriate shift then the locks must be changed.

Out of hours, the retrieval of a spare key will be at the discretion of the on-call pharmacist. Interim arrangements for supplying patient needs are outlined in this policy and may be more appropriate.

1.19 Patients' own Controlled Drugs

1.19.1 All controlled drugs, which a patient has brought into hospital are the legal property of that patient. Where the drugs belong to a patient who is taking them for reasons other than addiction e.g. analgesia, sedation, it is advisable to return the drugs to the patient's home with a reliable relative/carer. If this is not possible, the drugs should be stored in the ward controlled drugs cupboard and an entry made in a designated section of the ward register.

1.19.2 Where possible patients own drugs should be stored on a separate shelf to ward stock controlled drugs.
The following details should be recorded:

- Patient's name
- Drug name, form and strength
- Total quantity
- Date brought into hospital

1.19.3 Each separate drug for each patient must be recorded on a separate page of the CD register. Those areas handling large quantities of patients own drug may consider using a separate CD register for the recording of patients own drugs. Routine controlled drugs checks must also be applied to patients own drugs.

1.19.4 When the patient is discharged the controlled drug should be returned to the patient if clinically appropriate. The drug should be signed out of the register by a registered nurse/midwife and witnessed by another suitably qualified person. If the drug is not returned to the patient, it should be returned to the pharmacy for destruction with the ward pharmacist.

1.20 Administration of controlled Drugs

(i) Only persons deemed competent may administer controlled drugs to patients.

(ii) For all schedule 2 controlled drugs there must be two members of staff involved in the administration, one of whom must be a registered nurse (RN), midwife, doctor or ODP.

(iii) The second person i.e. the checker can be an RN, ODP, doctor, pharmacist or radiographer, level 1.

(iv) Two registrant procedure and recording in CD register is not required for schedule 3, 4 and 5 drugs **with the exception** in SBU of those drugs specified in section 1.24 below.

(v) Where a ward, department or clinical area is staffed by one registered practitioner, it is permissible for a HCSW and Radiographers' senior 1 to check controlled drugs with the registered practitioner. This must be only in **exceptional circumstances** and agreed beforehand with the relevant senior nurse and relevant professional lead. There must be a supporting statement signed by the senior nurse, professional lead and senior pharmacist for the managed unit

Within **specific settings**, previously agreed by the Health Board (e.g. Health Care Support Workers in HMP Swansea), an appropriately trained and competent individual can undertake the second checker function during the administration process of Controlled Drugs.

(vi) HCSW and radiographers' senior 1 are providing a second check to confirm that, with reference to the inpatient medication chart the following details are correct:

- Drug name, dose, expiry date and batch number
- Patient's demographic details.

However ultimate responsibility for the administration remains with the registered practitioner.

This process is only acceptable when there has been prior authorisation from the department head of nursing and is supported by a locally agreed policy. A list of those HCSW and Radiographers' senior 1 must be held by the department and be made available to the Accountable officer and Director of Nursing.

(vii) Student Nurses are not permitted to administer controlled drugs, as their role must remain observational only.

(viii) Administration of controlled drugs must be in accordance with the Health Board Medicines Policy.

(ix) **Controlled Drugs must not be administered if the prescription is unclear, illegible or ambiguous or there is any other reason for doubt (e.g. patient condition / response to previous doses).**

(x) It is important that controlled drugs are administered at the specified time and if not the reason must be documented. The reason for any doses drawn up but not then given should be documented in the controlled drug register.

(xi) The stock balance in the CD record book must be checked against the quantity in the CD cupboard. These must be identical. Discrepancies must be reported to the line manager, investigated immediately and other parties contacted when necessary/if not resolved. A similar line management approach should be used should the CD cupboard keys go missing. Incident forms must be completed where appropriate.

(xii) The CD must be prepared by a Registered Nurse/Midwife, ODP or doctor and checked by a second person deemed competent (as above) before administration.

(xiii) The person administering the drug must complete the entry in the CD record book and sign it **after** the drug has been administered.

(xiv) The second person must sign the CD book to confirm that the administration and appropriate disposal of excess / waste has been correctly carried out and recorded.

(xv) The administration record on the prescription sheet must be signed at the same time.

(xvi) Each different drug and preparation (i.e. form, strength etc.) must have a separate page in the CD record book. Therefore, if a dose requires the use of 2 strengths of a preparation both pages of the controlled drug register must be completed. All entries must be made in ink.

NB. Injectables should be for single use only unless the label specifically indicates it is licensed and intended for use on more than one occasion or to provide more than one dose on any one occasion.

1.20.1 Buprenorphine or methadone for the management of opioid dependence

Ensure that all patients in the inpatient setting are directly observed consuming their methadone or buprenorphine on the ward (note- for methadone, observe for at least 1 minute, for sublingual buprenorphine observe for at least 3 minutes, although this may take about 5 minutes). It is advisable to write in the note section of the drug chart "please supervise consumption" for any prescribed opioid substitute.

1.21 Controlled Drug Registers (See SOP CDW 11, CDT 11 & CDD14)

(i) Registers that meet current recording requirements will be maintained in the pharmacy and in all wards and departments where controlled drugs are stored. Registers must be bound (not loose leaf) with sequentially numbered pages.

(ii) Registers, requisitions, orders and private prescriptions for controlled drugs must be kept for two years from the date of the last entry whether in the original paper form or on a computer.

(iii) The CD Register may be used to record additional information / clarification in addition to the mandatory columns.

(iv) The CD Register must contain a **running balance** and the stock regularly checked at least once a day according to the agreed procedure.

1.22 Disposal & Destruction

The Health Board is responsible for ensuring appropriate arrangements are in place for securing the safe destruction and disposal of CDs.

All areas managing CDs must have appropriate arrangements in place for securing the safe destruction and disposal of CDs (including denaturing as appropriate).

All areas managing CDs must have robust arrangements in place to ensure the security of CD related waste

1.22.1 Return and Destruction of Stock Controlled Drugs and Patients Own Controlled Drugs

(i) This section of the policy is in accordance with current Home Office guidance, Waste Management Regulations and Environment Agency guidance. The methods used for denaturing are in accordance with national guidance.

(ii) Premises must register for a '*T28 waste exemption'* with Natural Resources Wales in order to allow the denaturing of CDs and to comply with the Misuse of Drug regulations (2001) - Natural Resources Wales \ Waste Exemption

(iii) Further guidance, including the types of waste and quantities covered by the exemption is available online at: https://www.gov.uk/guidance/waste-exemption-t28-sort-and-denature-controlled-drugs-for-disposal.

(iv) All instructions on the denaturing kit from the waste contractor, together with information outlined in the '*Medicines Ethics and Practice (MEP)'* must be followed as appropriate.

1.22.2 Ward Stock Drugs

Schedule 2 controlled drugs must be destroyed by an authorised witness.
Ward stocks of controlled drugs for destruction (e.g. Date expired/unable to be returned to pharmacy stock for re-issue – such as opened liquids) must be written out of the ward controlled drugs register, countersigned by a pharmacist and the registered practitioner in charge of the ward at the time. On return to the pharmacy department they must be entered into another register in the pharmacy department specifically for that purpose. – see Pharmacy SOP CDD5: Disposal/destruction of Controlled Drugs in the Pharmacy Department.

NB. Individual doses that are prepared and not administered/fully administered should be destroyed on the ward/department in the presence of a second person (who could be a pharmacist, registered practitioner or doctor). This includes the remains of partly used vials, which in the case of small volumes should be disposed of in a sharps bin. An entry of the destruction is to be made in the register with both parties witnessing the destruction.

1.22.3 Patients' Own Drugs supplied by Community Pharmacy/other legal entity

(i) Patient's own Schedule 2 and 3 controlled drugs may be destroyed in the **pharmacy department** by a pharmacist/registered pharmacy technician and witnessed by a second pharmacist/registered pharmacy technician, and a record of destruction will be made.

1.22.4 Named patient controlled drugs supplied by the hospital

(i) Schedule 2 Controlled Drugs stock can only be destroyed by an authorised witness. Schedule 3 drugs may be destroyed in the pharmacy department by a pharmacist/registered pharmacy technician, witnessed by a second pharmacist/registered pharmacy technician and a record made.

(ii) Patient's own controlled drugs that are for destruction must be disposed of in accordance with the Pharmacy SOP CDD5: Disposal/destruction of Controlled Drugs in the Pharmacy Department.

1.22.5 Persons Currently Authorised to Witness the Destruction of Controlled Drugs

These are specified in the Destruction CD guidance, Dangerous Drugs, Wales. The Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008.

1.22.6 Method of Destruction

(i) Recommended methods of destruction are provided by the General Pharmaceutical Council and include systems for denaturing. This is covered by the Pharmacy Department Controlled Drugs' SOP for destruction of CDs'.

(ii) Small volumes e.g. part ampoules/vials or doses drawn up but not given can be destroyed on the ward by emptying into a sharps bin with the then empty container. This can be done by and witnessed by authorised ward staff (registered nurse/midwife, operating department practitioner, pharmacist, doctor or anaesthetist).

(iii) Discontinued infusions/PCA syringes should be denatured on the ward. This must be carried out and witnessed by authorised ward/dept staff

Where the Service Group has made contractual arrangements with others to provide services on behalf of the health board, written assurance must be provided that they have appropriate arrangements for securing the safe destruction and disposal of CDs. Specifically, it must be clear that when an accredited Controlled Drug Authorised Witness is required to witness destruction of CDs, how this can be arranged.

1.23 Patient Controlled Analgesia/Epidurals

PCAs' / Epidurals for patients in theatres are recorded in the theatre CD record book. When a patient is transferred to a ward area there is no requirement to transfer the volume balance to the ward CD register. However, wastage of PCA/Epidurals must be recorded on a separate page of the ward CD register entitled PCA/Epidural/Infusion waste.

1.24 Controlled Drug Schedules

A useful source for information relating to drug schedules may be found at https://bnf.nice.org.uk/guidance/controlled-drugs-and-drug-dependence
In addition, the following should be noted:

Midazolam

Midazolam is a Schedule 3 controlled drug. This means that the following must apply as a minimum for the handling of midazolam:

- Signed requisitions are required in order to supply midazolam.
- Invoices are to be kept for two years.
- Midazolam can still be included in PGDs.
- CD prescription requirements apply.
- Prescriptions are valid for 28 days.
- The prescribers address must be in the UK.
- Repeats are not allowed
- Midazolam is not subject to safe custody requirements
- Record keeping is not necessary however; some areas based on risk assessment may decide to keep records of supply and administration in a separate section of the CD register.

- There is a separate SBU HB policy statement on the use of Midazolam. This document gives guidance on the use of low and high strength Midazolam and which areas of the organisation should routinely stock each product. This guidance is contained within Appendix 3.4 of this document.

Ketamine

Ketamine is classed as a schedule 2 controlled drug (CDPOM).

Note: Exemptions are in place to allow the continued use of ketamine by specified Healthcare professionals under Patient Group Directions.

Tramadol

Tramadol is classified as a Class C, Schedule 3 controlled drug (CD No register POM). The following will therefore apply: -

- Signed requisitions are required to order a supply of tramadol.
- Invoices are to be kept for two years.
- Tramadol can be included in PGDs.
- CD prescription requirements apply.
- Prescriptions are valid for 28 days.
- The prescribers address must be in the UK.
- Repeats are not allowed.
- Tramadol is not subject to safe custody requirements.

Pregabalin and Gabapentin

Pregabalin and Gabapentin are classed at schedule 3 controlled drugs (CD no register POM), however they will be included in the list of “exempted drugs” in the safe custody regulations and therefore they will not be required to be stored in the CD cupboard.

The following will therefore apply: -

- Signed requisitions are required to order Pregabalin and Gabapentin
- CD prescription requirements apply
- Prescriptions are limited to 30 days’ treatment
- Repeat prescriptions are not authorised
- Prescriptions must be dispensed within 28 days

- Safe custody regulations do not apply
- Gabapentin and Pregabalin may be included in PGDs
- The prescribers address must be in the UK
- Record keeping is not necessary
- Invoices are to be kept for 2 years

Temazepam

- Temazepam is required to meet full prescribing requirements for schedule 2 and 3 CDs. Further information on prescription requirement for Schedule 2 and 3 controlled drugs can be found in the Medicines Ethics and Practice (MEP)

  Record keeping is not necessary.

Phenobarbitone

- Signed requisitions are required in order to supply Phenobarbitone.
- Invoices are to be kept for two years.
- Phenobarbitone can still be included in PGDs.
- CD prescription requirements apply.
- Prescriptions are valid for 28 days.
- The prescribers address must be in the UK.
- Repeats are not allowed
- Phenobarbitone is not subject to safe custody requirements – but in SBU Health Board, good practice is to store the product in the inner section of the CD cupboard.
- Record keeping is not necessary. *In practice SBU Health Board advocates keeping records for the supply received and administration of Phenobarbitone.*

Buprenorphine

- Signed requisitions are required in order to supply Buprenorphine.
- Invoices are to be kept for two years.
- Buprenorphine can be included in PGDs.
- CD prescription requirements apply.
- Prescriptions are valid for 28 days.

- The prescribers address must be in the UK.
- Repeats are not allowed
- **Buprenorphine is subject to safe custody requirements.**
- Record keeping is not necessary. *In practice SBU Health Board advocates keeping records for the supply received and administration of Buprenorphine.*

Morphine Sulphate 10mg/5ml (oramorph)

Oramorph 10mg/5ml is not subject to safe custody requirements. However, in SBU Health Board it must be stored in the outer section of the CD cupboard. (In clinical areas where the CD cupboard does not include an outer section it must be stored in the CD cupboard).

A CD requisition book is not required to order stock.
Records in controlled drugs registers are not required.
Administration to patients may be a single nurse procedure measured using an oral syringe.

Note: Oramorph 100mg/5ml concentrated oral liquid is a schedule 2, controlled drug and is therefore subject to safe custody and prescribing regulations.

Mifepristone 200mg Tablets

- Mifepristone is not a controlled drug; however, the standard operating procedure for the supply of mifepristone for the termination of pregnancy requires the drug to be requisitioned on a controlled drug requisition book.
- Mifepristone details will be held in the pharmacy controlled drug register and all issues will be subject to recording in the register.
- Mifepristone must be stored in the controlled drug cupboard
- All issues to patients must be recorded on the appropriate page of the ward controlled drug register
- Mifepristone will be subject to same daily ward checks as all other controlled drugs and the pharmacy 3 to 6 monthly ward CD audits.

Penthrox (methoxyflurane inhalation vapour)

- Penthrox is not a controlled drug. However, to ensure appropriate use it will only be stored in the Controlled Drugs Cabinet of the Burns Theatre in Morriston Hospital.
- Penthrox does not need to be recorded in the controlled drug register.
- Penthrox does not need to be ordered using a CD drug requisition.
- Orders to pharmacy must be on a named patient basis using a proforma and prescribed on the inpatient drug chart.

1.25 Legislation NHS and private prescriptions for CDs:

(i) Prescriptions for schedule 2, 3 and 4 CDs are valid for 28 days from either the date of prescribing or a "valid from" date specified by the prescriber and written on the prescription.

(ii) There is a recommendation that prescriptions for schedule 2, 3 and 4 CDs are limited to a quantity necessary for up to 30 days' treatment. If a greater quantity is required in exceptional circumstances, this must be confirmed with the pharmacist, and the reason written on the prescription and in the register.

(iii) The handwriting requirements for schedule 2 and 3 CD prescriptions are not required. Only the signature needs to be in the doctors own handwriting.

(iv) Prescriptions with minor technical errors, but where the prescriber's intentions are clear, may be dispensed provided the pharmacist completes the details in indelible pen and signs the addition e.g. words and figures requirement for total quantity. The pharmacist may complete if only one has been given on the prescription.

(v) Prescriptions must contain a unique patient identification number (hospital number for hospital patients if the NHS number is not available). There is a space on NHS and private prescription forms for the collector to sign for receiving schedule 2 or 3 CDs. The pharmacist has the discretion not to supply if this section B is not signed.

(vi) The pharmacist must confirm the identity of the person collecting Schedule 2 CDs, and may ask for identification. The pharmacist must obtain the collectors name, address and proof of identification if they are a health care professional (HCP).

(vii) Good practice recommendation is that prescribers do not prescribe/administer CDs for themselves, close family or friends except in exceptional circumstances. See Guidance on Self Prescribing by Medical Staff.

1.25.1 Additional changes affecting private prescriptions: -

There are new prescription forms for private prescriptions for dispensing by a community pharmacy. These are called WP10PCD and WP10PCDSS are for schedule 2 and 3 CDs.

Copies of private prescriptions for schedule 2 or 3 CDs dispensed by a community pharmacy are sent to Health Solutions Wales at the end of each month for analysis.

1.25.2 Record keeping requirements: -

- CD registers may be kept in computerised form provided:
- the author of each entry is identified
- entries cannot be altered at a later date
- a log of all data entered is kept and can be recalled for audit purposes. Controls must be kept in place to minimise the risk of unauthorised or unnecessary access and adequate backups must be made.
- Registers, requisitions, orders and private prescriptions for CDs must be kept for 2 years whether in the original paper form or on a computer. References – section 8; Appendices – section …..
- The CD register can be used to record additional information to that required.
- The CD register should contain a running balance – good practice but likely to become mandatory. This facilitates reconciliation of stock levels/register balance.
- Records must be kept for all patient returned schedule 2 CDs (good practice to keep records for all patient returned CDs).

1.25.3 Inspection and Monitoring are: -

- An Accountable Officer who is responsible for the safe management of CDs within their organisation must be appointed by all NHS, and private organisations.

- Approved Standard Operating Procedures (SOPs) must be in place and adhered to governing the handling of CDs.
- GPhC inspectors must co-operate with other bodies and share relevant information (e.g. with the accountable officer).
- GPhC inspectors will incorporate, as good practice, CD monitoring and inspection as part of their routine visits.

The number and groups of people authorised to witness the destruction of CDs will be extended.

1.26 Automated Methadone dispensing service

All procedures are governed by specific SOPs.

1.27 Concerns/suspicion of diversion/mismanagement of Controlled Drugs

The Service Group must have a clear process to enable staff to raise concerns/suspicion of potential diversion/mismanagement of CDs. The Service Group must ensure that such concerns/suspicions are fully investigated (involving HR/Counter Fraud colleagues as appropriate, at the earliest opportunity for support and advice with the investigation). See also, Appendix 3.6 - Policy advice where there is an unexplained loss or suspected/actual diversion of medication on Wards and departments in Swansea Bay UHB.

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3.0 APPENDICES

3.1 VALID PRESCRIPTION FORMS

The following prescription forms can be dispensed by NHS pharmacy contractors in England & Wales:

Is this prescription form valid?

Only certain types of prescription forms can be dispensed on the NHS, so it is important for community pharmacy contractors to be able to identify which form types are valid and allowed, and which are not. Form types can be identified by the code on the bottom right of a prescription. The table below indicates the prescriptions forms that can be dispensed by NHS community pharmacies in England and Wales.

Forms originating in England

Colour of form	Form type	Who they are used by	Further information
Green	FP10SS	GP Community Practitioner Nurse Prescriber Nurse Independent/Supplementary Prescriber Independent Prescribers Supplementary Prescribers Hospital Unit	Prescriptions must be annotated with the type of prescriber issuing it, for example, community practitioner nurse prescriber (formerly known as district nurse/health visitors) or nurse independent prescriber. Forms annotated with the initials RD are repeat dispensing forms. Forms annotated with the initials RA are repeat authorisation forms. Further information can be found on our Who can prescribe what? page.
	FP10NC	GP	
	FP10HNC	Hospital Unit	
Blue	FP10MDA-SS	GP Nurse Independent/Supplementary Prescriber Independent Prescribers Supplementary Prescribers Hospital Unit	Prescriptions must be annotated with the type of prescriber issuing it. Further information can be found on our pages Who can prescribe what? and Instalment Dispensing.
	FP10MDA-S	GP	

	FP10MDA-SP	Independent Prescriber Supplementary Prescribers	
	FP10HMDA	Hospital Unit	
Yellow	FP10D	Dentist	Only items listed in the Dental Formulary (Part XVIIA of the Drug Tariff) can be prescribed on this prescription form. Dentists are strongly advised to prescribe generically; however, they can prescribe by its brand equivalent name provided it is not listed in Part XVIIIA of the Drug Tariff (the blacklist). Further information can be found on our Who can prescribe what? page.
Lilac	FP10PN	Community Practitioner Nurse Prescriber Nurse Independent/Supplementary Prescriber	Prescriptions must be annotated with the type of prescriber issuing it. Unless annotated with Independent/Supplementary prescriber, only items listed in the nurse formulary can be prescribed on this prescription. Further information can be found on our Who can prescribe what? page. FP10P-REC are used by OOH providers to record items supplied directly to a patient and not dispensed through a community pharmacy. These forms, are submitted to Pricing Authority directly by the OOH provider through their own account.
	FP10SP	Community Practitioner Nurse Prescriber Nurse Independent/Supplementary Prescriber	
	FP10P-REC (Non-FP10 supply form)	Out of Hours (OOH) Centre prescribers	
White online	FP10CDF	Controlled Drug requisition form	The buff coloured FP10CDF Controlled Drug requisition form to obtain Schedule 2 and 3 Controlled Drugs for stock from a community pharmacy

			has been replaced with a new approved mandatory requisition form which is available from the NHSBSA website. Requisitions must be received on the new mandatory form. Further information can be found on our Controlled Drug prescription forms and validity and Who can prescribe what? pages.
Pink	FP10PCDSS	Private prescribers issuing Schedule 2 and 3 Controlled Drugs dispensed by community pharmacy	Prescriptions must be annotated with the type of prescriber issuing it. Copies need to be sent to the Pricing Authority separately to NHS prescription forms at the end of the month for audit purposes. You will need a private dispensing code, which is separate to your normal OCS code, when you fill in the FP34PCD under A/C ID. Further information can be found on our Controlled Drug prescription forms and validity and Who can prescribe what? pages.

Forms originating in Wales

Form type	Colour of form	Who can use or what they are used for	Further information
WP10 WP10SS WP10SP WP10HP WP10HSP	**Green**	GPs, hospitals and supplementary prescribers.	Forms annotated with the initials RD are repeat dispensing forms. Forms annotated with the initials RA are repeat authorisation forms.
WP10D	**Green**	Dentists in primary care.	Only items listed in the dental formulary can be

			prescribed on this prescription.
WP10CN WP10PN	**Green**	Nurse prescribers.	Only items listed in the relevant formularies can be prescribed on this prescription.
WP10MDA WP10HP(AD)	**Green**	Instalment dispensing prescription form.	More information on can be found on our Instalment Dispensing page.

Forms originating in Scotland

Form type	Colour of form	Who can use or what they are used for
GP10 GP10SS	**Peach**	GPs.
GP10(N)	**Lilac**	Nurse prescribers.
GP14	**Yellow**	Dentists.
HBP	**Blue**	Issued in secondary care.
HBP(A)	**Pink**	

Forms originating in Northern Ireland

Form type	Colour of form	Who can use or what they are used for
HS21 HS21CS	**Shaded Green and Pink**	GPs.
HS21D	**Yellow**	Dentists.
HS21X HS21XCS	**Shaded Green and Pink**	Non-Medical Prescribers Nurse Independent Supplementary Prescribers Pharmacist Independent Supplementary Prescribers Optometrists Independent Supplementary Prescribers

HS21N HS21NCS	**Shaded Green and Pink**	Community practitioner nurse prescribers.

Please note – Instalment dispensing has no specific form type in Northern Ireland and can occur on HS21, HS21N, HS21X, SP1 & SP2 forms (SP1 & SP2 forms are used by Consultants in secondary care to provide substitute prescribing drugs in primary care, it would be unlikely for these forms to be presented to a pharmacy outside of Northern Ireland).

Forms originating in the Isle of Man

Form type	Colour of form	Who can use or what they are used for
HS10	**Pink**	GPs, dentists and hospital prescribers.
HS10MDA	**Blue**	Instalment dispensing form.
HS10	**Green (handwritten)**	Nurse prescribers.
HS10	**Pink (computer-generated)**	Nurse prescribers.
HS10	**Purple**	Pharmacy prescribers.
HS10SS	**Pink**	Hospital prescribers.

3.2 DRUG SCHEDULES

CLASSIFICATION

The 2001 Regulations classify CDs into five Schedules according to the different levels of control attributed to each:

- Schedule 1 (CD Lic POM)
- Schedule 2 (CD POM)
- Schedule 3 (CD No Register POM)
- Schedule 4 (CD Benz POM & CD Anab POM)
- Schedule 5 (CD INV P and CD INV POM)

The BNF includes CD classification information for Schedule 1 to 4 medicines within the monograph.

SCHEDULE 1
(CD LIC POM)
Most Schedule 1 drugs have no therapeutic use and a licence is generally required for their production, possession or supply. Examples include hallucinogenic drugs (e.g 'LSD'), ecstasy-type substances, raw opium and cannabis (for further information see section on Cannabis-based products for medicinal use in humans', moving some cannabis products from Schedule 1 to Schedule 2).

SCHEDULE 2
(CD POM)
Pharmacists and other classes of person named in the 2001 Regulations have a general authority to possess, supply and procure Schedule 2 CDs when acting in that capacity.

Schedule 2 includes opiates (e.g. diamorphine, morphine, methadone, oxycodone, pethidine) major stimulants (e.g. amfetamines). quinalbarbitone and ketamine.

SCHEDULE 3
(CD NO REGISTER POM)
Schedule 3 CDs include minor stimulants and other drugs (such as buprenorphine, temazepam, tramadol, midazolam and phenobarbital) that are less likely to be misused (and less harmful if misused) than those in Schedule 2.

From 1st April 2019, gabapentin and pregabalin were rescheduled as Schedule 3 CDs.

SCHEDULE 4
(CD BENZ POM OR CD ANAB POM)
Schedule 4 is split into two parts:

Part 1 (CD Benz POM)
Contains most of the benzodiazepines (such as diazepam), non –benzodiazepine hypnotics (such as zopiclone), and Sativex (a cannabinoid oromucosal mouth spray)

Part 11 (CD Anab POM)
Contains most of the anabolic and androgenic steroids, together with clenbuterol (an adrenoceptor stimulant) and growth hormones.

SCHEDULE 5
(CD INV POM OR CD INV P)
Schedule 5 contains preparations of certain CDs (such as codeine, pholcodine and morphine) that are exempt from full control when present in medicinal products of specifically low strengths.

For further details, refer to the table in Medicines Ethics and Practice

3.3 RECEIPT OF CONTROLLED DRUGS FORM

Reference:
001-08

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Bae Abertawe
Swansea Bay University Health Board

Receipt of Controlled Drugs

Background

The Government's response to the Shipman Inquiry's Fourth Report was set out in *Safer Management of Controlled Drugs.* The response accepted the need for strengthening the current systems for managing controlled drugs to minimise the risks to patient safety of the inappropriate use of controlled drugs. Controlled drugs are subject to special legislative controls because there is a potential for them to be abused or diverted, causing possible harm. However, as the Inquiry recognised, there have been major advances in the therapeutic use of controlled drugs in the last few years. Controlled drugs are now an essential part of modern clinical care. Strengthened controls must be implemented in a way that supports professionals and encourages good practice in the use of these important medicines when clinically required by patients.

It has become a legal and good professional practice for pharmacies to collect the following information when supplying controlled drugs. If you are unsure or would like further information, please ask to speak to a pharmacist.

Please complete following information:

Person responsible for collecting the medication (please tick)

- O Patient
- O Patient Representative
- O Healthcare professional acting on behalf of the patient in professional capacity

Name:

Address

Proof of identity Yes or No

Signature Date

3.4 HIGH STRENGTH MIDAZOLAM

Pharmacy Department

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Bae Abertawe
Swansea Bay University Health Board

High Strength Midazolam

BACKGROUND

In December 2008, the National Patient Safety Organisation issued a Rapid Response Report entitled *"Reducing risk of overdose with midazolam injection in adults"*.

Between November 2004 and November 2008, the NPSA received 498 incidents of adult patients being given the wrong dose of midazolam injection when used for **conscious sedation**. This includes the death of three patients. 48 incidents resulted in moderate harm to patients and the other 447 were low or no harm to the patients involved.

Midazolam is available in three strengths, a low dose 1mg/1ml and high dose strengths of 2mg/ml and 5mg/ml. The presentation of **high strength midazolam** as **2mg/ml** (5ml ampoule) or **5mg/ml** (2ml and 10ml ampoules) exceeds the dose required for most patients. There is a risk that the entire contents of high strength ampoules are administered to the patient when only a fraction of this dose is required.

The original decision of the SBUHB Medicines Management Group was to restrict the use of high strength Midazolam to designated areas within the former Trust to include Palliative Care and certain designated wards on the hospital sites. Palliative care patients are cared for in multiple settings outside of the Palliative care wards. This has led to delays in accessing high strength Midazolam. The original NPSA alert covered conscious sedation, **palliative care was outside the scope** of the Rapid Response Report. Subsequently the original criteria have been revised.

DECISION OF THE SBU HB MEDICINES MANAGEMENT GROUP

In response to the NPSA rapid response report, and following a risk assessment for the use of Midazolam within the SB hospitals, the SB Medicines Management Group decided that:

- High strength Midazolam **will** be accessible on all wards where palliative care takes place and Midazolam is **NOT** used for conscious sedation.

- Low strength Midazolam (1mg/ml) is restricted to those areas where conscious sedation is performed, For example ITU, Theatres, Endoscopy or minor surgery and, in the community for a range of dental procedures or interventions in community hospitals.
- Flumazenil must be stocked in all areas stocking **all** strengths of midazolam injection.

OBTAINING HIGH STRENGTH MIDAZOLAM IN NON-STOCK AREAS

On occasions, the use of high strength Midazolam will be justified on wards where the drug is not held as stock. The procedure to obtain a supply is outlined below:

In pharmacy working hours

- All requests for high strength Midazolam must be written as a requisition in the Ward Controlled Drug order book.

- The in-patient drug chart containing the prescription for high strength Midazolam supply should accompany the Controlled Drug order book to the pharmacy department. However, if the pharmacist has countersigned the ward CD requisition book on the ward, there is no need to send the chart to pharmacy.

- Once the patient prescribed the high strength Midazolam no longer requires the drug or has left the ward, any remaining drug should be returned to the pharmacy department.

Outside dispensary opening hours

- Outside pharmacy dispensary working hours, high strength Midazolam should be obtained from the area within the hospital designated to hold the drug as stock as detailed in the hospital CD policy (section 3.1):

    - A nurse from the ward that requires the high strength Midazolam must complete a requisition for the drug in the Ward Controlled Drug order book.

    - The senior nurse/duty manager/midwife must visit the area holding the stock with the Ward CD book and drug chart.

    - The nurse/midwife in charge of the supplying ward issues the high strength Midazolam from ward stock, and signs the CD order book to confirm the supply.

- The senior nurse/duty manager/midwife signs the CD order book to accept delivery, and the white copy of the CD requisition is removed from the book and held on the ward that provided the supply.

- The nurse/midwife in charge of the supplying ward accompanies the senior nurse/duty manager/midwife to the patient. The administration is witnessed and the inpatient medication chart signed by both supplying nurse/midwife and the most senior nurse/midwife on the receiving ward/dept.

3.5 Reporting a Controlled Drug related incident or concern

Purpose
To ensure that all Controlled Drug (CD) related incidents and concerns are reported and recorded in a consistent manner to enable accurate reporting to the SBUHB Accountable Officer for CDs.

Procedure/Process – In addition to the guidance below details on the actions to be followed where there are discrepancies involving controlled drugs are outlined in the main controlled drugs policy.

Reporting incidents:
Where an incident involving CDs has occurred this should be reported in accordance with the Health Board Incident policy and procedure via the Datix system.

When completing the Datix online incident report it is important to:

- Select the speciality which has responsibility for the area in which the incident took place. This may be a different speciality to the person reporting.
- **Ensure that 'controlled drugs' is selected in the 'Additional Incident Information' section.**
- If necessary, attach all relevant documentation to the incident report including e-mail correspondence etc.

When updating/following up an existing Datix incident report it is important to:

- Use the 'Notepad' function to record pertinent information relating to the incident. This will be time and date stamped with the name of person updating the notepad.
- Attach relevant documentation to the incident report including e-mail correspondence/preliminary reports etc. where appropriate.

Reporting concerns:
It is important that concerns involving the management of CDs are reported in order to address any underlying issues that could result in an incident occurring at a later date.

CD concerns should be reported as follows:

- Please report concerns about the management of Controlled Drugs to CDAO directly at SBU.CDAO@wales.nhs.uk or 01792-704068.
- Need further information or advice regarding the management of Controlled Drugs? Please contact your hospital pharmacy department or email SBU.cdao@wales.nhs.uk

Follow up and closing of incidents

Acute sector controlled drug incidents reported on Datix are reviewed on a six weekly basis, at a meeting between the relevant Pharmacy Manager and Delivery Unit Governance Lead (or other nominated senior member of staff).

The review will check that assurances for appropriate actions have been completed, once the incident is under investigation this must be completed within 30 days.

A report of all incidents is presented to the Accountable Officer at the CD Operational Meeting.

Appendix 3.6

Policy advice where there is an unexplained loss or suspected/actual diversion of medication on Wards and departments in Swansea Bay UHB.

CONTENTS

1.0	Introduction

1.1	This policy outlines the processes to be followed when stock discrepancies of medicines, including patients own drugs, in a ward or other clinical area are suspected or identified.

2.0	Purpose of policy

2.1	The purpose of this policy is to provide a process for investigating and managing unexplained loss or excessive use of medication on wards and departments in Swansea Bay UHB. The policy refers to the management of schedule 2-5 controlled drugs. However, the principles detailed in the policy can be applied to any other drugs in Health Board premises. Losses or excessive use can occur for many reasons including incorrect documentation or reconciliation in registers on drug charts and suspected or actual incidents of diversion of drugs by Health Board staff. This policy provides a recommended process for investigating potential loss or excessive use of medication. It also provides advice to be followed where there is suspicion of drug misappropriation or abuse by a member of Health Board staff.

3.0	Policy Statement

3.1	All staff must be aware of the correct policies and guidelines to be followed to ensure robust governance in the safe, secure and appropriate handling of medicines. Staff must be aware of the correct processes to follow in the event that there is a suspected loss or excessive use of medicines on the ward or department. Staff must also be vigilant for signs of drug misuse or abuse by Health Board staff. The contents of this policy provide advice and guidance where suspected loss or excessive use of medication is suspected.

4.0	Roles and Responsibilities

4.1	Committees 5.1.1 Medicines Policy Group are responsible for updating and maintaining this policy. The policy is endorsed by the Medicines Management Operational Group and Nursing and Midwifery Board.

4.2	Ward and departmental managers Ward and department managers are responsible for the storage and security of medicines and medicines keys in their area at all times. This may be delegated but overall responsibility remains with senior named registrant on duty for the shift.

5.0	**Procedure**

5.1	Unexplained loss or excessive use can be considered under the following categories: 1. A discrepancy between stock, individual named patient or patients own drugs and the controlled drugs register and/or inpatient prescription chart. 2. Unexplained increased use or loss of controlled drugs (CDs) or drugs liable to misuse (DLM) 3. Unauthorised access or use of CDs/DLM 4. Concerns relating to suspected diversion of CDs/DLM by Health Board staff. In all situations the ward manager / senior manager in charge must carry out an immediate investigation where there is: 1. A discrepancy between stock, individual named patient or patients own drugs and the controlled drugs register and/or inpatient prescription chart. a) Check that entries in the register have been calculated correctly and that entries have been made on the correct page. b) Reconcile doses of the relevant medication against the in-patient drug charts and register. This should include any other strengths/dose formulations of medication stocked on the ward/department as incorrect doses may have been administered. In some instances, drugs with similar names may also be included in the investigation. c) A pharmacy report on issues of relevant drug(s) to the ward /department will be provided for review. d) A member of the Senior management team of the delivery unit must also be informed It may be necessary to retrieve patient notes/drug charts where the patient has previously been discharged. 2. Unexplained increased use or loss of CDs/drugs liable to misuse (DLM) Controlled drugs and DLMs are monitored as part of the six monthly CD check completed by pharmacy and nominated registrant on the ward/department. Additionally, pharmacy staff as part of their routine supply service may identify an unusual pattern of use. Any unexplained loss or use must be reported immediately to a member of the senior pharmacy team, ward manager and matron for the

	ward/department. An investigation into the discrepancies will be instigated at the time of first reporting. The investigation will involve a) Procedures described in point 1 (above) b) Review whether there has been a change in case mix on the ward/department or a change in clinical pathway or treatment regimen that has resulted in a change in the use of medication. 3. Unauthorised access or use of CDs/DLM Where it has been determined that there has been unauthorised access to or use of CDs/DLM the investigation will involve all potential HB staff members Further guidance is given in section 5.2 (below) 4. Concerns relating to suspected diversion of CDs/DLM by Health Board staff. Where it has been determined that staff are involved in suspected diversion please refer to section 5.2 (below)
5.2	Where it has not been possible to identify a reason for unexplained loss or excessive use of medication through investigations into reconciliation, documentation errors, changes in case mix or known changes in patterns of drug use the suspected diversion of drugs or drug abuse by staff must be investigated. It may therefore be necessary to introduce additional controls and checks on relevant drugs on the ward/department. This will be agreed between pharmacy and the delivery unit following discussions with senior pharmacy and speciality managers. All changes to the management of stock, including ordering processes and documentation must be agreed by the senior pharmacy manager, senior manager for the ward/department and matron. Additional controls for consideration include: Remove current stock of the drug and move to named patient supply only. Where the drug balance and transactions are not currently documented in the CD register under current regulations (e.g. Schedule 4/5 drugs) consider maintaining records in the CD register in accordance with CD regulations. Where drugs are not stocked in the CD cupboard, consider relocating the stock to either the inner or outer section of the CD cupboard.

	Consider additional balance checks. This can include additional checks for CDs' over and above current policy requirements. Additionally, regular checks for DLMs will be instigated. A log will be maintained by pharmacy of any additional controls that have been implemented. The log will be retained and reviewed by the Accountable Officer for CDs Where additional controls for managing the drug are implemented a timeline must be agreed for the additional controls in place. This should not normally exceed a period of six months. The period must be agreed by the ward/departmental manager, the senior pharmacist and speciality manager. This should also be communicated to the Delivery Unit's quality and safety committee. All staff must be informed of the requirement to record stock receipts and administration of the medication involved. During this time-frame there must be regular audit of the medication by the ward/departmental manager and ward pharmacist An incident form must be completed in line with the Health Board's Incident Reporting Policy and Procedures. Where a member of staff wishes to raise concerns and/or the incident is considered serious in relation to the management of controlled drugs, then the accountable officer for controlled drugs may be contacted directly on 01792 704068 **De - escalation process** There should be a formal review meeting with a senior pharmacy lead, ward manager and matron. Depending on the background to any incident it may be necessary to involve a representative from Human Resources. There will be a review of the investigation findings, the monitoring data and record to note a formal close down of the monitoring including assurances. The monitoring log will be updated by pharmacy. The information will be formally reported to the Delivery Unit via the Quality and Safety Committee by the unit's governance lead. **Who to inform** In circumstances where HB staff are suspected of inappropriate access and or use of drugs the following personnel must be informed: Senior nursing or departmental staff and senior pharmacist.

	Clinical Director for Pharmacy and Medicines Management. In addition, further senior staff should be informed depending on the profession of the staff member suspected of theft. For example: Doctor: Inform Head of Service or Clinical Director Midwife: Inform supervisor of Midwives Nurse: Inform Clinical Lead or Matron / Head of Nursing Other practitioner e.g. physiotherapist: Inform Head of Service Student: Inform University tutor Other actions may be implemented at the discretion of the Senior site team. This may also include the involvement of the police or other agencies such as local counter fraud. If there is actual evidence of medicines theft or the member of staff admits to theft, the police should be contacted. The decision to contact the police must be taken by the site Senior team. If drugs cannot be located and there is no reason established for the absence this should be taken as theft and a there will need to be a discussion with counter fraud on contacting the police. Outside agencies may be also be involved where there has been forced entry and loss of whole containers of medicines and/ or medical gases.

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Swansea Bay University Health Board

6.0

Log of Schedule 3, 4 & 5 Medicines with increased controls

Site	Speciality	Ward / Department	Drug	Controls in place	Lead for Ward / Department	Reason for additional Controls	Start Date	Review Period	Action Post Review Period

3.7 CHECKLIST FOR CONTROLLED DRUGS

Ward / Department Controlled Drugs Audit Form

To Ward Manager: Ward/Dept:..... From:

All controlled drugs (CDs) and records held on wards/departments should be checked by Pharmacy on a three to six monthly basis. A check was carried out on your ward / department on:

I am passing the results on to you in writing so that you can inform your staff that:

Everything is in order, and that CD's are being ordered/stored/recorded following the correct procedures		There are problems which MUST BE corrected (see below) and rechecked within 1 month	

Audit Standard	Pass/Fail	Details (Include page numbers & dates)
1. Checking levels of CDs correspond to those recorded in the register. Including checking the calculation of balances.		
2. Confirming CD levels are checked on a daily basis.		
3. Confirming daily balance checks are signed for by two nurses		
4. Checking CDs are received into the register and signed for by two members of staff one of which must be a registered nurse. Ensuring balance received is entered into register		
5. Checking that two signatures are entered into the register for each administration of a CD. All details of administration must be completed accurately.		
6. Checking that details of transfers of CDs to a new page are recorded appropriately – page to…, page from…. date, form, strength etc. and signed by **two** members of staff.		
7. Check that the security arrangements for the storage of CDs and CD stationery is in line with Health Board policy.		
8. Check there are no crossings out or use of liquid paper for corrections		
9. Ensuring each page number in the register can be accounted for and stock level is counted to zero for pages not in use.		
10. Checking the audit trail for CDs returned to pharmacy (sample of 2).		
11. Check a sample of administrations on inpatient charts against the CD register		
12. Ensure that balances transferred to another page only occur when that page is completed.		
13. Review use of non stock CDs, looking at unusual patterns of usage, and current stock list.		
14. Ensure any patient own drugs are accounted for and signed into and out of the register		
15. Review current ward/department CD stock list. Ensure any updates are communicated to senior technician pharmacy		
16. Check naloxone is stored in the designated area on the ward.		
17. Other details noted (include notes on use of schedule 4/5 drugs: dihydrocodeine, codeine, co-codamol 30/500, co-dydramol, diazepam, lorazepam, zopiclone)		
Recommendations: Action taken by ward manager:		

Checks completed by:

1. Name / Signature / Title / Date:……..(Pharmacy)
2. Name / Signature / Title / Date:……..(Ward/Department)

N.B. *The Ward Manager MUST act on the above recommendations and report outcomes to their Senior Nurse/Manager within one month of check date.*

Appendix 3.8

Theatre Controlled Drug (CD) Audit Tool

Theatre …… Date…… Auditor/s……

Key: Observe = O Check = C Ask = A

Criteria	Data Source	Yes / No / NA	Comment	Action
1- Key Security				
1.1 - There are two signatures for the sign out of the CD keys in the Key Register on the day of audit, and a named individual noted as in charge of the keys (not applicable for Recovery and Obstetrics theatre as keys are held by a number of registrants during shift)	**A O**			
1.2 - There are two signatures for the sign in of the CD keys in the Key Register on the day preceding the audit	**A O**			
1.3 - CD Keys are kept separate from other keys	**C**			
1.4 - CD keys are in the possession of the registrant named in 1.1 above. (note: In recovery and obstetric theatre areas keys will remain in possession of any registrant during the shift)	**C**			
2- CD Ordering/Documentation				
2.1 - The CD order book, CD register and Reconciliation log book are stored	**A O**			

in the CD cupboard or in appropriately secure storage				
2.2 – All CDs are signed as received into the register by two registered members of staff	**C**			
2.3 – The amount received is entered into the register along with the serial number of the requisition and the balance is updated Guidance: Cross reference the CD register with the CD order book for 5 transactions.	**C**			
2.4 - Details of the transfer of CDs to a new page are recorded appropriately to include page to…., page from…., date, form, strength etc. and signed by two registered members of staff Guidance: Check 5 page transfers	**C**			
3 – Criteria	**Data Source**	**Yes / No / NA**	**Comment**	**Action**
3.1 – confirm that there are not any crossings out in the CD register. (y= no crossings out; N= crossing out) (Guidance:- If a mistake has been made in a CD register it should be bracketed so that the original entry is legible, marked as an “error” with an	**C**			

explanation provided in the discrepancy section and a new, correct entry made on the next line.)				
4 - Checking of CD stock Balance				
4.1 – A Two person CD reconciliation check was undertaken before the list started on the day of the audit and is signed as complete in the check log	**A C**			
4.2 – A correct CD balance was confirmed at the pre-list brief on the day of the audit	**A O**			
4.3 – A two person CD reconciliation check was undertaken at shift handover (if applicable)	**A C**			
4.4 – A two person CD reconciliation check has been signed as undertaken by two registrants at end of the list on the day preceding the audit, or the last list undertaken if the theatre has not been in use on the preceding day*	**A C**			
4.5 - There is a record that all reconciliation checks have been undertaken in the CD register or in the reconciliation check log, signed by two registrants. (go back 3 months)	**C**			
5- Administration Guidance: check 5 records for 5.2-5.5				

5.1 - There are no CDs left unattended / unsecured on any work surface (Y= no CDs left out; N= CDs left out)	**O**			
5.2 - There is an entry of the date, time, and patient's name and number for every transaction in the CD register. Records of drugs received from pharmacy are exempt.	**A C**			
5.3 - The registrant who made a supply against a patient record and the anaesthetist receiving it (witness) have both signed the register and the amount given is recorded**	**C**			
5.4 – In the intraoperative theatre setting the anaesthetist administering the drug has signed the CD register and the amount administered is recorded or In recovery or obstetrics theatres setting the administration has been signed for, the amount recorded; and signed as witnessed, by two discrete registrants**	**C**			
5.5 - The anaesthetist responsible for destruction of any non-administered drug and the registrant witnessing have both signed the CD register. **	**C**			

5.6 The amount of drug destroyed is recorded accurately – i.e. it is the amount remaining when the administered amount is deducted from the supplied amount.	**C**			

Checks completed by:

1. Name / Signature / Title / Date:……(Pharmacy)
2. Name / Signature / Title / Date:……(Ward/Department)

* Not applicable for recovery.

** In recovery and obstetrics the second person (witness) may be another registrant other than an anaesthetist.

Appendix 3.9

Record of CD Returns to pharmacy from Ward by pharmacy	**Ward:**		**Pharmacy and Medicines Management**
	Date:		

Drug (Name, Form, Strength)	**Quantity Returned**	**Requisition number or TTO or POD (include patients name)**	**Issuing out of ward/unit CD**		**Processing of CD Return in Pharmacy**	**Receipt into pharmacy custody**		**Returned on JAC (Name and Signature)**	**Balances match off Register and JAC**
			Signatory	Witness	D =Destroy R =Re-use	Signatory	Witness		

For guidance on using this record, please consult SOP-DP05. For guidance on returning CD's please, consult SOP CDW9 or CDT1

Appendix 3.10

CHECKLIST FOR CONTROLLED DRUGS – GP OOHs

Controlled Drugs Audit Form

All controlled drugs (CDs) and records held in GP OOHs should be checked by Pharmacy and a GP OOH registrant on a six monthly basis.

Audit Standard	Pass / Fail	Details (Include page numbers & dates)
1. Checking levels of CDs correspond to those recorded in the register. (Including checking the calculation of balances).		
2. Confirming CD levels are checked on a daily basis. (register is held electronically)		
3. Confirming daily balance checks are signed for by two individuals (1st person must be a registrant & 2nd may be non-registered if no registrant available).		
4. Checking CDs are received into the register and signed for by two members of staff. (1st person must be a registrant & 2nd may be non-registered if no registrant available). Ensure balance received is entered into register.		
5. Checking that two signatures are entered into the register for each administration or supply of a CD. (1st person must be a registrant & 2nd may be non-registered if no registrant available). All details of administration must be completed accurately.		
6. Checking that details of transfers of CDs to a new page are recorded appropriately – page to…, page from…. date, form, strength etc. and signed by **two** members of staff. (1st person must be a registrant & 2nd may be non-registered if no registrant available).		
7. Check that the security arrangements for the storage of CDs and CD stationery is in line with Health Board policy.		
8. Check there are no crossings out or use of liquid paper for corrections.		
9. Ensuring each page number in the register can be accounted for and stock level is counted to zero for pages not in use.		

10. Ensure that balances transferred to another page only occur when that page is completed and completed by two members of staff. (1st person must be a registrant & 2nd may be non-registered if no registrant available).		
11. Review current CD stock list. Ensure that stock levels are appropriate.		
12. Other details noted (include notes on use of schedule 4/5 drugs: e.g. co-codamol 30/500, diazepam).		
Recommendations: Action taken by GP OOHs:		

Check completed by:

Name: …… (Pharmacy)

Signature/ Date: ……

Name: …… (GP OOHs)

Signature/ Date……..

Appendix 3.11

Key Messages to Support Management of CDs in Theatres

http://howis.wales.nhs.uk/sites3/docmetadata.cfm?orgid=926&id=462719

COIN clinical online information network

Swansea Bay University Health Board

Authorisation Form for Publication onto COIN

PLEASE ENSURE THAT ALL QUESTIONS ARE ANSWERED – IF NOT APPLICABLE PLEASE PUT N/A

COIN ID.	CID398
Document Title.	Policy for the Management of Controlled Drugs
Name of Author.	Medicines Policy Group
Name of Lead Pharmacist.	Amy Jayham, Head of Pharmacy Operations
Is the document New, Revised or a Review of a previous version.	Revised (V21.03)
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Is the document relevant to the GP Portal.	No
Sign to confirm that the document has been authorised by an approved governance process in a specialty or delivery unit.	
If NICE guidance been considered/referenced when producing this document, please provide the title or reference number.	N/A
Please provide a brief description/abstract of the document.	This policy focusses on the management of Controlled Drugs (CDs) specifically across SBU and should be considered supplementary to the wider SBU Health Board Medicines Policy.
Equality Statement. *(All policies and procedures need to comply with CID76 Policy for the Management of Heath Board Wide Policies, Procedures and other Written Control Documents (WCD).*	Yes
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