Tees, Esk and Wear Valleys NHS
NHS Foundation Trust

Controlled Drugs Standard Operating Procedures

PHARM-0057-v5

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Contents

1 Purpose

By following this procedure staff will ensure that they:-

- Adhere to legislative requirements related to Controlled Drugs (CDs)
- Identify and manage risks related to the use of Controlled Drugs
- Are aware of their role and responsibilities in relation to using and managing CDs

Controlled Drugs are medicines regulated by the Misuse of Drugs Act 1971 and subsequent amendments. These regulations may be extended to other medicines that are liable to misuse by local agreement or at the direction of the Accountable Officer.

2 Related documents

This procedure describes what you need to do to implement the Controlled Drugs section of the Medicines Overarching Framework

The Medicines Overarching Framework defines the compliance requirements for safe, secure and appropriate handling of medicines which you must read, understand and be trained in before carrying out the procedures described in this document.

3 Controlled Drugs

The Misuse of Drugs Act 1971 and subsequent amendments, set out stricter legal controls around the possession and supply of specified drugs and drug-like substances that may be subject to misuse, diversion, being obtained illegally or are at risk of causing a higher level of harm than other medicines. These drugs and substances are termed Controlled Drugs (CDs). These legal controls govern how Controlled Drugs may be produced, supplied, prescribed, ordered, stored, administered, destroyed and disposed of.

4 Legislative Framework

Controls relating to CDs were tightened following the Shipman Inquiry in 2001 with the Government strengthening the arrangements for the management and use of Controlled Drugs. The Government made a number of recommendations to strengthen the governance arrangements for prescribing of Controlled Drugs and the ability to monitor their movement from prescriber, to dispenser, to patient (the 'audit trail'). However it is acknowledged that no system for the regulation of CDs would offer complete security against abuse.

Subsequent guidance ensured the statutory appointment of Accountable Officers (AOs) who have responsibility for the safe use and management of CDs within their trusts.

5 Accountable Officer

The Accountable Officer for CDs has overall responsibility for all aspects of the safe and secure management of CDs within the organisation. This appointment is a statutory requirement as identified by the Controlled Drugs (Supervision and Management of Use) Regulations 2006.

The Accountable Officer for TEWV is:

Christopher Williams

Chief Pharmacist
West Park Hospital
Tel: 07771 552084
christopher.williams@nhs.net

Any incident involving a CD must be reported immediately to the Accountable Officer (AO). In most instances the completion of a Datix report will meet this requirement and ensure the CD AO is notified, however, any significant unaccounted for loss of CDs should be escalated by a direct phonecall or email to the CD AO. For further information see the incident reporting flowchart.
In the absence of the CD AO, Richard Morris (Deputy Chief Pharmacist) is the deputy AO.

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6 Controlled Drug Schedules

The Misuse of Drugs Regulations 2001 classifies CDs into five Schedules according to the levels of control required. This is directly related to therapeutic use and level of risk; drugs with the highest abuse potential are categorised as Schedule 1, and those with the lowest abuse potential are in Schedule 5. Click on the links below to see the drugs included in each of the Schedules.
N.B. these lists are subject to amendment resulting from changes to legislation.

There may be occasions when there is a Trust or local area agreement to subject CDs to a higher level of restriction than those legally required due to increased risks being identified.

Some CDs are legally required to be stored in a CD cupboard but are not subject to the full legal record keeping requirements of usage or administration (Schedule 3 (CD no Register)). Within the Trust all CDs stored in CD cupboards will be subject to the same requirements as full schedule 2 CDs. This includes:

- complying with CD ordering requirements
- recording receipt and administration in the CD register
- Complying with CD destruction requirements

The most common drugs in this category are temazepam, buprenorphine and tramadol (see section 7).

Midazolam, pregabalin and gabapentin are Schedule 3 drugs (CD No Register). These drugs must be ordered & prescribed as a controlled drug, but do not need to be stored in the CD cupboard or entered in the CD register.

A brief summary of the CD requirements for commonly used drugs in each schedule can be found in appendix 6.

6.1 Schedule 1 drugs (CD Licence)

CD Lic: A substance controlled by the Misuse of Drugs Act to which the restrictions of the Regulations apply and, in addition, the production, possession and supply of which is limited in the public interest to purposes of research or other special purposes. A Home Office licence is required for such purposes.

6.2 Schedule 2 drugs (CD POM)

CD POM: A substance controlled by the Misuse of Drugs Act 1971 to which the principal restrictions of the Misuse of Drugs Regulations 2001 apply.

6.3 Schedule 3 drugs (CD no Register POM)

CD No Register POM: A substance controlled by the Misuse of Drugs Act to which the restrictions of the Regulations apply except that no entry in the Controlled Drugs Register is required and invoices must be retained for two years.

6.4 Schedule 4 drugs (split into 2 parts)

6.4.1 Part 1 (CD Benzodiazepines POM)

CD Benz POM: A substance controlled by the Misuse of Drugs Act to which the restrictions of the Regulations apply but with the following relaxation: prescription and labelling requirements do not apply (except those under the Medicines Act 1968), records in the CD register need not be kept by retailers, destruction requirements apply only to importers, exporters and manufacturers, there are no safe custody requirements.

6.4.2 Part 2 (CD Anabolic steroids POM)

CD Anab POM: A substance controlled by the Misuse of Drugs Act to which the restrictions of the Regulations apply but with the following relaxation: prescription and labelling requirements do not apply (except those under the Medicines Act 1968), records in the CD register need not be kept by retailers, destruction requirements apply only to importers, exporters and manufacturers, there are no safe custody requirements. There is no restriction on possession when contained in a medicinal product. A Home office import or export licence is required for the importation and exportation of these substances, unless they are imported or exported in the form of a medicinal product by a person for administration to himself.

6.5 Schedule 5 drugs (CD Invoice. P or CD Invoice POM)

CD Inv. POM: A substance controlled by the Misuse of Drugs Act but which is exempt from all restrictions under the Regulations except that the invoice or a copy of it must be kept for two years.

7 Specific Trust requirements for Schedule 3 drugs

Temazepam, buprenorphine and tramadol:

- Within TEWV, temazepam, buprenorphine and tramadol must be treated as a Schedule 2 Controlled Drugs (although legally they are Schedule 3 CDs).
- They are subject to regulations regarding ordering, storage, administration, recording and destruction.

Midazolam, gabapentin and pregabalin:

- Midazolam, gapapentin and pregabalin are schedule 3 Controlled Drugs (CD No register). They must be ordered and prescribed as a controlled drug
- There is no requirement for CD storage or for records of usage or administration to be maintained in the CD register. However, if an individual ward chooses (following a risk assessment) to store these drugs in the CD cupboard, then they must also be recorded in the CD register.

Particular attention must be made when dealing with injectable diamorphine or morphine preparations. The NPSA document 'Ensuring safer practice with high dose ampoules of diamorphine and morphine' states that good practice must ensure different strengths of these injections are stored separately and not together on the same shelf of the CD cupboard.

See also section 18.3 for circumstances involving the stepping up of controls relating to controlled drugs.

Temazepam, buprenorphine and tramadol must be treated as a full schedule 2 CD

Midazolam, gabapentin & pregabalin must be ordered as a CD, but is not subject to other CD requirements

8 Security & Storage

Any issues related to the security of Controlled Drug stocks should be discussed with the relevant Modern Matron and Pharmacist during working hours. Outside working hours it should be discussed with the Duty Manager who will involve the on call Pharmacist if appropriate.

8.1 Storage

8.1.1 CD Cupboards

- **All** CDs must be stored in a locked medication cupboard which can only be opened by the Appointed Practitioner in Charge (RN) or a person who can lawfully be in possession, such as a Pharmacist or a ward manager, or a person working under their authority.
- CD cupboards should conform to the British Standard reference BS2881 or be approved by the Pharmacy Department.
- The following standards apply to the storage of CDs which are subject to the full Controlled Drug requirements (i.e. schedule 2). They also apply to drugs from other Schedules which the Trust has designated to be treated as full CDs (see section 7).
- **As a clear rule, if CDs are stored in the CD cupboard they must be documented in full in the CD register, irrespective of legal record keeping requirements**.
- The CD cupboard must be dedicated to the storage of CDs and the following items only:
    - Medication:
        - Illicit substances awaiting collection/destruction
        - Patient's own Controlled Drugs
        - Leave/discharge supplies containing Controlled Drugs
    - Controlled Stationery:
        - Controlled Drug order book (see 10.5)
        - Controlled Drug register (see 10.5)
        - FP10 prescription forms and other controlled stationery as agreed with the pharmacy team
- Cupboards must be kept locked when not in use
- The lock must not be common to any other lock in the hospital

- Keys must only be available to authorised members of staff (i.e. an RN or a member of the pharmacy team in the course of their duties)
- CDs must be locked away when not in use
- Schedule 2 (& others as defined in section 7) CDs must not be stored in any generic medicines cupboard or trolley
- Discharge and leave CDs must be clearly separated from the ward CD stock (see 8.1.2)
- CDs awaiting destruction must be segregated from the CD stock
- N.B. CDs must not be stored in patients' own lockers unless the patient is self-medicating under a locally agreed procedure approved by the Chief Pharmacist (see self-administration section)

8.1.2 CDs for leave and discharge

- Any leave or discharge supplies that include a Schedule 2 (& as defined in section 7) CD must be stored in the Controlled Drug cupboard until the patient is ready to leave.
- They must be kept separate from the ward Controlled Drug stock, be clearly marked and must remain sealed in the original dispensed bag.
- See section 10.5 for record keeping requirements.
- For the process related to leave / discharge medicines please refer to the ordering, storage, security and disposal procedure (Hyperlink) within the Medicines Overarching Framework

8.2 CD Cupboard keys

- The Designated Practitioner (RN) in charge of the ward or unit is responsible for the CD keys throughout their span of duty
- The key for the CD cupboard must be kept separately from other ward keys
- The key must be kept on a key ring that is physically separate and readily identifiable
- The key may be delegated to other RNs within the team however the Appointed Practitioner (RN) in charge remains legally responsible for its safe keeping
- The CD key may be handed to an authorised member of the pharmacy team for the purpose of stock checking or ordering
- The CD key must be returned immediately after use to the RN in charge
- Keys must not be handed over to any unauthorised personnel, including medical staff
- If there is no RN in charge or present on the unit, the key must be handed to an RN in charge of a nearby unit. The keys whereabouts should be made known to all staff in both units including the manager
- If there are no Controlled Drugs stored in the cupboard, and there is no potential for this to change without warning, a locally agreed protocol may be used for the safe storage of the key. The protocol should be agreed with the ward/unit manager and a Pharmacist (see also section 10.5.2).
- Information on the process for dealing with missing CD cupboard keys is in Section 17

9 Roles and Responsibilities

All staff handling Controlled Drugs must be aware of their responsibilities in handling Controlled Drugs safely.

9.1 Prescribers

The prescriber is responsible and accountable for all prescriptions they write for CDs and ensuring they adhere to the legal and policy requirements. (see Section 10.1 for Prescribing Guidance)

9.2 Registered Nurses

In relation to all medicines, the Registered Nurse (Designated Practitioner) in charge of the ward or department is ultimately responsible for, and retains accountability for:

- the stock of all medicines held on their clinical area
- ensuring policies and procedures are followed correctly by all staff within their area of responsibility
- ensuring the security of medicines is maintained
- ensuring the stocks of CDs correspond with the details shown in the register
- the safe administration of medicines
- ensuring appropriate delegation of these duties to other RNs or suitably trained staff within the team

The RN's responsibilities in relation to CDs include:

- the receipt and appropriate storage of CDs (see section 8.1 for Guidance on storage of CD's and section 10.5 for Guidance of the receipt of CD's)
- entering new stock into the CD Register (see section 10.4 for guidance on CD recording)
- checking the stock balance of all CDs entered in the register at least once per week (see section 10.4.2 for guidance on CD stock checks)
- checking that the prescription chart is fully and correctly completed prior to administration
- the administration of CDs ensuring adherence to all legal and Trust requirements
- completing the register when CDs are administered (see section 10.5.3 for guidance on record keeping for the administration of CD's)
- the destruction of prepared but not used or part used CDs (see section 10.6.1 for guidance on destruction of CD's)
- coordinating the removal and/or destruction of larger quantities of CDs by appropriate personnel
- ensuring only personnel authorised to do so are involved in any of the CD processes

9.3 Pharmacists & Pharmacy Technicians

Pharmacists & Pharmacy Technicians are ultimately responsible for, and retain accountability for:

- Witnessing CD processes where appropriate (see section 9.4 for guidance on witness to CD processes)
- To ensure the legal requirements of CD Prescriptions (see section 10.1 for guidance on standards of prescribing)
- The dispensing of CDs in line with a valid prescription and legal requirements (see section 10.2 for guidance on dispensing CD's)

- Ordering / signing CD orders where appropriate (see section 10.3 for guidance on ordering CD's)
- Transfer the balance of Controlled Drugs to a new CD register where required (see section 10.4.1 for guidance on transferring a CD balance to a new register)
- The supply of CD order books and CD Registers (see section 10.4.3 for guidance on the supply of CD stationery)
- Safe destruction of larger amounts of CDs, e.g. out of date CDs, in date but no longer required CDs, returned leave/discharge CDs, patients' own CDs (see section 10.6 for guidance on the safe disposal of CD's)
- To oversee the transfer of patient named CD medicines between ward settings (see section 14 for guidance on the transfer of CD's)
- Advising on local procedures, CD incidents and CD errors where appropriate (see section 16 for guidance on CD incidents)
- Accessing CD cupboards as part of their duties, e.g. to undertake three monthly CD stock checks (see section 17 for guidance on Monitoring and controls)
- Advising on reporting procedures in line with CD flow chart and Accountable Officer requirements (see section 23 for the CD flowchart)
- Investigation of CD incidents

9.4 Witness to CD processes

- Any and all processes involving schedule 2 (& those defined in section 7) Controlled Drugs must be witnessed by an appropriate member of staff alongside the registered nurse.
- Ideally the witness should be a second registered nurse or associate nurse.
- In the absence of a second RN the witness should be either qualified to act as witness (e.g. doctor, Pharmacist or Pharmacy Technician) or have successfully completed the appropriate Trust training to authorise them to undertake this role (e.g. a member of non-registered nursing staff).
- There may be unplanned and unavoidable reasons for a non-registered, untrained staff member to witness CD activity. Where this is the case the service should undertake a risk assessment and inform the CDAO. If this is an on-going issue, steps must be taken to ensure provision of a trained witness is in place.
- The RN must ensure anyone involved in the witness role is authorised to do so (by one of the above statements), with the RN remaining accountable throughout the process.
    - The RN must lead all aspects and cannot relinquish the keys while involved in CD processes even to personnel who can otherwise hold the keys in the course of their duties (i.e. pharmacy staff).
    - Medical staff and non-registered nursing staff cannot hold medicine keys.
    - Medical staff should only be involved as a witness in exceptional circumstances.
- Please note, where an RN or other registered professional acts as witness; although not taking the lead for administration on these occasions, they remain fully accountable for their actions.
- The witness must be involved in the whole process and observe throughout, ensuring they challenge / question the process where appropriate.

10 CD Processes

This procedure covers all aspects of risk management and use of CDs including legally required explicit audit trails for prescribing, ordering, storage, record keeping, supply, transport, administration and destruction/disposal. To ensure compliance with legislation it is therefore essential that these procedures are fully adhered to for each stage of the process.

All processes, with the exception of prescribing, involving Controlled Drugs have to be witnessed, see section 9.4 for who can be involved as a witness. The witness must be involved in the whole process and observe throughout. Further information detailing the stages for each of the processes is provided below.

10.1 Prescribing

Prescribing CDs have specific legal and policy requirements and restrictions. For exact details of general prescribing principles please see the prescribing procedure (hyperlink) within the Medicines Overarching Framework

Within TEWV the following types of controlled drug prescribing will occur:

a) Prescribing on an "in-patient" / other medicines administration chart
b) Named-patient prescribing for an in-patient (i.e. a prescription to be dispensed rather than administered from) where stocks of CDs are not available
c) Leave / discharge prescriptions to be supplied by the pharmacy
d) Community based prescribing on an FP10 form

The guidance in the current edition of the British National Formulary should be followed.

It is illegal for a pharmacist to make a supply from an inaccurately written or incomplete script (see minor typographical exceptions in section 10.2).

Prescriptions for **schedule 2 and 3 controlled drugs** to be dispensed by a pharmacy (b, c & d above) may be computer generated, typed or hand written but must be signed by the prescriber in ink. The following information must also be stated:

- The name and address of the patient (for an in-patient, the address of the ward is appropriate)
- The drug name, form and, where appropriate, the strength of the preparation
- The dose and frequency of administration
- The total quantity of the preparation or the number of dose units, in words and figures
- The date of the prescription.
- N.B. the quantity prescribed should not exceed the equivalent of 30 days' supply
    - exceptionally, to cover a justifiable clinical need and after consideration of any risk, a prescription can be issued for a longer period, but the reasons for the decision should be recorded on the patient's notes
- All corrections and amendments must be written in the prescriber's own handwriting.

Examples illustrated in Appendix 9 Section 10

Under no circumstances can a carbon copy or faxed prescription be accepted to dispense or administer a Schedule 2 or 3 controlled drug.

It is an offence for a pharmacist to supply a controlled drug before, or more than 28 days after, the date specified on the prescription.

Prescribing CDs on a medicines administration chart will follow the principles set out in the prescribing procedure (hyperlink) within the Medicines Overarching Framework

Requests from community pharmacists to provide backdated prescription: It is unlawful to write a backdated prescription. Under no circumstances should back dated prescriptions be written to cover unauthorised supplies made by community pharmacist.

Doses of methadone and buprenorphine must be checked with Substance Misuse Services prior to prescribing any treatment for inpatients. Confirmation of any medication collected or supervised consumption administered must be made with the community pharmacist on the day of admission so that duplicate doses are not prescribed. The prescriber is responsible for ensuring that Substance Misuse Services and the community pharmacy are advised of the patient's admission so that community treatment is suspended. These services should also be informed about discharge arrangements in advance so that community treatment can be re-instated by Substance Misuse Services and arrangements are in place to ensure that there is no overlap in prescribing and administration.

NICE guidance recommends the following practices when prescribing controlled drugs:

- When making decisions about prescribing controlled drugs take into account:
  - the benefits of controlled drug treatment
  - the risks of prescribing, including dependency, overdose and diversion
  - all prescribed and non-prescribed medicines the person is taking (particularly any centrally acting agents) and whether the person may be opioid naive
  - evidence-based sources, such as NICE and the British National Formulary (BNF), for prescribing decisions when possible.
- When prescribing controlled drugs:
  - document clearly the indication and regimen for the controlled drug in the person's care record
  - check the person's current clinical needs and, if appropriate, adjust the dose until a good balance is achieved between benefits and harms
  - discuss with the person the arrangements for reviewing and monitoring treatment
  - be prepared to discuss the prescribing decision with other health professionals if further information is requested about the prescription.
- When prescribing 'when required' controlled drugs:
  - document clear instructions for when and how to take or use the drug in the person's care record
  - include dosage instructions on the prescription (with the maximum daily amount or minimal dose interval) so that this can be included on the label when dispensed
  - ask about and take into account any existing supplies the person has of 'when required' controlled drugs.
- When prescribing, reviewing or changing controlled drug prescriptions, prescribers should follow local (where available) or national guidelines and take into account the:
  - appropriate route
  - dose (including when dose conversions or dose equivalence is needed)
  - formulation (including changes to formulations).
  - If guidance on prescribing is not followed, document the reasons why in the person's care record.
- Document and give information to the person taking the controlled drug or the carer administering it, including:
  - how long the person is expected to use the drug
  - how long it will take to work
  - what it has been prescribed for

    - how to use controlled drugs when sustained-release and immediate-release formulations are prescribed together
    - how it may affect the person's ability to drive (see TEWV advice)
    - that it is to be used only by the person it is prescribed for.
- Inform people who are starting controlled drugs that they or their representative may need to show identification when they collect the controlled drugs from a community pharmacy
- Provide advice and information to people who are prescribed controlled drugs about how to store controlled drugs safely. Discuss storage options taking into account:
    - the person's preference for a lockable or non-lockable storage box
    - whether the controlled drugs will be accessible to people who should and should not have access to them
    - whether the storage method could increase the risk of controlled drug-related incidents, including patient safety incidents.
- When prescribing controlled drugs for use in the community, advise people how to safely dispose of:
    - unwanted controlled drugs at a community pharmacy
    - used controlled drugs.

10.2 Dispensing by pharmacy

All controlled drug dispensing processes will be covered by pharmacy standard operating procedures. For the purposes of this document, the information in this section is for information only.

Amending typographical errors

Pharmacists are able to amend prescriptions for Schedule 2 and 3 CDs where the prescription does not comply with the CD prescription requirements. The only changes that pharmacists can make are:

- minor spelling mistakes;
- minor typographical mistakes (this may include, for example, a number being substituted for a letter or two letters being inverted but where the prescriber's intention is still clear)
- Where the total quantity of the CD/number of dosage units is specified in either words or figures but not both, a pharmacist can add either the missing words or figures as required (but not both)

In doing this, pharmacist must exercise due diligence and be satisfied that the prescription is genuine and the CD is being supplied in accordance with the intention of the prescriber. The prescription must be amended in ink or otherwise indelibly and the pharmacist must mark the prescription so that the amendment is attributable to him or her, for example by signing the amendment. If there is more than one amendment on the same prescription, each amendment must be marked.

Where an amendment is made by one pharmacist and another pharmacist makes the supply, the Home Office has advised that the second pharmacist should also mark the amendment to indicate that he is also satisfied and it is attributable to him as well.

10.3 Ordering stock CDs for wards / departments

This section relates to the ordering of controlled drugs for ward / department. Controlled drugs can be obtained by the pharmacy dispensary. Where CDs cannot be obtained or cannot be

obtained in a timely manner from a TEWV dispensary, an FP10 can be used to obtain CDs for a specific named patient at a community pharmacy..

10.3.1 Ward / department ordering of CDs

Ward / service controlled drug orders will normally be prepared by a pharmacy technician or a registered nurse. The order can be signed by an authorised registered nurse or an authorised prescriber / pharmacist.

The specific detailed processes for ordering stock CDs are detailed in appendix 5.

- Stocks held on wards / departments should not be excessive and should be agreed with the pharmacy team.
- The Designated Practitioner (RN) in charge of the ward or unit is responsible for the ordering of all CD stocks for use in that area
- CDs can only be ordered from the pharmacy by submitting an order from the official CD order book, signed by an appropriate person. This will normally be the designated registered nurse, but can be a prescriber or pharmacist.
- All registered nurses, pharmacists and prescribers who may order Controlled Drugs must provide the Chief Pharmacist with a specimen signature
- In the absence of an authenticated signature the pharmacy will not process the order

The order must be written in duplicate in the CD order book and contain the following information:

- Date, name of hospital and ward or department
- Drug name, form, strength and ampoule size if more than one available
- Total quantity in words **and** figures
- For liquid preparations the total volume, i.e. millilitres (mls) should be stated in words and figures e.g*. 500 (five hundred) mls Methadone Mixture s/f = sugar free 1mg/1ml.*
- Signature, printed name and designation of the person ordering the medicine
- The order book **must** be sent to pharmacy prior to supply
- Only one preparation may be ordered per page.
- Wherever possible original packs should be ordered.

Scanned or faxed CD orders will only be used by the pharmacy to prepare a CD supply, but the supply will not be made until the original white copy is received by a member of the pharmacy team (including the delivery drivers). See appendix 5 for further details.

Completed CD order books must be kept for a minimum period of 2 years from the date of the last entry.

10.4 Ordering leave/discharge Prescriptions

Only medicines labelled with the patient name and appropriate directions can be given to patients to take home.

Ward stock medicines must not be used for this purpose.

This section relates to the ordering of CD's on a leave or discharge prescription for individual use of a patient who has authoirsed leave from the ward or to be discharged. They must be ordered in advance of the leave/discharge date to ensure supply. (for standards of prescribing see section 10.1) also examples of leave/discharge prescriptions see section….

10.5 Transport & Receipt

- Legislation sets down strict conditions around the transport, delivery and subsequent receipt of CDs to clinical areas.
- The process of receipt, documenting and storing CDs must be completed as soon as possible after the drugs are delivered to the ward/clinical area.
- Responsibility for the security of CD transfers to the ward/clinical area as soon as the sealed package is delivered and signed for.
- Record keeping for receipt of CDs must comply with the current legal framework.
- All CDs delivered to a ward/clinical area must be in a sealed bag or box
- CDs will normally be accepted by the Designated Practitioner (RN).
- When the Designated Practitioner (RN) is unavailable, CDs may be accepted by another appropriate member of Trust staff. When this happens the receipt of the package must be recorded on the ward by that member of staff, who must assume responsibility until the package can be handed over and signed for by the RN. The ward record must detail the date, name and signature of the person receiving the package and the name and signature of the RN ultimately accepting the package.
    - In order to maintain the audit trail accurate records must be kept containing the following information:
        - Date and time
        - Name, designation and signature of person receiving package
        - Name and signature of RN accepting package
        - Time received
    - While the responsibility for the package lies with the "appropriate member of trust staff", it must be stored in a safe area with limited access. This safe area should be locally agreed with a Pharmacist
- Where a sealed package is signed for, responsibility for the transport extends only as far as safe delivery of the sealed package.

10.5.1 For receipt of all stock CD's

- When receiving CDs on a ward or department from pharmacy the RN should ensure the following process for receipting CDs on the ward or department:
    - Check the contents of the bag against the requisition in the order book
    - The ward manager and pharmacy must be notified as soon as possible if any discrepancies are discovered once the delivery seal is broken. If outside of normal office hours they should be informed as soon as possible at the start of the next working day
    - Seals on the individually dispensed CDs should be left intact; manufacturer's unbroken seals/unbroken dispensing labels must be assumed to contain drugs of the quantity and description on the label.
        - A seal should only be broken when the pack is required for administration; tamper evident seals must not be broken for stock checking procedures
    - For stock orders: sign the duplicate pink sheet in the CD order book in the 'received by' section

- The CDs should be placed in the CD cupboard
- The CDs should be entered into the CD register in presence of and signed by the appropriate witness
- If the order is not correct then pharmacy should be informed immediately and a Datix form completed. The supply should still be entered as above to ensure a full audit trail. The entry should identify the discrepancy.

10.5.2 For receipt of all leave/discharge CD Prescriptions

- When receiving CDs on a ward or department from pharmacy the RN should ensure the following process for receipting CDs on the ward or department:
  - Check the contents of the bag against the prescription
  - The ward manager and pharmacy must be notified as soon as possible if any discrepancies are discovered once the delivery seal is broken. If outside of normal office hours they should be informed as soon as possible at the start of the next working day
  - Seals on the individually dispensed item should be left intact. A seal should not be broken for quantity checking and assume to contain the quantity as labelled. (seals should only be broken for administration purposes.
  - Sign the copy prescription to verify receipt of prescription
  - The CD must be placed in the CD cupboard
  - The CDs should be entered into the back of the CD register in presence of and signed by the appropriate witness. (see example in section….
  - If there are any discrepancies with the order pharmacy must be informed immediately and a Datix form completed. The entry into the register must identify the discrepancy
  - Be headed Leave/Discharge followed by the name of the drug, form and strength plus the name of the patient in brackets
  - Allocated one page per patient per drug.
  - Not to be entered into the register as ward stock and you should take care not to mix up with ward stock or Patient Own (POD)
  - Not be stored in patients' medicine lockers or medicine trolley (see exceptions in section 14).
  - Not be taken to Pharmacy.

The following details must be recorded for all supplies of Controlled Drugs received on the ward or department (essentially ensuring that each column in the CD register is completed):

- Date and time received
- Name of pharmacy making supply and the serial number of the requisition / prescription (where available) in the order book
- Quantity received
- Name, form and strength
- Signature of authorised person making the entry
- Signature of witness
- Balance in stock

If collecting CDs from the pharmacy, the member of staff should always carry their Trust identification with them and produce it on request.

Although it should not be common practice, if receiving/collecting CDs from a community pharmacy for either patient collection or delivery to a patient's home they should be stored within a

CD cupboard on site until ready to hand to the patient. The seal on the package should not be broken. If the service/setting does not have a CD cupboard they cannot hold CDs on site.

10.6 CD Records

All wards holding stocks of CDs must keep a comprehensive record of all CDs received, administered, destroyed and disposed of, in a CD register. Irrespective of legal record keeping requirements, if CDs are stored in the CD cupboard they **must** be documented in full in the CD register.

The Registered Nurse in charge of the ward or department is responsible for keeping the CD register up to date and in good order. The specific requirements are:

- It should be bound with sequentially numbered pages
- It must be kept in the Controlled Drug cupboard or a locked cupboard near to the CD cupboard with access restricted to authorised personnel only
- It must be kept for seven years from the date of the last entry and stored securely
- It must have an up-to-date index at the front of the book of all CDs held and these must correlate to the page numbers within the register (see appendix 3)
    - Where the index has not been updated, this should be corrected during the weekly CD check
- Entries must be made in chronological order and in black indelible ink
- There should be a separate page for each drug and strength so that a running balance can be kept (see section 10.5.3 for guidance on using multiple registers)
    - Stocks, named patient supplies & Patients Own Drugs must also be on separate pages. i.e. a stock supply and named patient supply of the same drug, strength and form must be kept on separate pages
- The full approved name of the drug, the strength and type of preparation (form) must be inserted at the top of the page
- Each entry must be signed by a registered nurse and must be witnessed by an appropriate other person
- On reaching the end of a page in the register the balance should be transferred to a new page with an annotation on each page to state the page number it is carried forward to and brought forward from (see appendix 3)
- The index at the front of the book should be updated each time a new page is commenced (this includes pages opened to document named patient supplies, patients' own CDs, suspected illicit substances and leave / discharge medicines)
- All stock CDs must be recorded in the CD register working from the front of the book towards the back, adding the page number to the index.
- All illicit substances should be entered into the CD register on a page allocated for suspected illicit substances at the back of the book . If a new page is required this should work forward to the front of the book, adding the page number to the index.
- Leave and/or discharge medicines that include CDs must be stored in the CD cupboard and entered into the CD register on a page allocated per patient for leave and discharges at the back of the book. If a new page is required work forward to the front of the book, adding the page number to the index. When entering leave/discharge medicines state the entry as *'leave package for (patient name), which includes (name, form and quantity of medicine) as per prescription (reference number)';* (see appendix 3).

- The seal on the bag **must not** be broken until the point of leave/discharge when the RN should open to explain administration requirements and side effects of the medication before handing over to the patient, (see ordering, storage, security and disposal procedure (hyperlink) within the Medicines Overarching Framework.

Stock supplies, named patient supplies, patients own CDs must be recorded on separate pages in the register.

Leave & discharge CDs must also be recorded on a specific page.

The back of the register can be used to record entry and destruction suspected illicit substances.

10.6.1 Transfer to a new CD Register

- When a new CD Register is required it should be obtained from Pharmacy
- Entries may be transferred into a new register by two appropriate practitioners (i.e. RN and RN,Pharmacist, Pharmacy technician and RN, or RN and appropriate witness) adhering to the following:
  - Page numbers of old and new books must be entered in both books i.e. *'transferred to new CD Register number, page no……*' and '*transferred from previous CD Register number, page no ….'*
- The details must be transferred to a new page in the new Controlled Drug register and the corresponding page in the old book cancelled and signed by both practitioners
- Care must be taken within this process to ensure no discrepancies are missed. Every page of the old register must be checked to ensure all records are transferred. If a discrepancy is discovered during this process then this must be investigated and reported (see section 17)

10.6.2 Stock Checks

CD stocks must be checked regularly. This is in addition to the checking requirements during the administration process. Stock checks must meet the following requirements:

- Regular CD stock checks should be carried out at least once per week or more frequently if determined by the RN in charge.
- The weekly stock check should take place on the same day each week, but can be carried out 24 hours either side where service need dictates
- A weekly stock check does not need to be performed if there are no CDs stored on the ward / department. Where this is the case, a clear visual control should be added to the CD cupboard to ensure it is clear that no CDs are stored. This should ideally be a tamper evident seal on the CD cupboard to ensure that no CDs have been received without notification. The tamper evident seal should be sufficient to prevent anyone adding contents without breaking it and should, otherwise, be clearly intact to show the cupboard is empty (e.g. a strip of micropore or sticky tape).
- These checks should be performed by checking the balance in the CD register against the contents of the cupboard (not the reverse). Every page of the register must be checked to ensure there are no incomplete records.

  - Every page in the CD register must be checked to establish the anticipated balance for each preparation (i.e. every page in the register which has an entry on it must be checked to ensure the balance has transferred to another page or that the amount stated on the page matches the amount in the cupboard – this includes zero balances).
- These checks should be carried out by a registered nurse witnessed by preferably a second registered nurse. In the absence of a second RN an approved witness can participate and must witness the full check
- The process must include the removal of all the stock from the CD cupboard before the checks start. The RN and witness should then start at page one of the ward CD register and work sequentially through the book checking each page against what is held in the cupboard
- Expiry date checking is part of the weekly check and any drug which has expired should be moved to the shelf kept for medication awaiting destruction. The most senior person involved in this checking process is responsible for informing the Pharmacy Team that a CD requires destruction.
- CD stock checks must include:
  - In date and expired stock / named patient supplies. Expired stock must remain in the running balance until destroyed.
  - Patients own medicines
  - Leave/discharge supplies, but must remain in the sealed bag as dispensed (see 10.4.1)
  - Illicit substances awaiting destruction
- As each CD is checked, it should be returned to the cupboard, this will enable any discrepancies to be detected in the entries recorded in the register and in the stock of drugs in the cupboard
- If there are any medicines with tamper-evident seals in the cupboard, these should not be broken for stock checking procedures; they must be assumed to contain the quantity and description on the label.
- Opened liquid stock should be measured by using a visual check on the bottle, unless there is doubt about the correct balance. If it seems that a discrepancy is likely then the liquid should be measured out using an appropriate measure suitable for the volume of liquid. Assume sealed bottles contain the volume stated by the manufacturer e.g. 100mls (for checking Methadone stock see section 11.3.2) The record must state if the balance was visually checked or was measured. Always consult with pharmacy for volume errors. Visual checking is an estimation of volume but this should be as accurate as possible. Always take into account the total amount originally dispensed, the total amount that has been administered and the amount remaining.
- Each item should be checked for the following:
  - The integrity of the medicine, i.e. the label is clear, the container is appropriate and the CD has not reached its expiry date and appears to be in good condition
  - The balance in the register matches the number in stock
- If the CD stock corresponds with the register balance the check can be recorded in the CD register:
  - Enter the date and time of the check.
  - If there are no discrepancies write ‘balance checked and correct’
  - Enter the two signatures (registered nurse and witness) in the “given by” and “witnessed by” columns of the register.

- Add the correct running stock balance

- Any discrepancies must be reported and investigated without delay (see section 17.1)
- Ensure that the visual control notice is attached to the outside of the CD cupboard and has been signed and dated as a note of the weekly check.

Weekly stock checks must take place (with a 24 hour tolerance) where CDs are kept.

A weekly stock check is not required if no CDs are stored. Controls must be in place to ensure weekly stock checks resume if CDs are received on to the ward. A weekly CD Audit checking tool (Appendix 7) and Visual control notice is available on InTouch for guidance

10.6.3 Controlled stationery

CD order books, registers and prescription forms are controlled stationery and can only be obtained from Pharmacy . Collectively they provide the audit trail for receipt, administration and destruction of CDs. They must be kept for a set minimum period of time from the date of last entry:

- Order books must be kept for a minimum of two years.
- CD registers must be kept for a minimum of seven years.

As controlled stationery, they must be locked away when not in use (they can be locked anywhere appropriate – it does not need to be a CD cupboard). A new order book should only be started when the previous order book has been fully used. Order books **cannot** be shared with another ward.

Normally, only one CD register should be in use at any time, however, it may be appropriate to have more than one register for different purposes (e.g. one for stocks, one for named patient supplies, one for patient's own), depending upon the volume of activity. This should be agreed with the ward pharmacy team.

10.6.4 Controlled Drug Invoices

Invoices for controlled drugs will be retained by the pharmacy team for a minimum of 6 years.

10.7 Administration

The procedure for administration is the same for CDs as for generic medicines (see the preparation and administration procedure (hyperlink) within the Medicines Overarching Framework); however the administration must be witnessed and then recorded in the CD register in addition to recording the administration on the prescription and administration record.

Ideally, two registered nurses should be involved in the administration of CDs. However, when this is not possible, an appropriate witness may be involved (see section 9.4). Both persons **must** be present throughout the entire procedure of preparation, checking, administration and/or disposal and recording.

Where administration is undertaken by a professional other than a registered nurse (e.g. an anaesthetist in an ECT suite), the principles below all apply. In these circumstances the doctor (or other professional) is taking the lead on administration with a RN or other appropriate person acting as a witness.

10.7.1 Prescription and administration record card

Both members of staff must:

- Check that all the information is completed on the prescription and administration card, including the allergy box – if the allergy box is empty the medicines **cannot** be administered
- Check prescription card is signed by the prescriber
- Check prescription to confirm dose is due
- Look at administration record on prescription card to ensure/confirm that the due dose has not already been given by other members of staff
- As required medication (PRN) – check the number of doses given in the previous 24hours to ensure the prescribed maximum daily dose is not exceeded, also taking account of any regular medication prescribed
- Check that what is prescribed tallies with details in the CD register

10.7.2 Preparation of the dose to be administered

The lead nurse (must be the RN if second person is an appropriate witness) must:

- Take the correct medication from the CD cupboard and cross check with the witness and the prescription and administration record
- Check that stock in the cupboard tallies with the CD Register for that particular drug; the witness should also check
- Prepare the dose to be administered
- Do not forget the '5Rs' - check it is for the right patient, right drug, dose, route and time and correct form
- Also remember to check the strength of the drug and the type of preparation, i.e. whether it is slow release or standard release
- Check all calculations. Both the RN and witness should check the calculations independently of each other. If the calculations differ it may be necessary to get a third party involved. Neither person should assume the other is correct.
- Once prepared, the RN and witness must check the remaining stock, this figure should match the stock level in the register minus the dose just prepared
- When administering liquid CDs, a visual check of the liquid remaining in the bottle should take place following preparation for administration. This involves an estimate of the quantity remaining by considering the total volume administered and the approximate proportion left in the bottle. Bottles of liquid CDs **must not** be poured out and measured at each administration as this can cause wastage at each measure and a subsequent shortage of the full amount dispensed and supplied

10.7.3 CD Register

- After preparing the dose the registered nurse must complete the entry in the CD register on the relevant page for the medicine removed from the CD cupboard
- The CD register must be signed immediately **following** administration, both RN and witness must sign using black indelible ink
- If the patient refuses the medicine this must be written clearly in the register the medicine must then be destroyed and disposed of correctly and both parties sign the entry (see 10.7)

- If part of a vial is administered, the amount given and the amount wasted must be recorded
- Any spillages must be accounted for and recorded in the register with both parties signing
- Any mistakes in the register must be corrected by **bracketing the error** in such a way that the original entry is clearly legible. The RN should mark the entry as '**written in error'** and both parties should sign. Tippex or other methods of obliteration must **never** be used to correct errors

The following must be recorded on the appropriate page in the CD register for **all** CD administrations:

- Date and time of administration
- Name of patient
- Quantity administered
- Balance of stock
- Signature of registered nurse administering
- Signature of appropriate witness

For examples of appropriate entries see appendix 3

10.7.4 Witnessing the administration of the medicine

Both the lead RN and the witness must stay together and observe the whole process of administration throughout. They must adhere to the following:

- Both practitioners must take the medication to the patient
- The patient must be positively identified, they should check the patient name against prescription and notes in addition to asking the patient to verify
- Tell the patient the name and dose of the drug before it is administered, unless the circumstances prevent this
- The patient must be observed to take the medication
- The lead RN administering must then sign for administration on the prescription and administration record
- They should both then sign the CD register **following** administration

All entries into the CD Register must be made immediately following administration

10.8 Destruction/disposal

- Registered Nurses can only destroy or dispose of small quantities of CDs within the parameters below (10.7.1).
- Larger quantities, patients' own supplies and surplus or expired ward stock can only be destroyed by approved personnel (all Pharmacists and Pharmacy Technicians are approved by the Accountable Officer) witnessed by an RN.
- The Pharmacy team should be notified of any CDs requiring destruction. Items requiring destruction should be segregated and quarantined to ensure it is not used in error. The item should be marked with the date pharmacy were informed. The item requiring

destruction needs to be retained within the running balance in the register until it is destroyed.

- Destruction of CDs must be recorded in the CD register and witnessed in the same manner as any other CD transaction.
- For disposal of illicit substances see Section 15
- For stock controlled drugs, when disposing of bottles containing irretrievable amounts of liquid drugs:
    - consider rinsing the bottle and disposing of the liquid into a pharmaceutical waste bin
    - dispose of the clean, empty container into the recycling waste.
- Disposal of irretrievable amounts of controlled drugs does not need to be recorded.

10.8.1 Disposal of small quantities that have been prepared for administration

Any Schedule 2 or Schedule 3 Controlled Drug (which is subject to CD register record keeping requirements) that has been prepared and not used, or only partly used, must be destroyed in the presence of an appropriate witness and an entry made in the Controlled Drugs register. The remaining stock of the Controlled Drug must be checked and recorded by both parties.

Only small amounts of CDs (i.e. individual doses), can be destroyed on wards by registered nurses, in the presence of an appropriate witness, in the following situations:

- Any surplus when the dose is smaller than the total quantity in the ampoule or when only part of a tablet is required
- When a dose is prepared/drawn up but not used
- When a patient refuses a dose or partial dose

The Home Office has advised that Schedule 2, 3 and 4 Part 1 Controlled Drugs must be denatured before being placed in waste containers to ensure it is irretrievable. Schedule 4 part 1 CD's include most of the benzodiazepines e.g. diazepam and lorazepam, in addition to zopiclone.

The unused or partially used remaining dose of tablet CDs and unused or partially used doses of liquid CDs, must be firstly denatured by crushing/grinding any solid dose formulation then placing either the liquid or crushed solid dose into a small amount of hot, soapy water (hot tap water and washing up liquid is sufficient) ensuring that the drug has been dissolved or dispersed. The resultant mixture should then be placed into the appropriate sharps bin.

In order to comply with the requirements of environmental laws any container used for the denaturing process (if not disposable) must be cleaned with a piece of paper towel and the towel disposed of in the sharps bin alongside the liquid; if denaturing using the disposable paper medicine pots the pot should be placed in the sharps bin alongside the liquid.

If it has been locally agreed to use CD destruction kits to ensure all denatured CDs are irretrievable, this can continue (see appendix 2).

The destruction of unused or partly used doses of Schedule 4 Part 1 and Schedule 3 Controlled Drugs which are not subject to CD register recordkeeping requirements do not have to be witnessed and do not have to be recorded, unless there is a local arrangement to treat drugs in these schedules as S2 Controlled Drugs.

Wards/departments/units are responsible for accessing, ordering and storing the relevant equipment from Cardea.

10.8.2 Disposal of patches following removal from patient

Patches containing CDs at times are required to be denatured and rendered irretrievable, e.g. patches that have fallen off or patches removed early due to dose titration. To keep the risk of misuse, abuse and diversion to a minimum and to ensure the safety of all patches, whether partially or fully used, the same process should be adhered to.

The RN destroying the patch should wear gloves to reduce the risk of exposure. The patch should be folded over on itself and stuck together (with the adhesive already on the patch). The patch should then be placed into a CD Destruction kit.

Where a patch has come off and **cannot be accounted for** this should be fully investigated and reported through the Accountable Officer following the flowchart for the reporting of CD incidents. A trust Datix form should also be completed. This is particularly important if the patch is new and still contains most of the prescribed medicine.

10.8.3 Disposal of large quantities, surplus or expired stock and patients' own supplies

10.8.3.1 CDs subject to recording in the CD register

A person authorised to witness destruction of CDs must ensure that the method of destruction renders the drug irretrievable prior to safe disposal. The method of destruction will depend on the nature and quantity of the Controlled Drug to be destroyed but should comply with those currently recommended by the GPhC/RPS [Guidance for Pharmacists on the safe destruction of CDs] – see appendix 2.

The Accountable Officer may approve and authorise named, senior staff or pharmacy staff to dispose of stock, named patient CDs or patients own CDs on a ward, using CD destruction kits.

The approved staff include Pharmacists and Pharmacy Technicians. Non-approved staff **must not** dispose of CDs. Registered Nurses are **not** included in the approved and authorised list. RNs will act as a witness to the destruction of controlled drugs to ensure one member of ward staff is involved in the destruction.

Destruction of surplus or expired Controlled Drugs must occur in a timely fashion, so that excessive quantities are not stored awaiting destruction.

These parameters apply to **all** CDs recorded within the CD register, irrespective of their Schedule.

10.8.3.2 Schedule 3 & 4 CDs not subject to recording in the CD register

Pharmacy technicians may destroy Schedule 4 Part 1 or Schedule 3 CDs (e.g. midazolam) on the ward or they may be removed to the Pharmacy Team office for denaturing and destruction.

If destroyed on the ward the destruction must be witnessed and recorded by the Registered Nurse in charge. An entry should be made in the back of the CD register to record the destruction.

If transferred to the pharmacy team office for destruction, removal from the ward must be recorded in a "medication transfer book" and witnessed by the Registered Nurse in charge. If appropriate the medicine may be transferred for use on another ward rather than destroyed. An appropriate audit trail should be made of this transfer. If destruction is required, once transferred to the pharmacy office, an entry should be made in a CD destruction book (this could be a CD register or other appropriate book). Destruction must be witnessed by a Pharmacy Technician, Pharmacist or medicines management nurse and recorded by both persons on the record. The record must be retained with the pharmacy for 2 years to provide a full audit trail.

Destruction should normally be done using a CD destruction kit following advice in appendix 2.

In date ward / department stock CDs no longer required for use cannot be returned to the supplying pharmacy.

Stock, Leave and discharge CDs and Patients own CDs that are no longer required can be destroyed on wards by pharmacy staff using the process as detailed in the disposal section

11 Methadone

11.1 Ordering methadone

- Methadone should be ordered as original packs in multiples of 100ml (e.g. 5 x 100ml)
- Larger bottles can be obtained if ordering for substance misuse services
- When documenting the amount received into the CD Register it is the total amount that should be documented, i.e. if 5 x 100ml is received, it is entered into the register as 500ml

11.2 Measuring Doses

- Trust approved oral syringes may only be used if the dose is 20ml or less
- Doses over 20ml must be measured using **only** a pharmacy approved measuring cylinder; do **not** use medicine pots or syringes, either oral or parenteral
- Measurement is correct when the lowest point of the surface of the mixture (meniscus) corresponds to the amount required
- Once measured, transfer the dose into a medicine pot / beaker prior to giving to the patient. If deemed appropriate it may be administered via an oral syringe but this should not be custom and practice
- If a spillage occurs during the measuring process this should be recorded in the register, with an estimate of the amount spilled with the remaining stock poured out and measured and the running balance adjusted. Following a spillage, you should, during working hours contact the ward Pharmacist for advice who may then sign to witness the spillage and adjusted balance, or may advise that a second registered nurse does this.

- Manufacturers will normally provide overage within the bottle as, due to the viscosity, some may be lost during the measuring process

11.3 Methadone and the CD Register

11.3.1 Methadone for in-patients on admission

- There are a number of tasks that must be completed on admission/ during admission and Leave or Discharge of a patient who is prescribed Methadone. These tasks are explained here in the MSS1 (Medicines Safety Series)

11.3.2 Administering doses of methadone

- The balance column in CD Register must always be arithmetically correct, i.e. the balance must be equal to the previous balance minus the dose to be administered.
  Contact Pharmacy for advice for any volume errors/discrepancies.

11.3.3 Checking stocks

- Balance checks:
  - Stock balances should generally be checked by visual inspection
  - Stocks should be visually checked every week preferably by two RNs but if necessary by an RN and appropriate witness
  - Periodic volume checks may be helpful but these should not be completed too frequently due to the potential for wastage
  - All balances must be confirmed to be correct on completion of a bottle
- Entries into the CD Register following visual stock checks should be written as follows: '*Stock visually checked and appears correct',* followed by the two signatures
- Do not make any immediate entries in the register if there is an obvious discrepancy
- It is common for methadone liquid to contain an overage in each bottle – an overage of up to 7ml may be expected from a 100ml bottle
- If an overage is found that is within the tolerance stated above then a correction can be made to the balance by one of the following, witnessed by an RN:
  - Ward manager (with up to date CD training)
  - Pharmacist
  - Pharmacy technician
- Before the correction is made, appendix 4 should be completed to ensure that other potential causes of the discrepancy have been excluded. Once this has been done, the register entry should state. "Overage of Xmls noted during stock check. Balance corrected."
- If the overage is greater than the tolerance stated above, or an underage then an investigation should be instigated and pharmacy should be contacted as soon as possible (see 11.3.3).
- Every three months the pharmacy department will check stocks as part of their Controlled Drug audit programme (see section 18.1)
- Following this check, the Pharmacist or Pharmacy Technician will make an entry in the register as follows: '*3 monthly CD stock check'* followed by either the visual check or the

volume check statement as appropriate. The Pharmacist or Pharmacy Technician will sign the entry and get it countersigned by the witnessing registered nurse

11.4. Correcting balances

It is not sufficient to write: *'stock checked and incorrect'* and amend the balance. If the balances do not tally between the CD register and the stock in the cupboard the RN should ensure the discrepancy is fully investigated. This should include checking the previous entries to ensure the arithmetic is correct and that the balances have been calculated correctly. The procedure in 11.3.2 should be followed if the balance is within tolerances. If this is not the case the RN should contact Pharmacy for advice and following the process for CD incidents.

12 Patient's Own CDs

The following parameters **DO NOT** include illicit substances; see section 16

In some circumstances it may be appropriate to use patient's own Controlled Drugs whilst they are in hospital. This decision should be made in line with the Patients Own Drug procedure. If they are appropriate to use they must:

- Be entered into the back of the ward Controlled Drug Register (see example in appendix 3)
- Be headed 'patient's own' followed by the name of the drug and dose, form and strength plus the name of the patient in brackets
- Allocated one page per patient per drug.
- **Not** to be entered into the register as ward stock and you should take care not to mix up with ward stock
- Be stored in the CD cupboard.
- **Not** be stored in patients' medicine lockers or medicine trolley (see exceptions in section 14).
- **Not** be taken to Pharmacy.

Patients own Controlled Drugs not required for use must still be entered in the back of the CD register. They should be either destroyed by the appropriate personnel OR returned to the patient's home. If the CDs are to be destroyed, a Pharmacist or Pharmacy Technician and RN should complete the process identified in Section 10.7.

12.1 Return of patient's own Controlled Drugs

Patients' own Controlled Drugs may be returned to the patient upon discharge if appropriate. The return must be documented in the patients' own section of the ward Controlled Drug register and signed and witnessed by relevant staff.

If the medicines are not safe and / or appropriate for use, then the patient should be advised the medicines should be destroyed (see section 10.7).

13 Self-Administration of CDs

Schedule 2 and schedule 3 CDs requiring safe custody storage should not be included in schemes where patients self-administer their medicines, unless their inclusion is deemed in patients best

interest and a risk assessment is completed and documented by MDT including pharmacy and approved by the CD Accountable Officer or deputy.

Locally designated CDs may be included provided a local procedure has been agreed with the Chief Pharmacist and is in place. Any local agreements must be forwarded to the relevant pharmacy team to ensure a central record is maintained.

- As required medication in the form of injectable's, CD's or medicines for managing behaviour that may challenge are not part of self-medication, however, there may be occasions when a supply of as required medicine is needed to facilitate leave or discharge.
- Any requests for as required medication should be agreed by the MDT and a small supply arranged. There will need to be a clear plan agreed of how this will be monitored.
- Any self administration CD's cannot be added to a compliance aid but ordered and supplied in a separate container.

In addition, any self administration of as required CD medication must be stored in the Controlled Drug cupboard. They must be kept separate from the ward Controlled Drug stock and logged within the ward CD register, and be clearly marked.

If there are any CD's that are not included in the Self administration the RN must administer.

For further details on self-administration parameters and requirements see the Preparation and Administration of Medicine procedure (hyperlink) within the Medicines Overarching Framework.

14 Moving CDs from one clinical area to another

- During opening hours contact pharmacy if a supply of Controlled Drugs is required.
- Controlled Drugs that have been supplied as ward stock **cannot** be transferred from one ward/department to another except in exceptional circumstances out of hours and only with the permission of the on call Pharmacists (see below for details)
- Ward stock from another unit can be used to give a patient an individual dose. The process for this should be:
    - The RN from the ward with the patient will administer the medication and the RN from the ward with the CD stock must witness the process
    - The administration must be recorded in the CD register of the ward with the stock, clearly outlining which ward the patient is on (next to the entry for the patient name)
    - Depending upon the circumstances one of the following can happen:
    - The patient attends the CD stock-holding ward with the RN and the dose is administered on that ward
    - Both RNs take the product and register from the stock-holding ward and administer the dose on the ward with the patient. Both RNs must then return the stock to the stock-holding ward ensuring that all records have been made.
- The following CDs can be transferred, providing a clear audit trail is available within the CD registers on both the transferring and receiving ward:
    - Patient's own Controlled Drugs (supplies that the patient has brought into hospital with them) can be transferred with the patient to another ward.
    - Individual patient supplies of Controlled Drugs (supplies obtained during admission that are labelled with the patient's name and administration instructions) can be transferred with the patient to another ward.
    - The "medication transfer book" should be used to facilitate the transfer and ensure a full audit trail.

- During opening hours contact pharmacy for advice about transferring patient's own or individual patient supplies.
- Out of hours contact the on-call Pharmacist if transferring a patient to a ward that does not have the stocks of Controlled Drugs required for the patient. They will provide advice on exceptional arrangements that may be needed to ensure patient care is not compromised e.g. when the only access to urgently required medication is from another Trust site.

15 Illicit substances

TEWV NHS Foundation Trust strives to be an illicit substance free zone. This includes all substances / drugs / medicines of any category other than those specifically prescribed for the patient.

Any illicit substances found on Trust property need to be reported via Datix and the Accountable Officer informed.

The Psychoactive Substances Act (PSA) makes it an offence to produce, supply or offer to supply any psychoactive substance if the substance is likely to be used for its psychoactive effects and regardless of its potential for harm. The only exemptions to the PSA are those substances already controlled by the Misuse of Drugs Act, nicotine, alcohol, caffeine and medicinal products. Put simply any substance is illegal to produce or supply if it is likely to be used to get high.

Possession of a psychoactive substance is not an offence, except in a 'custodial institution' (prison, young offender centre, removal centre etc.). The definition of custodial institution does not include Mental Health secure units. Possession with intent to supply and importing / exporting a psychoactive substance are all offences under the PSA. Despite not being an offence to possess, the product should still be removed and destroyed as per defined processes.

The police may be notified and may prosecute any person found to be in possession of (except if part of PSA), dealing in or taking substances thought to be of an illicit nature. If you are in any doubt as to whether the police should be informed then you should contact a senior manager within your service or a member of the pharmacy team to get advice on dealing with a situation involving such substances.

For further details around reporting and managing illicit substances on Trust property see the Medicines Overarching Framework and Management of Substance Misuse on Trust Premises

15.1 On Trust sites

If any substance thought to be of an illicit nature is either found on the ward or taken from a patient the following procedure should be followed:

- The substance should be sealed in an envelope
- The envelope should be endorsed with a **description** of the substance, together with where and when it was found.
- You **should not** attempt to identify or name the substance. For example 'a small block of brown substance/white powder/tablet' is a sufficient description

- Both the RN and an appropriate witness should sign across the seal of the envelope and an entry must be made at the back of the CD Register headed 'suspected illicit substances'.
- The substance should be stored in the CD cupboard until either collected by the police or destroyed by a Pharmacist or Pharmacy Technician (following the process described in 10.7.3).
    - The involvement of the police is different depending upon local arrangements.
- Collection or destruction must be recorded against the entry in the CD register and signed and dated by the police, Pharmacist or Pharmacy Technician and appropriate witness
- If the substance is associated with any particular patient a description of the substance and the circumstances should be recorded in PARIS
- The illicit substance **must not** be:
    - sent to pharmacy
    - returned to the patient or relative / carer

If any substance is found in a Trust community site the Pharmacy Team should be contacted for advice on how to proceed.

Link to Management of Substance Misuse on Trust Premises

15.2 In the patient's home

If at any time during a home visit a patient requests the practitioner to remove illicit substances from their home for destruction/disposal they should decline; they **cannot** remove these from the patient's home as they have no legal authority to do so. If the patient feels at risk from keeping these substances in their home the practitioner can either:

- Encourage the patient to take to the local police station / contact the local police – the patient should be informed that this may result in prosecution
- Encourage the patient to denature the drugs using hot soapy water and take to a community pharmacy for disposal. The practitioner **cannot** be involved or be responsible for the denaturing. If encouraging this the practitioner should ensure they make comprehensive records and inform relevant members of the MDT

16 CD Incidents

16.1 A discrepancy in the CD register

The balances in the Controlled Drug register should always tally with the amounts in the Controlled Drug cupboard. If they do not the discrepancy must be reported, investigated and resolved. Any discrepancy must be reported to the ward manager and ward Pharmacist /Pharmacy Technician and investigated **without delay.** It is important to remember that a discrepancy can indicate misuse.

The administration process should be stopped immediately and the discrepancy thoroughly investigated.

- The 2 individuals that have discovered the discrepancy must try and identify the cause.
- The most senior member of staff who detects the discrepancy must:
    - Complete the "Checklist to investigate a CD Schedule 2 and 3 Stock Discrepancy" (see appendix 4).
    - Inform the appointed practitioner in charge of the ward/department
- If the discrepancy is traced the register should be amended:
    - Do not cross out errors or amend any previous entries in the register.
    - Put an asterix (*) next to the error and then another asterix in the margin or bottom of page with a brief explanation e.g. calculation error.
    - Add the correct balance.
    - Add the signatures of the RN and witness.
- If the discrepancy is identified as a system error, training need or environmental issue, actions must be taken to minimise re-occurrence.

Unresolved Stock Discrepancies

When no omissions or errors have been detected (following above), the senior practitioner must:

- Follow the process in Appendix 1
- Record 'discrepancy noted' in the register and the actual stock level.
- Sign against the entry so other administrations can be made and patient care is not compromised.
- Speak to staff on duty at the time, as soon as practical, to clarify whether all records have all been made or any untoward occurrences have taken place that may not have been recorded.
- Notify the pharmacy team and Accountable Officer as soon as possible.
- Submit a Datix incident report.
- The Accountable Officer will review the completed checklist to decide if further investigation is required.

All discrepancies should be investigated using appendix 4 and 1 as a guide.

Unresolved discrepancies must be reported on Datix and notified to the CD AO

16.2 Refusal of prepared medicine

Best practice is to check the patient is willing to take the medicine before it is prepared, more so with patients known to refuse doses frequently. This reduces unnecessary waste and additional record keeping. If the dose is refused after preparation the RN must complete the appropriate code on the administration record card. They should dispose of the CD in the appropriate way (see section 10.7.1). They should then make an entry in the register to say the dose was refused and destroyed; both the RN and witness must sign.

16.3 Incidents

These must be reported appropriately; the attached flow chart for CD incidents explains in detail the process to deal with incidents. Due to legal requirements these should be reported in a timely manner and if required investigate appropriately. Incidents or discrepancies that have not been

resolved locally (i.e. correcting an arithmetic error) should be reported as soon as possible to the Trust Accountable Officer.

16.4 Missing CD cupboard keys

If at any time the CD keys cannot be found, urgent efforts must be made to find and retrieve them as quickly as possible. This should include an immediate search of the environment and contacting all staff who have recently been or are currently on duty.

If they cannot be found the RN should inform the Modern Matron or duty manager (out of hours) and pharmacy (out of hours the on-call Pharmacist must be contacted as soon as possible). Patient care must not be compromised and the security of CD stocks must be maintained. If necessary, maintenance should be contacted to change the locks. A trust Datix report must be completed and the Accountable Officer informed. If appropriate the police should be contacted.

17 Monitoring & Controls

17.1 Audit

The pharmacy team undertake a quarterly audit on each ward / department that store controlled drugs. The audit covers a range of criteria designed to assess compliance against these SOPs. Audit results are considered and cascaded as follows:

- Feedback from pharmacy team member to ward manager and modern matron upon completion of the audit. Any remedial measures should be identified, if necessary, at this stage.
- The collected results from all wards and departments will be cascaded via email to all ward managers and modern matrons once all audits have been completed.
- An annual audit report (including an action plan) will be completed and cascaded through the audit groups with issues escalated as appropriate to QuAGs.

17.2 Usage monitoring

Processes are in place to monitor controlled drug (all schedules) usage from the following sources:

- Supply from community pharmacies against FP10s
- Supply from contracted pharmacies to wards & departments including:
    - Stock supplies
    - Named patient supplies
    - Leaves & discharges

Where there are any concerns noted from monitoring this data, an investigation will be triggered. As necessary, this will involve senior managers, pharmacy staff, security services and the police.

17.3 Stepping up controls

It may be necessary to take localised decisions (e.g. a specific ward / department or a specific hospital) to increase the controls related to controlled drugs. The decisions should be based upon a risk assessment (see 18.4). The risk assessment may determine whether controlled drugs in Schedule 3, 4 or 5 should be handled in the same way as controlled drugs in Schedule 2. It may also introduce additional or alternate measures to enhance controls. The risk assessment will normally be completed by the ward manager, matron and a senior member of the pharmacy team.

Depending upon the circumstance, it may be necessary to involve additional roles to complete the risk assessment. The risk assessment may include:

- frequency and quantities of controlled drugs used
- storage facilities available
- whether the security setting is low, medium or high risk
- the controls in place for checking for discrepancies in stock balances
- frequency of staff turnover
- staff access to controlled drugs
- any data from relevant reported incidents

After an appropriate time period (agreed as part of the above process) the risk assessment should be reviewed to consider whether the controls can be stepped down.

17.4 Risk assessments

There are a number of references to risk assessments within these SOPs. The standard TEWV risk assessment form can be used and should be tailored to the individual circumstances.

17.5 Reporting and learning

Controlled Drug Local Intelligence Networks (CDLIN)

The CD AO for TEWV reports to a number of CD LINs for different geographical areas of the trust. A quarterly report of CD issues / incidents is provided by the CD AO, to the relevant CD LIN on a quarterly basis. The report includes reported incidents, lessons learned and any other concerns. The CD LIN also provides an opportunity for information to be shared amongst other local organisations including (but not limited to); hospital trusts, primary care, hospices, police and private healthcare organisations.

Drug & Therapeutics Committee (DTC) and Safer Medication Practice Group (SMPG)

An annual CD report will be received by SMPG for comment before submission to the DTC. The report will include a summary of incidents, audit findings and CD usage. Any concerns will be escalated through normal governance processes.

18 Definitions/abbreviations

Term	Definition
Appointed Practitioner in Charge	• Registered Nurse in charge of the ward, department or unit with 24 hour responsibility for that ward, team or department
Appropriate other/witness	• A second practitioner who is either qualified to act as witness or has received the appropriate training to authorise them to undertake this role. Qualified practitioners include doctors and Pharmacists. Trained and authorised practitioners include non-registered nursing staff and pharmacy technicians.
CD	• Controlled Drugs: dangerous or otherwise harmful drugs with additional regulatory restrictions as identified in both the Medicines Act 1968 and Misuse of Drugs Act 1971 and associate regulations

CD Schedules	• Controlled medicines classified (by law) and rated into five schedules based on their benefit when used in medical treatment and their harm if misused; risk of abuse. Schedule one has the highest level of control, Schedule five the lowest.
Controlled Stationery	• All stationery used to obtain medicines (e.g. pharmacy order books, Trust prescription forms and FP10 prescription forms) which if fall into the wrong hands could be fraudulently used to obtain medicines
Denature (medicine)	• Take away or alter the natural quality; to change the properties of the medicine to ensure it is no longer viable
Designated Practitioner in Charge	• The senior registered nurse on duty for the ward or department who has been identified as the nurse in charge for a particular span of duty
Destroy (medicine)	• Put an end to the existence by damaging it thereby making it irretrievable
POM	• Prescription only medicine
RN	• Registered Nurse: a nurse employed by the Trust who has a current and valid registration with the NMC (Nursing & Midwifery Council).
SOP	• Standard Operating Procedure: detailed, written instructions to ensure the uniformity of performance related to a specific function

19 References

NICE NG46: Controlled drugs: safe use and management

Royal Pharmaceutical Society of Great B ritain: Guidance for Pharmacists on the safe destruction of Controlled Drugs England, Scotland and Wales *September 2007*

Safer management of Controlled Drugs: The Government's Response to the Fourth report of the Shipman Inquiry DH 2004

Safer Management of Controlled Drugs *A guide to good practice in secondary care (England) October 2007* (Note – hyperlink doesn't work, but document still exists)

Royal Pharmaceutical Society: key to the legal classification of medicines for human use

20 Document control

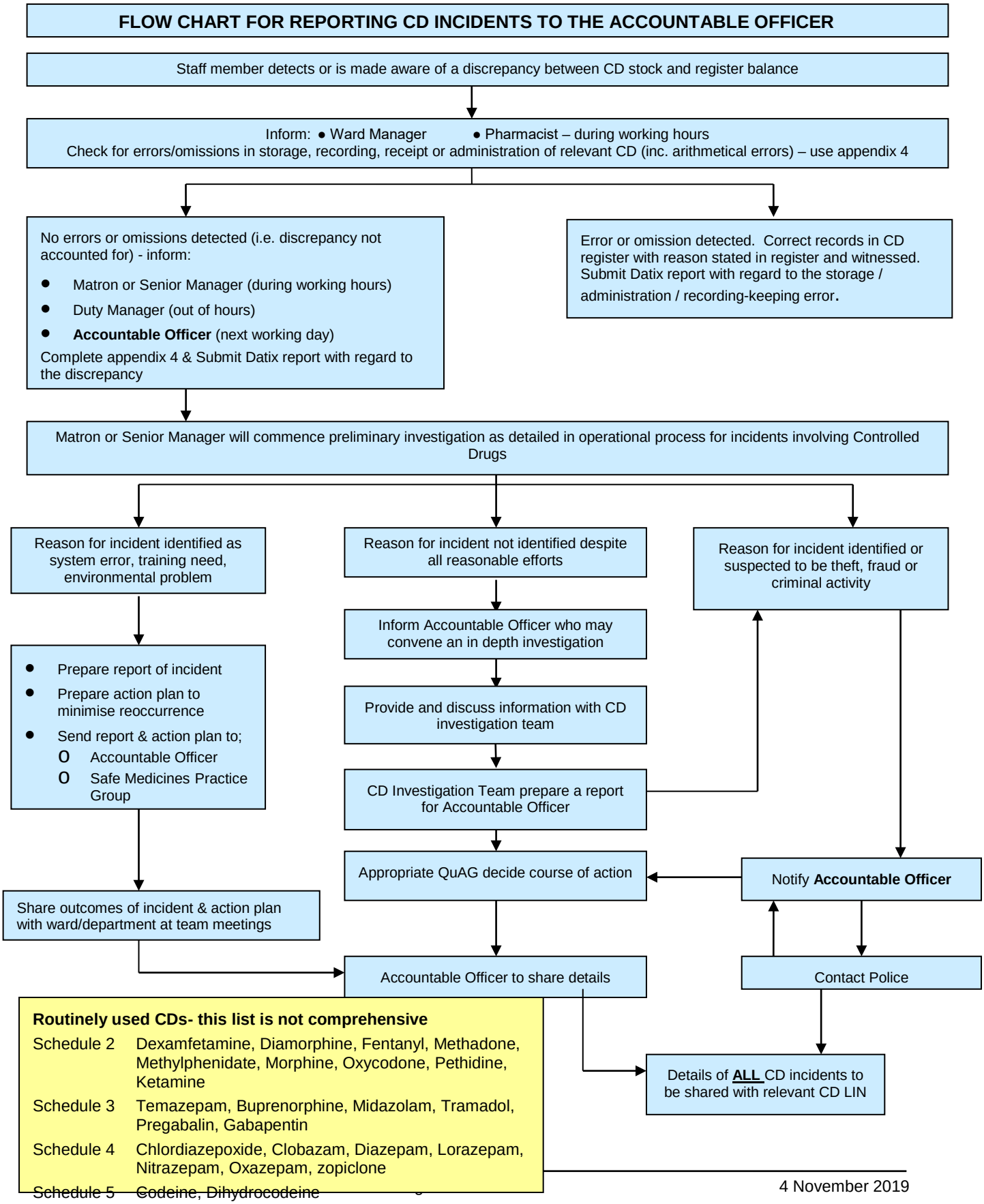
Date of approval:	26 September 2019 (for publication on 4 November 2019)	
Next review date:	01 October 2022	
This document replaces:	Version 4.1	
Lead:	Name	Title
	Christopher Williams Claire Spinks	Chief Pharmacist Lead Pharmacy Technician (Procurement)
Members of working party:	Name	Title
	Pharmacy Leadership Team Meeting Members	Lead Pharmacist and Technicians & Lead Nurse for Medicines Management
This document has been agreed and accepted by: (Director)	Name	Title
	Ruth Hill	Chief Operating Officer
This document was approved by:	Name of committee/group	Date
	Drugs and Therapeutics Committee	26 September 2019
This document was ratified by:	Name of committee/group	Date
	N/A	
An equality analysis was completed on this document on:	Equality impact assessment covered under Medicines Overarching Framework	

Change record

Version	Date	Amendment details	Status
1.0	June 2014	New procedure	Superseded
2.0	July 2014	Formatting and grammatical errors, 2 further definitions, liquid CDs to be denatured	Superseded
3.0	Nov 2014	Procedural clarification amendments to sections 9.4, 10.7.1, 10.7.3, 14, 15& Appendix 2 Hyperlinks updated	Superseded
3.0	May 2015	Type error on p11 and appendix 3 corrected	Superseded
4.0	July 2016	Full revision in line with NICE guidance. Minor amendments throughout. Significant updates to section 9.4, 10.1, 10.2, 10.3, 10.5.2, 11.3.2, 14, 15, 16(new). App 4, 5 & 6 also new.	Superseded
4.1	March 2019	Changes on page 5-7, 39 and 51 to reflect new	Superseded

		legislation for pregabalin and gabapentin and amend midazolam in line with these drugs	
5	September 2019	Removed all references to contracted pharmacy. Added guidance on Prescribing table and examples of CD prescriptions. Added CD weekly checking tool. Added link to Methadone MSS. Update CD supply order process flow. Added an Appendix: Prescription legal requirement chart. Added an Appendix :Examples of Prescribing. Note: this version approved 26 September 2019 for publication on 4 November 2019.	Approved

21 Appendix 1 – CD incident reporting flowchart



22 Appendix 2 – HOW TO… destroy Schedule 2 and 3 Controlled Drugs (CDs) using a destruction kit

All Controlled Drugs must be denatured before being placed into a sharps bin

1. **CD Destruction kit**
   - Schedule 2 and 3 CDs must be rendered irretrievable / denatured using a CD destruction kit.
   - "CD destruction kit" is a generic term applied to what is sometimes referred to as a DOOP kit or Controlled Drugs Denaturing Kit.
   - CD destruction kits of various sizes are available to order via Cardea.

2. **Procedure for Destroying Schedule 2 & 3 Controlled Drugs**
   a) Wear gloves
   b) Shake the CD destruction kit to loosen the settled granules
   c) Add the CDs to half the capacity of the kit using the method shown below for each formulation

Formulation	Method	Comments
Tablets, capsules and lozenges	Remove from outer packaging, remove from blister packaging and place intact into the CD destruction kit. Single tablets or capsules that may have fallen on the ground or been removed from the packaging but not administered require immediate destruction and must not be allowed to remain in a non-congealed kit at risk of retrieval and reuse.	Do not crush tablets before adding to the kit.
Liquids	Pour directly from the bottle, measure or syringe pump into the CD destruction kit. Wash out bottles or measures with a small amount of water and add liquid to CD destruction kit.	Discard empty bottles in the domestic waste. If denaturing multiple forms of CDs, denature liquids at the end of the process as the desiccant in the CD destruction kit will start to congeal quickly.
Powders / Sachets	Open and add contents of the sachets into the CD destruction kit.	Beware of inhalation of dust from powders. Discard the outer packaging into a clinical waste bin.
Patches	Carefully remove from outer packaging, fold in half with the sticky side inwards and place in the CD destruction kit.	Discard the patch adhesive backing and patch packet in a clinical waste bin.
Ampoules (liquid contents)	Open and empty contents into the CD destruction kit by shaking or by using a needle and/or syringe.	Add empty ampoules to the CD destruction kit.
Ampoules (powder contents)	Open, add water with a syringe to ampoule powder and add reconstituted contents to the CD destruction kit.	Add empty ampoules to the CD destruction kit.

Part used Liquid Ampoules	Refer to section 3	
Large volume infusion/injection	Cut bag above bung in port access and pour contents into CD destruction kit.	Place packaging in a clinical waste bin.
Vials with bungs	Reconstitute contents with water using needle and syringe .Add the contents to CD destruction kit	Do not remove bung. Add vials to CD destruction kit.

d) Fill the CD destruction kit to capacity level with water; do not overfill
e) Replace lid securely
f) Shake thoroughly to disperse. Contents will congeal in 3 – 5 minutes.
g) Dispose in the designated pharmaceutical waste bin
h) Any equipment used to draw up the CD i.e. syringes should be disposed of according to Trust procedure

3. **Individual doses of CD prepared but not administered and part used ampoules (see also 10.7.1)**
   a) The amount to be disposed of from the syringe or ampoule should be discharged into a CD destruction kit.
   b) The liquid will congeal in a small area of the kit.
   c) The CD destruction kit lid must be securely tightened and stored in the CD cupboard until required again.
   d) This method will enable the CD destruction kit to be used for 3 to 5 small additions of liquid before needing to dispose of the CD destruction kit
   e) The practitioner using this method must determine when no more liquid can be discharged into the CD destruction kit and make up to capacity with water to congeal the contents.
   f) The kit must then be disposed of as detailed above.

23 Appendix 3 – Examples of CD Register entries

Sample controlled drug register, including:

INDEX
Example of stock checks
Example of receipt of meds
Example of disposal of small quantity disposal
Example of leave or discharge meds
Example of illicit substances

INDEX

Tees, Esk and Wear Valleys NHS
NHS Foundation Trust

NAME, FORM OF PREPARATION AND STRENGTH FENTANYL PATCHES 75MICROGRAM PER PATCH (PAGE NO)

AMOUNT(S) OBTAINED				AMOUNTS ADMINISTERED						
Amount	Date Received	Serial No. of Requisition		Date	Time	Patients Name	Amount Given	Given by (signature)	Witnessed by (signature)	STOCK BALANCE
Carried forward from page number.....										Balance on transfer
10(TEN)	1/8/21	3100				Received from Pharmacy				10
				2/8/21	08.00	CHARLES ALEXANDRA	1 patch(75mcg)			9
				3/8/21	14.00	CHARLES ALEXANDRA	1 patch(75mcg)			8
				4/8/21	21.00	Stock checked + correct				8

Carried over to page number .....

Tees, Esk and Wear Valleys NHS

NHS Foundation Trust

NAME, FORM OF PREPARATION AND STRENGTH METHADONE HYDROCHLORIDE SUGAR FREE ORAL SOLUTION 1 MILLIGRAM IN 1ML (PAGE NO)

AMOUNT(S) OBTAINED				AMOUNTS ADMINISTERED						
Amount	Date Received	Serial No. of Requisition		Date	Time	Patients Name	Amount Given	Given by (signature)	Witnessed by (signature)	STOCK BALANCE
Carried forward from page number										Balance on transfer
				1/8/21	10:00	JOHN KEEL	60ML	MS	PBC	60mls
				2/8/21	10:00	JOHN KEEL	60ML	PM	MS	0mls
500mls (FIVE HUNDRED)	2/8/21	0142				Received from Pharmacy		MS	CS	500mls

Carried over to page number .....

Tees, Esk and Wear Valleys NHS

NHS Foundation Trust

NAME, FORM OF PREPARATION AND STRENGTH MORPHINE SULPHATE 5 MILLIGRAM M/R (MST CONTINUS TABLETS) (PAGE NO)

AMOUNT(S) OBTAINED				AMOUNTS ADMINISTERED						
Amount	Date Received	Serial No. of Requisition		Date	Time	Patients Name	Amount Given	Given by (signature)	Witnessed by (signature)	STOCK BALANCE
Carried forward from page number.....										Balance on transfer
60	1/8/21	1072				Received from Pharmacy		JS	DS	60
				2/8/21	08.00	BILL WILLIAMS	5mg (1)	SS	JC	59
				2/8/21	20.00	Tablet dropped + disposed	5mg (1)	DTC	MR	58
				2/8/21	20.00	BILL WILLIAMS	5mg (1)	DTC	MR	57

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Tees, Esk and Wear Valleys NHS
NHS Foundation Trust

NAME, FORM OF PREPARATION AND STRENGTH....UNKNOWN ILLICIT SUBSTANCE....(PAGE NO)

AMOUNT(S) OBTAINED				AMOUNTS ADMINISTERED						
Amount	Date Received	Serial No. of Requisition		Date	Time	Patients Name	Amount Given	Given by (signature)	Witnessed by (signature)	STOCK BALANCE
						Carried forward from page number..........				Balance on transfer
SMALL	1/8/21	N/A				KYLE ROGERS		[signature]	[signature]	SMALL
QUANTITY						FOUND IN PATIENTS BEDROOM				QUANTITY
OF WHITE										OF WHITE
POWDER										POWDER.

Carried over to page number ....

24 Appendix 4: Checklist to Investigate a CD Schedule 2 or 3 Balance Discrepancy

Ward/Department:	**Date:**
Controlled Drug involved in the discrepancy.	
Medicine name:	Strength:
Preparation (e.g. tabs / patches etc.)	
Quantity in cupboard:	Quantity in Register:
Is an original pack missing (e.g. box of tablets, ampoules , patches or liquid)	Yes/No
Other notes:	

CD Cupboard or other storage area check

- ☐ Have you removed and checked all of the physical CD stock held in the CD cupboard with the balances in the register to ensure there are no other discrepancies?
- ☐ Have you checked that no medicines have been trapped behind cupboard fixtures etc.?
- ☐ Have you checked that the missing CD has not been stored in the wrong place (e.g. in the routine medicine cupboard)?
- ☐ Have you checked all other relevant storage areas?

CD Register Check

- ☐ What was the last date the stock balance was correct, according to the CD register. Date:_____
- ☐ Are all of the calculations correct (addition or subtraction) in the register?
- ☐ Do all balance transfers from page to page tally?
- ☐ Have all administrations to patient(s) been recorded? Review the usage on the ward *(looking at relevant patient(s) drug charts)*
- ☐ Have all CDs been recorded on receipt from pharmacy *(check the CD register against the CD order book / prescriptions to investigate when the CD was last ordered).*
- ☐ Have all Named Patient Drugs been recorded in the correct part of the register?
- ☐ Have all Patients' Own Drugs been recorded in the correct part of the register?

Has the CD discrepancy been found in the register?	☐ **Yes** ☐ **No**

If **YES:**	If **NO**
• Do not cross out or alter the entry in the register • If an incorrect entry has been made, (draw brackets around the mistake) and make a concise explanation in the margin or at the foot of the page • Make a correct entry of the balance on the next line and have this witnessed by another registered healthcare professional • Complete a Datix incident report	• Annotate the register with 'discrepancy noted' and record the actual stock level • Sign against the entry, so other administrations can be made and patient care is not compromised • The deficit or surplus should be noted on the CD checking record where appropriate • Further action must be taken as detailed in Section 16.1 (and appendix 1) of the CD SOPs • Complete a Datix incident report

Any other explanation or information to support the investigation

☐ Have you spoken to staff on duty at the time to determine whether any untoward occurrences may have contributed to, or impacted on the discrepancy? (Spillages or tablets falling on floor etc.)

Please give details below where applicable.

Summary – please tick or complete where applicable

☐ I have investigated the incorrect stock balance and have found the discrepancy

☐ I have investigated the incorrect stock balance and unable to find a reason for it.
Follow SOP Appendix 1 for further action.

☐ I have informed the following Senior Staff:

Signature(s) and designation of staff completing investigation.

Please forward this report via your ward pharmacy team to:
Chris Williams, Chief Pharmacist, West Park

Pharmacy Use Only - Outcome

Brief summary of outcome of the discrepancy and following actions

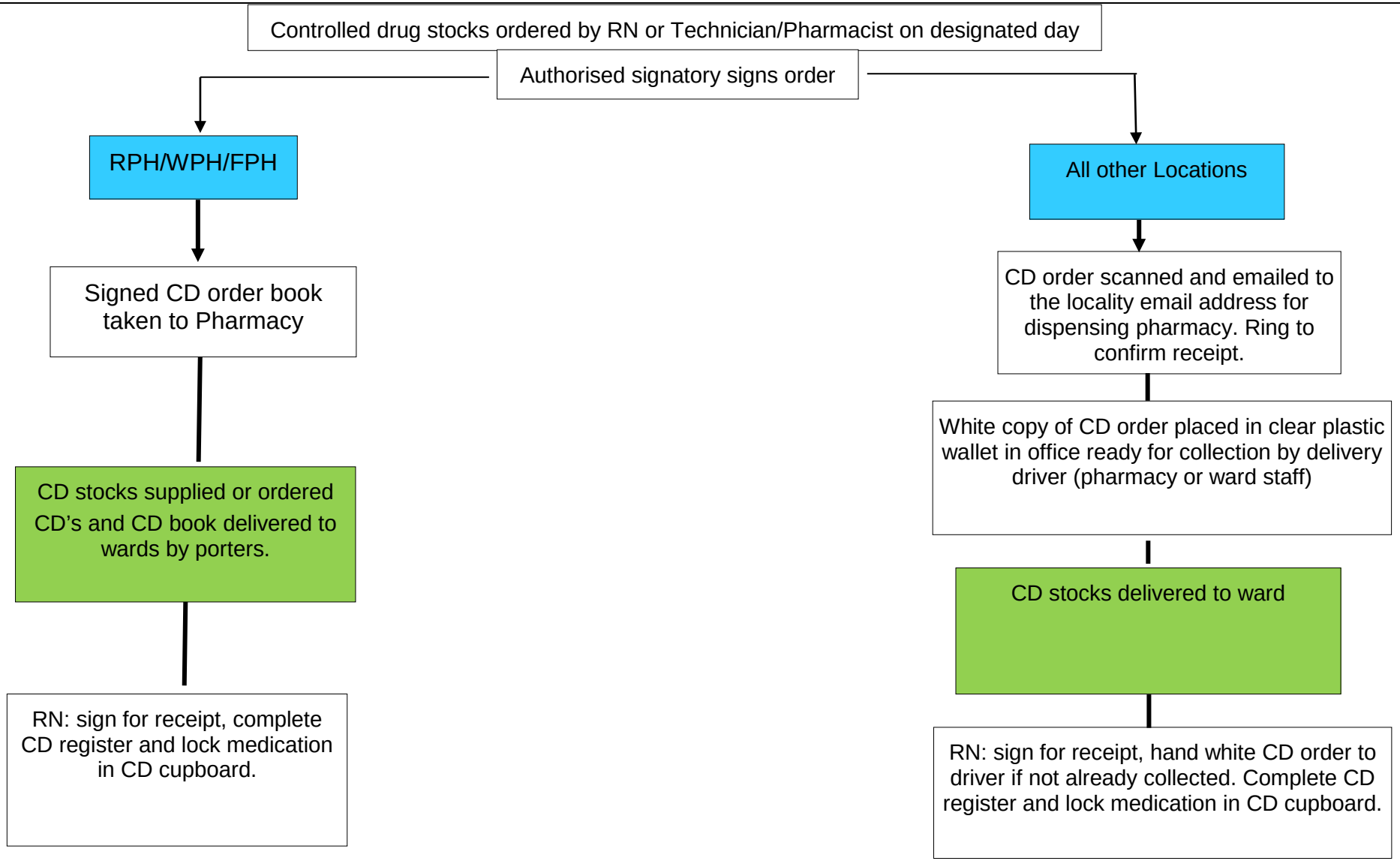
Datix report number:

Signature(s) of pharmacy staff:
Date:

Communication/feedback regarding outcome sent to :

Signature of Accountable Officer (Chief Pharmacist)
Date:

25 Appendix 5: CD Stock supply order process



Rx = Full prescription writing requirements
Order = Order stock in CD Order Book
CDR = Controlled Drug Register Entry Required
Storage = Store in a CD cupboard
Destruct = Denaturing required

26 Appendix 6: A brief guide – CD requirements for commonly used CDs

	Controlled Drug	Rx	Order	CDR	Storage	Destruct	Notes	Alternate names
Schedule 2	Methadone	✓	✓	✓	✓	✓		Physeptone
	Morphine	✓	✓	✓	✓	✓		MST, Zomorph, Oramorph Conc. 20mg/1ml, Sevredol, Morphgesic, MXL
	Oxycodone	✓	✓	✓	✓	✓		Oxycontin, Oxynorm, Longtec, Shortec, Oxylan, Targinact
	Fentanyl	✓	✓	✓	✓	✓		Durogesic, Matrifen, Actiq
	Ketamine	✓	✓	✓	✓	✓		
	Methylphenidate	✓	✓	✓	✓	✓		Ritalin, Concerta, Equasym, Medikinet, Xenidate
	Dexamfetamine	✓	✓	✓	✓	✓		
	Lisdexamfetamine	✓	✓	✓	✓	✓		Elvanse
	Pethidine	✓	✓	✓	✓	✓		
	Hydromorphone	✓	✓	✓	✓	✓		Palladone
	Diamorphine	✓	✓	✓	✓	✓		
	Tapentadol	✓	✓	✓	✓	✓		Palexia
Schedule 3	Tramadol	✓	✓	✓	✓	✓		Tramacet, Zydol
	Buprenorphine	✓	✓	✓	✓	✓		BuTrans, Transtec, Hapoctasin, Butec, Subutex, Suboxone, Temgesic
	Temazepam	✓	✓	✓	✓	✓		
	Pregabalin	✓	✓			✓		Alzain, Axalid, Lecaent, Lyrica, Rewisca
	Gabapentin	✓	✓			✓		Neurontin
	Midazolam	✓	✓			✓		Buccolam
S4	Class: Benzodiazepines					✓	**Store Lorazepam IM in Fridge**	Lorazepam, Diazepam, Clonazepam, Zopiclone, Chlordiazepoxide, Nitrazepam, Oxazepam
S4ii	Class: Anabolic Steroids							Testosterone
S5	Schedule 5 (CD Invoice)							Codeine, Dihydrocodeine, Oramorph 10mg/5ml

*NB – this list is not comprehensive. If unsure, please ask a member of the pharmacy team.

27 Appendix 7: Weekly CD Audit Tool

Weekly CD Checks - Completion Tool (V1.0 - 16/10/17)

- See section 10.5.2 of the CD SOPs for more detail.
- The weekly stock check should take place on the same day each week, but can be carried out 24 hours either side where service need dictates.
- The check should be initialled as complete when the aspect is compliant. Where possible, errors should be corrected (refer to the SOPS for instructions on how to do this correctly) at the time of the check. Remedial actions should be recorded in the final column. Any discrepancies must be reported and investigated without delay (see section 17.1)
- These checks should be performed by checking the balance in the CD register against the contents of the cupboard (not the reverse).

Check	Initial complete	Concerns / exceptions noted
The CD cupboard meets requirements (see section 8.1.1)		
Only approved items are stored in the cupboard (see section 8.1.1)		
All items have been removed from the CD cupboard (including stocks, PODs, leave / discharge, named patient meds, illicit)		
Each page of the register has been checked sequentially		
The name, form and strength of drug is stated on the top of each page		
All completed pages have had the balance transferred correctly to a new page		
The index has been updated to reflect the current “active” page for each drug in the register		
The balance of each drug is correct (including zero balances)		
Each drug is in date or is out of date and quarantined, with notification to the pharmacy team for destruction		
Each item has been returned to the CD cupboard once it has been checked against the register balance		
There are no items left that are without an entry in the CD register		
There are no open balances in the register without the corresponding amount of drug		
The items are all clearly labelled and appear to be in good condition		
All pages are free from amendments OR amendments have been made in line with SOPs		
Received drugs have all columns completed (date, quantity, reference & received from)		
The pink copy of the stock order book has been signed upon receipt of drugs		
There are two signatures for each entry		
The weekly check has been recorded on each active page of the register		
The weekly CD check visual control notice has been signed and dated		

Weekly CD Check completed by: Witnessed by: Date:

Completed tool received by ward manager: Date:

29 Appendix 8: Prescription Legal Requirements

Legal requirement	Ward stock order	Inpatient (non-stock) order	Leave & discharge prescription	Outpatient &FP10 prescription
Indelible	✓	✓	✓	✓
Name & address of patient	Hospital & ward name	Patient & ward name	Patient & ward name	✓
Drug name, form & strength of preparation (e.g. pregabalin 50mg capsules)	✓	✓	✓	✓
Dose and frequency clearly defined (not "as directed")	×	✓	✓	✓
Total quantity of the preparation or the number of dose units, in words and figures	✓	✓	✓	✓
Quantity not to exceed 30 days' supply (DoH recommendation, not legal requirement)	Original pack	✓	✓	✓
Signature (by hand) of prescriber/authorised person	✓	✓	✓	✓
Printed name and designation of prescriber/authorised person	✓	✓	✓	✓
Prescriber's address	Hospital & ward name	Hospital & ward name	Hospital & ward name	✓
Date	✓	✓	✓	✓
No other medicines on the prescription/order	✓	✓	✓	✓
Prescription valid for 28 days only	×	×	✓	✓

30 Appendix 9: Examples of Prescribing