STANDARD OPERATING PROCEDURES TO SUPPORT THE POLICY FOR THE MANAGEMENT OF CONTROLLED DRUGS IN SWANSEA BAY UNIVERSITY HEALTH BOARD

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1.0 INTRODUCTION

1.1 Health Board procedures will include details of the ordering, collection/transport, receipt, storage, administration, handover of keys, returns, checking/audit trail, destruction and disposal, use of patient's own CDs, borrowing of CDs out of hours in an emergency, and dealing with patients/staff suspected of illicit drug usage.

1.2 These SOPs should be approved by the Accountable Officer (or delegated individual) as they are accountable for all systems for the safe management of CDs within the Health Board. They should also ensure that all staff are aware of these SOPs as part of a training programme.

1.3 Pharmacy Procedures will also be in place covering responsibilities within the pharmacy and the interface with wards/departments/patients and external agencies. The Pharmacy Procedure should also include details of stock control/security, issue and supply to patients, control of CD stationery and signature verification.

1.4 The regulations also require Accountable Officers to complete a periodic declaration covering whether or not their organisation keeps stocks of controlled drugs and whether there are special circumstances that might explain any seemingly unusual patterns of prescribing or supply. A self-assessment of CD management will be completed including the availability of appropriate Standing Operating Procedures.

SECTION TWO

2.0 WARD PROCEDURES FOR THE HANDLING AND STORAGE OF CONTROLLED DRUGS AT SBU HEALTH BOARD

2.0.1 Introduction

These procedures have been introduced following the publication of the Safer Management of Controlled Drugs (CDs) in Secondary Care, by the Department of Health which were set up following the Shipman enquiry. The 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 in wards by bringing current arrangements & practice into line with the (new) regulatory frameworks. In addition, the SOPs provide a reference tool for new & existing staff in relation to this topic.

2.0.2 Because of their potential for abuse or diversion, with potential harm or criminal activity, CD's are subject to special statutory controls. These legislative controls have been further strengthened by recent governance guidance from relevant organisations as mentioned above. These SOPs detail the responsibilities, procedures, and good practice required to safely & accountably manage CD's on wards, in such a way as not to impede on the appropriate use of CD's to meet patient need.

2.0.3 Scope of these CD Standard Operating Procedures

These Standard Operating Procedures (SOPs) apply to all staff involved in the ordering, receipt, dispensing, checking, delivery, destruction or audit of controlled drugs within SBU Health Board. This SOP covers every aspect of the CD journey from Pharmacy to a patient, including prescribing, supply, ordering, storage, security, administration and disposal of medicines as well as alert, investigative, & documentation systems in the event of discrepancies, deviations from SOP, or other problems.

2.0.4 Responsibility

All pharmacists, qualified technicians, pre-registration pharmacy graduates and student technicians under supervision handling controlled drugs at the SBU Health Board pharmacy departments are expected to follow these procedures. These procedures also apply to nurses and midwives handling, delivering, receiving or witnessing the destruction of controlled drugs. The responsibility for establishing and maintaining a system for the security of medicines used within wards and the operating department lies with the *Accountable Officer*.

Under the present Regulations, the most senior registered nurse or midwife in charge of a ward is legally responsible for the safe & appropriate management of CD's. The Ward Manager ultimately has overall responsibility for this, but these duties are normally delegated to the most senior registered nurse/ midwife on duty on a day to day basis. This person can delegate control of access (i.e. key-holding) to the CD cupboard to another, such as a registered nurse/ midwife or doctor, each of whom are

professionally accountable for their own actions. However, legal responsibility remains with the registered nurse or midwife in-charge. Similar considerations apply to the requisitioning and checking of CD's.

2.1 WARD SOP CDW1: ORDERING OF CONTROLLED DRUGS FOR WARD/DEPARTMENT STOCKS

Purpose

The purpose of this CD SOP is to ensure that staff are aware of the process for ordering controlled drugs from the pharmacy department for use on wards at the Health Board. CD's held in each ward as stock items should reflect current patterns of usage of CD's in that ward, and modifications at appropriate intervals should be agreed between the responsible pharmacist, the ward manager, and appropriate medical/nursing staff. The CD's list should be listed in the front pages of each individual ward CD Drug Register.

Procedure / Process

The controlled order book specified for the ward must be used for the ordering of controlled drugs using a separate page for each item. An authorised registered nurse, midwife or ODP can generate an order for the required controlled drugs.

1. Controlled drugs must be ordered in the controlled drug order book specific to that ward or department. Order books from other areas cannot be used.
2. A separate page must be used for each item ordered.
3. Place the carbon paper in between the top and lower page with the carbon placed down. If the carbon paper is missing, then an identical entry should be made on the top and bottom sheets.
4. If the CD is on the stocklist, then the order may be sent directly to pharmacy.
5. If the CD is not usually kept as stock, the in-patient medication chart for the patient requiring the drug must accompany the order book.
6. When a non-stock CD is no longer required it must be returned to pharmacy at the earliest possible opportunity.
7. Orders must contain the following details:-
    - Hospital name.
    - Ward or department name
    - Name, form strength, volume, quantity of the controlled drug to be ordered. (Only agreed abbreviations should be used.)
    - Signature of person ordering
    - Person ordering should print name also
    - Date of the order.
8. The person who accepts the CDs for transit should sign for receipt on the tear out / white copy. This white copy must be retained in pharmacy and stored accordingly.
9. The person who receives the CDs on the ward must sign the pink duplicate copy of the requisition retained in the order book and should, ideally, not be the same person that ordered the CDs in question.

Notes

- Ward stocks must NEVER be issued to patients by ward staff for the purpose of taking home on discharge.
- Should an area have more than one controlled drugs cabinet then each cabinet must have an order book and register, specific to that cabinet.

- Controlled drugs order books, like all controlled stationery, must be kept in a secure place. Should an order book go missing, the most senior registered practitioner in charge must inform the Head of Nursing/Directorate Manager and pharmacy. An incident report form must be completed.
- In the event of an emergency, where the CD order book cannot be accessed, emergency orders can be placed in an “ad hoc order book” which is held by pharmacy.
- Controlled Drugs must be ordered directly from pharmacy and cannot be supplied as stock between ward/departments. In an emergency and when authorised by the duty manager in conjunction with the emergency duty pharmacist the following course of action should be employed:-
  - If the CD is available elsewhere in the Health Board, the senior nurse/midwife/duty manager must visit the area holding the stock with the drug chart. The nurse/midwife in charge of the ward completes the CD register entry, which is countersigned by the senior nurse/midwife/duty manager.

  The nurse/midwife in charge of the supplying ward accompanies the senior nurse/midwife/duty manager 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/department.

2.2 WARD SOP CDW2: PROCEDURE FOR THE COLLECTION OF CONTROLLED DRUGS FROM PHARMACY

Purpose

The purpose of this CD SOP is to ensure that staffs across the Health Board are aware of the process for collecting controlled drugs from the pharmacy department.

Procedure / Process

1. When the controlled drugs are ready in pharmacy and are to be collected by the ward or department, pharmacy will ring the ward to collect if the CDs are not to be delivered by the pharmacy, qualified or unqualified.
2. The ward sends down an approved qualified or unqualified member of staff, (the messenger), to collect the controlled drugs. The approved member must present HB identification.
3. The messenger, with a member of the pharmacy staff, checks the controlled drugs. This will be by an actual check of the drugs dispensed against the order in the requisition book. This check will include:-
   - the correct drug
   - the correct form
   - the correct presentation size, (e.g. 1ml or 10ml amps)
   - the correct strength
   - the drug is in date

- the correct quantity (this would include opening packages which are unsealed and counting the contents)

4. If all items are correct, the messenger signs and dates each page ordered and the messenger must check the unique security/seal/log number that is recorded on the order books requisition.
5. The top copy (white copy) is torn out and left with the pharmacy.
6. The ordered stock should be transferred up to the ward by the messenger in a sealed container.
7. The messenger delivers the CD(s) to the ward and hands them directly, and in person, to a registered practitioner. The authorised person will then check and then print and sign for receipt of the CD's in the presence of the messenger. The pink copy should be annotated with the signature of the receiver. At this point the CD's become the responsibility of the member of staff signing for receipt. Any discrepancy must be reported to pharmacy immediately. Security of the CDs must be maintained at all times.

Notes

- Both qualified and non-qualified staff who the ward/departmental manager considers competent, including health care assistants and porters, can undertake collection of controlled drugs for ward stock. The member of staff however, must be an official Health Board employee and possess the full permanent Health Board identity badge. This badge must be on full display when receiving the controlled drugs from pharmacy.
- When collection is made by non qualified staff, they are acting in the capacity of a "messenger."
- Pharmacy may refuse to supply CDs to any member of staff, not in possession of a Health Board ID badge.
- Couriers collecting controlled drugs for transport to areas outside of the hospital site must only be those working for companies approved by the Heath Board and therefore covered by the appropriate Service Level Agreement (SLA). The identity of the driver must be confirmed and recorded in accordance with the SOP.

2.3 WARD SOP CDW3: PROCEDURE FOR THE RECEIPT OF CONTROLLED DRUGS ON WARDS/DEPARTMENTS

Purpose

The purpose of this CD SOP is to ensure that all staff are aware of the procedure for managing the receipt of controlled drugs on wards at SBU Health Board.

Procedure / Process

1. Whenever possible, different persons should be responsible for the requisitioning & receipt of CD's. When delivered to wards/departments, CD's should never be left unattended and should be handed over to locally-agreed appropriate & identifiable individuals.

2. On arrival at the ward/department, a non-qualified messenger must hand the goods to an authorised receiver who must inspect each individual item, check there is the correct quantity and product, check the expiry date and sign the receipt section on the pink copy of each order sheet in the presence of the messenger. When qualified staff collect CDs from pharmacy and have signed the white copy, it would be good practice for another qualified member of staff to sign the pink copy to confirm receipt on the ward. For stock schedule 2/3 CDs the 'Accepted by' section in the CD requisition books must be completed in the presence of the person making the delivery before they release the supply to the person accepting the delivery. The person must print and sign the paperwork.
3. The authorised person receiving the controlled drugs, and a witness, (registered or an approved non registered member of staff), must enter each item in the controlled drugs register on their allocated pages and the final balance must be checked and countersigned. The entry must include at least:
    - the date
    - quantity received
    - requisition number
    - signature of receiver
    - new stock level
    - signature and countersignature of the witness confirming correct balance in register

    NB: Whole sealed boxes of controlled drug injections received from pharmacy, can be assumed to contain the quantity specified on the label until the seal is broken. The box does not need to be opened to check the quantity, but may be received as the quantity specified on the label.

Notes

- Once the controlled drugs have reached the ward or department they become the ultimate responsibility of the person who at that time is in charge of the ward or department.
- Any discrepancies must be reported to pharmacy immediately and an incident form completed.
- A separate part of the register must be used for different preparations and presentations of controlled drug with the drug identification being written at the top of each page including the strength.
- No cancellation, obliteration or alteration of any entry may be made.
- Corrections must made be by way of marginal notes or footnotes which must be signed and dated.
- Errors in the register are to be bracketed and endorsed "error", signed and countersigned by a witness.
- All records must be stored for two years from the date of the last entry in the register.
- It is good practice for the ordering and receiving of controlled drugs not to be done by the same person where possible.

2.4 WARD SOP CDW4: PROCEDURE FOR THE ADMINISTRATION OF CONTROLLED DRUGS TO PATIENTS

Purpose

The purpose of this CD SOP is to ensure that all staff are aware of the correct procedure for documenting the administration of controlled drugs to patients at the Health Board.

Procedure / Process

NPSA advice

The NPSA advises that when opioid medicines are prescribed, dispensed or administered, in anything other than acute emergencies, healthcare practitioner concerned, or their clinical supervisor, should:

- Confirm any recent opioid dose, formulation, frequency of administration and any other analgesic medicines prescribed for the patient. This may be done for example through discussion with the patient or their representative (although not in the case of treatment for addiction), the prescriber or through medication records.
- Ensure where a dose increase is intended, that the calculated dose is safe for the patient (e.g. for oral morphine or oxycodone in adult patients, not **normally** more than 50% higher than the previous dose).
- Ensure they are familiar with the following characteristics of that medicine and formulation: usual starting dose, frequency of administration, standard dosing increments, symptoms of overdose, common side effects.

Administration process

1. Controlled drugs ordered for ward stock can only be administered to patients on that ward against an inpatient prescription written by an authorised prescriber employed by the Health Board or acting as a locum for the Health Board or those staff in possession of a Honorary Contract with the Health Board.
2. An entry must be made in the controlled drugs register against the item each time a dose is administered.
3. Wards /units /departments should finish one box of ampoules before opening the next, to aid stock control and daily counts. When the seal of a box of controlled drug injections is opened, if any of the ampoules are found to be broken or missing, a record must be made in the Controlled Drug Record Book in the usual way by two registered practitioners. If there is no identifiable cause for missing stock, the ward pharmacist must be notified immediately. In all cases of loss or breakage, the ward nurses/midwives discovering the loss must complete an incident form.
4. The entry must include :-
    - the date
    - the time
    - patient name and hospital number or NHS number
    - amount given
    - signature of staff member administering
    - signature of witness to the administration
    - balance (should be countersigned as correct)

5. The administration of controlled drugs in hospital is a two person procedure. The first person should be a registered nurse/ midwife or doctor. The second person checking may be any of the above, or a pharmacist, radiographer senior 1, a registered ODP or an appropriately trained healthcare support worker – HCSW. (Refer to section 1.15 of the Main CD Policy).
6. Both persons MUST check and witness the entire procedure from preparation to actual administration and both must sign and date the prescription form and the controlled drug register.
   In certain ward areas where patients are individually nursed or located in cubicles e.g. critical care units it may not be possible for a nurse/midwife to leave the patient to go to the CD cupboard. In these circumstances one registered nurse/midwife must witness the entire procedure from preparation to actual administration. A second registered practitioner may witness the assembly of drugs and handover to another registered practitioner who is looking after the patient.
7. When part of a dose is administered, e.g. 5mg morphine, from a 10mg ampoule, the fact that 5mg is wasted should be entered in the CD register and witnessed by another member of staff.
8. When a liquid CD bottle is completed the balance should be amended to account for tolerable discrepancies due to manufacturing fill processes and loss during dose measurement. Any suspicious discrepancy or that greater than 10% must be investigated appropriately and referred to the senior manager and pharmacy. Amendments should be carried out by two registered practitioners as detailed below:
   - A new line is entered in the controlled drug register
   - Entry will state date, time, ‘end of bottle balance amendment’ and the actual balance.
   - This is signed by the first registered practitioner.
   - The second registered practitioner countersigns this entry.

Notes

- Controlled drugs ordered for ward stock can only be administered to patients on that ward and cannot be transferred to patients on another ward except in an emergency and when authorised by the duty manager in consultation with the on-call pharmacist.
- Administration of CDs to patients should take place in accordance with the directions in the Health Board Medicines Policy.
- Should a dose be wasted (e.g. a liquid dose measured and then refused by the patient) then the dose should be destroyed by emptying into a sharps bin which is then treated as mixed pharmaceutical waste/sharps. An authorised member of the ward staff must witness the destruction. The destruction of the wasted dose must be documented in the controlled drugs register and the entry countersigned by the witness.
- If the dose prescribed is made up of two presentations then two entries are required in the CD Register, each entry giving the patient’s total dose as well as the quantity /dose booked out for that item.
- When administering medicines intended for oral / enteral route:

- Only use oral / enteral syringes that cannot be connected to intravenous catheters or ports.
- Do not use intravenous syringes to measure and administer oral liquid medicines.
- Ensure that stocks of oral / enteral syringes are available in relevant clinical areas.
- When patients or carers need to administer oral liquid medicines with an oral syringe, ensure they are supplied and counselled on the use of the oral or enteral syringe.

2.5 WARD SOP CDW5: PROCEDURE FOR THE BALANCE CHECKING OF CONTROLLED DRUGS ON WARDS/DEPARTMENTS

Purpose

The purpose of this CD SOP is to ensure that staff are aware of the correct procedure for balance checking controlled drugs on wards and departments across the Health Board. A running balance check must be made each time there is stock movement of a controlled drug, that is, administration of a CD to a patient, however, this CD SOP describes routine checks which should be undertaken regularly.

Procedure / Process

1. The balance of controlled drugs is to be checked at least every 24 hours by two Registered Nurses or Midwife. Where there is only a single registered nurse or midwife present the second person maybe an approved non-registrant.
2. Each page of the controlled drug register must be checked and any balance present, including patient's own, must be reconciled against the contents of the controlled drug cupboard by the nurse/ midwife in charge and a witness. Any controlled drug in the cupboard not recorded in the register must be treated as a discrepancy and investigated as advised below.
3. An entry in the controlled drugs register must be made stating that the balance has been checked and should be signed/date/time by both the person checking and the witness.
4. Because the designated nurse / midwife in charge will change from shift to shift it would seem appropriate to reconcile the stock at shift change, the check being undertaken by the nurse / midwife in charge of both shifts. This should be at least once in every 24 hour period.
5. Recording of checks must be in a designated section of the CD register or a separate book, that are the responsibility of the registered practitioner in charge of the ward/department. These records must be retained for two years from the last date of entry and be capable of being produced for inspection at any time.
6. On discovering a discrepancy, action should include:
    - Recounting balance again and by another individual authorised to do so.
    - Rechecking all entries have been made
    - Rechecking the balance has been calculated correctly

- Stock has not been separated and stored in another area of the controlled drugs cabinet
- Checking patients known to be prescribed the medication in question, to ascertain whether doses are recorded as being administered, but not recorded in the CD register.

Notes

- Any discrepancies must be fully investigated.
- A sealed box of ampoules should not be opened until needed for use. Two members of authorised staff should then witness and record any breakage or shortage. Similarly, a CD ampoule inadvertently smashed after removal from the CD box should be recorded on a separate line in the CD Register, and witnessed accordingly.
- A 10% or less differential is considered acceptable in the case of liquids.
- If the discrepancy remains, the nurse or midwife in charge of the ward must be informed. If the discrepancy cannot be resolved the ward manager must be informed and pharmacy involved.
- In the event of discrepancies or apparent loss, the nurse or midwife in charge of a ward or department is responsible for ensuring that pharmacy is informed on the next working day and an incident report form completed.
- Serious Incidents are to be reported to the Senior Nursing Manager for that area and the Accountable Officer on the next working day. An incident form must be completed.

2.6 WARD SOP CDW6: MANAGEMENT OF CONTROLLED DRUG CUPBOARD KEYS

Purpose

The purpose of this CD SOP is to ensure that staffs are aware of the correct procedures for managing controlled drug keys across the Health Board.

Procedure / Process

Possession and handover of keys

1. The controlled drug keys must be in the possession of an authorised staff member at all times.
2. At handover, the keys must be returned to the shift leader of that shift who in turn will pass them over to the shift leader taking over.
3. Controlled drug keys **must not** be handled by health care assistants. At the discretion of the ward sister/charge nurse/midwife, the controlled drug keys may be handled by bank or agency Registered Nurses/midwives who ***regularly*** work on the ward/unit/ department.
4. The controlled drug keys to both the outer and inner CD cabinets must be kept separate from all other keys used on the ward or department. Note – access to the controlled drug cupboards is a two person procedure.

Loss of keys

1. Loss of keys must be reported to the Ward/Department manager and Directorate Head of Nursing following a thorough search of the ward/department.
2. If spares are available, they may be accessed.
3. An incident form must be submitted and locks changed if considered a security risk (liaise with the site security manager).

Notes

- The registered practitioner or midwife in charge is responsible for the CD keys.
- Key-holding may be delegated to other suitably-trained, registered healthcare professionals but the legal responsibility rests with the registered practitioner or midwife in charge.
- The controlled drug key should be returned to the registered practitioner or midwife in charge immediately after use by another registered member of staff.

For the purpose of stock checking, the CD key may be handed to the Pharmacist or any other authorised member of the pharmacy staff (e.g. the pharmacy technician responsible for stock control of medicines on the ward) but access and verification of stock balance remains a two person procedure

2.7 WARD SOP CDW7: PROCEDURE FOR THE HANDLING OF PATIENTS' OWN CONTROLLED DRUGS

Purpose

The purpose of this CD SOP is to ensure that staffs are aware of the correct procedures for handling patients' own CDs across the Health Board.

Procedure / Process

If the medicines are not needed on the ward: One of the following options should be taken and all actions recorded:-

1. If the patient wishes, the medicines may be returned home via an identified adult. Responsibility for security is given to that adult. If the medicines are not safe and/or not appropriate for use, then the patient and/or patient's agent should be advised and they should be encouraged to allow them to be sent to pharmacy for safe destruction.
2. If the patient or the patient's carer agrees, medicines may be sent to the pharmacy for safe destruction. The pharmacist should take responsibility for the removal of patients' own CDs from a ward, their destruction and recording of said destruction and the record of destruction must be countersigned by a witness.

Notes

Controlled drugs belonging to patients should, as with other patient's own medication, be treated as patient's own property. There may be instances, as with other patient's own medication, when patient's own controlled drugs may require to be administered. In these

circumstances the criteria below on using patient's own controlled drugs needs to be followed.

If the medicines are needed on the ward:

1. The drugs should be checked for suitability according to the Health Board Policy for Patient's Own Drugs (POD's).
2. Where patients self-administer their own medicines including controlled drugs – CDs should be stored in the ward CD cabinet and not in the bedside locker. Access should be a two person procedure – both of whom should be members of Health Board staff.
3. Recording of patients own drugs must be in accordance with section 1.14.3 of the Main CD Policy.

Storage of Parents Own Controlled Drugs

Controlled drugs of parents of children who are patients within the Health Board and are unable to leave the premises may need to store their drugs on the ward. These drugs must be stored in the ward controlled drug cupboard. An entry must be made in a designated section of the ward controlled drug register.

The medication may be given to the parent on request from the parent and returned to the ward controlled drug cupboard immediately, once a dose has been taken by the parent. One registered nurse/midwife and the parent must sign the register each time the stock is removed and returned to the cupboard. A separate entry is required for each transaction. The container(s) of medication will be included in the daily controlled drug stock check, but nurses/midwives are not expected to record a balance of dose units. A senior manager (service manager or nominated deputy) must be informed when a parents' controlled drug is being stored on the ward.

Note: The role of the Health Board in the process is to store the medication safely on behalf of the parent.

Notes

- When pharmacy is closed, the CDs should be entered into the register and stored in a sealed bag within the ward / theatre CD cabinet. When pharmacy opens on the next weekday, the ward pharmacist should be informed and asked to remove the drugs for destruction.
- Controlled Drugs belonging to patients may only be used when the presentation is identifiable and in a tamper proof (blister) packaging or presentations.
- Ward stock should be ordered at the next available opportunity unless the patient is only in for a short stay and it would not be feasible to obtain hospital stock.
- Palliative care patients who may require an admission to hospital for medication assessment and patients with a chronic / long term pain problem who are self medicating are amongst those who may need to use their own controlled drug medication.
- If a patient dies, controlled drugs belonging to that patient cannot be legitimately handed back to a relative and should be disposed of via pharmacy according to Health Board policy.

- If a patient's therapy is changed and / or they no longer require a controlled drug preparation, then it is justifiable to ask for the drugs to be destroyed in the presence of a pharmacist/according to local policy. The patient or their next of kin should be informed of this action.

2.8 WARD SOP CDW8: PROCEDURE FOR THE DESTRUCTION OF CONTROLLED DRUGS AT WARD LEVEL

Purpose

The purpose of this CD SOP is to ensure that staff across the Health Board are aware of the correct procedures for the destruction of controlled drugs at ward level. Staff also need to be aware of which controlled drugs can be destroyed at ward level, and which need to be destroyed in the Pharmacy Department.

A CD ceases to be classified as such once it is denatured or dissipated, is not re-useable, or has been rendered irretrievable. Once disposed of, it should be unrecognisable as a CD. Unused part doses of CD should be destroyed promptly, and the CD to be discarded should be rendered irretrievable by fully emptying the contents of the ampoule/vial/syringe into a sharps bin or clinical waste bag. The emptied vial or ampoule should then also be placed in the sharps bin. Smashed CD ampoules should be discarded into a sharps bin. Emptying of waste CD's into sinks or drainage systems is not permitted. Out of date products must be returned to the issuing pharmacy for recording and disposal in accordance with existing legislation.

Procedure / Process

Controlled Drugs which can be destroyed at ward level include:

- Individual doses that are prepared and not administered (State the reason why not administered.)
- The remains of partly used vials or PCA devices. (This must be actioned before the device is returned to Theatre).
- The remains of part doses (e.g. 25mg from a 50mg ampoule).
- Complete ampoules that have been damaged or smashed.

1. Controlled drugs for destruction at ward level (see notes below) are to be destroyed in the presence of a witness who could include another authorised nurse / midwife, pharmacist, doctor, radiographer senior 1, a registered ODP or an appropriately skilled HCSW.
2. An entry of the destruction is to be made in the register and countersigned by both parties witnessing the destruction.
3. Destruction of small volumes of liquids (including PCAs) should be by emptying into a sharps bin which is then labelled as mixed pharmaceutical waste/sharps.
4. When removing a patch that contains a controlled drug e.g. fentanyl or buprenorphine; fold the patch so that the adhesive sticks to itself. Place the folded patch into original outer pouch. This pouch should then be placed in a yellow sharps bin for disposal. This should be completed before a new patch is applied.

NB: The destruction of the contents of PCA devices should be witnessed and the drug(s) and volumes disposed of must be recorded in the CD register. This record should match that recorded on the PCA prescription chart or the inpatient medication chart (where a PCA prescription chart is not in use).

Notes

- All out of date ward stocks of controlled drugs are to be returned to pharmacy for destruction by the Health Board Authorised Person.

2.9 WARD SOP CDW9: PROCEDURE FOR RETURNING CONTROLLED DRUGS BACK TO PHARMACY

Purpose

The purpose of this CD SOP is to ensure that staff across the Health Board are aware of the correct procedure for returning controlled drugs to the Pharmacy Department.

Procedure / Process

1. When a controlled drug is no longer required by a ward, the ward must give notice to pharmacy for its removal.
2. The item is booked out of the controlled drug register and the new balance written against the entry. This must be a two person procedure with both staff members signing the register.
3. Removal of all controlled drugs - whether they are ward stock or patient's own must be counted and / or measured in the presence of the registered practitioner making the entry and the pharmacist or ward technician returning the drugs.
4. The balance entry must be countersigned both by the nurse/midwife making the entry and the pharmacist or technician removing the drug.
5. The record of return of controlled drugs to pharmacy form of Main CD Policy (appendix 3.9) must be completed by ward/department and pharmacy registrants.
6. The drug will be processed on return to pharmacy, the record form to confirm receipt completed and the record form stored in the pharmacy department.

Ward Closure

(i) For wards permanently closing arrangements should be made with pharmacy to return all drugs to the pharmacy and ensure safe custody of drug cupboard keys.

(ii) Wards closing for short periods of time, (e.g. over Christmas) must arrange with pharmacy to remove all controlled drugs for storage in pharmacy. Staff must perform a stock check and sign in the relevant section of the CD register.
The drugs and CD Register are stored in the pharmacy. On re-opening, the drugs and CD register are returned to the ward/dept, and a stock check undertaken immediately.
For non- controlled drugs, a risk assessment must be undertaken to determine if the drugs may be left in locked cupboards in the ward/dept.

Notes

- Controlled Drugs that are left to become date-expired constitute a waste of resources.
- All ward stock of controlled drugs no longer required on the ward / department must be returned to pharmacy for destruction or for reissue if appropriate at the earliest opportunity.
- Arrangements for the removal of controlled drugs and storage of controlled stationery during ward closures/moves and subsequent re-stocking should be made in advance with the ward pharmacist and dispensary manager.
- If controlled drugs belonging to the patients are to be sent to pharmacy/destroyed an entry should be made against the record of the storage, and the removal countersigned/dated by the pharmacist and authorised nurse/midwife witness.
- Before a patient's own medicine is sent to pharmacy, including controlled drugs, the permission of the patient or their guardian must be granted.

2.10 WARD SOP CDW10: PROCEDURE FOR DEALING WITH PRE-FILLED PCA/PCEA/EPIDURAL SYRINGES AND OPIATE INFUSIONS

Purpose

The purpose of this CD SOP is to ensure that staffs are aware of the necessary documentation for the use of controlled drug PCAs at the Health Board.

Procedure / Process

1. Patients returning from theatre with a continuous opiate infusion, patient controlled analgesia (PCA), patient controlled epidural analgesia (PCEA) or epidural will have the record of the administration of controlled drug recorded in the theatres Controlled Drug Record Book, thus no record of the PCA/PCEA/Epidural is required in the receiving ward Controlled Drug Record Book. **However, a record of destruction needs to be entered on the appropriate page in the ward controlled drug register. This must be the separate page identified for waste of such PCA'a/Epidurals/Infusions.**
2. Part contents of opiate infusions/PCA/PCEA/Epidural that were initially set up and issued in theatres but no longer needed, must be destroyed on the ward where the patient resides.
3. Opiate infusions/PCA/PCEA/Epidural containing residual unused injection must be emptied into an in-use sharps bin along with the empty syringe. Empty bags can be disposed of in a clinical waste bag as per procedure for disposing of empty infusion bags. This must be witnessed by a second person, and one of the pair should be the practitioner looking after the patient.
4. The **estimated** volume of unused injection/infusion must be written in the relevant section of the ward Controlled Drug Register in the Wastage section stating "destroyed contents of PCA/PCEA/Epidural originating from theatre (or ward/unit)" and signed by both practitioners.

2.11 WARD SOP CDW11: CONTROLLED DRUG REGISTERS

Purpose:
The purpose of this CD SOP is to make staff aware of the correct procedures for using controlled drug registers.

Scope:
This SOP applies to all staff using CD registers.

Procedure / Process:

1. A separate section of the CD Register will be used for different formulations or concentrations of each drug.
2. Entries should be made in chronological order.
3. Every entry and correction must be in ink or be otherwise indelible.
4. All entries should be signed by a registered nurse, midwife or ODP and should be witnessed preferably by second registered nurse, midwife, ODP, pharmacist, radiographer senior 1 or an appropriately skilled HCSW.
5. On reaching the end of a page in the CD register, the balance should be transferred to another page. The new page number should be added to the bottom of the finished page and the index updated. When transferring the balance of a controlled drug to a new page in the register. Record from page to page, the date of the transfer, form and strength of the preparation and ensure that it is signed by two members of staff.
6. If a mistake is made it should be bracketed in such a way that the original entry is still clearly legible. The new entry should then be made on the next line. This should be signed, dated and witnessed by a second registered nurse, midwife or other registered professional or by an appropriately trained healthcare assistant. The witness should also sign the correction NB: Crossing out or the use of correction fluid is not allowed.
7. After every administration, the stock balance of an individual preparation should be confirmed to be correct and the running balance recorded in the controlled drug record book. The entry should be signed and dated.

2.12 WARD SOP CDW12: GENERAL MEASURES FOR THE STORAGE OF CDS

Purpose
To inform staff of the general measure required for the storage of CDs in the ward setting.

Scope
Applies to all staff handling CDs in the ward setting.

Procedure / Process

1. Cupboards must be kept locked when not in use.
2. The lock must not be common to any other lock in the hospital.
3. Keys must only be available to authorised members of staff.
4. The cupboard should be dedicated to the storage of CDs, not other items.
5. No other medicines or items should normally be stored in the CD cupboard. Occasionally, in response to local circumstances the Health Board may decide to allow other drugs that are not CDs to be stored in the CD cupboard.
6. CDs must be locked away when not in use.
7. There must be arrangements for keeping the keys secure. This is particularly important for areas such as day surgery units and day wards that are not operational at all times.
8. In certain circumstances, for example when CD discharge medicines (TTOs) are sent to the ward several hours before the patient leaves, the medicines may be stored in the CD cupboard. These medicines should be segregated from the ward CD stock where facilities allow.
   It is the responsibility of the registrant who accepts and signs for the CDs to ensure that the patient/carer is given the TTO immediately. If this is not possible the CD must be stored in the CD cupboard and entered into the ward CD register in the patient's own section.

2.13 WARD SOP CDW13: CONTROLLED DRUG STATIONERY

Purpose

All stationery which is used to order, return or distribute controlled drugs (CD stationery) should be stored securely and access to it should be restricted. These measures are important to guard against unauthorised use of the stationery to obtain CDs for inappropriate purposes.

Definition of CD stationery

CD stationery includes:

- Controlled drug requisition books
- Controlled drug register
- Local CD documents such as CD returns advice notes, pharmacy distribution documents

Scope

Applies to all staff ordering CD stationery.

Procedure / Process

Secure storage of CD stationery

CD stationery which is kept in wards, theatres or departments should be kept in a locked cupboard or drawer whenever possible. Stocks of CD stationery held in pharmacy departments should be kept in a secure area that is locked when there is no one present.

Supply of CD stationery

CD stationery should be issued from the pharmacy and a record of the issue point for that ward/department completed.

A record should be kept in the pharmacy for the supply of CD stationery. It should include:

- Date
- Ward/department
- Type of stationery issued
- Quantity
- The serial numbers of the stationery allocated by pharmacy.
- Signature of the member of pharmacy staff making the supply

Any unused stationery returned to pharmacy will be recorded as a return, with the details above, in the supply record.

Loss or theft of CD stationery

Loss or theft of any controlled stationery which may be used to order CDs should be reported immediately to the Pharmacy Manager and Accountable Officer.

Use of CD stationery

Only one CD requisition book per ward or department should normally be in use. However, areas with more than one CD cupboard will have a separate requisition book and register for each cupboard. Each ward or department should normally only have one CD record book in use at any one time, except those with more than one cupboard, where there would be one record book per cupboard. A new register should not be started until the previous one is full. When a new CD register is started, the balance of CDs in stock should be written into the new book promptly by ward staff. This transfer should be witnessed by a registered nurse or midwife or authorised member of staff e.g. pharmacy technician. Completed ward requisition books and CD register books must be retained for a minimum of two years from the date of the last entry.

Archiving of controlled drug records

Every requisition, order or private prescription on which a Controlled Drug is supplied must be preserved by the Pharmacy department for a minimum period of two years from the date on which the last delivery under it was made

The time periods for archiving CD documentation are:

Requisitions	2 years from last entry
Registers and controlled drug requisition books	2 years from last entry
Extemporaneous preparation worksheets	13 years
Aseptic worksheets (adult)	13 years
Aseptic worksheets (paediatric)	26 years
External orders and delivery notes	2 years
Prescriptions (inpatients)	2 years
Prescriptions (outpatients)	2 years
Clinical trials	5 years after end of trial

(may be longer for some trials)

- Destruction of CDs 7 years

Future Regulations may increase the period of time for the storage of records. Readers are advised to refer to Welsh Assembly Government and RPSGB websites for up to-date information.

2.14 WARD SOP CDW14: PROCEDURE FOR DEALING WITH STAFF WHO ARE SUSPECTED OF CONTROLLED DRUG ABUSE

Purpose

CD diversion for the purposes of substance abuse constitutes a serious health and employment problem. Those affected are in need of urgent assistance and can seek help from their Union or BMA representative, Occupational Health, their General Practitioner, or a number of other sources.

Scope

This SOP applies to all staff working at the Health Board.

Procedure / Process

1. If a Health Board employee, including those who prescribe, is suspected of abusing controlled drugs, then these suspicions should be shared with a more senior staff member.
2. The Accountable Officer or deputy should be contacted directly to discuss suspicions of this nature, particularly if the staff member feels unable to discuss the matter within their own department/directorate.
   All actions concerning this will be dealt with confidentially and will follow the agreed Corporate procedure relating to this issue.

SECTION THREE

3.0 PROCEDURES FOR THE HANDLING AND STORAGE OF CONTROLLED DRUGS AT THE SBU HEALTH BOARD THEATRES

Introduction

These SOPs ensure that CD's are available for use when clinically required by patients in the Health Board Operating Departments ('Theatres') whilst simultaneously ensuring local governance arrangements for CDs are in place and in line with the guidance provided by the Association of Anaesthetists of Great Britain & Ireland (AAGBI) and the Department of Health.

The potential for abuse or diversion of CDs, the potential for harm and the potential for criminal activity mean that CD's are subject to specific statutory controls that must be adhered to during their management.

Supporting documentation

AAGBI Guidelines - Controlled drugs in Perioperative care 2006

The safe and secure handling of medicines: A team approach. A revision of the 1988 Duthrie report. The Royal Pharamceutical Society of Great Britain. 2005

Controlled Drugs (Supervision of management and use) Regulations 2013: Information about the Regulations. DOH, Feb 2013.

Misuse of Drugs Act 2001(Amendment) (No.2) Regulations 2015

Medicines and Healthcare Regulations 2012

Misuse of Drugs Act 1971

Scope of these CD Standard Operating Procedures

These Standard Operating Procedures (SOPs) apply to all staff involved in the ordering, receipt, dispensing, checking, delivery, destruction or audit of controlled drugs within the SB University Health Board and those acting as messengers between the Pharmacy and Theatres. These SOPs cover the CD journey from Pharmacy to a patient within 'Theatres', including ordering, receipt, responsibilities, safe storage, access, dispensing, administration, disposal/destruction and record keeping. Additionally, they encompass alerts, investigative & documentation systems in the event of discrepancies and deviations from SOPs'. They also cover delivery of CDs to the clinical area and collection of CD's from the Pharmacy Department.

Responsibility

All pharmacy and theatres registrants who handle controlled drugs at SBU Health Board as part of their must follow these procedures. These procedures also apply to all staff handling, delivering, receiving or witnessing the destruction of controlled drugs.

The responsibility for establishing and maintaining a system for the security of medicines used within the Operating Department lies with the *Controlled Drugs Accountable Officer (CDAO)*, in consultation with the Theatre Manager and registrants (registered nurse, midwife, Operating Department Practitioner (ODP) or Anaesthetist).

Accountable individuals

The Theatre Manager, registrants and anaesthetists involved in each case are responsible for the safe and appropriate management of CDs and ensuring documentation is completed in line with the Theatres' CD policies.

The registrant in charge of an operating theatre is responsible for Controlled Drug Governance and management during their shift.

3.1 THEATRE SOP CDT1: PROCEDURE FOR THE ORDERING OF CONTROLLED DRUGS FOR THEATRE STOCKS

Purpose

The purpose of this CD SOP is to ensure that staff are aware of the process for ordering controlled drugs from the pharmacy department for use in the Health Board theatres.

Controlled drug stocks

CD's held in each theatre as stock items must reflect the current clinical use of CD's in that theatre. Regular updates must be agreed between the member of pharmacy staff responsible for the theatre, the operating department manager, and appropriate medical/nursing staff**.**

Procedure / Process

1. The Theatre Manager is responsible for the safe and appropriate management of CD stock in the operating department and must operate a robust system for ensuring the reconciliation of all CD orders and receipts, and their appropriateness.
2. Controlled drugs must be ordered in the controlled drug order book specific to that Theatre/Recovery Unit's CD cabinet. Order books from other areas must not be used.
3. Orders are to be placed by the registrant who has responsibility for the clinical area.
4. A separate page must be used for each item ordered.
5. Place the carbon paper in between the top and lower page with the carbon placed down. If the carbon paper is missing, then an identical entry must be made on the top and bottom sheets.
6. Orders must contain the following details :-
    a. Hospital name
    b. Theatre name - specify the cabinet if more than one within that area.
    c. Name, form, strength, volume, quantity of the controlled drug to be ordered. (Only agreed abbreviations as per the SBU HB Medicines Policy should be used.)
    d. Signature of person ordering
    e. Person ordering should also print their name.
    f. Date of the order.
7. CD's should ideally be ordered during weekday pharmacy working hours – requests on weekends should be restricted to emergency supplies only.
8. Controlled Drugs must be ordered directly from pharmacy and cannot be obtained from other controlled drug cabinets on the wards other theatres or anywhere else in the Health Board. An exception to this is in an out of hours situation, having been authorised by the site duty manager in conjunction with the emergency duty pharmacist.

Exceptions to this area:-

1. The transfer of Fentanyl epidural bags from the recovery unit for specified, individual patient use against a written instruction.

2. For a supply situation arising when the pharmacy department is closed, the transfer having been authorised by the senior registrant in charge of theatres in conjunction with the emergency duty pharmacist.

3.2 THEATRE SOP CDT2: PROCEDURE FOR THE COLLECTION OF CONTROLLED DRUGS FROM PHARMACY

Purpose

The purpose of this CD SOP is to ensure that theatre and pharmacy staff are aware of the process for collecting controlled drugs from the pharmacy department for delivery to theatres.

Procedure / Process

1. Delivery can be undertaken by any member of SBU staff. This is likely to be portering staff, Pharmacy staff or theatres staff. They will be known as the messenger.
2. Dispensed CDs will be prepared for delivery by a member of pharmacy staff.
3. The messenger must present a valid SBU Health Board identification. (Pharmacy may refuse to release CDs to any member of staff not in possession of a Health Board ID badge.)
4. The messenger, with a member of the pharmacy staff, will check to confirm that the CD being supplied is correct against the order placed.
5. This check must include:-
    - The drug
    - The form
    - The presentation size, (e.g. 1ml or 10ml amps)
    - The strength
    - Expiry date
    - The quantity (sealed packs do not need to be opened, it should be assumed that the contents are correct as per the product labelling, however a check needs to be taken to ensure tampering with the seal has not occurred)
6. If all items are correct, the messenger signs and dates; in the accepted for delivery section, each completed order page of the requisition book, on the white copy; ensuring the carbon sheet is in place.
7. The CDs are placed in a transport bag which has a recognised individual serial number or is to be sealed using a tag with an individual serial number. The serial number of the transport bag must be recorded on every page of the requisition book where an order has been placed.
8. The top order copy (white copy) is torn out of the CD requisition book and left with the pharmacy to file. The requisition book is placed in the transport bag. The transport bag is sealed.
9. The serial number of each transport bag prepared for delivery must be recorded on a delivery transport log, to include:
    - Theatre number
    - Serial number of transport bag
    - Messenger’s name

- Messenger's signature

10. The ordered stock and requisition book are transferred up to theatres by the messenger in the sealed transport bags, with a copy of the delivery log.

3.3 THEATRE SOP CDT3: PROCEDURE FOR THE RECEIPT OF CONTROLLED DRUGS IN THEATRES

Purpose

The purpose of this CD SOP is to ensure that all staff are aware of the procedure for managing the receipt of controlled drugs in theatres.

Procedure / Process

1. The Theatres manager is responsible for the safe and appropriate management of CD stock in the Department and must operate a robust system for ensuring the reconciliation of all CD orders and receipts and their appropriateness.
2. CD's must not be left unattended during delivery to theatres.
3. The messenger (see SOP CDT2) must hand the transport bag for delivery to the designated theatres CD receiver; who must be a registrant.
4. The transport bags are to remain sealed at this time and the serial numbers are to be checked against the delivery log.
5. If the serial number matches the number in the delivery log then the delivery log should be signed, timed and dated by the receiver.
6. The messenger must return the delivery log to the pharmacy dept.
7. The receiver must take the sealed transport bag to the named theatres.
8. The transport bag should be handed to the registrant in charge of the named theatre.
9. The registrant in charge should check that the transport bag is sealed.
10. The seal should now be broken in the presence of the receiver and each CD received should be checked against the requisition book order.
    - The serial number of the transport bag, (number written on the pink order form) should be confirmed as the same number as the serial number on the transport bag.
    - The items received correspond with those on the order sheets. Check:
        - The drug
        - The form
        - The presentation size, (e.g. 1ml or 10ml amps)
        - The strength
        - Expiry date
        - The quantity
    - If everything is present and correct, then the order form in the CD Requisition book (pink copy) should be signed in the 'received by' section.

11. The registrant receiving the controlled drugs, and a second registrant, must enter each item in the controlled drugs register on their allocated pages and the final balance checked and countersigned. The entry must include:

- The date
- Quantity received in words, not figures.
- Requisition number.
- Signature
- New stock level
- Signature of the witness, confirming that the correct balance has been entered in the register.

12. Any sealed boxes of controlled drugs received from pharmacy, can be assumed to contain the quantity specified on the label until the seal is broken. The box does not need to be opened to check the quantity.

3.4 THEATRE SOP CDT4: PROCEDURE FOR THE RECORDING OF PREPARATION OF CONTROLLED DRUGS IN THEATRES

Purpose
The purpose of this CD SOP is to ensure that all staff are aware of the correct procedure for documenting the preparation of controlled drugs in theatres.

Procedure/Process
All CDs will be issued against the following:

- A registered prescribers verbal request
  - A valid signed and dated instruction should be written as soon as feasibly possible
- A registered prescribers signed and dated written instruction

At the time of removal of controlled drugs from the CD cupboard against a verbal or written instruction, a legible record of issue must be made in the supply row of the CD register. This entry must include:

- The patient's name
- Patient's hospital number / NHS number
- The quantity of CD supplied (mg, g etc.)
- Time of supply
- Signature of the registrant and witness involved in the supply process
- An updated running stock balance (confirmed by physical stock reconciliation at the point of preparation)

CDs drawn up for administration must be labelled in accordance with the anaesthesia labelling standards. http://www.aagbi.org/sites/default/files/SYRINGE%20LABELLING%202014.pdf

3.5 THEATRE SOP CDT5: PROCEDURE FOR THE RECORDING OF ADMINISTRATION OF CONTROLLED DRUGS TO PATIENTS IN THEATRES

Purpose

The purpose of this CD SOP is to ensure that all staff are aware of the correct procedure for documenting the administration of controlled drugs to patients in theatres

Procedure / Process

1. In the intra-operative setting, a legible record of administration, including dose & time, should be made on the appropriate intra-operative chart as soon as possible after administration by the person who administered the CD. Where 2 or more anaesthetists are responsible for the anaesthetic and CD administration, initialling of separate doses should occur.
2. A concurrent record of CD administration must be maintained in the CD register by the administering anaesthetist. A final reconciliation of the total dose administered at the end of an individual patient's procedure must be recorded in the administration row in the register against the patient details entered at the time of the CD issue. The administration records on patients' intra-operative charts and the corresponding register entries must match up in all instances.
3. Witnessing of the intra-operative administration of incremental CD doses by anaesthetic medical staff has been agreed as likely to hinder clinical need & patient safety and therefore does not need to be observed.
4. CD's must not be left unattended/unsecured on any work surface under any circumstances.

3.6 THEATRE SOP CDT6: PROCEDURE FOR THE RECORDING OF ADMINISTRATION OF CONTROLLED DRUGS TO PATIENTS IN RECOVERY

Purpose

The purpose of this CD SOP is to ensure that all staff are aware of the correct procedure for documenting the administration of controlled drugs to patients in recovery.

Procedure / Process

1. In recovery a CD may be administered to a patient against an inpatient prescription written by an authorised prescriber employed by the Health Board. This may be prescribed on either an anaesthetic chart or a medication administration chart.
2. The administration of controlled drugs in recovery is a two person procedure. The first person should be a registered nurse/midwife, ODP or doctor. The second person checking may be any of the above.
3. Both persons MUST check and witness the entire procedure from preparation to first dose administration and both most sign and date the prescription chart and the controlled drug register.

4. An entry must be made in the controlled drugs register each time a dose is administered.
5. The entry must include:
    - The date
    - The time
    - Patient name and hospital number or NHS number
    - Amount given (g, mg)
    - Signature of staff member administering
    - Signature of witness to the administration
    - Balance (should be countersigned as correct)

    When part of a dose is administered, e.g. 5mg morphine, from a 10mg ampoule the 5mg wasted and destroyed should be entered into the CD register in the 'destruction' section and be countersigned by another registrant.
    Wasted doses should be destroyed by emptying into a sharps bin which is then treated as mixed pharmaceutical waste/sharps. A registrant must witness the destruction and sign the CD register as per above.
6. The administration of incremental doses of Morphine or fentanyl by registered practitioners in theatre recovery, un-witnessed, is permissible as a single nurse procedure. The initial dose must have been witnessed as a two person procedure. The registered practitioner must have a detailed working knowledge of incremental dose administration of morphine and fentanyl in this setting. The incremental prescription must be written on the 'PRN' section of the drug chart to facilitate the recording of all administered doses.
7. CD's must not be left unattended/unsecured on any work surface under any circumstances.

3.7 THEATRE SOP CDT7: PROCEDURE FOR THE DESTRUCTION OF CONTROLLED DRUGS IN THEATRES

Purpose
The purpose of this CD SOP is to ensure that staff know the correct procedure for the destruction of controlled drugs in theatres. It ensures that staff know which controlled drugs can be destroyed in theatres and those that must be returned to pharmacy for denaturing.

Procedure / Process
Unopened ampoules (for example, patient cancellation after the supply of a CD was made as per CDT SOP4) must be returned to the CD cupboard and the return recorded and signed for in the CD Register witnessed and signed for by a second registrant.

Controlled Drugs which **can** be destroyed in Theatres are:

- Individual doses that are prepared and not administered (The reason for non administration must be recorded in the CD register.)
- The remains of partly used PCA devices.

- The remains of part doses (e.g. 25mg from a 50mg ampoule).
- Ampoules that have been damaged or smashed – this must be recorded and witnessed by two registrants.

Controlled Drugs which **cannot** be destroyed in Theatres are:

- All out of date/unwanted theatre CD stock
- Substances recovered from a patient's body cavity during surgery, that are suspected to be CD's - should be labelled & secured until advice can be sought from Pharmacy.

How to destroy CDs in theatre.

1. Destruction of small volumes of liquids (including PCAs) should be by emptying into a sharps bin. Used vials or ampoules should then also be placed in the sharps bin. This must be done promptly – it is not acceptable to leave CDs awaiting destruction unattended.
2. The destruction of a CD must be signed against the individual patient entry that the drug relates to. The destruction must be recorded and witnessed in the destruction row of the CD register by the anaesthetist and a second registrant. It is acknowledged that in longer cases there may be more than one anaesthetist involved. In these instances, either anaesthetist may take responsibility for the destruction as the first registrant.
   The witness should sign to confirm that the volume discarded in the syringe is the same volume recorded in the CD register.
   It is acknowledged that the drug contents of the liquid discarded cannot be verified by the witness.

3.8 THEATRE SOP CDT8: PROCEDURE FOR THE RECONCILIATION OF CONTROLLED DRUGS IN THEATRES

Purpose

The purpose of this CD SOP is to ensure that staff are aware of the correct procedure for reconciliation of the physical CD stock against the CD register record in theatres.

Procedure / Process

1. It is the responsibility of the registrant who has custody of the controlled drug cupboard keys for a given theatre to:
   - Reconcile the physical stock of CDs against the CD register record at the point of taking custody of the CD cupboard keys.
   - Reconcile the physical stock of CDs against the CD register record at the point of relinquishing custody of the CD cupboard keys to another registrant.
   - Reconcile the physical stock of CDs against the CD register record at the point of completing the list and returning the keys back to the key safe.
   - In a Theatre/Recovery area which is **not** in use the registrant responsible for the keys has the choice to either –

a) Ensure that the balance of controlled drugs is physically checked at least once every 24 hours by two registrants or
b) Ensure the tamper proof seal on the controlled cupboard is still secure and integrity undisturbed every 24 hours*.

Note: in areas which are closed on a regular basis at weekends it is acceptable to complete checks at the end of the session on Friday and then at the start of the session on Monday. This practice must be agreed with the senior manager responsible for the area and pharmacy.

2. Reconciliation must be witnessed by another registrant.
3. The reconciliation process is as follows:
   - Every active page in the CD register and all CD stock must be reconciled to ensure that all the CD Cupboard contents are accounted for by CD register entries and that the running balances in the CD register are correct.
   - For open packets the content must be confirmed as present and intact. The ampoule must be confirmed as not broken or in other way tampered with.
   - The registrant in charge and the witness must enter a record of the reconciliation process in the reconciliation log book *(see image 1 below)* to include:
     - Time
     - Date
     - Reason for check
     - Signature and name of registrant
     - Signature and name of witness

For recovery and obstetrics theatre it is accepted that it is not practical to complete a full CD reconciliation each time the CD key is delegated to another registrant.
Instead a full CD reconciliation must be completed at the end of each shift, either at close down or handover.

DATE	TIME	PRINT NAME	SIGNATURE	TICK REASON				LOCKING CUPBOARD	DISCREPANCIES			ACTIONS TAKEN
				START OF LIST	BREAK	SHIFT CHANGE	END OF LIST	SECURITY TAPE NUMBER	DATE	PAGE	DRUG	COMMENTS
		CHECK 1										
		CHECK2										
		CHECK 1										
		CHECK2										
		CHECK 1										
		CHECK2										
		CHECK 1										

Image 1 – SBU Theatres' CD reconciliation log

**NB. If seals are to be used*

1. *Upon closing the CD cupboard at the end of a shift, following the final reconciliation process, the cupboard must be sealed with an individually numbered tamper proof seal. The seal number must be recorded next to the signatures of the two registrants completing the reconciliation process at this time; and the seal number must also be recorded in the* ***controlled drug key log book*** *at the time that the key is booked into the key safe.*

2. *The next time the cupboard is opened, the seal number on the cupboard must be checked with the number recorded in the key safe register as well as the number recorded in the CD* ***reconciliation log book.***
3. *The individually numbered seal must be positioned so that all aspects of it can be viewed (and number checked) prior to removing. E.g. – over the door opening or over the key lock.*

3.9 THEATRE SOP CDT9: PROCEDURE FOR THE MANAGEMENT OF CONTROLLED DRUGS' CUPBOARDS' KEYS

Purpose

The purpose of this CD SOP is to ensure staff are aware of the correct procedures for managing controlled drug cupboard keys within individual theatres, obstetrics theatre and recovery.

Procedure

Possession and handover of keys for individual theatres

1. The Theatre Manager is ultimately responsible for the custody of controlled drugs within the theatres department, and their access must be restricted through robust key control.
2. Responsibility for access to individual theatres CD cupboards and the associated key custody may be delegated to a specified registrant in charge of a specific theatre.
3. CD keys must be kept separate from all other keys
4. When individual theatres are out of use, their CD cupboard keys must be stored in a central key safe.
5. Access to the central key safe must be under the control of the designated master key holder. A record of the person holding the key to the central key safe at any given time must be made in a dedicated `Controlled Drug key cupboard key holder log'.
6. The central key safe is to remain locked at all times except for the issue and return of keys.
7. An additional register (`Controlled Drug key log book`) for recording the allocation of theatres` CD cupboard keys must be maintained. A separate page in the register must be used for recording the key allocation for each theatre's CD cupboard.
8. An entry must be made in the 'theatres CD key register' each time a key is allocated or returned to the central key safe by the designated master key holder.
   The entry must include:
   - Name and signature of the registrant allocated or returning the key
   - Name and signature of the designated master key holder, issuing or receiving the key
   - Time and date of the transaction
9. Controlled drug keys can only be under the custody of registrants who are SBU employees.

10. Allocated keys are to remain under the control of the individual to whom they were recorded as 'issued to' in the `Controlled Drug key log book` at all times until they are returned to the central key safe and entered as returned in the log book.
    The exception is when there is handover of key control between registrants whilst the theatre remains operational. To ensure a current record of key custody is maintained any key handover must be documented in the CD checks book.
    A check must be carried out at the point of hand over, in line with the reconciliation policy and both registrants must sign and print their names to record who has handed the keys to whom, at what time and date.
11. The CD cupboard must only be opened for checking, removal or receipt of controlled drugs. It must remain locked at all other times. It is the responsibility of the allocated key holder to ensure that this is maintained.
12. A final reconciliation of stock in the CD cupboard must be completed at the end of the shift when the theatre is 'shut down'. This should be recorded in the CD reconciliation log book.
13. The key for the CD cupboard must be returned to the central key safe and an entry made in the controlled drug key log book

<u>Possession and handover of keys within recovery and obstetrics theatres</u>

1. The registered practitioner or midwife in charge (also known as the shift leader) is responsible for the CD keys.
2. Key-holding may be delegated to other suitably-trained, registered healthcare professionals but the legal responsibility rests with the registered practitioner or midwife in charge.
3. The controlled drug key should be returned to the registered practitioner or midwife in charge immediately after use by another registered member of staff.
4. The controlled drug keys must be in the possession of an authorised staff member at all times.
5. For obstetrics theatre, at handover, the keys must be returned to the shift leader of that shift who in turn will pass them over to the shift leader taking over. A full reconciliation of CD stock must be completed at shift handover and documented in the CD reconciliation log book.
6. The controlled drug keys to both the outer and inner CD cabinets must be kept separate from all other keys used in the departments. Note – access to the controlled drug cupboards is a two person procedure

<u>Theatre Units that are closed overnight, or for extended periods (weekends, bank holidays etc.)</u>

1. All CD cupboards should have a full reconciliation of stock prior to the cupboard being locked and the unit closed.
2. The keys for the CD cupboard must be locked in a key safe located in a suitable area.
3. The CD key log book must be completed to indicate that the keys for the unit have been returned to the key safe.

Loss of keys

1. Any loss or unaccountability of a CD key must be reported to the theatre manager and pharmacy and an incident form must be submitted.
2. Urgent efforts should be made to retrieve lost keys, enlisting the help of all relevant staff.
3. Upon locating a lost key, reconciliation of the cupboard contents as per the reconciliation policy must be undertaken by the designated person in charge in charge of the central key safe and a second registrant.
4. If the key(s) cannot be found, then the Pharmacy & Controlled Drugs Accountable Officer must be informed as soon as possible.
5. Locks must be changed if the loss is considered a security risk. Discuss this with senior pharmacy and nursing managers.

Spare Keys

There should be no spare keys available to Theatre staff.
Should the key be lost then the lock must be replaced.

DATE	TIME	CURRENT HOLDER SIGNATURE	PRINT NAME	HANDED OVER TO... SIGNATURE	PRINT NAME

Image 2 – Main key holder log

Carried forward from page _____ for THEATRE _____

DATE	TIME	SIGN OUT		DATE	TIME	SIGN IN	
		PRINT NAME	SIGNATURE			PRINT NAME	SIGNATURE
		1				1	
		2				2	
		1				1	
		2				2	
		1				1	
		2				2	
		1				1	

Image 3 – Theatre key allocation log

3.10 THEATRE SOP CDT10: PROCEDURE FOR THE MANAGEMENT OF CONTROLLED DRUGS PROCESS' DISCREPANCIES

Purpose:
The purpose of this CD SOP is to ensure staff are aware of the correct procedure upon discovering a discrepancy

Procedure / Process
Procedure to follow when discrepancies identified as part of reconciliation process:

- Undertake the reconciliation process again
- Recheck all entries have been made in the CD Register
- Check all prescribed entries on the anaesthetic chart/notes/drug chart to ensure entries have been recorded in the CD register.
- Check that the running balance has been calculated correctly
- Check that stock has not been separated

Procedure to be followed where a discrepancy is noted in stock arriving from pharmacy:

- Recheck the CD Order Book against the stock received as per CDT SOP3
- Contact pharmacy to confirm records are complete i.e. the white filed copy of the order matches the pink carbon copy

Procedure to be followed where a discrepancy is noted following a patient case:

- Confirm the record keeping is complete and correct between CD register and inter-operative chart, in liaison with the anaesthetist.

Procedure to be followed if a cupboard seal is found to have been tampered with during routine checks or upon opening up at the start of a shift:

- Inform the senior staff member on duty.
- Carry out a full cupboard contents check in line with the reconciliation procedure (CDT - SOP 4.7).
- Complete an incident form, even if the content is found to be correct on checking.

Where a discrepancy has still not been resolved after following the above recommendations you must immediately report this to senior management and complete an incident form.

For guidance on how to amend incorrect entries, **see SOP 4.12 Point 6.**

3.11 THEATRE SOP CDT11: SUBSTANCE ABUSE

Purpose
The purpose of this SOP is to ensure that staff know how to respond to suspicion of substance misuse.

Procedure / Process

1. If a Health Board employee is suspected of abusing controlled drugs, then suspicions must be reported to your line manager or to the Health Board Controlled Drugs Accountable Officer.
2. All actions concerning this will be dealt with sensitively following the agreed Corporate Health Board procedure relating to this issue.

3.12 THEATRE SOP CDT12: PROCEDURE FOR RETURNING CONTROLLED DRUGS BACK TO PHARMACY

Purpose

The purpose of this CD SOP is to ensure that theatres` staff are aware of the correct procedure for returning controlled drugs to the Pharmacy Department.

Procedure / Process

1. When it is necessary to return a controlled drug, notice must be given to pharmacy for its removal.
2. A member of pharmacy staff will come to the relevant theatre to arrange the transfer. **Controlled drugs and registers must not be removed from the cupboard and taken to the pharmacy department**.
3. The process of removal will be carried out by the registrant in charge of the cupboard at that time and the pharmacy staff member. The registrant in charge of the cupboard should ask to see the pharmacy staff` health board identification.
4. Following reconciliation of the specific page in the register and the cupboard contents, the item will be booked out of the controlled drug register, including the reason for return, and the new balance will be entered.
5. The balance entry must be countersigned both by the registered practitioner making the entry and the pharmacist or pharmacy technician removing the drug.

3.13 THEATRE SOP CDT13: PROCEDURE FOR THE COMPLETION OF CONTROLLED DRUG REGISTERS

Purpose

The purpose of this CD SOP is to make staff aware of the correct procedures for using controlled drug registers in theatres**.**

Procedure / Process:

1. Entries should be made in chronological order.
2. A separate section of the CD Register will be used for different formulations or concentrations of each drug.
3. Every entry must be in ink or be otherwise indelible.
4. All entries should be signed by a registrant and must be witnessed by a second registrant.

5. On reaching the end of a page in the CD register, the balance should be transferred to another page. The new page number should be added to the bottom of the finished page and the index updated. This transfer must be a two person procedure as detailed in point 4 above.
6. If a mistake is made it should be bracketed so that the original entry is still clearly legible.
   A new entry should be made on the next line.
   The entry must be signed and dated and witnessed and signed by a second registrant.
   If the discrepancy needs further explanation, then an entry should be made in the discrepancy section in the back of the register.
   Crossing out entries or the use of correction fluid is not allowed.
7. When recording CDs received from pharmacy a diagonal signature for both the receiving registrant and the witness crossing all three lines must be entered into the register. All three rows must be completed for the running total so there are no gaps in the running total. See first example below.
8. Theatres registers have **Supplied, Administered and Destroyed columns** for each transaction in the drug record pages. The recording of this information is a legal requirement under the Department of Health Safer Management of Controlled Drugs regulations. All transactions for supply and destruction must be witnessed and double signed. The record of administration section will be signed by a single registrant as witnessing doses is not practical in the intra-operative setting. Note the CD register has a blocked out witness section (blue box) to account for this practice. An example of these entries is shown below. (Image 3).
9. After every preparation as per SOP CDT4, the stock balance of the individual item involved must be confirmed to be correct and the running balance recorded in the controlled drug record book. The entry should be signed and dated, witnessed and counter signed.
10. Where there is no part dose requiring destruction, the supply (S) and administration (A) will be completed. The row for recording destruction should be recorded as 0mg. The balance must be recorded in the “Balance” column against all three rows. See example below (Image 3).
11. When a part dose is administered, all three rows in the register must be completed to clearly account for supply, administration and destruction of the controlled drug. Each entry (supply, administration & destruction) must be signed for, and the supply and destruction witnessed. The amount recorded as administered must correlate with the entry on the intra-operative record chart or the drug chart used.
12. Each page of the CD Register must have the complete title of the preparation being recorded, including the name, form, and strength of the product, for example Morphine 10mg/ml 1ml ampoule.
13. The registrant in charge of the theatre is responsible for keeping the CD Register(s) up to date and in good order. The anaesthetist administering is responsible for completion of the administration and destruction columns.
14. As controlled drugs’ registers are controlled stationery they can only be obtained through Pharmacy.

Drug Name (generic)	Form	Strength	Ampoule Size (if applicable)
Fentanyl	injection	50mcg/ml	2ml

Amount received (in words)	Requisition Serial Number	Date	Patient's Name and Hospital Number	Amount S = Supplied A = Administered D = Destroyed		Time (24 hour Clock)	Responsible Person	Responsible Person 2	Stock Balance (in numbers)
		Carried forward from page number 27				Signed:	1. [illegible]	2. [illegible]	4
TEN	014	20/7/19	Recieved from Pharmacy	S A D		10:00	[illegible]	[illegible]	10+4=14
		21/7/19	Patient One NØØØØ1	S A D	100mcg 50mcg 50mcg	08:00 08:15 09:00	[illegible]	[illegible]	13
		26/7/19	Patient Two NØØØØ2	S A D	100mcg 100mcg Ømcg	11:00 11:10 —	[illegible]	[illegible]	12
	*	26/7/19	Patient Three	S A D	10mg				
				S A D					
				S A D					
				S A D					
				S A D					
				S A D					
				S A D					

* Entered in error - Should be in Morphine register page 6 [illegible]/Oz

Page carried forward to.....

Image 4 – Example of SBU Theatres' CD register entries.

3.14 THEATRE SOP CDT14: STORAGE OF CONTROLLED DRUGS IN THEATRES.

Purpose

The purpose of this CD SOP is to inform staff of the requirements for the storage of CDs in the theatres.

Procedure / Process:

1. The CD's for use in each theatre and the Recovery Unit will be kept in dedicated secure cupboards or locked fridges in each area and will be accompanied by a separate record book (a CD Register).
2. CD cupboards and fridges must be locked when not in use.
3. When individual theatres are not in use, the keys for each CD theatre cupboard will be secured in the central key safe as per SOP CDT9.
4. Each CD cupboard lock must be unique.
5. Keys must remain under the control of the individual identified in the CD key register. See CDT SOP9.
6. The cupboard should be dedicated to the storage of CDs. Occasionally, in response to local circumstances health care organisations may decide to allow other drugs that

are not CDs to be stored in the CD cupboard. This includes mifepristone and misoprostol at some sites in the Health Board.

7. CDs must be locked away when not in use.
8. CD cupboards must meet the necessary legal requirements. The standards and statutory regulations for safes & cabinets used to store CD's (e.g. BS 2881) are detailed in British Standard BS 2881. Further details are available from www.bsi-global.com

3.15 THEATRE SOP CDT15: CONTROLLED DRUG STATIONERY

Purpose

To inform staff of the security requirements regarding CD stationary in theatres

Procedure / Process:

1. CD stationary is the responsibility of the theatre manager.
2. All CD stationery must be secured when not in use.
3. CD stationery in theatres includes:
    - Controlled drug requisition books
    - Controlled drug registers
    - Local CD documents such as the controlled drugs reconciliation log book.
4. CD stationery will be issued from the pharmacy against the request of the Theatre Manager. When pharmacy staff are aware that a CD requisition book is coming to the end of its supply of requisitions, they may issue a replacement book.
5. Any loss of any controlled stationery or page noted to be missing should be reported immediately to the pharmacy manager and Controlled Drugs Accountable Officer and an incident form completed.
6. Only one CD requisition book per theatre/recovery unit must be in use. Areas with more than one CD cupboard will have a separate requisition book for each cupboard or fridge.
7. Each theatre/recovery unit must have only one CD register in use at any one time. The exception is when there is more than one CD cupboard, where there would be one register in use per cupboard or CD fridge.
8. A new register **must not** be started until the previous one is full or damaged. When a new CD register is started, the balance of CDs in stock must be written into the new book promptly by a registrant. This transfer must be witnessed and signed by a second registrant.

Archiving of controlled drug records

The time periods for archiving CD documentation are:

○ CD Registers (with destruction records in)	7 years
○ Controlled drug requisition books	2 years from last entry
○ Theatres CD Check log book	7 years (with accompanying register)

3.16 THEATRE SOP CDT16: THEATRES CONTROLLED DRUG POLICY AUDIT

Purpose
To inform staff of the audit requirements for CDs in theatres

Procedure / Process:
Each Theatre must be audited using the theatre controlled drug policy compliance tool on a **3** monthly basis.

It is the Theatre Manager's responsibility to ensure that the audit is carried out in all theatres and that any deviations from the policy are acted upon to ensure compliance with legal and standard operating procedure guidance. Audit results must be cascaded along appropriate pathways within each Delivery Unit including to the Delivery Units' Quality & Safety Committee.

Pharmacy will provide external assurance and support that correct processes within the policy are being adhered to.

The Audit from can be found in Appendix 3.8 of the Controlled Drugs Policy.

SECTION FOUR

4.0 PHARMACY PROCEDURES FOR THE HANDLING AND STORAGE OF CONTROLLED DRUGS AT THE SBU HEALTH BOARD

Scope of these CD Standard Operating Procedures

These Standard Operating Procedures (SOPs) apply to all staff involved in the ordering, receipt, dispensing, checking, delivery, destruction or audit of controlled drugs within the SBU Health Board Pharmacy Departments. They also cover delivery of CDs by Porters, and Pharmacy Staff to the clinical area and collection of CD's from the Pharmacy Department by Ward / Clinical Area staff. The witnesses to the destruction of CDs are also covered by these SOPs.

Responsibility

All pharmacists, qualified technicians, pre-registration pharmacy graduates and student technicians under supervision handling controlled drugs at the SBU Health Board pharmacy departments are expected to follow these procedures. These procedures also apply to non-pharmacy staff handling, delivering, receiving or witnessing the destruction of controlled drugs.

4.1 PHARMACY SOP CDD1: ACCEPTING A CONTROLLED DRUG ORDER INTO STOCK

Purpose
To ensure that all controlled drug orders accepted into stock are accurately received against the original order and the appropriate information is recorded in the register and on the Pharmacy Computer system.

Procedure / Process
Accepting CDs from the delivery driver: A Pharmacist or Technician must sign for receipt of the Controlled Drugs (CDs) and check the items delivered against the delivery note. It is good practice to record receipt in the CD register at the first opportunity, which must be completed that working day. The order should not, ideally, be received by the same individual who placed the original order. The CDs should then be placed in the appropriate area, to await a check against the original order.

Checking against paperwork:
On receipt, the item(s) should be checked against SBU Health Board paperwork and wholesaler / supplier paperwork. If correct, the delivery NOTE should be signed and filed in the usual manner.
Tamper-evident seals on packs should be left intact when they are received from the supplier as they facilitate efficient routine balance checks. If when the tamper evident seal is broken, the contents do not match the expected amount stated on the pack, the supplier should be contacted.
If an item received is incorrect, it should be quarantined in the CD cupboard, along with the relevant paperwork and the senior technician overseeing CDs and the purchasing team / supplier should be informed immediately. If it is an item that is regularly used at SBU Health Board sites, then there may be an option to retain the item for use following discussion with the supplier. Otherwise, arrange with the supplier to return the item.
The invoice copy should be signed to indicate that the items have been received as follows: Received by: signature, name (printed) and the date entered.

Entry into the CD register
All items received should be entered into the receipts section of the CD register. There should be two entries, the first in the receipts section. The second in the individual section. Only qualified technicians and pharmacists are allowed to enter items into the CD register unsupervised. Student technicians and pre-registration pharmacists may enter items into the CD register under supervision and each entry must be countersigned by the supervisor.
For CDs received into stock the following details must be recorded in the CD register:

- The date on which the CD was received
- The name and address of the supplier, e.g. wholesaler, pharmacy
- The quantity received
- The name, form and strength of the CD
- Batch number

The stock balance in the register should be checked against both the quantity in the CD cabinet and the balance shown in the pharmacy stock control system and a record of the reconciliation recorded against the balance in the register.

4.2 PHARMACY SOP CDD2: THE SUPPLY OF CONTROLLED DRUGS ON DISCHARGE MEDICATION OR OUPATIENT PRESCIPTIONS TO PATIENTS, PATIENTS' REPRESENTATIVES, OR HEALTHCARE PROFESSIONALS

Purpose

To ensure that any person collecting Controlled Drugs from Pharmacy provides identification and that correct documentation is recorded and stored. From July 2006, there has been a requirement for persons asked to supply CDs on prescription to seek to establish whether the person collecting the medicine is the patient, their representative or a healthcare professional acting in his professional capacity on behalf of the patient.

Procedure/Process

Dispensing: The prescription should be dispensed in accordance with the procedures in the dispensary as normal.

Following the final check, the prescription should be placed in a bag. The top copy of the prescription should be attached to the front of the bag and placed in the correct location for collection. The prescription details should be entered in the relevant book or individual recording sheet dependent on hospital site.

Details must include

- Date
- Ward
- Patients Name
- Drug Name
- Form
- Strength
- Quantity
- Pharmacy signature
- Signature of collector or person delivering – names should also be printed.

For TTH's delivered to the ward the individual sheet or book must be signed by the receiving member of staff, returned to the department and individual sheets filed in the appropriate location where applicable.

Waiting Outpatient prescriptions should be "bagged up" at the hatch during the counselling process. If the prescription is not collected within a reasonable time frame, it should be kept in the CD cupboard until collection.

Collection of CDs by patients or patients' representatives

If the CD(s) is to be collected by a patient, also ensure that they are aware of the need to bring identification. One of the forms of identification below should be seen, if this is not possible the decision to issue the CD(s) to the patient should be the discretion of the dispensary manager or deputies, or the senior pharmacist. Where the person collecting the CD is the patient or the patient's representative, the person supplying the CD:

- May request evidence of that person's identity and
- May refuse to supply the medicine if they are not satisfied as to the identity of the person.

Collection of CDs by a healthcare professional

If the CD(s) is to be collected by a healthcare professional, ensure they are aware of the need to bring identification. For SBU Health Board and other professional staff, this should be their official identification. Where the person collecting the CD is a healthcare professional acting in their professional capacity on behalf of the patient, the member of pharmacy staff supplying the CD:

- Must obtain the person's name and address
- Must, unless he is acquainted with that person, request evidence of that person's identity; but may supply the medicine even if they are not satisfied as to the identity of the person. Any strengthening of controls has been balanced with ensuring that patients have access to medicines they need and have been prescribed for them.
- The requirements placed on the pharmacy staff member supplying the CDs allows them discretion not to ask patients or patient representatives for proof of identity if for example they have concerns that to do so may compromise patient confidentiality or deter patients from having their medicine dispensed.

It is a requirement to record the following information in the CD register or until revised registers are available the 'Receipt of Controlled Drugs' form (see Appendix 3.3) for Schedule 2 CDs supplied on prescription:

- Whether the person who collected the CD was the patient, the patient's representative or a health care professional acting on behalf of the patient
- If the person who collected the CD was a health care professional acting on behalf of the patient, that person's name and address
- If the person who collected the CD was the patient or their representative, whether evidence of identity was requested (as a matter of good practice a note as to why the pharmacy staff member supplying the CD did not ask may be included but this is not mandatory). And whether evidence of identity was provided by the person collecting the CD. The patient's date of birth may be used as a second check if necessary.

Acceptable forms of identification include:

- Driving Licence, including Photocard section
- Official photo ID
- Passport
- Cheque guarantee, debit or credit card
- Birth/marriage certificate

- Cheque book
- Utility bills (two different ones but not mobile phone statements)
- Pension or benefit book
- Council tax payment book
- Recent bank or building society statement (within previous six months)
- Bank or building society book
- Store charge card (not loyalty card)
- Council rent book
- National savings book

4.3 PHARMACY SOP CDD3: ORDERING CONTROLLED DRUGS FROM A PHARMACEUTICAL SUPPLIER

Purpose
To provide guidance on the safe ordering of all controlled drugs.

Procedure / Process
If items are urgently required they should be ordered from a local supplier
If items on hospital contract direct from manufacturer are needed urgently order a small amount locally

Ordering Controlled Drugs

Known Risks
- Items may be ordered from the wrong supplier
- Incorrect item or packsizes may be ordered
- Inc*orrect quantities may be ordered.*

4.4 PHARMACY SOP CDD4: ADJUSTMENT OF EXPIRED STOCK CONTROLLED DRUGS

Purpose
To update the CD register and pharmacy computer records when products expire.

Procedure/Process
All expired stocks of CDs must be recorded in the CD register and on the pharmacy computer system. Adjustments can be performed by the appropriate pharmacist or senior technician.

1. An entry is made in the individual section of the register for the particular item. This includes quantity, reason, and the new balance.
2. An entry is made in the CD destruction book. This includes the drug name, form, strength and quantity to be destroyed. The next numerical reference is assigned to

the item. The reference number is put on the item or bag that contains the item for destruction.

NB: When the item is actually destroyed, the individual carrying out the destruction and the witness to the destruction will sign and date the entry.

Known Risks:

- The expired item is not recorded in the register
- The new stock balance for the expired item is not updated on the pharmacy system
- The entry is recorded on the wrong page in the register
- The balance in the register is calculated and recorded incorrectly.

4.5 PHARMACY SOP CDD5: DISPOSAL / DESTRUCTION OF CONTROLLED DRUGS IN THE PHARMACY DEPARTMENT

Purpose

To ensure that all CDs are appropriately stored ready for destruction, disposed of using a suitable method in the presence of an external authorised person, and where appropriate, all destructions are recorded in the CD register. Destruction of controlled drugs should occur with sufficient frequency to ensure that excessive quantities are not stored awaiting destruction.

Procedure/Process

Storage of stock CDs awaiting destruction

Until they can be destroyed, obsolete, expired and unwanted stock CDs requiring safe custody, according to arrangements appropriate to their schedule, must be kept segregated from other CDs in a CD cupboard. Stock CDs awaiting destruction should be clearly marked in order to minimise the risk of errors and inadvertent supply.

Methods of disposal for CDs

CDs for destruction should be placed in suitable waste containers, which are then sent for incineration and should not be disposed of in the sewerage system. The containers containing waste should be labelled, “contains pharmaceutical waste – for incineration”. All CDs in Schedule 2 and those CDs in Schedule 3 that are subject to safe custody requirements (for example temazepam, diethylpropion, buprenorphine and flunitrazepam) must be rendered irretrievable (e.g. by denaturing) before being placed into waste containers Wherever practicable, CD denaturing kits should be used to denature CDs. Where this is not possible or practical other methods of denaturing may be used. Details of suitable methods for destruction of CDs in different dosage forms can be found in;
Guidance for Pharmacists on the safe destruction of Controlled Drugs: England, Scotland and Wales. (www.rpsgb.org.uk/pdfs/cdsafedestructionguid.pdf) and it is strongly recommended that these methods are used.

Small amounts of CDs, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or when a dose is drawn up but not used, should be rendered irretrievable by emptying the contents into a sharps bin. The emptied vial or ampoule should then also be placed in the sharps bin. The other option would be to use denaturing kits following a risk assessment.

When products are prepared extemporaneously, in these circumstances, the CD has already been issued to the extemporaneous preparation area or aseptic preparation area and is no longer part of the pharmacy CD stock. A full audit trail should be maintained. The worksheet should show the amount used and the amount wasted, for example: “2.5ml used 0.5ml wasted”.

As a matter of good practice, the emptying of the part dose into the sharps bin should be witnessed and recorded on the worksheet. Both people should sign the worksheet.

Destruction of CDs
CDs should be disposed of in such a way that the drug is denatured or rendered irretrievable so that it cannot be reconstituted or used again. Any pharmacy held stock of obsolete, expired or unwanted CDs not returned by patients, **that requires destruction can only be destroyed in the presence of an authorised person.** This must be completed in accordance with the SBU Health Board Controlled Drug Authorised Witness Protocol and SOP: Witnessing the Destruction of Controlled Drugs by SBU Health Board Accredited Authorised Witnesses (CDAWs) Standard Operating Procedure
Witnessing the Destruction of Controlled Drugs by Authorised Witnesses Protocol;
These individuals must be independent of the routine supply and administration of controlled drugs.

Further guidance can be found in Dangerous Drugs (Wales) The Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008

Register Entries for destruction of stock CDs
When stock CDs are destroyed, the following details must be entered into the CD register:

- Drug name
- Drug form
- Drug strength
- Quantity of drug being destroyed
- Date of destruction
- Signature of the authorised person in whose presence the drug was destroyed
- Signature of the person carrying out the destruction

Destruction of Patients Own controlled drugs.
These are CDs that have been prescribed for, and dispensed by another organisation outside SBU Health Board to a named patient and then returned unused or part-used by the patient or their representative to the pharmacy. This would also apply to patients discharged

and subsequently re-admitted. CDs that have been returned by patients do not form part of the pharmacy stock and can be destroyed without the presence of an Authorised Person. Although recording of patient-returned CDs is not a current legal requirement in relation to the Misuse of Drugs Regulations 2001, as amended, The Controlled Drugs (Supervision of Management and Use) Regulations 2006 require Standard Operating Procedures to be in place for maintaining a record of the CDs specified in Schedule 2 that have been returned by patients.

Storage of patient's own CDs awaiting destruction
CDs requiring safe custody awaiting destruction should be stored in the controlled drug cabinet separately from pharmacy stock CDs.

A record of CDs returned by patients should be kept and a record of destruction should be made. Both recording and destruction must be witnessed by a pharmacist or pharmacy technician.

Records of destruction of patients' own CDs
It is recommended that a separate book is designated for that purpose. It is recommended that the following details are recorded:

- Date of return of the CDs
- Name, quantity, strength and form of the CDs
- Name and signature of the person who received the CDs
- Patient's name and address (if known)
- Names and signatures of the person and witness destroying the CDs
- Date of destruction

Known Risks:

- Items stored for destruction have not been recorded in the destruction or individual item section of the register.
- Inability to destroy CDs due to availability of an authorised external witness
- Patients own controlled drugs not being recorded or destroyed when returned to the dispensary
- Controlled Drug packs not labelled with a reference number, that is, relating to the entry in the CD register

4.6 PHARMACY SOP CDD6: DISCREPANCIES IN CONTROLLED DRUG REGISTERS AND BALANCES

Purpose
To identify any discrepancies of controlled drugs held within the dispensary ensuring they are investigated and resolved immediately.

Procedure/Process
The person issuing the Controlled Drugs must check the balance on the shelf against that recorded in the CD register. If the balances are correct and matching, then the individual concerned should initial the running balance column in the register itself.

When checking controlled drugs, the pharmacist or CD technician must calculate the new balance and confirm with the balance in the register before endorsing the entry.
The balance recorded in the hardcopy register and/or, where relevant, the electronic register/pharmacy stock control system, should be reconciled against the stock of every product in the CD cupboard each time dispensing takes place. If one or more of these levels does not tally, the discrepancy must be investigated and resolved without delay. It is important to remember that a discrepancy may indicate misuse. There should be a careful check of transactions in the register against requisitions received and in the stock control system to trace an error or omission.

If an error is traced then a register entry should be made, clearly stating the reason for the entry, the reference of the error or the omission, the date of the error or omission and the signature of both the person carrying out the amendment and the witness.
If no error or omission can be traced, a clinical incident form should be completed and the Health Board Accountable Officer should be informed. The Accountable Officer will decide on an appropriate course of action.

Known Risks:
- Entry not made at all when issuing or receiving controlled drugs
- Entry made on the wrong product / package section
- Balance is incorrectly calculated and recorded
- Balance misread
- Pharmacist or CD checking technician does not confirm the balance before endorsing the entry.
- The discrepancy is not brought to the attention of the relevant staff.

4.7 PHARMACY SOP CDD7: CHECKS OF CD STOCKS PERFORMED BY PHARMACY STAFF

Purpose
To ensure that CD stocks and balances are checked regularly. Health Board-wide inspection of Controlled Drugs for all wards and departments holding CDs across the Health Board will be carried out on a three to six monthly basis. The “Controlled Drug Inspection Recording Form” should be signed for each inspection. A checklist is available in the Controlled Drugs Policy appendix.

Procedure/Process:

Checks of CD stocks held in wards, theatres or departments
All stocks of CDs held in wards and departments should be checked by a pharmacist or pharmacy technician at least every three-six months and at other times when requested by the ward or department manager.
The CD audit form should be completed and the stock check procedure should cover the following:

- A check that the levels of drugs in stock tally with the balances recorded in the CD register. Each individual product entry in the CD register should be reconciled with the CD stock content in the CD cupboard.
- A review of the security and quality of record keeping
- A check for exceptional usage of CDs
- A check of the physical security arrangement for the storage of CDs and CD stationery.

NB: A check of patients' own CDs held on the ward at the time if deemed appropriate.
A record of the stock check should be made clearly in ink in the left hand column of the ward CD register. Endorse as "Pharmacy Stock check" signed and dated by pharmacy and witness.

Known Risks:

- Stock checks are performed but discrepancies are not dealt with immediately
- Stock checks are not performed regularly
- Incorrect inspection may result in unnecessary investigation into missing CDs.

4.8 PHARMACY SOP CDD8: RECORD-KEEPING IN THE CD REGISTER

Purpose
To ensure that all issues and receipts of CDs are entered into the CD register.

Procedure/Process
Register entries must be made in consecutive, chronological order. The entry must be made on the day when the drug is received or supplied, or if this is not possible, on the next day.
Entries must be in ink or be otherwise indelible
If a mistake is made the entry should not be crossed out, deleted, obliterated or defaced; liquid paper must not be used. If an error is found, it must be bracketed and accompanied by a clearly recognised signature; the balance shown should be accurate and easily read. A footnote should be added to explain the alteration.

The following staff may complete the CD register:

- Any registered pharmacist under their own authority
- Any appropriately trained member of Pharmacy staff, ideally a registered pharmacy technician.

- Any person who is being trained by, and under the supervision of a competent member of pharmacy staff (trained technician or a pharmacist). The supervisor should countersign all until the trainee is deemed competent.

Each drug form and strength should be on a different page in the register both for issues and for receipts. The drug name, form and strength must be written at the top of the page. An index should be kept at the front of the register.
The 2001 Regulations were amended in July 2006 to make clear that the record keeping requirements of the CD Regulations are a minimum and do not prevent any person required to keep a register from including additional relevant information.

Known Risks

- Entry is not made on the day it is issued or supplied. Any correction will therefore not be in chronological order.
- The entry is made in the wrong section, that is, different packsize, strength and drug form. Two sections of the register are then incorrect.
- Not all the required information is recorded in the entry.

4.9 PHARMACY SOP CDD9: ISSUING OF STOCK CDs TO WARDS AND DEPARTMENTS

Purpose
Ensure all legal and local requirements are followed when issuing CDs.

Procedure/Process

Prior to dispensing CDs
There must be a check that the requisition is valid, that is, complete and signed by an authorised signatory.

- Incomplete or inaccurate requisitions may be amended in the dispensary where strengths, quantities or volumes requested are missing or alternative quantities or volumes of product may need to be supplied provided a **discussion has taken place with the ward**. For alternative products or incomplete signatures, the requisition should be returned to the ward for amendment or completion.
- When issuing CDs to an individual patient, normal dispensing routines and procedures should be followed.
- Entries must be made in the register in accordance with CD SOP CDD8.
- For CDs supplied, the register entry must also include:
  - Date of transaction
  - Name and address of person/department supplied
  - Licence or authority of person/department supplied
  - Amount supplied: this could be in number of dose units for tablets or injections, other recognized quantities for other preparations, such as mL for liquids or grammes for powders, or could even be the number of

whole packs (as in number of bottles of oramorph 100mL), depending on how the page in the register describes each product.
- Form in which supplied
- Name of patient, if individually dispensed
- Batch number

Arrangements for transfer of the CDs to the ward or department must be followed as per SOP CDW2: Procedure for the Collection of Controlled Drugs from Pharmacy or SOP CDD10: Delivery of Controlled Drugs to Clinical Areas.

Labelling of CDs for issue to patients

The label should state:

- Drug name, form and strength
- Quantity
- Department / ward name or number
- Date of issue
- Expiry date if dispensed from bulk. (NB: Certain preparations have a reduced expiry once opened, e.g., Oramorph). Extra sticky labels explaining this should be attached to each item.
- "Keep out of reach and sight of children"
- Address of pharmacy

Labelling of CDs for ward stocks

In-house additional labels should be attached to each item, including the ward / clinic, requisition number and the date. Each carton, syringe or bottle must be labelled individually. In addition, labels may also be placed on outer wrappers or containers. Checks should be made as per normal dispensing procedures.

Electronic systems

Where electronic systems for the requisitioning of CDs are introduced, safeguards in the software should be put in place to ensure that:

- Only individuals who are authorised to requisition CDs from the pharmacy can do so
- Entries cannot be altered at a later date
- A log of all data entered is kept and can be recalled for audit purposes.

Known Risks:

- Potential dispensing errors if procedures are not adhered to including:
  - Incorrect items booked out
  - Incorrectly picked or selected items,
  - not all orders fulfilled
  - items dispensed against an invalid order

4.10 PHARMACY SOP CDD10: TRANSPORT OF CDs FROM PHARMACY TO CLINICAL AREAS

Purpose
Ensure the security of Controlled Drugs is maintained throughout the delivery process until receipt on in the clinical area.

Procedure/Process
The hospital porter / courier delivers controlled drugs at specified intervals throughout the day. Each CD order for delivery is listed on the CD order requisition book and signed for when the CD is accepted for delivery. Each white sheet must be signed in the accepted for delivery section and the white sheet torn out and retained in pharmacy.
If the ward staff require the CDs outside the scheduled delivery, they are required to collect the item themselves, and sign the CD requisition book on collection of their items. See SOP CDW2: Procedure for the Collection of Controlled Drugs from Pharmacy.
When the porter delivers the bag to the ward, a registered practitioner signs the received by section of the duplicate (pink copy) CD requisition book.

NB: Controlled Drugs should not be left unattended during deliveries and must not be left on a ward without a signature for receipt.

Known Risks:

- Loss of controlled drugs if procedure is not followed.

4.11 PHARMACY SOP CDD11: WITNESSING CD DESTRUCTION IN THE PHARMACY

Purpose
To ensure that senior Health Board staffs understand their role in the witnessing of the destruction of controlled drugs in the pharmacy department. This applies to expired pharmacy stock, ward stock returned to pharmacy and unknown substances. Patients own drugs returned to pharmacy can be destroyed without the presence of an authorised person

Procedure/Process
The CD technician will help with the destruction by getting all the drugs ready in the right number order and will assist.

- Get the relevant section for destruction book.
- Work methodically through each item and check the item against the number in the book
- Count the item on a triangle or capsule counter or measure the liquid quantity in a measure.
- When satisfied you have the correct number you can dispose of the medication, tablets, capsules in the appropriate container, patches cut in half and placed in the appropriate container. Powders can be added direct to the container.

- Ampoules must have the top snapped off and placed in the container
- PCA syringes can be squirted into the container.
- Patches can be cut and folded.
- Liquids can be disposed of into the container.
- When finished each item must be signed and witnessed.
- When the whole list is finished put a line across the book and sign, and date and say destruction complete.

Known Risks
Inappropriate destruction of CDs causes a break in the audit trail and potential for errors.

Destruction of controlled drugs, in most circumstances needs to be witnessed by an authorised witness. These exception to this is the destruction of patient own returned controlled drugs. This may be destroyed by a registrant with a second registrant, acting as the witness to the destruction.

Controlled drugs for destruction in the pharmacy department must be recorded in the relevant section of the controlled drugs register.

The following table summarises the denaturing (destruction) and witness requirements on controlled drugs.

	Is Denaturing Required?	Is an Authorised Witness required?	Record Keeping
Patient-returned controlled drugs	Yes, if schedule 2, 3 or 4 (part 1)	No. However it is preferable for denaturing to be witnessed by another member of staff familiar with Controlled Drugs (preferably a registered health professional)	A record should not be made in the Controlled Drugs register but records of patient-returned Schedule 2 Controlled Drugs and their subsequent destruction should be recorded in a separate record for this purpose.
Expired / Obsolete / Unwanted stock	Yes, if schedule 2, 3 or 4 (part 1)	Yes, if Schedule 2. For Schedule 3 medicines it would be good practice to have another member of staff witness the denaturing.	An entry should be made in the Controlled Drug register for Schedule 2 Controlled Drugs.

4.12 PHARMACY SOP CDD12: RETURNING CONTROLLED DRUGS TO THE SUPPLIER

Purpose
To ensure all Controlled drugs are returned to individual suppliers in accordance with local and supplier procedures

Procedure/Process

Suppliers will have their own individual policy on returning controlled drugs. Liaise with the individual companies to confirm their policy. Any controlled drugs that have been picked and sent in error by the supplier can be returned if agreed with supplier.

If an item has been ordered in error by the pharmacy then most suppliers do not allow them to be returned, however, it is worth liaising with the individual company to see if they will agree to a one-off return.

On identification of an order error notify the supplier with the following details:

- Explain reason for return: incorrect drug/form/strength/quantity sent by the supplier
- Order Number (found on the order paperwork)
- Pick number (some companies will ask for an individual reference number on the delivery sheet)
- Confirm what paperwork is required (varies according to individual companies)
- Confirm when the CDs will be collected
- Confirm when the original requested CDs will be delivered

The CDs should be quarantined. Fill in the appropriate paperwork, pack the CDs together with the paperwork and leave in the quarantined area. Inform all relevant dispensary staff of medication to be returned and when this will happen.

Upon collection of Controlled Drugs by the company driver, pharmacy staff should complete the appropriate paperwork and obtain the drivers signature to confirm the supplies have been collected and returned to the supplier.

Known Risks:

- Items must be quarantined to prevent incorrect item being mixed up with Pharmacy stock
- If the items are not left in the allocated place, then stock may be thought to be ‘Missing’ and unable to be returned to supplier
- Paperwork may not be filled in correctly or incorrect paperwork used, resulting in the company drivers refusing to return the CDs

4.13 PHARMACY SOP CDD13: GENERAL MEASURES FOR THE STORAGE OF CDs

Purpose:

To inform pharmacy staff of the general measures required for the storage of CDs in the pharmacy department and across the Health Board.

Procedure / Process:

1. Cupboards must be kept locked when not in use.
2. The lock must not be common to any other lock in the hospital.

3. Keys must only be available to authorised members of staff and at any time the key-holder should be readily identifiable.
4. The cupboard should be dedicated to the storage of CDs.
5. No other medicines or items should normally be stored in the CD cupboard. Occasionally, in response to local circumstances health care organisations may decide to allow other drugs that are not CDs to be stored in the CD cupboard. This includes mifepristone.
6. CDs must be locked away when not in use.
7. There must be arrangements for keeping the keys secure. This is particularly important for areas such as day surgery units and five day wards that are not operational at all times.
8. In certain circumstances, for example when CD discharge medicines (TTOs) are sent to the ward several hours before the patient leaves, the medicines may be stored in the CD cupboard. **These medicines should be stored in the ward CD cupboard segregated from the ward CD stock.**
   It is the responsibility of the registrant who accepts and signs for the CDs to ensure that the patient/carer is given the TTO immediately. If this is not possible the CD must be stored in the CD cupboard and entered into the ward CD register in the patient's own section.

4.14 PHARMACY SOP CDD14: CONTROLLED DRUG REGISTERS

Purpose:
To ensure that staff are aware of the rules and regulations surrounding the use of controlled drug registers.

Procedure / Process:

- Entries should be made in chronological order.
- Every entry and correction must be in ink or be otherwise indelible.
- All entries should be signed by a registered pharmacist, doctor, dentist, registered nurse, midwife or ODP and should be witnessed preferably by second registered nurse, midwife or ODP. If a second registered nurse, midwife or ODP is not available, then the transaction can be witnessed by another registered practitioner (e.g. doctor, dentist, pharmacist, pharmacy technician) or by an appropriately trained healthcare assistant.
- On reaching the end of a page in the CD register, the balance should be transferred to another page. The new page number should be added to the bottom of the finished page and the index updated. As a matter of good practice this transfer may be witnessed.
- If a mistake is made it should be bracketed in such a way that the original entry is still clearly legible. The new entry should then be made on the next line. This should be signed, dated and where possible, witnessed by a second registered nurse, midwife or other registered professional or by an appropriately trained

healthcare assistant. The witness should also sign the correction NB: Crossing out or the use of correction fluid is not allowed.

- Separate sections for registers used on wards, departments, theatres and clinics should be identified for the recording of, patients' own drugs, waste, and the recording of CD stock balance checks. Pharmacy will have their own system for recording these records.
- After every administration, the stock balance of an individual preparation should be confirmed to be correct and the running balance recorded in the controlled drug record book. The entry should be signed and dated.

4.15 PHARMACY SOP CDD15: PROCEDURE FOR DEALING WITH STAFF WHO ARE SUSPECTED OF CONTROLLED DRUG ABUSE

Purpose:
CD diversion for the purposes of substance abuse constitutes a serious health and employment problem. Healthcare staff who have access to CD's are at particular risk. Those affected are in need of urgent assistance and can seek help from their Union or BMA representative, Occupational Health, their General Practitioner, or a number of other sources.
Further information about the identification and management of colleagues with a substance abuse problem is available from a variety of online resources.

Procedure / Process:

1. If a Health Board employee, including those who prescribe, is suspected of abusing controlled drugs, then these suspicions should be shared with a more senior staff member.
2. The Health Board Accountable Officer should be contacted directly to discuss suspicions of this nature, particularly if the staff member feels unable to discuss the matter within their own department/directorate.
3. All actions concerning this will be dealt with confidentially and will follow the agreed Corporate

4.16 PHARMACY SOP CDD16: CONTROLLED DRUG STATIONERY

Purpose
All stationery which is used to order, return or distribute controlled drugs (CD stationery) should be stored securely and access to it should be restricted. These measures are important to guard against unauthorised use of the stationery to obtain CDs for inappropriate purposes.

Definition of CD stationery
CD stationery includes:

- Controlled drug requisition books

- Controlled drug ward registers
- Local CD documents such as CD returns advice notes, pharmacy distribution documents.

Procedure / Process:

Secure storage of CD stationery

CD stationery which is kept in wards, theatres or departments should be kept in a locked cupboard or drawer. Stocks of CD stationery held in pharmacy departments should be kept in a secure area that is locked when there is no one present.

Supply of CD stationery

CD stationery should be issued from the pharmacy and signed by the member of staff issuing the stationary. Wards and theatres should requisition CD stationery from pharmacy in all cases. Where pharmacy staffs are aware that a CD requisition book is coming to the end of its supply of requisitions, a pharmacist or pharmacy technician may issue the appropriate stationary. A registered nurse, midwife or ODP may request new CD stationary.

A record should be kept of the supply of CD stationery. It should include:

- Date
- Ward/department
- Type of stationery issued
- Quantity
- The serial numbers of the stationery allocated by pharmacy.
- Signature of the member of pharmacy staff making the supply
- Any unused stationery returned to pharmacy will be recorded as a return, with the details above, in the supply record.

Loss or theft of CD stationery

Loss or theft of any controlled stationery which may be used to order CDs should be reported immediately to the Pharmacy Manager and Accountable Officer.

Use of CD stationery

Only one CD requisition book per ward or department should normally be in use however, areas with more than one CD cupboard will have a separate requisition book for each cupboard or fridge. Each ward or department should normally only have one CD register book in use at any one time, except those with more than one cupboard or fridge, where there would be one register book per cupboard or fridge. A new register should not be started until the previous one is full. When a new CD register is started, the balance of CDs in stock should be written into the new book promptly by ward staff. This transfer should be witnessed by a registered nurse or midwife or authorised member of staff e.g. pharmacy technician. Completed ward requisition books and CD record books must be retained for a minimum of two years from the date of the last entry.

Archiving of controlled drug records

Every requisition, order or private prescription on which a Controlled Drug is supplied must be preserved by the Pharmacy department for a minimum period of two years from the date on which the last delivery under it was made. Although the mandatory period for keeping

requisitions is two years, health care organisations may wish to store them for longer periods, as cases often come to court at a much later date. The time periods for archiving CD documentation are:

○ Requisitions	2 years from last entry
○ Registers and controlled drug requisition books	2 years from last entry
○ Extemporaneous preparation worksheets	13 years
○ Aseptic worksheets (adult)	13 years
○ Aseptic worksheets (paediatric)	26 years
○ External orders and delivery notes	2 years
○ Prescriptions (inpatients)	2 years
○ Prescriptions (outpatients)	2 years
○ Clinical trials (may be longer for some trials)	5 years after end of trial
○ Destruction of CDs	7 years

Future Regulations may increase the period of time for the storage of records. Readers are advised to refer to Department of Health and RPSGB websites for up to-date information

4.17 PHARMACY SOP CDD17: CLINICAL CHECKING OF PRESCRIPTIONS FOR OPIOID MEDICINES

Purpose

To support patient safety in response to the NPSA Rapid Response Report (RRR) No. NPSA/2008/RRR05. This RRR is aimed at reducing dosing errors with opioid medicines in light of reports received by the NPSA of medication errors.

Procedure / Process:

When opioid medicines are prescribed, dispensed or administered, in anything other than acute emergencies, healthcare practitioner concerned, or their clinical supervisor, should:

- Confirm any recent opioid dose, formulation, frequency of administration and any other analgesic medicines prescribed for the patient. This may be done for example through discussion with the patient or their representative (although not in the case of treatment for addiction), the prescriber or through medication records.
- Ensure where a dose increase is intended, that the calculated dose is safe for the patient (e.g. for oral morphine or oxycodone in adult patients, not **normally** more than 50% higher than the previous dose).

Ensure they are familiar with the characteristics of that medicine and formulation: usual starting dose, frequency of administration, standard dosing increments, symptoms

SECTION FIVE
5.0 PRESCRIBING PROCEDURES

5.1 PRESCRIBERS SOP CDRX1: PRESCRIBING OPIOID MEDICINES FOR PATIENTS

Purpose
To support patient safety in response to the NPSA Rapid Response Report (RRR) No. NPSA/2008/RRR05. This RRR is aimed at reducing dosing errors with opioid medicines in light of reports received by the NPSA of medication errors.

Procedure / Process:
When opioid medicines are prescribed, dispensed or administered, in anything other than acute emergencies, healthcare practitioner concerned, or their clinical supervisor, should:

- Confirm any recent opioid dose, formulation, frequency of administration and any other analgesic medicines prescribed for the patient. This may be done for example through discussion with the patient or their representative (although not in the case of treatment for addiction), the prescriber or through medication records.
- Ensure where a dose increase is intended, that the calculated dose is safe for the patient (e.g. for oral morphine or oxycodone in adult patients, not **normally** more than 50% higher than the previous dose).
- Ensure they are familiar with the characteristics of that medicine and formulation: usual starting dose, frequency of administration, standard dosing increments, symptoms of overdose, common side effects.

5.2 PRESCRIBERS SOP CDRX2: REGULATIONS FOR WRITING A CONTROLLED DRUG PRESCRIPTION

Purpose
To inform prescribers of the legal requirements for prescribing controlled drugs.

Procedure / Process:
Prescribing of controlled drugs is tightly controlled by the law.

- Controlled Drugs must be prescribed in accordance with the Health Board policy for the prescribing of medicines as described in the Medicines Policy. All prescriptions must have a unique patient identification number (NHS Number / Hospital Number).
- 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.
- Prescriptions for Outpatients should be limited to a maximum of 30 days’ supply. Under normal circumstances a shorter supply is usually prescribed, for example 7 days. If a longer period is required, the reasons for this must be recorded on the prescription.
- Prescriptions for Outpatients 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).

- Controlled drugs for inpatients can be written up and administered from the inpatient medication chart without the need for full prescription requirements expected for an outpatient/discharge prescription.
  - Prescriptions must be on official Health Board prescription stationery and in indelible ink – carbon copies/faxes for out-patient or discharge 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) However, faxed/carbon copy prescriptions may be accepted by pharmacy to enable assembly of the prescription in advance, but the original copy **must** be received before the final release of the prescription.
- Electronic prescribing of controlled drugs for inpatients follows the same process as that for other medicines. Particular care must be taken when selecting these medicines from the electronic list due to the variations in presentation and the implication in relation to their bioavailability/release characteristics.
- 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 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.
- Specimen signatures must be obtained by medical staffing on appointment of medical staff and be available for cross checking. The responsibility for providing the Accountable Officer with specimen signatures, lies with the Medical Director. Non medical prescribers signatures will be retained in the Non Medical Prescribers Register.

NB. Should a patient who receives an out-patient/discharge prescription containing controlled drugs be requiring to travel abroad, they may require a Home Office export licence depending on the amount. Applications should be supported by a letter from the prescribing doctor and sent to the Home Office
(tel. 0171 273 3806 for further advice/details required/address to apply to)

NB: It is an offence for a prescriber to issue an incomplete 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.

5.3 PRESCRIBERS SOP CDRX3: HOW TO WRITE A CONTROLLED DRUG PRESCRIPTION

Purpose
To inform prescribers of the legal requirements and practicalities for prescribing controlled drugs.

Procedure / Process*:
Prescription requirements: Prescriptions for Controlled Drugs that are subject to prescription requirements must be indelible, and must be **signed** and **dated** by the prescriber and specify the prescriber's address.
The prescription must always state:

- the name and address of the patient;
- in the case of a preparation, the form and where appropriate the strength of the preparation;
- either the total quantity (in both words and figures) of the preparation, or the number (in both words and figures) of dosage units, as appropriate, to be supplied; in any other case, the total quantity (in both words and figures) of the Controlled Drug to be supplied;
- the dose;

A pharmacist is not allowed to dispense a Controlled Drug unless all the information required by law is given on the prescription. In the case of a prescription for a Controlled Drug in Schedule 2 or 3, a pharmacist can amend the prescription if it specifies the total quantity only in words or in figures or if it contains minor typographical errors, provided that such amendments are indelible and clearly attributable to the pharmacist making them. Failure to comply with the regulations concerning the writing of prescriptions will result in inconvenience to patients and delay in supplying the necessary medicine.
A prescription may order a Controlled Drug to be dispensed by instalments; the amount of instalments and the intervals to be observed must be specified. Prescriptions ordering ‘repeats' on the same form are **not** permitted for Controlled Drugs in Schedules 2 or 3. A prescription for a Controlled Drug in Schedules 2, 3, or 4 is valid for 28 days from the date stated thereon.

Private prescriptions
Private prescriptions for Controlled Drugs in Schedules 2 and 3 must be written on specially designated forms as specified in Appendix 3.1 of the Controlled Drugs Policy. These are provided by the Business Services Centre prescriptions must specify the prescriber's identification number. Prescriptions to be supplied by a pharmacist in hospital are exempt from the requirement for private prescriptions.

SECTION SIX
6.0 COMMUNITY NURSES AND MIDWIVES

6.1 COMMUNITY SOP CDCOM1: COMMUNITY NURSES AND MANAGEMENT OF CONTROLLED DRUGS

Purpose
To ensure correct ordering, storage, administration and disposal of Controlled Drugs by community nurses.

Procedure/Process

Administration of Controlled Drugs by Registered nurse in Community.
A community nurse must be in receipt of a written instruction from the General Practitioner or Consultant before controlled drugs are administered.
Patients' notes must be completed in regard to date, time, dosage, site and quantity left with the patient/relative.
In the community (the patient's home) the administration of controlled drugs is a single person procedure. The controlled drug may only be administered to the patient for whom it is prescribed. If a prepared dose of a controlled drug is not used, a patient refuses the drug or the registered nurse has any concerns with regard to any discrepancies in the supply and what has been previously administered, the GP should be informed. Appropriate records must be maintained, including a record of the remaining supply of controlled drug prescribed.
Note: National Patient Safety Agency (NPSA) guidance recommends that where a registered nurse is operating as a lone worker and administering controlled drugs, wherever possible and appropriate the patient/carer/relative should be requested to provide a second check.

Disposal of medicinal products in the community

(i) Under no circumstances should community nurses take surplus medicinal products into their possession or make any further use of them.
(ii) It is the duty of community nurses to advise their patients and relatives on the correct destruction/disposal of unwanted medicinal products. **Unwanted medicinal products should be returned to the Community Pharmacist for destruction**
(iii) **A record of destruction** should be made in the patient's case notes.
(iv) Community Nurses can advise a family member or carer to return unwanted or unused control drugs to the Community Pharmacist

6.2 COMMUNITY SOP CDCOM2: MIDWIVES AND MANAGEMENT OF CONTROLLED DRUGS

Purpose
To ensure correct ordering, storage, administration and disposal of Controlled Drugs by midwives.

Procedure/Process

Ordering & Supply of Pethidine Injection by community Midwives

Pethidine Injection may be obtained on the approved midwife's supply order. Records of supply and usage must be entered in the Controlled Drugs Register. This Register must be maintained by the midwife and handed to the Supervisor of Midwives on leaving the Health Board.

Disposal of Pethidine injection by Community Midwives

(i) Pethidine inject, which is time-expired, must be returned to the pharmacy for disposal. The midwife must record full details of what was destroyed in his/her Controlled Drug Record Book.

(ii) When a midwife is in possession of re-usable stock which is no longer required, this shall be returned to the Pharmacist from whom it was obtained, or to an appropriate Medical Officer, but not to a Supervisor of Midwives.

(iii) Where controlled drugs are supplied directly to the mother, on prescription from the GP, the responsibility for the destruction of the drug is that of the mother. The Midwife can advise the mother to destroy the drug, whilst in the presences of the Midwife, or return the drug to Pharmacy. The Midwife cannot do this for the mother. Any advice given must be recorded in the mother's notes.

Midwives and Controlled Drugs

1. A registered midwife may possess diamorphine, morphine, pethidine and pentazocine in her own right so far as is necessary for the practice of her profession. See the Misuse of Drugs Regulations 2001 at http://www.opsi.gov.uk/si/si2001/20013998.htm
2. Supplies of diamorphine, morphine, pethidine and pentazocine may only be made to her on the authority of a midwife's supply order signed by the Supervisor of Midwives, or other Appropriate Medical Officer who is a doctor authorised in writing by the local supervising authority.
3. The Supervisor of Midwives or other Appropriate Medical Officer should be satisfied that locally agreed procedure is being followed before signing the supply order (e.g. that the amount being requested is appropriate etc).
4. The order must specify the name and occupation of the midwife, the purpose for which the Controlled Drug is required and the total quantity to be obtained. Supplies of pethidine, pentazocine, morphine and diamorphine may be obtained from a hospital pharmacy. However, this is only when classed as within the course of the business of the hospital the midwife works in, or it is a registered hospital pharmacy, or it holds a wholesale dealer's license. The pharmacist who makes the supply should ensure that medicines are only supplied on the instruction of an authorised person. The pharmacist must retain the midwife's supply order for two years.
5. Midwives should record full details of supplies of diamorphine, morphine and pethidine received and administered in their Controlled Drugs Register. This register should be used solely for that purpose and be made available for inspection as required by the Supervisor of Midwives.

6. Once medicines are received – by midwives working in the community or independent midwives – they become the responsibility of the midwife, and should be stored safely and securely.
7. Where it is necessary for midwives to keep medicines in their homes, the medicines should be placed in a secure, locked receptacle. If necessary, this should be provided by the employing body.
8. Administration of Controlled Drugs by midwives should be in accordance with locally agreed procedures. A record of administration of the Controlled Drugs should also be kept in the patient's records.

Returns and disposal

When a midwife is in possession of re-usable stock which is no longer required, this shall be returned to the Pharmacists from whom it was obtained, or to an appropriate Medical Officer, but not to a Supervisor of Midwives. See section 18 of the Midwives Rules and Standards (2012).

Where controlled drugs are supplied directly to the mother, on prescription from the GP, the responsibility for the destruction of the drug is that of the mother. The Midwife can advise the mother to destroy the drug, whilst in the presences of the Midwife, or return the drug to Pharmacy. The Midwife cannot do this for the mother. Any advice given must be recorded in the mother's notes.

SECTION SEVEN
STANDARD OPERATING PROCEDURES

7.1 SOP for the management of Controlled Drugs by the Emergency Medical Retrieval and Transfer Services and Acute Critical Care Transfer Service (EMRTS and ACCTS)

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

Procedure Name:	**SOP for the EMRTS service**

Introduction

This SOP describes how controlled drugs should be managed for the retrieval and transfer services hosted by Swansea Bay, specifically:

- EMRTS bases, vehicles and aircraft
- ACCTS bases and vehicles

EMRTS and ACCTS attends critically ill and injured patients who often require advanced analgesia and/or anaesthesia. The use of controlled drugs within this SOP is designed to ensure that these drugs are provided in an efficient and timely fashion in congruence with guidelines, regulations, and legal requirements. The SOPs are to support *CID398 Policy for Management of Controlled Drugs and should be referred to for further information.*

Scope

This SOP applies to all staff involved in the ordering, receipt, dispensing, checking, delivery, destruction, or audit of controlled drugs within the SB University Health Board and those acting as messengers between pharmacy and service areas. The SOP covers every aspect of the CD journey from pharmacy to a patient within EMRTS and ACCTS including ordering, receipt, responsibilities, safe storage, access, dispensing, administration, disposal/destruction, record keeping, as well as alert, investigative, & documentation systems in the event of discrepancies, deviations from SOP, or other problems. It does not extend to the receiving of CDs into the SBU Health Board organisation and subsequent transport within the organisation, which are covered under separate SOP's. It also covers delivery of CDs by Porters, Hospital Courier and Pharmacy Staff to the clinical area and collection of CDs from the pharmacy department by EMRTS and ACCTS personnel.

Responsibility

The responsibility for establishing and maintaining a system for the security of medicines used lies with the *Accountable Officer*, in consultation with the EMRTS National Director, chair of the Medicines Management committee and appropriate medical, paramedical, pharmacy and nursing staff.

Accountable individuals
The registered nurses, paramedics or doctors working on a shift at an EMRTS or ACCTS base are responsible for the safe and appropriate management of CDs.

The registered nurses, paramedics or doctors working on a shift at an EMRTS or ACCTS base are responsible for the security and safe keeping of the keys to any cupboard. When not in active use, the keys should be kept in the designated key safes.

7.1.1 Procedure for the ordering of controlled drugs by EMRTS and ACCTS

Purpose
The purpose of this CD SOP is to ensure that staff are aware of the process for ordering controlled drugs from the pharmacy department for use by EMRTS and ACCTS.

Ordering of Controlled drugs
CD's held at each EMRTS and ACCTS base as stock items should reflect current patterns of usage of CD's for that base, and modifications at appropriate intervals should be agreed between the member of pharmacy staff responsible for EMRTS and ACCTS, the Lead Practitioner, and appropriate paramedical, registered nursing and medical staff. These CD's should be listed in the front pages of each individual CD Drug Register, along with a relevant working page index for the register.

Procedure / Process
The controlled drug order book (Requisition Book) specified for the EMRTS or ACCTS base must be used for the ordering of controlled drugs using a separate page for each item. An authorised registered practitioner can generate an order for the required controlled drugs

1. Controlled drugs must be ordered in the controlled drug order book specific to that base. Order books from other areas cannot be used.
2. A separate page must be used for each item ordered.
3. Place the carbon paper in between the top and lower page with the carbon placed down. If the carbon paper is missing, then an identical entry should be made on the top and bottom sheets.
4. Orders must contain the following details: -
    - EMRTS or ACCTS base name
    - Name, form strength, volume, quantity of the controlled drug to be ordered. (Only agreed abbreviations should be used.)
    - Signature of person ordering
    - Person ordering must also print their name.
    - Date of the order.

5. The person who accepts the CDs for transit should sign for receipt on the tear out / white copy. This white copy should be retained in pharmacy and stored accordingly.
6. The person who receives the CDs at the base should sign the pink duplicate copy of the requisition retained in the order book and should, ideally, not be the same person that ordered the CDs in question.
7. Each separate Order for CDs from Pharmacy for EMRTS or ACCTS bases will be made in their allocated CD order book, by a registered practitioner.
8. CDs should ideally be ordered during normal pharmacy working hours – requests on weekends should be restricted to emergency supplies only.

Notes
Controlled drugs order books, like all controlled stationery, must be kept in a secure place. Should an order book go missing, the duty crew must inform the base lead practitioner, Operations Manager, who will also then make contact with pharmacy. An incident report form (DATIX) must also be completed.

In the event of an emergency, where the CD order book cannot be accessed, emergency orders can be placed in an “ad hoc order book” which is held by pharmacy.

An up-to-date list of EMRTS and ACCTS registered practitioners authorised to order CDs must be maintained in the hospital pharmacy.

7.1.2 Procedure for the Receipt of the Drugs onto the EMRTS and ACCTS base

Purpose
The purpose of this SOP is to ensure that staff across EMRTS and ACCTS are aware of the process for receiving controlled drugs from the pharmacy department.

Procedure / Process
1. Whenever possible, different registrants should be responsible for the requisitioning & receipt of CD’s. If delivered to the base, CDs should never be left unattended and must be handed over to a registered practitioner
2. Upon receipt, the registrant should check each item of CDs received against the requisition, and the duplicate sheet (pink copy) in the CD Requisition book should be signed in the ‘received by’ section. The number of units received must be recorded. Any tamper-evident seals on packs should be left intact and subsequently only broken when the pack is required for administration.
3. After a cycle count of the CDs in the Omnicell, the CD register running balances should be updated, and the requisitioned CDs secured within the Omnicell. In situations when there is only one registrant on site, the second person may be

an SBU-employed, or an approved non-registrant (such as an Admin Officer/Store-person)

4. Whole sealed boxes of controlled drug injections received from pharmacy can be assumed to contain the quantity specified on the label until the seal is broken. The box does not need to be opened to check the quantity but may be received as the quantity specified on the label.
5. The registered practitioner receiving the controlled drugs, and a witness, (registered or an approved non-registered member of staff) must enter each item into the Omnicell and the final balance cycle counted and witnessed. Entry in the Omnicell system must include at least:
    - the date
    - quantity received in words, not figures.
    - requisition number.
    - Serial number of transit seal
    - signature of receiver
    - new stock level
    - electronic signature of first registrant and countersignature of the witness confirming correct balance in the Omnicell.
6. The CDs must be stored in the Omnicell and not left unattended and unsecured.

Omnicell procedure for restocking CDs from Pharmacy

1.

Log in to the system using your fingerprint.
To log into the system if your fingerprint does not work:

- Enter your **User ID**
- Press **Enter** on the keyboard
- Enter your **Password**
-  Press **Enter** on the Keyboard

2.

- Select **Main Menu**
- Select **Inventory Menus**
- Select **Normal Restock**

3.	 *Every time an order is generated a new **CPC** number is created. The restock paperwork should have the same CPC number on it. This should be used to identify the correct order. The **Date and time** the order was generated is also displayed.* *Note: CD's and general stock will always be on separate orders.*
4.	Select the required **Pharmacy CDs Restock** and • Enter witness credentials when prompted • Open the door where the flashing light is located • Press the button with flashing light • You will be prompted to perform a countback • Confirming the quantity to be restocked • Placing the item in the correct location using the guiding lights • Press button again to confirm
5.	• Repeat process for any other drugs that need restocking
6.	• Once you have completed all transactions ensure you **log out/Exit**
7.	• If any of the countback values were different from that stored in cabinet a discrepancy receipt will be issued – this will need to be investigated and resolved.

Notes

Once the controlled drugs have reached the base, they become the ultimate responsibility of the accepting registrant, who at that time is responsible for all the controlled drugs on the base. In the event the duty crew are out, the base administrator must place the CDs in the "Emergency" CD cupboard and inform the duty crew. Any discrepancies noted must be reported to the pharmacy immediately once identified, and a Datix form completed.

7.1.3 Procedure for the administration of controlled drugs to patients

Purpose

The purpose of this SOP is to ensure that staff working for EMRTS, and ACCTS are aware of the process for administration of controlled drugs to patients.

Administration process

1. In the prehospital and retrieval setting, a legible record of administration, including dose & time, should be made on the appropriate patient clinical record (paper or electronic) as soon as possible after administration by the person who administered the CD.
2. CDs should not be left unattended/unsecured during the prehospital care of the patient.
3. EMRTS and ACCTS staff should finish one box of ampoules before opening the next, to aid stock control and daily counts. When the seal of a box of controlled drug injections is opened, if any of the ampoules are found to be broken or missing, an entry must be made on the Omnicell using the “Broken/Damaged” option within the patient list. If there is no identifiable cause for missing stock, the Pharmacy must be notified immediately, and a Datix form completed.
4. The Patient Clinical Record entry must include: -
    - patient name (or Welsh Ambulance Services Trust) incident number if name unknown)
    - amount administered to patients(s)
    - Name of witness staff member
5. When part of a dose of a CD is administered, e.g., 5mg morphine, from a 10mg ampoule, the fact that 5mg is wasted/dooped must be entered into the Omnicell on return to base and additionally witnessed by a second registrant. This waste will be documented into the Omnicell individual register against the in-use emergency anaesthesia Rapid Sequence Induction (RSI) module. (Please refer to section 9.8.4 for a description of the RSI modules). A drop-down list of areas where the remaining dose of the CD has been disposed of will be accessible on Omnicell. (i.e., Dooped at Hospital)

Standard Operating Procedure – Recording Partial CD Waste into the Omnicell Cabinet

1.

Log in to the system using your fingerprint.
To log into the system if your fingerprint does not work:

- Enter your **User ID**
- Press **Enter** on the keyboard
- Enter your **Password**
-  Press **Enter** on the Keyboard

2.

- Locate and select the required Patient / Incident from the **Local list.**
- **The list is in reverse-chronological order, so you will have to search for the current incident number/patient name by using the keyboard to enter the incident demographics. Alternatively, staff can use the scroll down arrow until the details are located.**

3.

- Press the **Waste Drugs** button

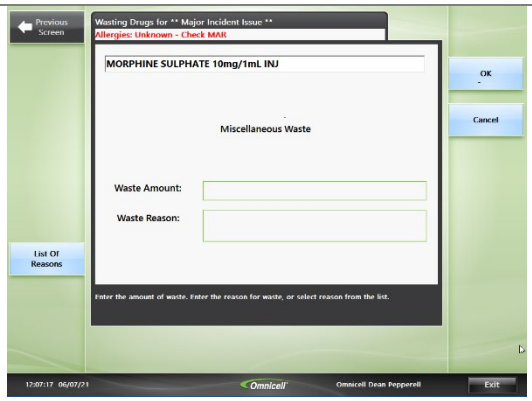
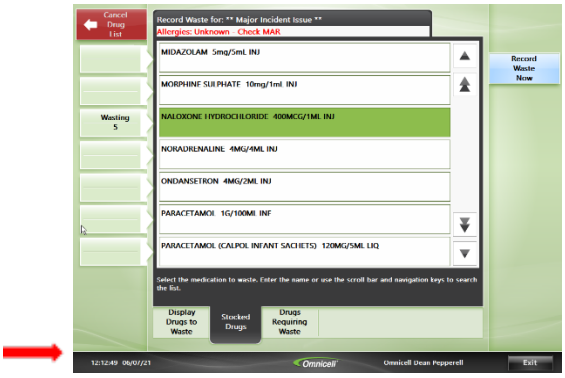
4.

- Select the **Stocked Drugs tab**
- Select the required CD from the list

You may see the following warning:
Open PMA's exist for this patient, do you want to waste this item against one of these PMA's or create a miscellaneous waste.

- Select Misc. Waste if this screen displays

5.

	 • Enter Waste Amount as a figure (e.g., 5 for 5MG) • ⬅ Enter Waste Reason by pressing List of Reasons and choosing from list – add location to reason if required.
6.	• A witness will be required before you can proceed
7.	• Repeat steps 4 to 6 for any other CD's that require Partial Waste Recorded
8.	• Once all CD's have been entered  • Select **Record Waste Now**
9.	• Once you have completed all transactions ensure you **log out/Exit**

Notes

Administration of CDs to patients should take place in accordance with the direction in the Health Board Medicines Policy. Should a part used dose of a pre-drawn CD need to be wasted, then the dose must be destroyed by emptying it into a suitable denaturing area. An authorised member of EMRTS and ACCTS staff must witness the destruction.

7.1.4 Procedure for the Management of drug packs/modules at base containing drugs for administration at the scene of an incident

Purpose

The purpose of this SOP is to ensure that staff working for EMRTS and ACCTS are aware of the process for the management of drug modules at the scene of an incident.

Controlled drugs stored at the bases at the EMRTS and ACCTS bases will be used to stock modules which are taken for administration to patients at the scene of an incident. Controlled drugs may or may not be used at the incident but are made available for the clinicians if they are required.

Standard Operating Procedure – Issue of an RSI Bag from Omnicell Cabinet

1.	 Log in to the system using your fingerprint. To log into the system if your fingerprint does not work: • Enter your **User ID** • Press **Enter** on the keyboard • Enter your **Password** •  Press **Enter** on the Keyboard
2.	• Locate and select the relevant **RSI Bag** from the **Local list** 

3.	 • Once the RSI Bag has been selected press the **Remove Kits** button
4.	 • • Select the relevant **RSI Bag** from the list *Quantities to dispense are auto populated but may be **edited** or **deleted** prior to issuing.*
5.	• Select **Remove Now**
6.	• Open the door using the guiding lights to gain access to the items • A witness will be required to proceed • A countback for each item will be needed to confirm quantity before removal
7.	• Once you have completed the transaction ensure you **log out by pressing Exit**

Process

Each EMRTS base will require the following modules to perform their duties:

Dafen
RSI Module – Doc
RSI Module – CCP (Critical Care Practitioners)
Drug Module – General (x3)
Drug Module – Pregnancy (x3)

Welshpool
RSI Module – Doc
RSI Module – CCP
Drug Module – General (x2)
Drug Module – Pregnancy (x2)

Caernarfon
RSI Module – Doc
RSI Module – CCP
Drug Module – General (x2)
Drug Module – Pregnancy (x2)

Cardiff
RSI Module – Doc
RSI Module – CCP
RSI Module - ACCTS
HTP Drug Module
Drug Module – General (x2)
Drug Module – Pregnancy (x2)
Drug Module – ACCTS (x2)

Bangor
RSI Module – Doc (x2)
Drug Module – ACCTS (x2)

During the shift period (normally undertaken at the start), Omnicell cycle counts will need to be performed on each of the RSI modules containing CDs, alongside any other areas within the Omnicell cabinet that also contain CDs (Such as Major Incident /Quarantine Area stock). A report of these daily cycle counts will be generated and will be accessible for retrospective audit to ensure compliance with CD Governance

Standard Operating Procedure for completion of Daily CD Cycle Counts on Omnicell Cabinet

1.	•  Log in using **Fingerprint** or **User ID** and **Password** • Press **Main Menu** button • Select **Inventory Menus** •   Select **Cycle Count**
2.	 • Cabinet should default to Guided Cycle Count, but if not, select **Guided Cycle Count.**
3.	•  Select **All** and make sure **Control Level 2** is selected. • Select **Count Now**
4.	• Follow the guiding lights to each location. (A witness will be required before the door / bin lid can be opened)

5.	• Open the door / bin • Count the quantity on hand • Enter a quantity
	 If quantity entered is different from that stored in the cabinet a warning of **Is this the correct count?** will display • Select **Yes** to confirm correct • Select **No** to enter quantity again
6.	• Close the door / bin. *Note: You will be guided through all **control level 2** (CD) items stored in the cabinet (including those stored in RSI Bags) You can exit the guided count at any point and when the same user logs back in the count can be resumed from the cycle count menu by pressing **Resume Count.***
7.	• Once all CD's have been counted press **Exit**
8.	• If any items counted differed from the quantity stored in the cabinet a discrepancy receipt will be produced. This will need to be investigated and resolved. (See section 7.1.5)

Procedure for preparing drugs for daily shift

At the beginning of each shift, the following controlled medication should be pre-drawn into syringes:

EMRTS Shifts
200mg ketamine in 20ml (aspirated into a 30ml Luer-type syringe)
500 micrograms fentanyl (aspirated into a Luer-type 10ml syringe)
5mg of midazolam (aspirated into a 5ml Luer-type syringe)

Once products are drawn and aspirated, tamper-evident caps must be fitted to the syringes, and they should be placed within the RSI drug modules.
The RSI module should be kept in the crew's possession throughout the day and taken to incidents, as necessary.

ACCTS shifts only

There is no requirement to routinely pre-draw-controlled drugs for ACCTS shifts. Practitioners may draw up drugs en-route to a mission based on the clinical information provided and their own judgement of the likelihood of requiring those drugs.

The RSI module should either be kept on the crew's person throughout the day or be locked inside the BS2881-approved controlled drugs cupboard within the transfer vehicle, which itself must also be locked.

Managing Controlled Drugs During a Mission:

Controlled drugs should be prescribed and administered by an appropriate practitioner in accordance with the SBU "Management of Controlled Drugs" policy. An entry must be made in the Patient Clinical Record (PCR), if used, and on the EMRTS database as appropriate.

- Patient's name (where known)
- EMRTS PCR number (in the event the name is not known)
- Date
- Time administered
- Quantity of drug administered
- Signature of registered practitioner administering the drug
- Signature of witness (registered practitioner)

Managing Controlled Drugs After Attending a Mission:

Any CDs that have been part issued to named patients may be destroyed by EMRTS or ACCTS registrants by discarding them into a sharps bin or a suitably approved doop jar.

Unused pre drawn syringes of controlled drugs must be returned to quarantine area in the presence of a second witness for destruction later in the presence of a suitable trained **Controlled Drugs Authorised Witness (CDAW)** who is independent to the team who have drawn up the drugs. The following procedure should be followed

Standard Operating Procedure – Issue CD from RSI Bag – Patient Use or Quarantine

1.	 Log in to the system using your fingerprint. To log into the system if your fingerprint does not work: • Enter your **User ID** • Press **Enter** on the keyboard • Enter your **Password** •  Press **Enter** on the Keyboard
2.	• Locate and select the patient from the **Local or Global lists** • If the CD being issued is an Unused item to be Quarantined select **Unused CD Replacement** • **Remember to WASTE any unused CD against the Patient before you Issue the Replacement**  *If the patient cannot be found on either the global or the local list the patient will need to be added and merged at a later stage. (See section 3 below)*

3.

NEW PATIENT ONLY SECTION: If the patient cannot be located on either the **global** or **local** list, they will have to be added via the **Add New Patient** function.

Once the patient's record appears on the **local/global list** the system will merge the two records together.

Mandatory fields will be marked with an * and must be completed, these include **Patient Surname, Forename** and **ID Number** which is the **incident number. If name is not known enter Unknown.**

4.

Issuing Drugs:

- Once the patient has been selected press the **Remove Drugs** button

5.

- From the **Stocked Drugs tab** select the RSI bag variant of the CD you have used (e.g. R1 Morphine Sulphate) - type in the first few letters on the keypad or use the **up** and **down** arrows to search for the drug then press to select

	Note: the letters you type appear near the bottom of the touch screen, directly under the drug names.
6.	 • Enter the amount used. E.g., 1 Vial • Select **OK**
7.	• Repeat steps 5 and 6 for any other CD's used on the patient
8.	 • Select **Remove Now**
9.	 You will be warned that a **Witness** will be required. *All CDs require a witness for each transaction according to facility policy. The witness will be required log in using either their fingerprint or User ID and password.* • Select **Continue**

10.	• Work through the drugs using the guiding lights to gain access to the items • A witness will need to use their Fingerprint or ID and Password before the transaction can continue • A Countback will be required before continuing – this will be how many are remaining in the RSI Bag - if the quantity entered differs from amount stored in database you will be asked to confirm the count is correct.  *Note: the guiding lights will guide the user in a LEAN picking order rather than the order in which the items were issued.* *If the items are located in the same zone or drawer the user can move to the Next Item without closing the drawer or door by selecting the **Next Item** button. If the door or drawer is closed you will be prompted by the guiding lights to re-open.*
11.	• Once you have completed all transactions ensure you **log out/Exit**
12.	• If any of the countback values were different from that stored in cabinet a discrepancy receipt will be issued – this will need to be investigated and resolved. (See section 7.1.5)

For restocking during the shift or at the end of the shift, drugs will be booked out from the main CD area within the Omnicell to the current RSI module that is in use with the duty team (either RSI DOC/RSI CCP or RSI ACCTS). This must be completed by a registrant and witnessed by a second registrant.

Standard Operating Procedure – Issue Replacement CD to RSI Bag

1.

Log in to the system using your fingerprint.
To log into the system if your fingerprint does not work:

- Enter your **User ID**
- Press **Enter** on the keyboard
- Enter your **Password**
-  Press **Enter** on the Keyboard

2.

- Locate and select the patient from the **Local or Global lists**
- If the CD is replacing an Unused item that has been Quarantined select **Unused CD Replacement**

If the patient cannot be found on either the global or the local list the patient will need to be added and merged at a later stage. (See section 3 below)

3.

NEW PATIENT ONLY SECTION: If the patient cannot be located on either the **global** or **local** list they will have to be added via the **Add New Patient** function.

Once the patient's record appears on the **local/global list** the system will merge the two records together.

Mandatory fields will be marked with an * and must be completed, these include **Patient Surname, Forename,** and **ID Number** which is the **incident number. If name is not known enter Unknown.**

4.

Issuing Drugs:

- Once the patient has been selected press the **Remove Drugs** button

5.

- From the **Stocked Drugs tab** type in the first few letters on the keypad or use the **up** and **down** arrows to search for the drug then press to select

Note: the letters you type appear near the bottom of

	the touch screen, directly under the drug names.
6.	 • Enter the amount required. E.g., 1 Vial Select **OK**
7.	• Repeat steps 5 and 6 for any other CD's required
8.	 • Show the **Display Drugs to Remove** tab. This shows the currently selected items. *This step is not needed to remove meds.* • Select **Remove Now**
9.	 You will be warned that a **Witness** will be required. *All CDs require a witness for each transaction according to facility policy. The witness will be required to log in using either their fingerprint or User ID and password.*

	• Select **Continue**
10.	• Work through the drawer using the guiding lights to gain access to the items • A witness will need to use their Fingerprint or ID and Password before the bin lid can be opened • Once bin lid is opened a Countback will be required before removing any drugs from the bin – if the quantity entered differs from amount stored in database you will be asked to confirm the count is correct.  *Note: the guiding lights will guide the user in a LEAN picking order rather than the order in which the items were issued.* *If the items are located in the same zone or drawer the user can move to the Next Item without closing the drawer or door by selecting the **Next Item** button. If the door or drawer is closed you will be prompted by the guiding lights to re-open.*
11.	• Once you have completed all transactions ensure you **log out/Exit**
12.	• If any of the countback values were different from that stored in cabinet a discrepancy receipt will be issued – this will need to be investigated and resolved. (See section 7.1.5)

End of Shift Routine

At the end of a shift the RSI module (Doc/ACCTS or CCP module) containing the controlled drugs should be returned and stored within the Omnicell Cabinet the

Standard Operating Procedure – Return RSI Bag to Cabinet

1.

Log in to the system using your fingerprint.
To log into the system if your fingerprint does not work:

- Enter your **User ID**
- Press **Enter** on the keyboard
- Enter your **Password**
-  Press **Enter** on the Keyboard

2.

- Locate and select the required RSI bag from the **Local list**

3.

	• Press the **Return Drugs** button
4.	 • Select the **Stocked Drugs tab** • Select the required CDs from the list – use the correct RSI bag variant of the drug (e.g., R1 MIDAZOLAM for RSI Doc Bag 1)  *You may see the following warning:* *Open PMAs exist for this patient, do you want to return this item against one of these PMA's or create a miscellaneous return.* • Select Misc. Return if this screen displays • Enter Quantity to Return (should by full quota of each CD as any top-up required will have already been actioned) • Select OK
5.	• Repeat step 4 for all CDs in RSI Bag
6.	 • Select **Return Now**
7.	• A witness will be required before you can proceed • A countback will be required to confirm existing quantity for each item • Press **Next Item** until all returned
8.	• Place RSI bag in cabinet and close door
9.	• Once you have completed all transactions ensure you **log out/Exit**

1 0	• If any of the countback values were different from that stored in cabinet a discrepancy receipt will be issued – this will need to be investigated and resolved (See section 7.1.5)

7.1.5 Procedure for the balance checking of controlled drugs at EMRTS and ACCTS bases

Purpose

The purpose of this SOP is to ensure that staff working for EMRTS, and ACCTS are aware of the process for balance checking of controlled drugs.

Procedure/Process

1. stock balance of all the CDs in the relevant base area should be checked, reconciled, and recorded within the Omnicell once every 24 hours. The responsibility for this lies with the registered practitioners undertaking the shift.

2. This check for each CD must be performed at the same time by two authorised personnel (registered practitioners).

3. If there is a CD discrepancy the Omnicell will generate a printout/report, and an email will be generated to service and base leads.

4. On discovering a discrepancy, the duty team actions should include:
   - Recounting balance again and if possible, by another individual who is authorised to do so.
   - Recheck all entries that have been made
   - Rechecking the balance has been calculated correctly

5. Where balances are determined not to be correct, an attempt should be made to reconcile the CDs used for each patient treated by the service in a reasonable time, with the items missing from the CD register

6. If a discrepancy still cannot be resolved, a Datix form should be completed by the registered practitioner identifying the discrepancy, who should also inform the base manager, Lead CCP, Operations Manager/Operations Director. Pharmacy should be informed by the base manager immediately, or if out of hours, before the end of the next working day.

7. Discrepancy reports generated by the Omnicell can only be resolved by the nominated lead for each base.

8. Where discrepancies regarding CD's drugs are occurring at regular intervals, or if there is a degree of suspicious activity, Swansea Bay Counter Fraud team will be contacted. Advice will be sought and provided, which may involve contact with the police who in turn may elect then to carry out a full investigation.

Standard Operating Procedure – Perform Daily CD Cycle Count at Cabinet

1.	 • Log in using **Fingerprint** or **User ID** and **Password** • Press **Main Menu** button • Select **Inventory Menus** •   Select **Cycle Count**
2.	 • Cabinet should default to Guided Cycle Count, but if not select **Guided Cycle Count.**
3.	 • Select **All** and make sure **Control**

	Level 2 is selected. • Select **Count Now**
4.	• Follow the guiding lights to each location. (A witness will be required before the door / bin lid can be opened)
5.	• Open the door / bin • Count the quantity on hand • Enter a quantity
	 If quantity entered is different from that stored in the cabinet a warning of **Is this the correct count?** will display • Select **Yes** to confirm correct • Select **No** to enter quantity again
6.	• Close the door / bin. *Note: You will be guided through all **control level 2** (CD) items stored in the cabinet (including those stored in RSI Bags) You can exit the guided count at any point and when the same user logs back in the count can be resumed from the cycle count menu by pressing **Resume Count.***
7.	• Once all CD's have been counted press **Exit**
8.	• If any items counted differed from the quantity stored in the cabinet a discrepancy receipt will be produced. This will need to be investigated and resolved.

Standard Operating Procedure – Resolve Discrepancy at Cabinet (Lead CCP`s Only)

1.	• **Log in** • Select **Main Menu** •  Select **Resolve Discrep**
2.	 • Select **Control Level 2** • **Resolve Discrep**
3.	• Discrepancy details will be displayed on screen, either type the reason for the discrepancy in the box using the keyboard, or select **List of Resolve Reasons** and select the appropriate reason from the list 
4.	• Select **Resolve Discrep** (Have the user log in in as a witness if required)
5.	• If there are further discrepancies to be resolved, the next one will be displayed on the screen. Repeat process from step 3

	• Once all discrepancies have been resolved, a message will show on screen saying 'No more discrepancies. Select **OK** • Press **Exit**

7.1.6 Management of Controlled Drug Cupboard Keys and Omnicell Override Keys

Purpose

The purpose of this SOP is to ensure that staff working for EMRTS, and ACCTS are aware of the process the management of the Emergency CD storage cupboard/Omnicell Override keys.

Possession and handover of keys

1. The registrants undertaking the shift are directly responsible for the key(s).
2. Each base will maintain a lockable CD cupboard that may be used in the event of an emergency, or if a situation arises when an out of area team needs to secure their RSI drug module overnight.
3. If spares are available, they may be accessed. The base keeps two sets of CD keys. The second set of keys must be stored securely with access only possible by a registered practitioner. A full auditable trail of access and use should be in place.
4. When the base is not in use, the keys for the CD storage cupboard/Omnicell Override will be secured in a safe in accordance with locally agreed practice. The keys for these will be kept in a locked safe, distinct from the safe which houses the keys for the doors to the storerooms where the CD cupboard/Omnicell are kept
5. Once accessed, the keys always become the responsibility of a named registrant of the duty base crew when on base. When tasked to an incident, they should be secured as in (3) above.

On occasions, I.e., for the purpose of audit or maintenance, the CD/Omnicell Override key may be handed over to an authorised member of the Pharmacy/Omnicell staff, who will then need to be supervised by a nominated registrant.

Loss of Keys:

6. In the event of missing/lost CD Cupboard/Omnicell keys, urgent efforts should be made to retrieve the keys as speedily as possible, enlisting the help of all relevant staff (on or off duty) as soon as possible. If the key(s) cannot be found, then the Base Lead CCP/Operations manager and Pharmacy & the Controlled Drug Accountable Officer should be informed as soon as possible. A Datix should also be completed.
7. The CD cupboard must only be opened for checking, removal, or receipt of controlled drugs. It must remain locked at all other times.

8. At the end of the shift, the keys must be returned to the safe, which must remain locked.

Notes
The registered practitioners undertaking a shift are responsible for the CD key. Key-holding may be delegated to other suitably trained, registered healthcare professionals however the legal responsibility rests with the registered duty practitioners undertaking that shift.

The controlled drug key should be returned to the registered practitioner undertaking the shift immediately after use by another registered member of staff.
Serious Incidents are to be reported to the EMRTS base manager, the Operations Director/Manager, and the Accountable Officer on the next working day. A Datix form must be completed

7.1.7 Substance Abuse

CD diversion for the purposes of substance abuse constitutes a serious health and employment problem. Healthcare staff who have access to CDs are at particular risk. Those affected need urgent assistance and can seek help from their Union or BMA representative, Occupational Health, their General Practitioner, or several other sources.

This SOP applies to all staff working at the Health Board.

Procedure / Process
1. If an EMRTS or ACCTS member of staff, including those who prescribe, is suspected of abusing controlled drugs, then these suspicions should be shared with the base lead, Operations Director/Manager or National Clinical Director as appropriate.
2. The Health Board Accountable Officer should be contacted directly to discuss suspicions of this nature, particularly if the EMRTS team member feels unable to discuss the matter within the service.
3. All actions concerning this will be dealt with confidentially and will follow the agreed Corporate Health Board procedure relating to this issue.

7.1.8 Procedure for the destruction of controlled drugs within the EMRTS and ACCTS service

Purpose
The purpose of this CD SOP is to ensure that staff within EMRTS, and ACCTS are aware of the correct procedures for the destruction of controlled drugs. Staff need to

be aware of which controlled drugs can be disposed of without the requirement of a Controlled Drug Authorised Witness, and those that must be quarantined for later destruction in the presence of a CDAW.

"A CD ceases to be classified as such once it is denatured or dissipated, is not re-useable, or has been rendered irretrievable. Once disposed of it should be unrecognisable as a CD".

Procedure / Process
Controlled Drugs which **can be destroyed** at the EMRTS and ACCTS base **without** a Controlled Drugs Authorised Witness (CDAW) are:

- Individual doses that are prepared for a patient and partially used. (The amount of waste CD must be registered against the patient, or incident number, if the patient details are not known.)

- Complete ampoules which have been damaged or smashed; a **DATIX** must also be submitted for these.

All other controlled drugs must be destroyed in the presence of a trained Controlled Drug Authorised Witness (CDAW).

CDs that require destruction with a CDAW present:

- Pre-drawn syringes that have not been issued to a patient that have been placed in the quarantined cupboard (I.e. Unused/non-issued daily pre-draws)
- Unwanted or expired stock due for destruction

All CD`s that require destruction in the presence of a CDAW must be returned to the Omnicell Quarantine Area for weekly denaturing/destruction.

Quarantined Drugs for Destruction

1. Controlled drugs for destruction held in Quarantine areas within the Omnicell are to be destroyed in the presence of a suitably trained Controlled Drugs Authorised Witness (CDAW).
2. Regarding the limitations of the CDAW it should be noted that:
    - There must be an appropriate separation of roles and responsibilities
    - A CDAW cannot witness the destruction of CDs that have been supplied to/by them.
    - A CDAW cannot witness the destruction of CDs where they have been involved in the checking, dispensing or preparation process. Within the EMRTS setting this would include when a staff member has been involved in or witnessed the drawing up of a CD into a syringe for use at a later date

- In extremely unusual circumstances where the quantities of CD stock to be destroyed poses an immediate risk to patient safety and/or EMRTS is no longer able to physically store the CDs according to safe custody regulations, the restrictions above will not apply. However, where this scenario occurs an audit of the physical stock of CDs against the CD register must be undertaken and documented in the CD register by another person before the CDAW can witness the destruction of the CDs. This must also be recorded as an incident via Datix on each occasion
- N.B. The purpose of the above limitations is to ensure there is appropriate separation of roles and responsibility and to enable CDAWs to act objectively. Therefore, the CDAW must apply their own personal judgement and discretion to individual circumstances. CDAWs must ensure that the above limitations are adhered to and that they are able to explain their decision-making process.

3. An entry of the emptying of the Quarantined CDs must be made in the Omnicell register by an approved registrant/Controlled Drugs Authorised Witness (CDAW) and counter witnessed by a second registrant.

4. Drugs being destroyed in the presence of a CDAW should be emptied into an approved DOOP container on the base. Once all items are removed from the Quarantine Area then the denaturing jar should be activated (as per instructions) and closed. During the denaturing process, jars must be kept locked and secured within CD rooms. Once the denaturing processes are complete, the denaturing jar must be placed within a designated clinical waste bin for later collection by a suitably appointed waste collector.

Standard Operating Procedure – Removal of Quarantined CDs from Cabinet

1.

Log in to the system using your fingerprint.

To log into the system if your fingerprint does not work:

- Enter your **User ID**
- Press **Enter** on the keyboard
- Enter your **Password**
-  Press **Enter** on the Keyboard

2.

- Select **Main Menu**
- Select **Inventory Menus**
-  Select **Destock**

3.

- Press the **Destock Drugs** button
- *Destock is used to remove items for disposal or return to Pharmacy.*

4.

- Select Required Drug for Destock
- *Quarantined CD's will begin with QA in description.*

5.

- Select Quantity to Remove and click **OK**

- 

Click **Destock Drugs Now**

6.

- Follow guiding lights to item

	• A witness will be required before the bin can be opened, and a Countback will be requested to confirm quantity before anything is removed
7.	• Repeat steps 4, 5 and 6 for any other Quarantine CD's requiring removal
8.	• Once you have completed all transactions ensure you **log out/Exit**
9.	• If any of the countback values were different from that stored in cabinet a discrepancy receipt will be issued – this will need to be investigated and resolved.

Destruction of Controlled Drugs witnessed by Controlled Drugs Authorised Witness (CDAW)

Pre-drawn and expired controlled drugs stock must be destroyed in the presence of those who are designated as a trained Controlled Drugs Authorised Witness (CDAW). It is envisaged that most EMRTS and ACCTS practitioners will be trained as a Controlled Drugs Authorised Witness (CDAW), and on any one shift at least one registrant will be a Controlled Drugs Authorised Witness (CDAW).
Drugs kept in the Omnicell quarantined controlled drug area are those ready for weekly destruction.

The syringe should be inspected to ensure that the tamper-evident caps are in place and intact.

The role of the CDAW is to witness the destruction of CDs, however it is important that they understand the process of appropriate destruction so that advice can be offered to those undertaking the destruction.

Process:

1. The CDAW must be able to produce their written authority from the SBUHB CDAO to act as a CDAW when asked.
2. A copy of the SOP for 'Witnessing the destruction of Controlled Drugs by SBUHB accredited Controlled Drugs Authorised Witnesses' (EMRTS premises) must be available at the premises
3. Prior to undertaking any CD destruction, a CD cycle count guided by the Omnicell, must be undertaken to ensure the correct quantity of medication is present. In the event of a discrepancy being identified the duty team will work with the Responsible Person (base Lead CCP) to investigate the issue further:
4. If the discrepancy is resolved, the balance should be corrected by the Responsible Person in the appropriate manner and documented according to the current legal requirements. The discrepancy must also be reported via Datix. The destruction of CDs may then proceed.
5. If the discrepancy remains unresolved / unexplained, CD destruction cannot proceed and an incident report must be filed via Datix and investigated by the Responsible Person. The Responsible Person will discuss any

unresolved/unexplained discrepancies following investigation with the CDAO to agree any further action required.

6. If the CD records pertaining to the CDs to be destroyed, are accurate, destruction may proceed.
7. The Responsible Person must provide the SBUHB CDAO with a record of all CD stock destroyed in the presence of a SBUHB accredited CDAW on a quarterly basis. This report must be sent to SBUAuthorised.Witness@wales.nhs.uk.
8. All parts of the destruction and recording process must occur in the presence of the CDAW. The CDAW may issue instructions to all involved to ensure the process of destruction is safe and correct.
9. The CDAW must ensure that the EMRTS member of staff destroying the CDs uses an appropriate method of destruction.
10. Only approved licensed CD denaturing kits may be used to ensure that Schedule 2, 3 and 4 (part 1) CDs are rendered irretrievable. No other method of destruction may be used. CDAWs should ensure that an unused denaturing kit is used.
11. The EMRTS member of staff undertaking the CD destruction must ensure that any CDs being destroyed are denatured and rendered irretrievable before being placed into pharmaceutical waste containers for incineration. Any instructions on the denaturing kit must be followed as appropriate.
12. It is recommended that any liquid dosage forms are added to the denaturing kit last. This is to ensure that the inactivation process is not started before all CDs being destroyed have been added to the kit.
13. Once all CDs being destroyed have been added to the kit, water should be added as necessary in accordance with the denaturing kit manufacturer's instructions and the kit sealed and shaken. The CDAW should witness this step.
14. Pending collection by the licensed pharmaceutical waste carrier, the denaturing kit should be stored securely according to internal EMRTS procedures in a locked room.
15. It is the duty of the Responsible Person, to arrange appropriate disposal of the denatured CDs. The Responsible Person must liaise with the licensed pharmaceutical waste carrier regarding type of containers and codes to be used.

In addition to unused daily pre-draws, stock that is out of date, or no longer required, can also be removed from stock to an approved Quarantine area and destroyed in the presence of a suitably trained Controlled Drugs Authorised Witness (CDAW).

If there is no Controlled Drugs Authorised Witness (CDAW) available to witness the denature of these products, then the CDs **must be** returned to the issuing pharmacy for recording and disposal in accordance with section 7.1.9 below.

7.1.9 Procedure for returning controlled drugs to pharmacy if no Controlled Drugs Authorised Witness (CDAW) is available.

Purpose

The purpose of this SOP is to ensure that staff working for EMRTS, and ACCTS are aware of the process for returning controlled drugs to the hospital pharmacy department.

Procedure / Process

1. When a controlled drug is no longer required by the EMRTS/ACCTS service and is not being destroyed on site by an CDAW the base manager or nominated pharmacy lead must give notice to pharmacy for its removal.
2. The item is booked out of the CD Quarantine area and the new balance cycle counted against the CD entry
3. Removal of all controlled drugs must be counted and / or measured in the presence of a second registrant (doctor, registered nurse, or paramedic)
4. A transport log must be completed by the registrant while the CDs are booked out of the Omnicell.
5. The CDs being returned must be entered onto a transport log which must include the following details:
    - Name of signature of registrant returning the controlled drugs.
    - Name, form, strength and quantity of drug being returned.
    - The name and signature of the driver collecting the drugs
    - The date and time of the collection
    - Name and signature of pharmacy registrant accepting the delivery at the hospital pharmacy
    - Date and time of receipt at the hospital pharmacy.

Both EMRTS or ACCTS staff **and** the driver must check and sign for each individual CD for collection. Where the CD is being returned by a member of EMRTS or ACCTS staff he/she must sign the “collected by” section of the log.

The CDs must be always stored securely in the vehicle and returned directly to the pharmacy. They must not be left in the vehicle unattended or overnight.

Vehicles and drivers used for the transport of CDs:

Only use vehicles with effective locking systems and appropriate anti-theft devices for the level of risk.
Vehicles must be maintained in good condition and in accordance with manufacturers' recommendations.
Comprehensive instructions must be available for staff to deal with routine and emergency situations.
Drivers must have identity cards that can be checked at the collection and delivery points.
Drivers are prohibited from transporting unauthorised passengers and making visits to their homes and unauthorised locations.

Notes

Controlled Drugs that are left to become date-expired constitute a waste of resources.
All stock of controlled drugs no longer required must be returned to pharmacy for destruction or for reissue if appropriate if they are not being destroyed by an AW on site.
Arrangements for the removal of controlled drugs and storage of controlled stationery during base closures/moves and subsequent re-stocking should be made in advance with the hospital pharmacy

7.1.10 Procedure for the safe storage of CDs in Omnicell and CD Cupboards.

Purpose
The purpose of this SOP is to ensure that staff working for EMRTS, and ACCTS are aware of the procedures for the safe storage of CDs in CD Cupboards and Omnicell's

Procedure / Process:

1. The CD's at each EMRTS and ACCTS base will be primarily kept in a dedicated Omnicell at each base, however in addition, there will be a CD cupboard for use in an emergency situation.
2. Omnicells should be closed and logged out when not in use. CD cupboards must be kept locked when not in use.
3. The keys for each CD cupboard, and the override keys for the Omnicell, will be secured according to local practice agreed by the base manager and pharmacy.
4. The lock of the key safe must not be common to any other lock on site
5. Keys must only be available to authorised members of staff
6. The Emergency CD cupboard should only be dedicated to the storage of CDs.
7. No other medicines or items should be stored in the CD cupboard.
8. There must be arrangements for keeping the keys secure.

Notes
The standards and statutory regulations for safes & cabinets used to store CD's (e.g., BS2881) are detailed in British Standard BS 2881. Further details are available from www.bsiglobal.Com

Keys for controlled drugs cupboard and the Omnicell override must be kept separately to all other keys, and remain the responsibility of the lead registrant on duty. This includes any keys used to access secure storage of any spare CD keys.

7.1.11 Procedure for the use of Controlled Drug Stationary

Purpose
The purpose of this SOP is to ensure that staff working for EMRTS, and ACCTS are aware of the procedures for the use of controlled drug stationary.

All stationery which is used to order, return or distribute controlled drugs (CD stationery) should be stored securely and access to it should be restricted. These measures are important to guard against unauthorised use of the stationery to obtain CDs for inappropriate purposes.
For CDs stored in the Omnicell's, an electronic register is maintained by the system and reports on use in standard CD register format are available for interrogation.

Definition of CD stationery
CD stationery includes:

- Controlled drug requisition books
- Controlled drug registers
- Local CD documents such as CD returns advice notes, pharmacy distribution documents, transport logs.

Procedure / Process:

Secure storage of CD stationery
CD stationery which is kept on base should be kept in a locked cupboard or drawer. Stocks of CD stationery held in pharmacy departments should be kept in a secure area that is locked when there is no one present.

Supply of CD stationery
CD stationery must be issued from the pharmacy against a request from an appropriate registered member of staff. Where pharmacy staff are aware that a CD requisition book is coming to the end of its supply of requisitions, they may issue a replacement book. All issues of Controlled stationary must be recorded with their unique number allocated by pharmacy, recorded and signed in the controlled drug stationary issue book/register.

A record should be kept of the supply of CD stationery. It should include:
Date
Base name
Type of stationery issued
Quantity
The allocated unique number of stationery
Signature of the member of pharmacy staff supplying the stationary.
Any unused stationery returned to the pharmacy will be recorded as a return, with the details above, in the supply record.

Loss or theft of CD stationery
Loss or theft of any controlled stationery which may be used to order CDs should be reported immediately to the pharmacy manager and Accountable Officer, and a Datix completed.
The e mail address for the accountable officer is:
Sbu.cdao@wales.nhs.uk

Use of CD stationery
Only one CD requisition book base should normally be in use. However, areas with more than one CD cupboard will have a separate requisition book for each cupboard. Each base should normally only have one main CD register in use at any one time and one register for each individual CD-containing module.

A new register **should not** be started until the previous one is full. When a new CD register is started, the balance of CDs in stock must be written into the new book promptly by the duty crew. This transfer should be witnessed by a registered practitioner or authorised member of staff. Completed CD requisition books and CD record registers must be retained for a minimum of two years from the date of the last entry.

Archiving of controlled drug records
Every requisition, order or private prescription on which a Controlled Drug is supplied must be preserved by the Pharmacy department for a minimum period of two years from the date on which the last delivery under it was made. Although the mandatory period for keeping requisitions is two years, health care organisations may wish to store them for longer periods, as cases often come to court at a much later date. The time periods for archiving CD documentation are:

- Requisitions 2 years
- Registers and controlled drug requisition books 2 years from last entry or 13 years if also contain records of destruction.
- Extemporaneous preparation worksheets 13 years
- Aseptic worksheets (adult) 13 years
- Aseptic worksheets (paediatric) 26 years
- External orders and delivery notes 2 years
- Prescriptions (inpatients) 2 years
- Prescriptions (outpatients) 2 years
- Clinical trials 5 years minimum (maybe longer for some trials)
- Destruction of CDs 7 years
  Future Regulations may increase the period for the storage of records. Readers are advised to refer to Department of Health and GPhC websites for up-to-date information

7.1.12 Prescribing CDs

The 2001 Regulations (as amended) provide that any person may administer to a patient, in accordance with the direction of a medical practitioner, any drug specified in schedules 2-5.

The Doctor on duty at the base is usually responsible for prescribing CDs for use in the EMRTS and ACCTS setting. However, other medical staff or non- medical prescribers may also be involved (e.g., Nurse Independent Prescribers or paramedic independent prescribers)

In the prehospital setting, the accepted prescription of controlled drugs administered to the patient during their care should be the Patient's report form. (PCR), which may be electronic where appropriate and necessary.

7.2 SOP for the management of CDs with automated cabinets

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

SOP for Issuing CDs in the Dispensary

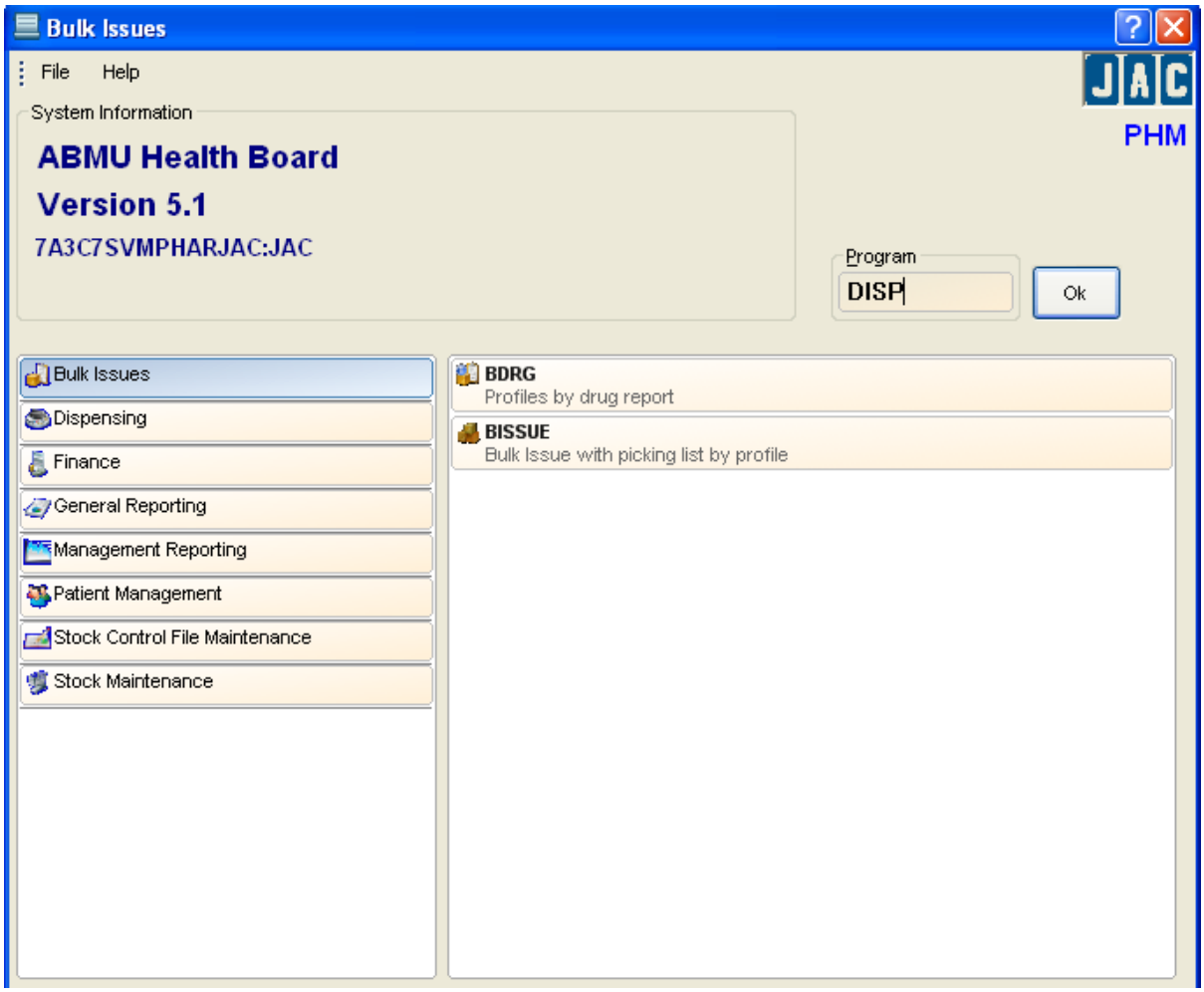
Before starting dispensing

- Ensure that the following information has been completed on the CD requisition:-
    - Hospital Name and Ward.
    - Drug name, form, strength and quantity to be issued.
    - Requestor has signed and printed their name on the requisition.
    - If any of the above are not present on the requisition, contact ward to confirm details and/or come to the department to amend requisition book.
- Check that the requestors name is listed in the reference file of authorised CD signatories.
    - If the name is not listed, contact the ward to request that the member of staff comes to pharmacy to complete the form to become an authorised signatory.
- Check the drug requested is on the CD stock list for that ward.
    - If it is not stock, a clinical check must be obtained, before proceeding anything further.

Generating labels for Ward Stock CDs on the JAC system

- Click the JAC icon on the computer, and the JAC login screen will appear.
    - Enter your Username and Password, and click the OK button.

A screen similar to the one below will now appear.

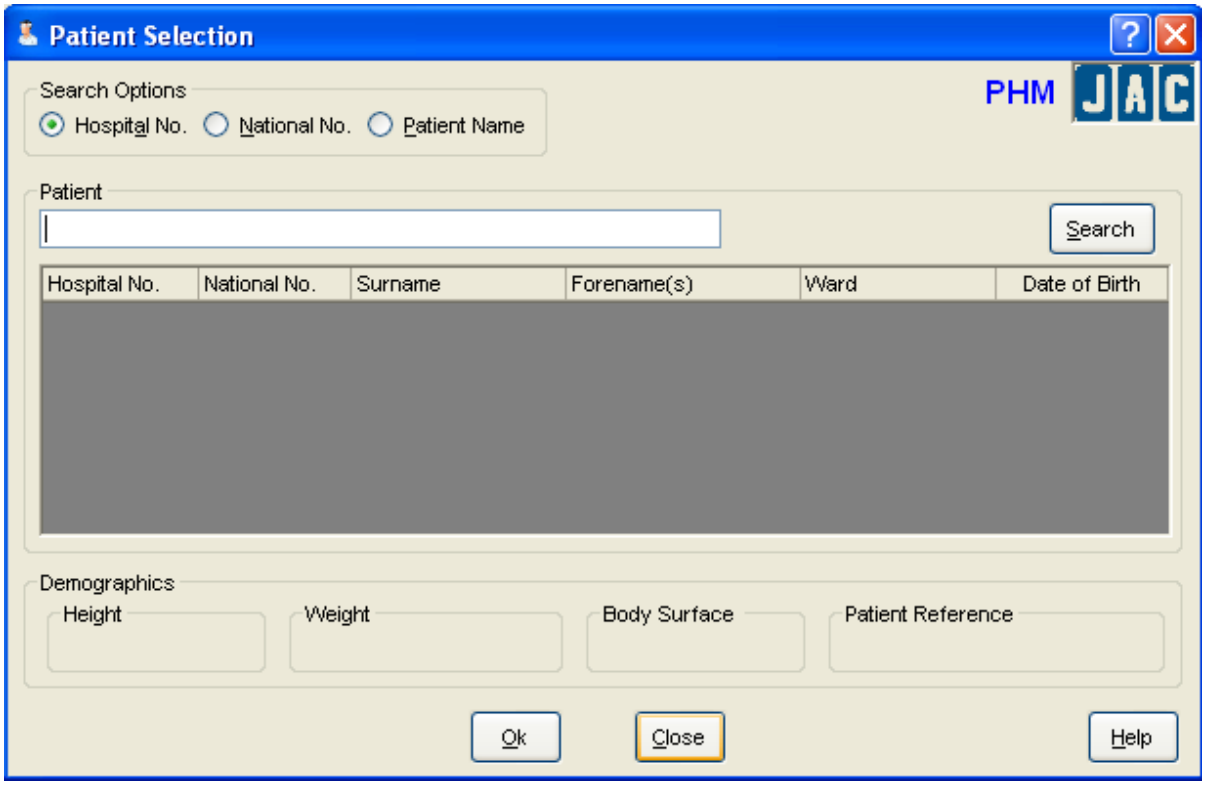


- To dispense Controlled Drugs, use the DISP program.
- You can access this program by typing DISP in the Program box (as shown) and click OK.

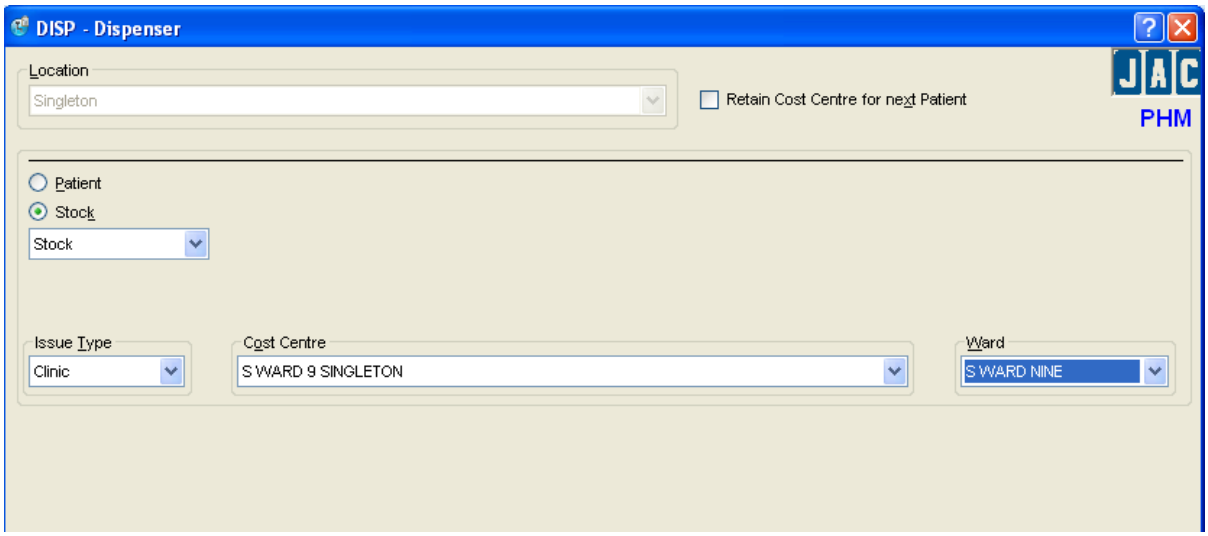
Alternatively select ‘dispensing’ tab on left hand side and then select DISP program.
NOTE: ENSURE CAPS LOCK IS ON WHEN USING JAC

- The first screen of the DISP program is “Patient Selection”

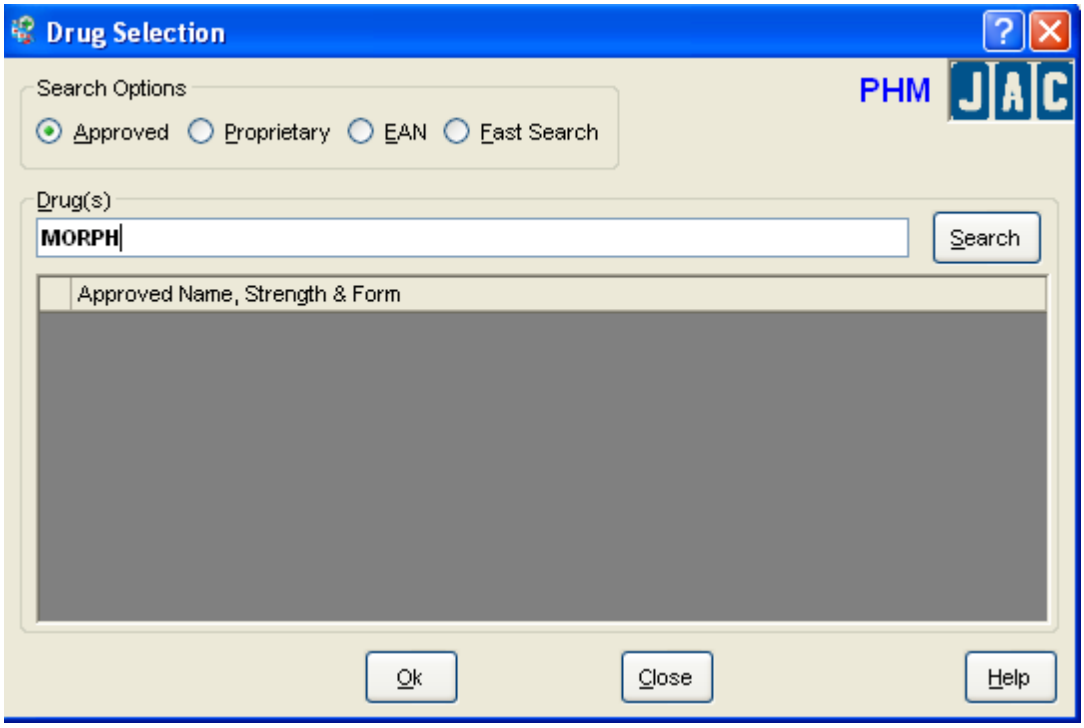
  - As we are issuing the CDs to the ward, and not to an individual patient, no information need be entered on this screen. Click the Close button to proceed.



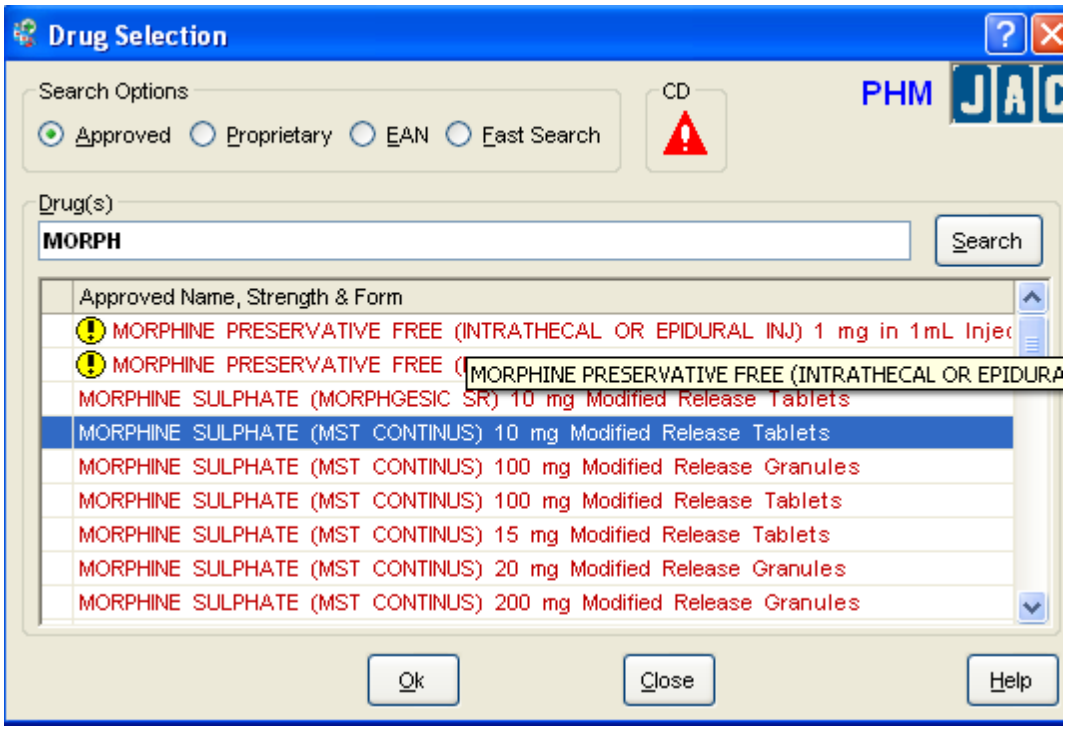
- On the “DISP – Dispenser” screen, the following information must be selected from the four drop down lists:
  - Stock - Select “Stock”
  - Issue Type - Select “Clinic”
  - Cost Centre - Select the ward/clinic/area to which the CDs are being issued.
  - Ward - As for Cost centre – usually this is populated automatically on selection of Cost Centre



- Once this information has been inputted, click the Select Drug button, and the Drug Selection screen will appear on screen.



- Ensure that the Approved Radio button is selected in the Search Options box.
- Enter the first few characters of the drug (generic name) you wish to dispense in the Drug(s) box, and click the Search button.
- This brings up a list of drugs that begin with the characters that you have searched for.
- Scroll the list and select the drug that you require (which highlights in blue), and select OK.



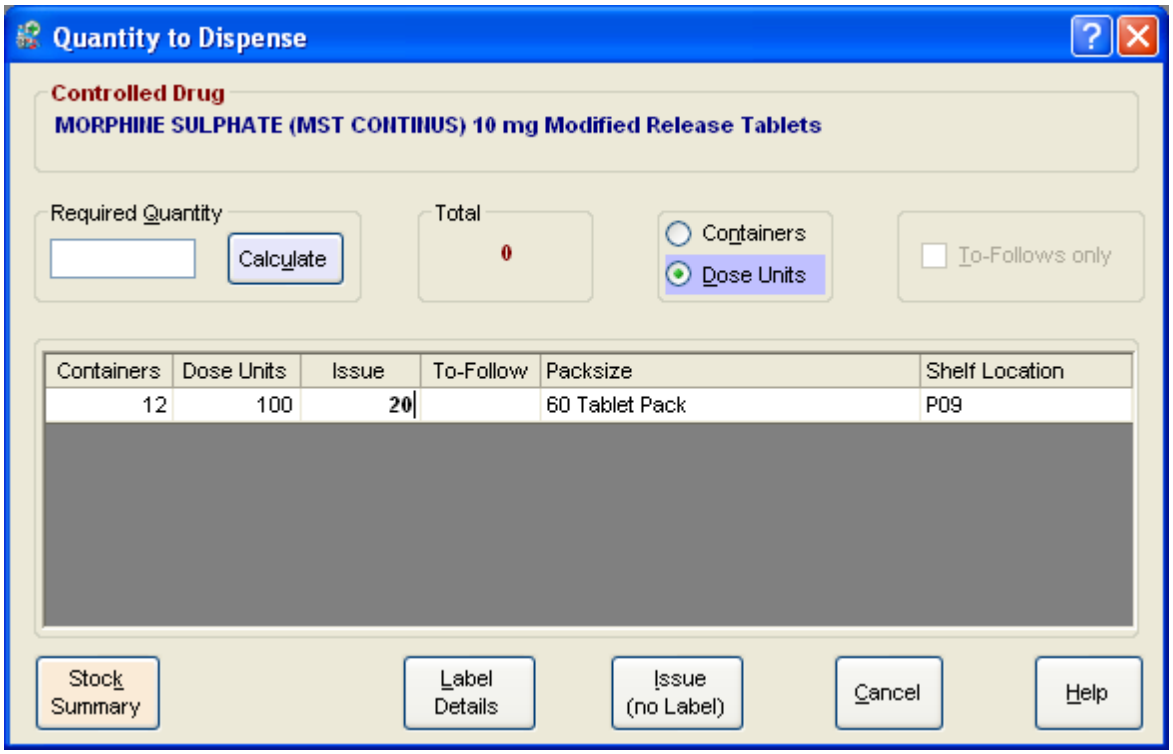
- The next screen to appear is “Quantity to Dispense”
  - Note the balance of stock on the screen and record on the top left hand side of the white copy of the CD requisition.

- On JAC, stock is separated into Containers and Dose Units.
- To calculate the total balance, both need to be taken into account.
- For example, for the MST 10mg below:

12 containers x 60 tablets (see Pack size) = 720

100 dose units = 100

Total Balance = 820

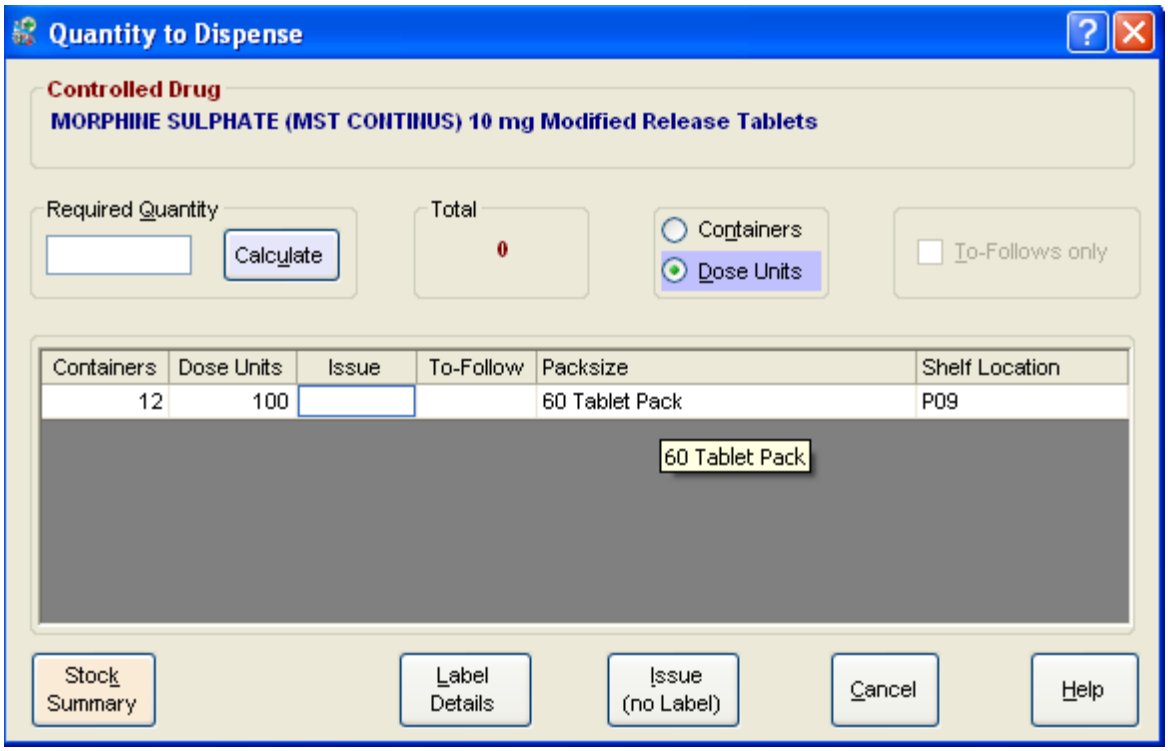


- Enter the quantity to be dispensed in the Issue box, and click the Label Details button.

- Take care when entering the quantity, as stock can be issued as Containers or Dose Units.

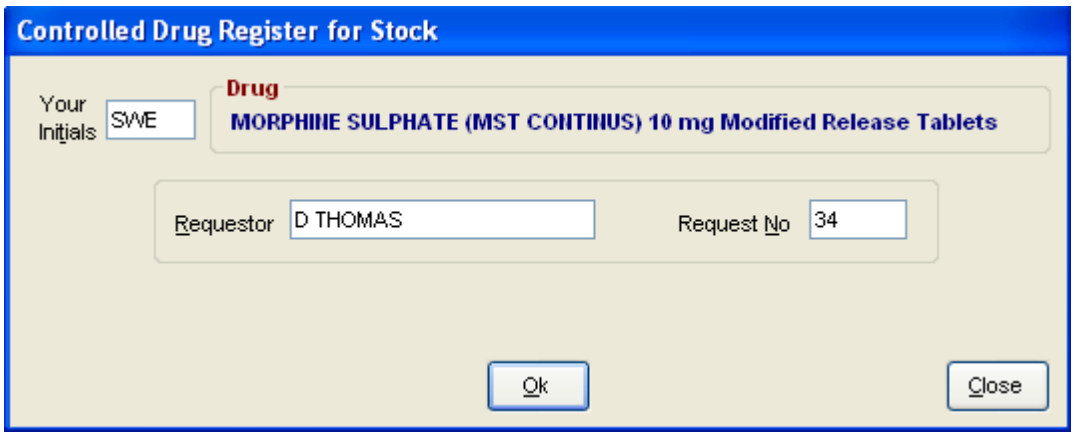
 Note whether the Radio Button is clicked on Containers or Dose Units.

- For the example below, Dose Units has been selected, therefore placing 20 in the Issue box will issue 20 dose units.
- If the Container button had been selected, entering 20 would result in 20 packs being issued – a total of 1200 tablets.



➢ If the item is a special product then it may ask you for the batch number of the product, ensure you check the batch details are entered to match the product.

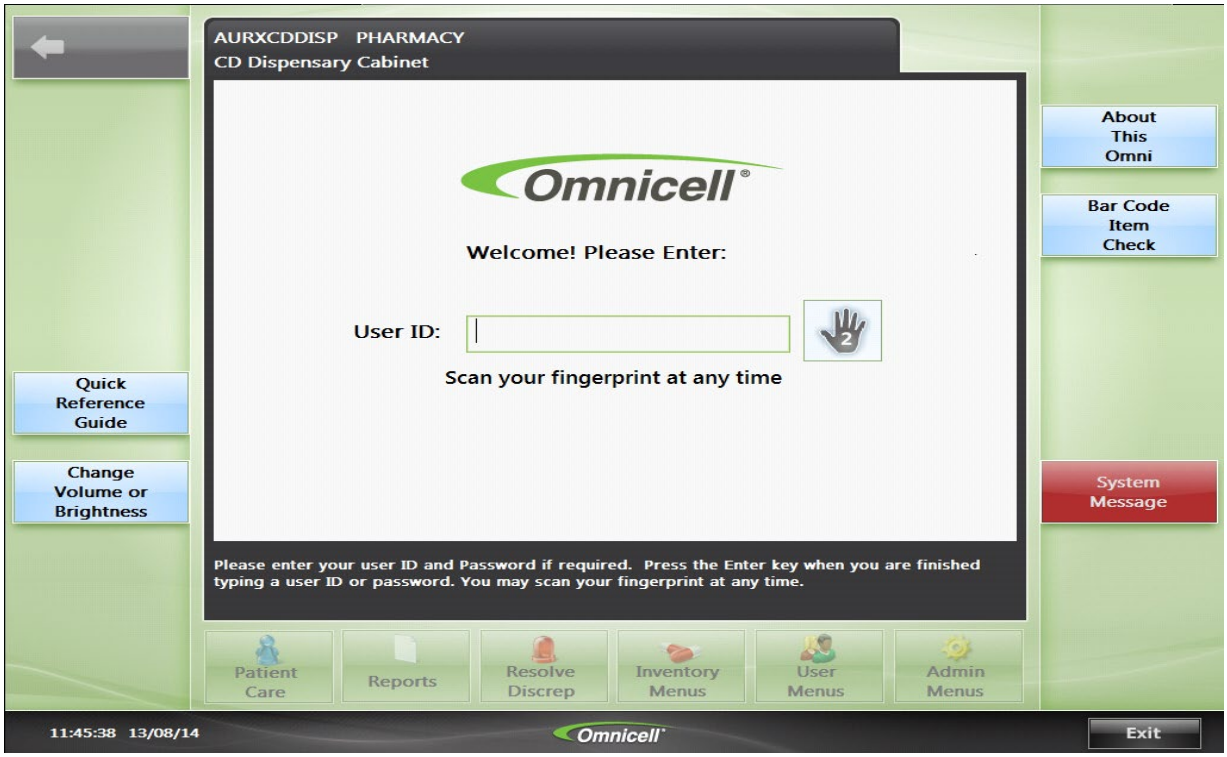
➢ On the next screen (Controlled Drug Register for Stock), you will be asked to enter your initials, the requestor details and the request (requisition) number. Once this has been completed, click Ok.



➢ Depending on the Controlled Drug being issued, the Supplementary Labels screen may appear.

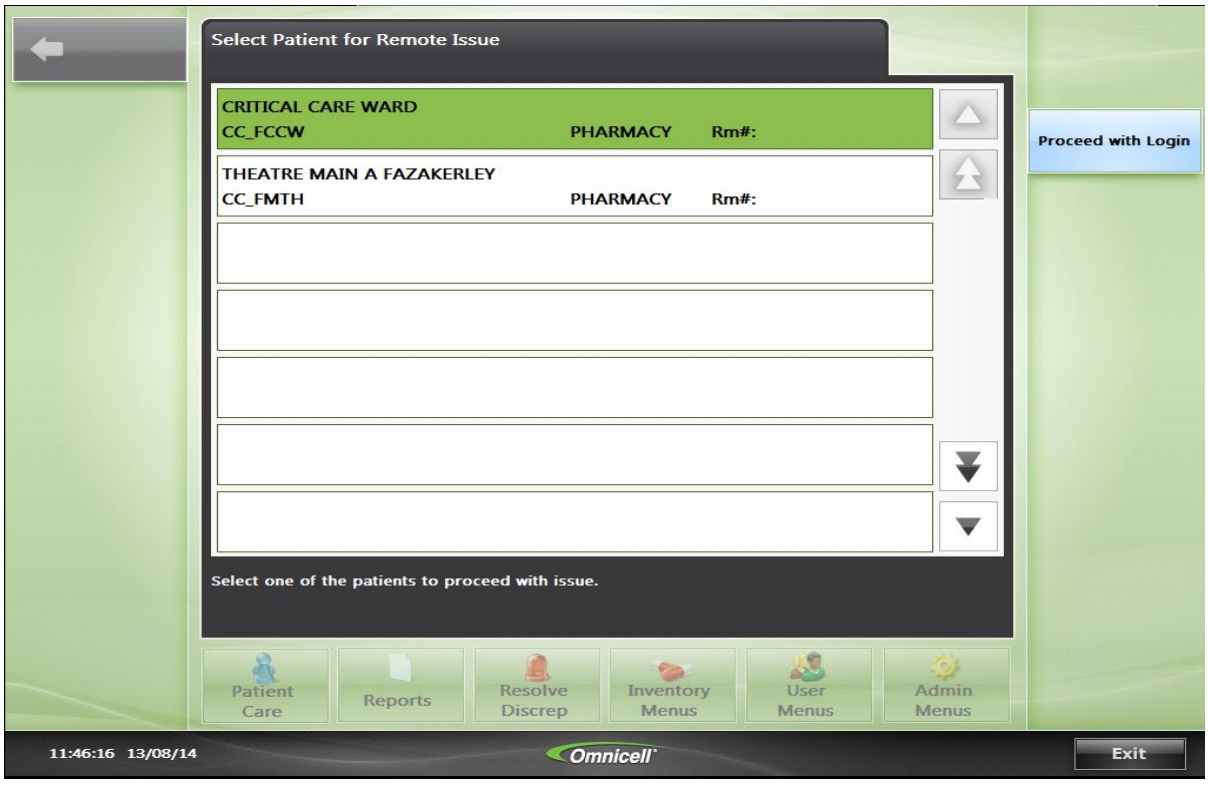
- As we do not wish any supplementary labels to appear on the label, the None box should be clicked.

1. Once completed booking the items out via JAC proceed to log on to the Omnicell CD cabinet using your login details or your finger print.

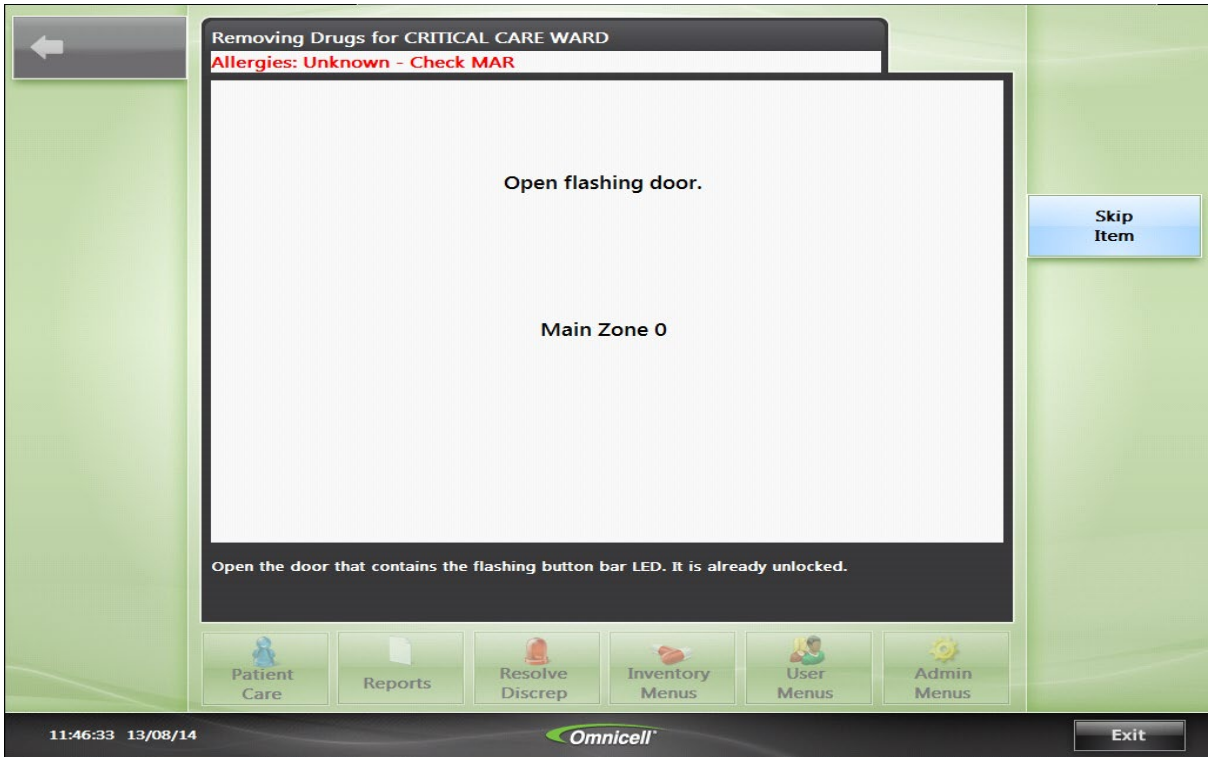


2. The following screen will be displayed once the order has been sent from JAC, select the ISSUE button

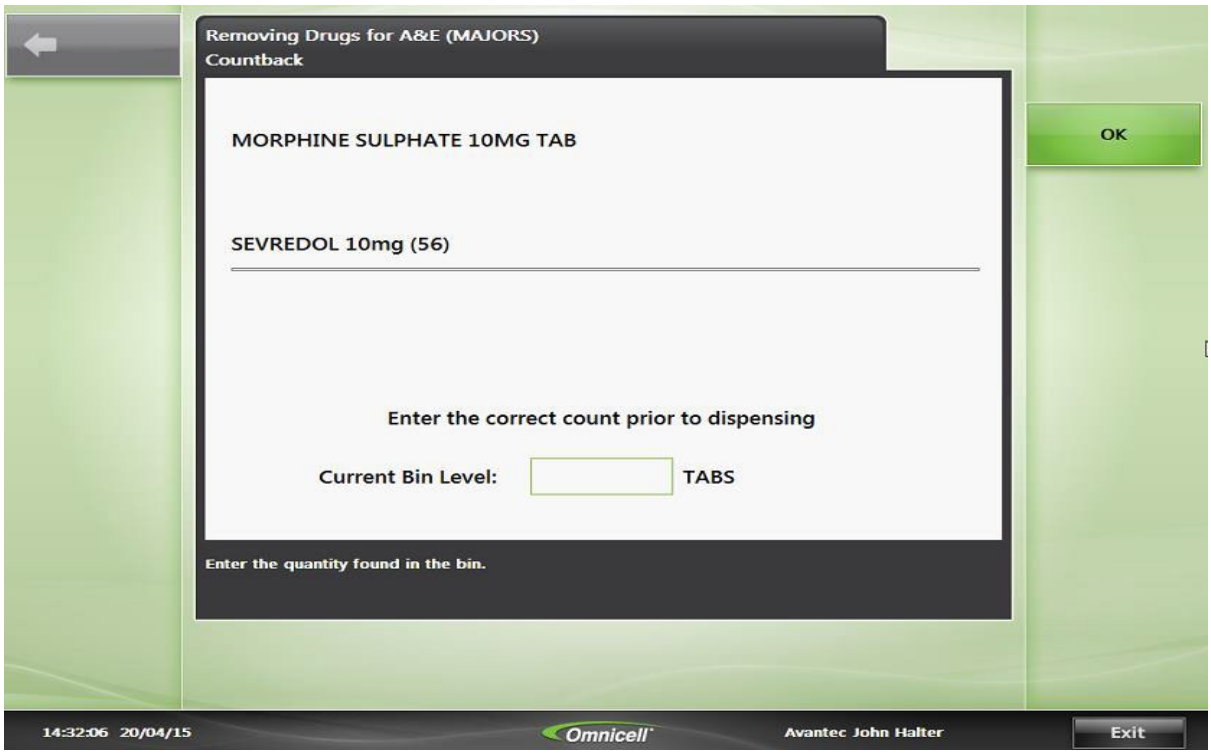
3. A list of wards or patient names will be displayed that have items to be picked
Select the appropriate ward or patient



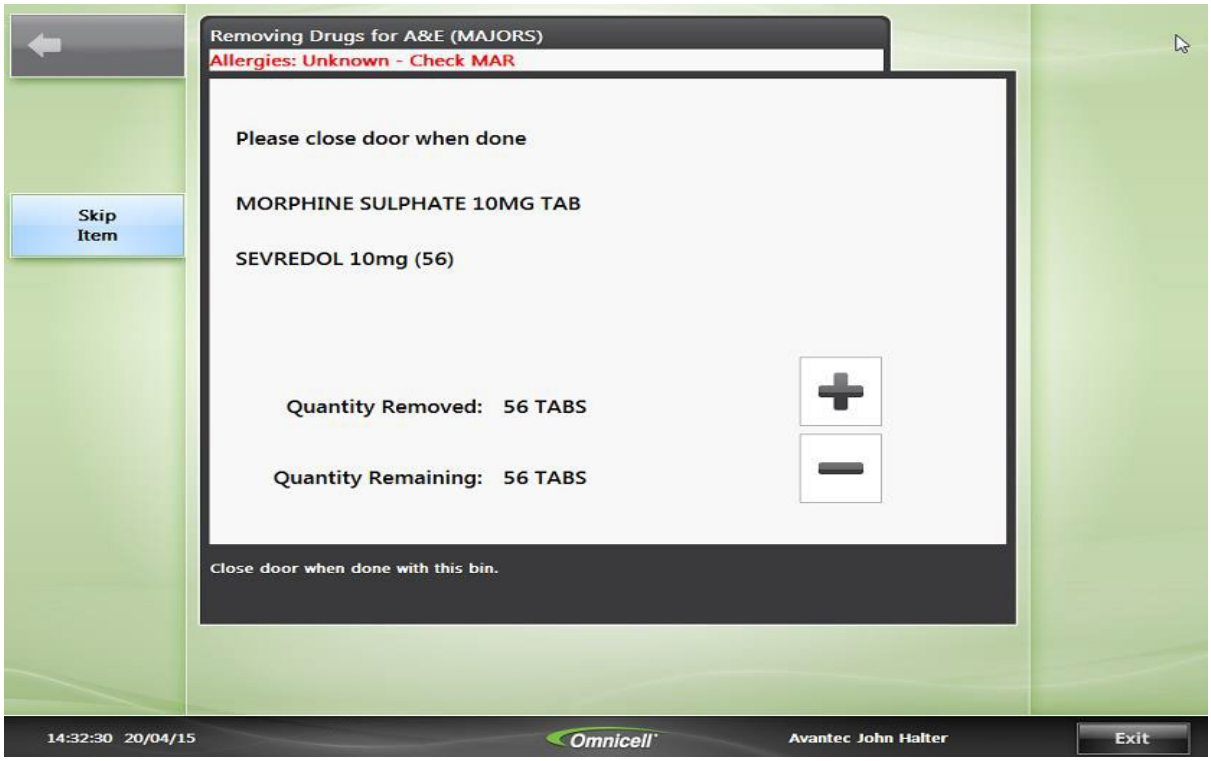
4. The following screen will be displayed and all lights in the cabinet the item is located in will be flashing, N.B. If there is only one patient/ward to be issued, you will come straight to this screen.
Open the cabinet door, the remaining green light indicates the location of the item



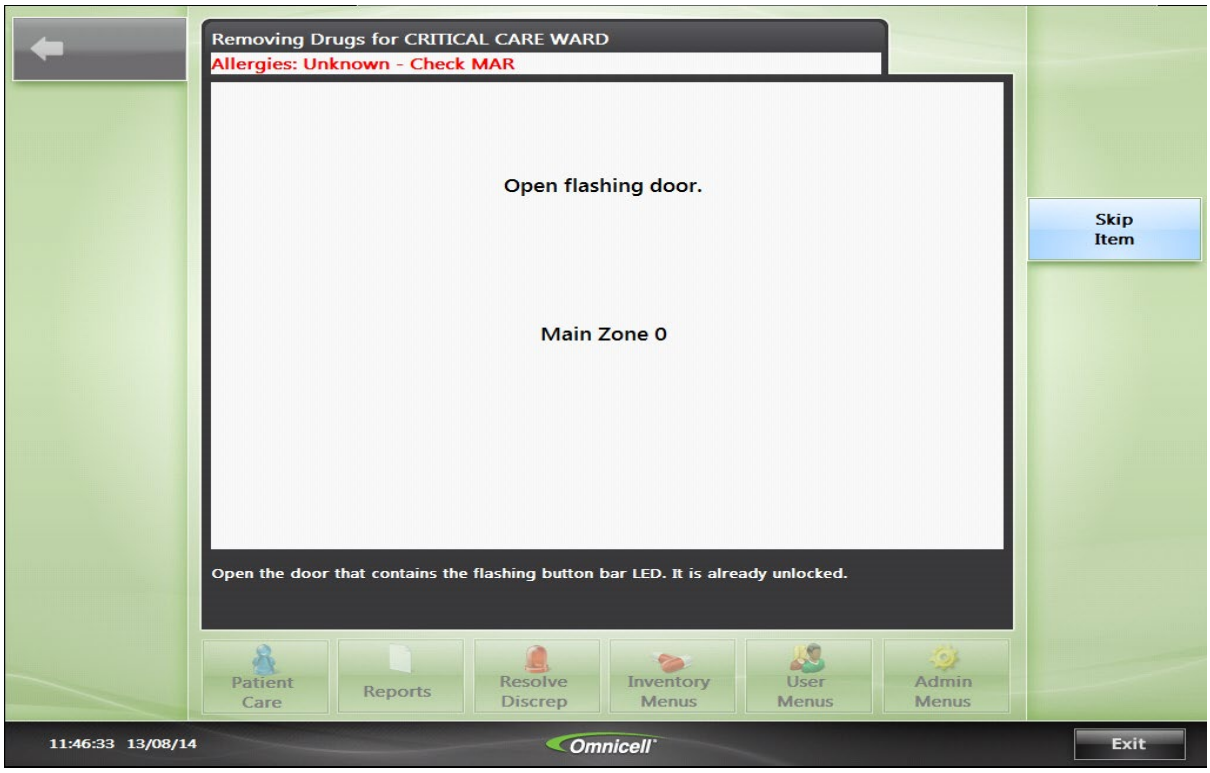
5. Count the current stock BEFORE dispensing and ensure that it matches the JAC figure you have note in the CD order book, if correct enter the number counted, if a discrepancy is noted you MUST inform a senior member of staff immediately before proceeding.



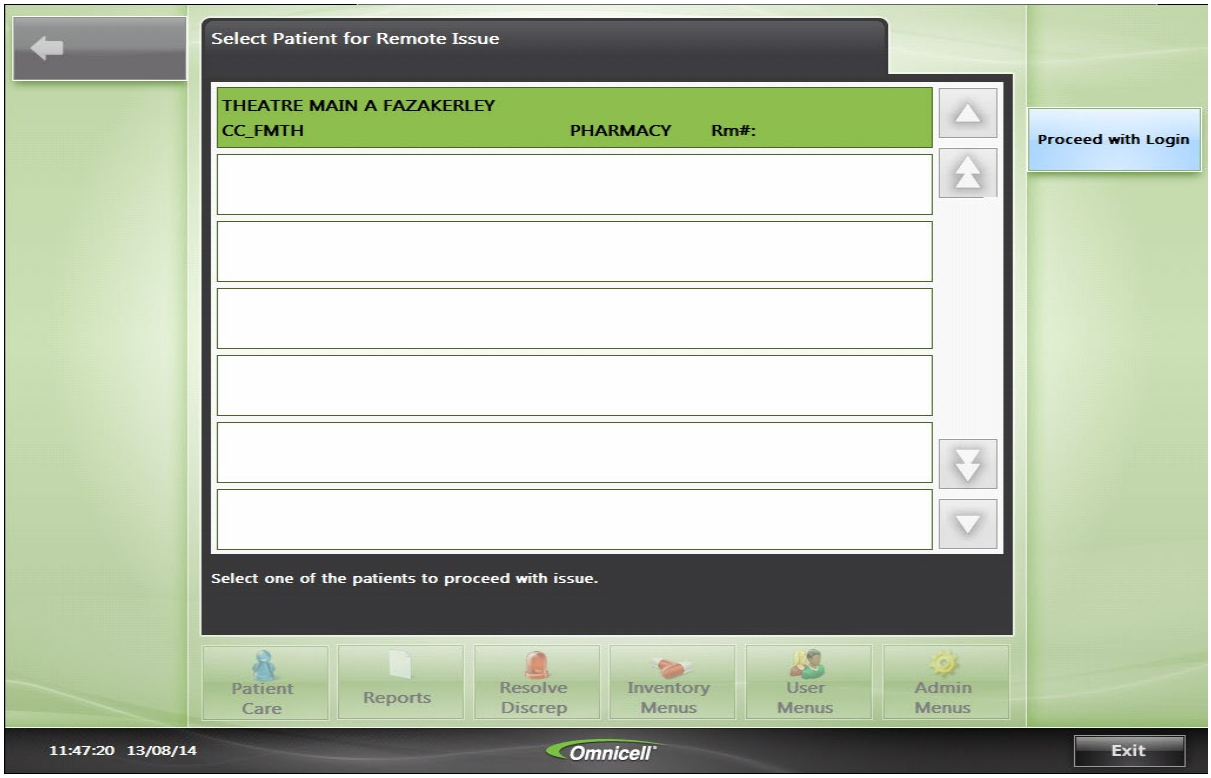
6. Remove the required quantity of the item from the tray and close the door; this completes the process for dispensing this item.



7. If there is more than one item to be picked for the Patient/ward the next cabinet will start to flash and the following screen will be displayed, repeat the above process



8. When all items have been picked for the selected ward/patient the screen will move onto the next ward/patient.



9. Once all request are picked EXIT the program

7.3 GP out of hours

GIG CYMRU NHS WALES
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Swansea Bay University Health Board

Standard Operating Procedure

Procedure for access and management of medication for GP out of hours (GPOOH)

Purpose

This SOP describes the process for accessing and managing all medicines including scheduled controlled drugs (CDs) in the GPOOHs bases at Morriston and Neath Port Talbot Hospitals.

Ordering and supply of medicines

Morriston: Stock Medication

1. Pharmacy visit on agreed day(s), review stock requirements and reconcile issues against prescriptions.
2. Pharmacy assemble the order, deliver and store the medication in the appropriate medication cupboard

Morriston: Controlled Drugs

1. The CD requisition book to be completed by registrant in GPOOHs.
2. Requisition book to be sent to Morriston Hospital Pharmacy between 9am – 5pm (Monday – Friday).
3. CDs are prepared by Pharmacy by 5pm on Friday and stored in the pharmacy CD cupboard.
4. On Saturday morning, pharmacy will liaise with GPOOHs to arrange delivery to GPOOHs
5. A registrant in GPOOHs will accept and sign for delivery of the controlled drugs.
6. The registrant will record the delivery in the CD register, check, update stock levels and store the medication in the CD cupboard.

Neath Port Talbot: Stock Medication

1. Pharmacy visit on agreed day(s), review stock requirements and reconcile issues against prescription.
2. Pharmacy assemble the order, deliver and store the medication in the appropriate medication cupboard.

Neath Port Talbot: Controlled drugs

i) On Friday evening, the GP will complete the CD requisition book (when required).
ii) On Saturday morning, the receptionist on duty will take the order book to the pharmacy.
iii) The controlled drugs are prepared by pharmacy.
iv) When the order is ready pharmacy will liaise with GPOOHs to accept delivery
v) The order will be taken by pharmacy to GPOOHs,
vi) A registrant in GPOOHs will accept and sign for delivery of the controlled drugs.
vii) The registrant will record the delivery in the CD register, check, update stock levels and store the medication in the CD cupboard.

Process for management of Controlled drugs

1. Controlled drugs are stored in a CD cupboard in GPOOHs.
2. Keys for the CD cupboard are stored in a separate key safe. Only GPs will have the key code number. Non-registered staff must not be able to access these keys.
3. If a CD is required, the GP will first prescribe the drug in the Adastra system and the prescription printed.

Supply for a patient attending GPOOHs

The CD is accessed from the CD cupboard and an entry completed in the CD register

As the GP will often be the sole registrant on duty a single signature only may be recorded. However, it is considered good practice for a second registrant to sign if possible.

The stock level of the CD must be checked with the register and signed as correct. Any discrepancies must immediately be reported to the pharmacy. Out of hours the on call pharmacist may be contacted via the switchboard at Morriston Hospital on 01792 702222

The CD cupboard must be locked and the key returned to the key safe.

The CD is then administered to the patient.

Supply for Registrants requesting CDs from GPOOHs.

Most commonly, this will be a request from district nurses requiring CDs for patients on syringe drivers where either there is a request for a newly prescribed syringe driver out of hours or there is an expected shortage of medication that could not have been foreseen in core hours. This will be in the form of a WP10 prescription written for the patient.

The CD is accessed from the CD cupboard and an entry completed in the CD register by the GP on duty dealing with the request.

The registrant attending GPOOHs and requesting the CD will confirm that the CD is correct and also sign the CD register as a witness.

The stock level of the CD must be checked with the register and signed as correct. This must be confirmed by the requesting registrant. Any discrepancies **must be reported immediately** to the on call pharmacist.

The CD cupboard must be locked and the key returned to the key safe.

Return of Controlled Drugs to GPOOHs

CDs that have been supplied to community registrants by GPOOHs and are subsequently no longer required cannot be re–used and will need to be destroyed.

CDs recently issued by GPOOHs can only be returned to the GPOOHs site that made the original supply.

The community registrant and GP will check the drug, quantity and enter into the separate section of the register identified for medication returns/destruction.

They MUST NOT be returned into stock for use by other patients and must be clearly identified and segregated from other CD stock when stored in the CD cupboard.

The stock must be removed by pharmacy where is will be processed in accordance with the regulations.

Checking of controlled drug balances

The following check of CD stock must be completed:

i) Check of stock with register record each time a CD is supplied.

ii) Daily checks of all CD stocks by a single GP to be witnessed by a second person who may be a non-registrant. Stocks in the cupboard must be reconciled with the CD register. This process involves removing the CDs from the cupboard and then reconciling each page in use of the CD register with stock.
The check must be recorded on the daily balance check schedule which must be monitored by GPOOHs leads at least weekly to ensure compliance with policy.

iii) Six monthly CD checks by pharmacy and a member of the GPOOHs team.

9th August 2021

7.4 SOPs to Support Management of Controlled Drugs in H.M.P. Swansea Healthcare

http://howis.wales.nhs.uk/sites3/page.cfm?orgid=988&pid=73940

7.5

GIG CYMRU NHS WALES
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Swansea Bay University Health Board

Pharmacy and Medicines Management

Standard Operating Procedure

Controlled Drugs for the Wales and West Acute Transport for Children (WATCh) Team

GIG CYMRU NHS WALES
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Swansea Bay University Health Board

PHARMACY AND MEDICINES MANAGEMENT

STANDARD OPERATING PROCEDURES

Procedure Name:	Controlled Drugs for the WATCh Transport Team

1. The WATCh team no longer carry controlled drugs with them when attending referring centres. Each referring centre in SBUHB has identified key clinical areas where the following drugs are kept and the team carry a sheet detailing this information.

Drug	Strengths
Fentanyl	50 mcg/ml – 2 ml and 10 ml amps
Ketamine	10 mg/ml 50 mg/ml 100 mg/ml amps
Morphine	10 mg/ml 30 mg/ml amps 100 mg/50 ml bottles
Midazolam	5 mg/ml 1 mg/ml (50 ml bottles or 5 ml amps)
Potassium Chloride	20 mmol/10 ml
Phenobarbitone	30 mg/ml or 200 mg/ml

2. Controlled drugs may be requested by the WATCh team for patients in the following instances:

   a) The patient is receiving mechanical ventilation and requires continuous infusions of analgesia, sedation and muscle relaxants to facilitate safe transfer.
   b) The child is not receiving mechanical ventilation but has a clinical need for a continuous infusion of either analgesia e.g. Morphine or sedation e.g. Midazolam to facilitate safe transfer.
   c) The child is receiving high dependency care and the team need to make preparation for a potential escalation of therapies during transfer, which may necessitate intubation and mechanical ventilation in the ambulance.

3. **Process**

   3.1 <u>Bolus Drugs – Preparation for escalation of therapies</u>

   1. Bolus drugs should be calculated and prescribed on the patient's WATCh record by registered WATCh prescribers.

   2. Adhering to SBUHB guidelines for the management of controlled drugs the calculated drug doses should be drawn up in clearly labelled syringes **jointly**

between WATCh and the local team. This must be a two registrant procedure. Whole ampoules must not be taken off site by the WATCh team.

3. Controlled drug registers must be completed and signed such that the individuals involved in the process are clearly identifiable. WATCh practitioners must put their last name and WATCh in brackets after their signature. This must be a two registrant procedure.

4. The WATCh team will have responsibility for the prepared doses of controlled drugs until the point of use and/or disposal.

3.2 Continuous Infusions – Prior to leaving referring centre

1. Infusions should be calculated and prescribed on the patient's All Wales drug chart by registered SBUHB prescribers.

2. Infusions are prepared by either local team prior to the arrival of WATCh or jointly with the WATCh team after their arrival (clinical condition dependent). This must be a two registrant procedure.

3. Where infusions have been commenced prior to the arrival of WATCh, these do not need to be changed before the team leaves with the patient.

4. It is the responsibility of the WATCh team members to clearly understand the doses/infusion rates being used by the local team. Before transferring the infusions to their transport syringe pumps, infusions must be clearly labelled.

5. The infusions must be prescribed in the patient's WATCh record once they are being administered via the transport syringe pumps. The prescribing on the WATCh record must be completed by registered WATCh prescribers.

4. **Disposal**

It is the responsibility of the WATCh team members to dispose of any controlled drugs according to the hosting site's policy once they have left the referral centre.

5. **Documentation**

Each referring centre in SBUHB will keep an up to date list (see Appendix 1) of WATCh team signatures in their identified key clinical areas and pharmacy departments.

Appendix 1

Staff Specimen Signature for Pharm

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Swansea Bay University Health Board

Staff Specimen Signature for Pharmacy

Name (please print):	Role:	Base Hospital:	Usual Signature:	Usual Initials:	Date:

Approved by
Name:
Role:
Signature
Date:

7.6

Supply of Controlled Drugs to Remote Learning Disabilities Units

Standard Operating Procedures

PURPOSE OF THIS SOP

To outline the process for supplying Controlled Drugs (CDs) to Learning Disabilities inpatient residential units remotely located from main hospital sites.

Background

Learning disability units are geographically spread across the ABMU area and parts of RCT and Cardiff. Prior to April 2021 there wasn't a direct route from Cefn Coed Hospital Pharmacy Department to the learning disability units, thus it wasn't possible to send Controlled Drugs (CD's).

From April 2021, Swansea Bay University Health Board will have transport going directly to the bungalows, therefore CD's can be ordered, supplied and delivered through Cefn Coed Pharmacy department.

PROCEDURE/PROCESS

1. At least 48 hours prior to the scheduled delivery, the nurse in charge of the unit must e-mail the pharmacy department at SBU.PharmacyCCH@wales.nhs.uk to order their CD's. (If the CDs are needed before the scheduled delivery day, then the nurse in charge must contact the pharmacy department to arrange an unscheduled delivery by transport.)

2. Within the e-mail the following details must be present:
    a. Name, strength and form of the CD
    b. Quantity required
    c. Name of the nurse ordering
    d. When the medication is needed by

3. The responsible pharmacist for the dispensary in CCH will transcribe the order into the relevant CD ordering book which is held in the pharmacy department.

4. Controlled Drug medication dispensed as per SOP DP-07.

5. SBUHB Transport will collect the controlled drugs and the controlled drugs order book from CCH on the nominated day, deliver directly to the learning disabilities unit.

6. The nurse in charge will accept the controlled drugs by signing the pink copy of the controlled drugs ordering book and booking the medication into the relevant Controlled Drugs register on the unit.

7. The controlled drugs order book will be handed back to the transport driver and returned to the pharmacy department.

Procedure Name: Supply of Controlled Drugs to Remote Learning Disabilities

Procedure Number: SOP-DP58

Written by: Dafydd Thomas
Approved by: Sue Jones
Authorised by: NA

Date of Original Version: 12 April 2021
Current Version Number: 1
Date of Current Version: 12 April 2021
Review Date: 12 April 2024

7.7

GIG CYMRU NHS WALES
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Swansea Bay University Health Board

Administration of Buvidal (Buprenorphine) Injection to Patients at Home

Standard Operating Procedures

PURPOSE OF THIS SOP

To outline the process for Community Drug and Alcohol Team (CDAT) nursing staff administering Buvidal (buprenorphine) injection to patients at home, who are unable to attend the CDAT Buvidal Clinic.

Background

In September 2019, Buvidal was approved by AWMSG for treating opioid dependence. It must only be prescribed by a specialist substance misuse consultant. It is supplied to the Community Drug and Alcohol Team (CDAT) by Cefn Coed and NPT Hospital Pharmacy departments as 'stock' on presentation of a Controlled Drug requisition.

Most patients are expected to attend a Buvidal Clinic at CDAT. However, a small number of patients are unable to attend CDAT for administration of Buvidal and therefore it is administered to patients in their home.

PROCEDURE/PROCESS

1. Buvidal should only be administered at the patient's home if it has been agreed by CDAT that there is a documented reason for them being unable to attend clinic.

2. Immediately prior to leaving for the patient's home, the Buvidal dose must be signed out of the CDAT Controlled Drugs (CD) register by a nurse and a second appropriate health care professional due to administer the medication.

3. The following must be documented in the CD register:
    - The name of the patient to be administered the dose
    - Time
    - Date
    - "For home administration"

4. The following items should be transported directly to the patient's home in a suitable bag/ container:
    - Buvidal dose
    - Medication administration chart
    - Sharps bin
    - Appropriate PPE

5. On administration of the Buvidal dose, the same nurse and appropriate second health care professional should sign the administration chart to indicate the dose has been administered.

6. The empty, pre-filled syringe, must be safely disposed in an appropriate sharps bin.

7. The sharps bin and medication administration chart must be returned directly to CDAT.

8. If the dose is not administered as planned (e.g. declined by the patient, or it is not appropriate for it to be administered) , the dose should be returned to CDAT immediately.

9. On return to CDAT, the Buvidal dose should be signed back into the CD register by the nurse and appropriate second health care professional and annotated 'Not administered'.

10. The nurse must document non administration in the patient's record, and inform the relevant prescriber and follow up on any further actions required.

Procedure Name: Administration of Buvidal (Buprenorphine) Injection to Patients at Home

Procedure Number:

Written by: Rhiannon Lewis: Specialist Mental Health Pharmacist, Alex Drohan: CDAT Manager
Approved by: Sue Jones, Head of Pharmacy Mental Health & Learning Disabilities
Authorised by: MH & LD Q&S committee

Date of Original Version: 11/8/21 **Date of Current Version: 11/8/21**
Current Version Number: 1 **Review Date: 11/8/23**

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

7.8

STANDARD OPERTING PROCEDURES

PROCEDURE FOR THE COLLECTION OF CONTROLLED DRUGS (CDs) FROM PHARMACY FOR Community Drug & Alcohol Teams (CDAT)

Purpose

The purpose of this CD SOP is to ensure that CDAT and pharmacy staff are aware of the process for collecting controlled drugs, which have been ordered, in advance from the pharmacy department for delivery to CDAT.

Procedure/ process

1. Delivery can be undertaken by any member of SBU CDAT staff. This may be Health care support workers, portering staff or nursing staff. They will be referred to as the messenger.

2. CDs will be dispensed by pharmacy staff against a requisition, in advance of collection and delivery.

3. The messenger must present a valid SBU Health Board identification. (Pharmacy may refuse to release CDs to any member of staff not in possession of a Health Board ID badge.)

4. The messenger, with a member of the pharmacy staff, will check to confirm that the CD being supplied is correct against the order placed.

5. This check must include-

- The drug
- The form
- The presentation size, (e.g. 1ml or 10ml amps)
- The strength
- Expiry date
- The quantity (sealed packs do not need to be opened, it should be assumed that the contents are correct as per the product labelling, however a check needs to be taken to ensure tampering with the seal has not occurred).

6. If all items are correct, the messenger signs and dates; in the 'accepted for delivery' section, on the appropriate page of the requisition book, on the white copy; ensuring the carbon sheet is in place. The details are also recorded in the 'Controlled drug delivery log book' and signed by the messenger and the member of pharmacy staff issuing the order.

7. The CDs are placed in a sealed CD transport bag, which has a recognised individualised serial number. The serial number of the bag is noted on the CD requisition.

8. The top order copy (white copy) is torn out of the CD requisition book is retained in pharmacy as a legal record of supply, and retained for 2 years. The requisition book is placed in the CD transport bag. The transport bag is sealed.

9. The CD transport bag is placed inside a locked box for transportation by the messenger.

10. The ordered stock and requisition book are transported to CDAT bases by the messenger in the sealed transport bags within the locked box.

11. The messenger will transport the CDs in the sealed bag, directly to the CDAT site, and they will park in an allocated space in close proximity to the entrance.

PROCEDURE FOR THE RECEIPT OF CONTROLLED DRUGS IN CDAT

Purpose / process

The purpose of this CD SOP is to ensure that all staff are aware of the procedure for managing the receipt of controlled drugs in CDAT.

Procedure

1. The CDAT manager is responsible for the safe and appropriate management of CD stock in the Department and must operate a robust system for ensuring the reconciliation of all CD orders and receipts and their appropriateness.

2. CD's must not be left unattended at any time until securely stored as per SBUHB CD policy.

3. On arrival at CDAT bases, the messenger must ensure a second registrant is available to co-sign receipt of the CD delivery. On removal of the transport bag from the locked box, both registrants should check the transport bag is sealed.

4. Each CD received should be checked against the requisition book order to confirm:

- The drug
- The form
- The presentation size, (e.g. 1ml or 10ml amps
- The strength
- Expiry date
- The quantity (sealed packs do not need to be opened, it should be assumed that the contents are correct as per the product labelling, however a check needs to be taken to ensure tampering with the seal has not occurred).

5. If everything is present and correct, then the order form in the CD Requisition book (pink copy) must be signed in the 'received by' section.

6. The registrant receiving the controlled drugs, and a second registrant, must enter each item in the controlled drugs register on their allocated pages and the final balance checked and countersigned.

PROCEDURE FOR THE MANAGEMENT OF CONTROLLED DRUGS' CUPBOARDS' KEYS FOR CDAT

Purpose

The purpose of this CD SOP is to ensure staff are aware of the correct procedures for managing controlled drug cupboard keys within individual bases of both Swansea and NPT CDAT.

Procedure/ process

1. The Team Manager (Registrant) is ultimately responsible for the custody of controlled drugs within the CDAT department, and their access must be restricted through robust key control.
2. CD keys must be kept separate from all other keys.
3. When CD cupboard keys are out of use, they must be stored in a central key safe.
4. Only registered staff have access to the code for the key safe.
5. An entry must be made in the 'CDAT CD key register' each time the CD key is removed from the key safe. This entry must include the date, time and name of the registrant along with their signature.
6. Allocated keys are to remain the responsibility of the individual to whom they were recorded as 'issued to' in the `Controlled Drug key log book` at all times until they are returned to the central key safe and entered as returned in the log book.
7. The CD cupboard must only be opened for checking, removal or receipt of controlled drugs. It must remain locked at all other times.
8. Note – access to the controlled drug cupboards is a two-person procedure.
9. Any loss or unaccountability of a CD key must immediately be reported to the CDAT manager and pharmacy and an incident form must be submitted.

10. Urgent efforts should be made to retrieve lost keys, enlisting the help of all relevant staff. Upon locating a lost key, reconciliation of the cupboard contents as per the reconciliation policy must be undertaken by the designated person in charge and a second registrant.
11. If the key(s) cannot be found, then the Pharmacy & Controlled Drugs Accountable Officer must be informed as soon as possible.
12. Locks must be changed if the loss is considered a security risk. Discuss this with senior pharmacy and nursing managers.

Spare Keys

The spare key is kept in Cefn Coed Hospital pharmacy Department and may only be accessed if requested by the CDAT manager / deputy.

Written by: CDAT Clinical Nurse Managers

Approved by: IPMM SMT

Date Approved: July 2023

Review date: July 2026

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

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Name and Signature of Lead Pharmacist.	Amy Jayham, Head of Pharmacy Services
Please specify whether the document is New, Revised or Supersedes a previous version.	Revised
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Please sign to confirm that the document has been authorised by an approved governance process in a specialty or delivery unit.	Yes
Has NICE guidance been considered/referenced when producing this guidance? If yes, please state the title or reference number.	
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(1) All policies need to comply with the Policy for the production, consultation, approval, publication and dissemination of strategies, policies, protocols, procedures and guidelines

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