NHS
South Yorkshire
Integrated Care Board

Good Practice Guide:
Safe Management of Controlled Drugs in Care Homes

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Introduction

This guide intends to provide care homes with information required to support safe management of controlled drugs (CDs) in line with current legislation, CQC fundamental standards[1], safeguards and good practice guidance as recommended in NICE SC1 Managing Medicines in Care Homes[2] and NICE Guidelines NG46 Controlled Drugs – Safe Use and Management[3].
Each home should have a policy in place to cover all processes relating to CDs specific to that home.

Identifying a Controlled Drug

Medicines are classified as being a 'controlled drug' when they are subject to control under the Misuse of Drugs legislation.
The Schedule that a drug is classified under specifies which particular controls are imposed on them by law including those relating to record keeping, safe storage, destruction or disposal.
Schedule 2 CDs have controls imposed on them relating to all elements whilst Schedule 3 CDs have some exemptions (such as safe storage requirements).
To avoid confusion it is suggested that good practice would be to treat all Schedule 3 CDs as if they had all controls imposed on them i.e. the same as Schedule 2 CDs (See **Appendix I**)

Medicines arrive in care homes via several different routes making it difficult to identify those classified as controlled drugs. The following points may be considered:

- The manufacturer's original packs of medicines will bear the symbols POM CD
- British National Formulary (https://bnf.nice.org.uk/) uses symbols in the 'Medicinal Form' section of controlled drugs to identify which schedule relates to that particular drug
  e.g. CD3 for preparations in Schedule 3

  More information can be found on the medicines guidance page of the electronic BNF: Controlled drugs and drug dependence | Medicines guidance | BNF | NICE
- Examples of Schedule 2 & 3 controlled drugs can be found in **Appendix I**
- Check with the supplying community pharmacy
- CDs received from the community pharmacy should be packed separately to non CDs and a CD delivery note will require to be signed by appropriate care staff

Ordering

- Prescription requests for CDs for a specific resident can be made to the GP in the same manner as for other medication. The GP is consulted for appropriate treatment and quantities.
- No more than one month supply to be ordered at one time

[1] http://www.cqc.org.uk/what-we-do/how-we-do-our-job/fundamental-standards
[2] https://www.nice.org.uk/guidance/SC1/chapter/1-Recommendations
[3] https://www.nice.org.uk/guidance/ng46

- Care is required when considering the quantity of CD's required for the patient and should be reviewed regularly since, for palliative care, the patient's needs may change.

- Overstocking of CDs should be avoided in order to reduce waste, prevent difficulties with storage space and also reduce the time involved in stock balance checks.

- Carefully check that the received prescription matches the request as any mistakes or discrepancies found at a later point may delay the supply of CDs to the resident

- CDs prescriptions do not have to be handwritten, they can be computer generated. The prescription requires the form (e.g. tablet/capsule/patch), the quantity in words and figures, the date, full directions and must be signed by the prescriber.

- A checklist of prescribing requirements can be found in Appendix III

Receipt

- Check the CDs received are correct against copies of the original request or prescription. This check includes:
  - Drug name
  - Quantity – Where possible, physically count tablets, capsules, ampoules, prefilled syringes and patches ensuring that the quantity received matches the quantity on the label and on the Medicines Administration Chart (MAR). For liquids, check that the seal has not been tampered with. Staff are not expected to measure the volume of part filled bottles (unless this is stipulated in the individual care home policy).
  - Formulation – Tablets, capsules, patches, injections, liquids, etc.
  - Strength – milligram per unit dose or volume.
  - Expiry date of preparation
  - Preparation fit for use i.e., no damage
  - Clear dose instructions

- After the checks have been performed and are correct, the MAR can be signed identifying the quantity received and dated by the receiving member of staff.

- Any discrepancies to be reported immediately to the care home manager and the community pharmacist

- On receipt of the CD, the drug name, the strength, the formulation, the date, quantity and source must be entered into the CD register **as soon as possible** and signed by the receiving member of staff. A second suitably trained member of staff must also sign as a witness. The medication must be stored safely in the CD cabinet as soon as possible after receipt and paperwork completed

- If the CD is collected from the pharmacy by a member of the care home staff there should be a procedure in place that provides an audit trail. The collecting member of staff will be required to present acceptable ID.

Record Keeping

- The CD register is a bound book with numbered pages.
- The CD register must be used to record the receipt, administration, disposal and transfer of controlled drugs held by the care home.
- The entry must be made as soon as possible on the same day.
- The CD register should not be used for any other purpose.

- The CD register must be kept in a secure place when not in use.
- A separate page must be used for each form, strength of each medication and resident. The name, strength and form of each medication and the name of the resident should be recorded at the top of each page.
- The CD register should include an index page, indicating for individual residents, on which page of the CD register each CD can be found.
- Entries must be in chronological order.
- Entries must not be cancelled, altered, “Tippexed” or crossed out. Corrections must be made using marginal notes or footnotes which are signed and dated.
- All entries should be signed and dated by the member of staff making the entry and witnessed by a suitably trained member of care home staff (where practical to do so) who should also sign the entry .
- The administration of a CD should be recorded in the CD register indicating the name of the resident, the dose given and time administered.
- The running balance should be kept to ensure that irregularities or discrepancies are identified as quickly as possible. The balance should be updated each time an entry is made. It is good practice to check all stock (including zero balances where appropriate) after every dispensing where possible, with a minimum of weekly checks.
- The CD register should be kept for two years from the last entry. Good practice would be to retain the CD register for longer as cases can take several years to come to light or before they go to court.
- When transferring the drug record to a new page in the CD register the amount remaining should be identified with ‘carried forward from page x’ written clearly on the new page.

See Tables 1 to 3 (page 4) for examples of entries in the CD register

Electronic CD registers are permitted as an alternative. Legislation requires that computerised entries must be:

- Attributable to the person who created the record
- Secure
- Cannot be altered at a later time
- Capable of being audited
- Compliant with best practice
- Accessible from the care home and capable of being printed.

Table 1

Alfred Smith	**Morphine Sulphate 10mg tablets**			**page 1**	
Date	Quantity/ dose	Time given	Given by	Checked by	balance
1/12/2020 20x 10mg tablets received from Hills pharmacy *j smith* f black					20
1/12/2020	1 x 10mg	22.00hrs	*j smith*	f black	19
2/12/2020	1 x 10mg	9.00hrs	*MJjohnson*	s. Jones	18
2/12/2020	1 x 10mg	13.00hrs	*MJjohnson*	s. Jones	16*
2/12/2020	1 x 10mg	17.00hrs	*MJjohnson*	s. Jones	15
2/12/2020	* Error in subtraction *j smith* *MJjohnson*				16
3/12/2020	Stock check performed by *MJjohnson* *j smith*				16
4/12/2020	Stock check performed by f black s. Jones				16
5/12/2020	Stock check performed by f black s. Jones				16
6/12/2020	Stock checked performed by *j smith* *MJjohnson*				16
8/12/2020	Resident medication reviewed by GP and no longer required 16 x 10mg morphine sulphate returned to pharmacy [a] for destruction by *MJjohnson* *J Parsons* Reg No.14786 (Driver, Smiths pharmacy)				0

[a] **NB** Example given for Residential Homes returning unwanted CDs to pharmacy (see Disposing of CDs page 4)

Table 2

John Green	**Oxycodone 5mg /5ml**			**page 4**	
Date	Quantity/dose	Time given	Given by	Checked by	Balance
2/12/2020 100ml received from Hills pharmacy *j smith* f black 100ml measured 100ml					
2/12/2020	5mg =5ml	14.30hrs	*MJjohnson*	s. Jones	95ml
2/12/2020	5mg=5ml	18.45 hours	*MJjohnson*	s. Jones	90ml
2/12/2020	5mg=5ml	23.00hours	*S Taylor*	D Davis	85ml
3/12/2020	5mg =5ml	15.15hours	*S Taylor*	D Davis	80ml
3/12/2020	Stock check performed by *MJjohnson* *j smith* 78ml measured				78ml*
2ml discrepancy due to measuring liquid at regular intervals therefore inevitably loses small volume through procedure.					

It is acceptable to have discrepancy + or – 10% of volume remaining if liquid is used regularly

Table 3

Alice Wood	**Diamorphine 30mg ampoules**			**page 8**	
Date	Quantity/dose	Time given	Given by	Checked by	balance
2/12/2020 5 ampoules received from Hills pharmacy *j smith* f black 5 ampoules					
2/12/2020	25mg	15.00hrs	*MJjohnson*	s. Jones	4 amps
5mg discarded *MJjohnson* s. Jones					

Storage

- All CDs must be held in a central location within the care home in a Home Office approved cabinet designed specifically for CDs and which complies with requirements under the Misuse of Drugs Act Safe Custody regulations:
  - Locked non-portable cabinet
  - Metal construction of specified gauge
  - Fixed to either to a solid wall or a stud wall that has a steel plate mounted behind it
  - Fixed with either rag or rawl bolts.
- When purchasing a CD cabinet formal confirmation that it meets legal requirements should be requested from suppliers.
- It is a commonly held belief that a CD cupboard must be a 'cupboard within a cupboard' but this is **not** the case.
- Keys for CD cabinet should be kept in the possession of the person in charge of medicines at all times when not in use. When not in their actual possession, the person in charge of medicines must always know where the keys actually are or who does have them.
- Homes should consider maintaining a register for the keys with time, date and signature. Also at end of shift they should be stored in a locked safe with limited access to authorised personnel only

Administration

- In a home registered to provide nursing care the administration of CDs should only be undertaken by a registered nurse. In a home registered to provide personal care the administration of CDs can be undertaken by a suitably trained care worker. Wherever practical, administration should be witnessed and signed by another suitably trained member of staff
- Before administering the medicine, the resident's identity, the drug, dose, route expiry date and the time should be checked with a suitably trained witness
- Immediately following administration, the nurse or carer and the witness must both sign the resident's administration chart.
- Where a separate administration card is used e.g. BD BodyGuard™ T Syringe
- Pump Community Administered Medication Record (pink card), administration should be cross referenced on the MAR chart - see Syringe Pump Administered Medication Record.
- The time the dose was given and the quantity used to give the dose must be recorded in the CD register after each dose is administered. Wherever practical this must be witnessed (see Table 1 and 2).
- Where part of an ampoule is administered the disposal of the remaining portion should be witnessed and recorded in the CD register (see table 3).
- The remaining balance should be counted, recorded and witnessed in the CD register after each dose is administered (see Table1 and 2).
- The administration and recording process should be fully completed for each resident, before moving on to the next.
- When a CD prescribed on a 'when required' basis is administered, the time of administration and the dose given should be recorded and initialled on the MAR sheet as well as the CD register.
- Homes should have a clear procedure in place that covers the method for recording administration where regular and when required (PRN) doses of the same CD are

prescribed. The regular and PRN doses should be recorded as 2 separate entries on the MAR chart/ administration chart to provide adequate facility for recording administration

Community Administered Medication Record (Pink Card)

The 'Pink Card' is principally used to record the administration of medicines by visiting community nurses for patients in residential care. However, it may be used in nursing homes by nursing staff according to their own care home processes following robust governance arrangements.

Administration by visiting Healthcare Professional (Residential Care)

- Where a visiting healthcare professional e.g., a community nurse is scheduled to administer a CD by injection, the care home staff should book out the required amount of the CD (in the register) following their normal processes **then** hand it to the visiting healthcare professional.
- The care home, not the visiting healthcare professional, is responsible for maintaining the CD register **and** the MAR chart.
- The visiting healthcare professional must record the administration on the "Community Administered Medication Record (Pink Card)" and make this available to the care home.
- The pink card should be cross referenced on the MAR chart by the care staff responsible for administering medicines.
- The "Pink Card" signed by the visiting health care professional must be left in the care home until the treatment is discontinued. On completion of treatment the visiting health care professional may then take this card away. However, since a record should be kept by the care home, the pink card should be photocopied.
- The visiting healthcare professional should consider seeing the resident in the presence of care home staff responsible for administering medicines to the resident. This will provide assurance to the care home that a drug has been administered

Routine stock checks

- A running balance should be kept to ensure irregularities or discrepancies are identified as soon as possible
- To ensure all stocks have been entered in the register, physical stocks of all CDs should be reconciled with the running balance in the register on a regular basis e.g. daily or weekly, according to care home policy
- Each drug and quantity is checked, signed and countersigned by the competent staff members checking the CDs (see Table 1 and 2)
- Any discrepancy to be recorded and reported immediately to care home manager or deputy and follow care home policy

Dealing with incidents (discrepancies, near misses and errors)

- Where an incident is found, it should be reported **immediately** to the care home manager or deputy who should investigate promptly – see Appendix II.
- All incidents (all unresolved discrepancies, near misses and errors) must be reported to NHS England Controlled Drugs Accountable Officer via the on-line reporting tool (www.cdreporting.co.uk)
- If a discrepancy is found to be an error of subtraction or addition in the calculation of stock balance, the following procedure should be followed:
  - Do not change the balance column or use correction fluid.
  - Under the last entry, details of the following should be made:
    - The date
    - The error in subtraction / addition (indicated with an asterisk*)
    - The correct balance

  - The signature of the member of staff and the witnessing member of staff (see Table 1)
- If the discrepancy cannot be identified, the pharmacist who is providing a service to the home should be contacted to establish whether there have been any unrecorded returns of CDs.

Disposal

Disposal of part ampoules or refused doses: the care home should have a procedure for managing their safe disposal and record keeping.

When a resident dies, as with all medicines, CDs should be kept for one week in case the coroner requests them.

Residential Homes

- When CDs have passed their expiry date or are no longer required they should be returned to the relevant pharmacy at the earliest opportunity for appropriate destruction.
- When a resident dies, as with all medicines, CDs should be sealed in a clearly identified bag and locked in the CD cabinet for one week in case the coroner requests them. They should then be returned to the relevant pharmacy at the earliest opportunity for appropriate destruction.
- Clear records should be made in the CD register of any items returned to pharmacy and signatures obtained from pharmacy staff
- Syringe Drivers – 'Good Practice Guideline' is for homes to keep syringe and contents in sealed bag locked in the CD cabinet for 7 days as with rest of medicines. The time the syringe is started and the volume left could 'indicate' the rate at which the driver was set – if further investigation warranted.

Nursing Homes

- Unwanted CDs must be deactivated in the nursing home setting
- Deactivating kits are obtained from the waste disposal contractor or community pharmacy. Follow the directions on the deactivating kits
- The form and quantities of CDs being deactivated must be recorded in the CD register. This is to be witnessed according to the homes procedure. Both the member of staff deactivating the CD and the witness must sign the CD register.
- After adding the CD, the deactivation kit should be sealed and stored in CD cupboard overnight (to make the CDs irretrievable) and then placed in the yellow non-hazardous waste bin for disposal.

Residents Looking After their Own Medication

- Residents can self-administer CDs if a risk assessment is undertaken and they are considered suitable to do so.
- The ability of a resident to self-administer must be reviewed periodically and if the residents circumstances change.
- For residents who self-administer, the CDs should be stored in a locked non-portable receptacle (cabinet or draw) in the residents room.
- There is no need for a record to be kept in the CD register if the resident is wholly independent i.e. ordering and collecting their own drugs.
- If the supply and collection of the residents CDs are undertaken by the home then a clear record of the following must be made in the CD register
  - Receipt from pharmacy

- Supply to resident
- Subsequent disposal of unwanted CD

DOs and DON'Ts of Controlled Drugs: Quick Guide

DO:

- Store all CDs in a cupboard which conforms to the Misuse of Drugs Act
- Keep keys to the CD cupboard on the person in charge of medication at all times
- Have a bound CD 'register', or approved electronic CD register, to record receipt, administration and disposal of CDs
- Check if any new medicines received in the home are CDs but be aware that some medicines that the home treats as CDs may not be delivered separately. E.g., Oramorph 10mg in 5ml.
- Store and record Oramorph® 10mg in 5ml as a CD (good practice)
- Record all CDs in the register as soon as they are received, including those brought in by residents on admission
- Record different formulations in the appropriate manner
- Ensure wherever practical a witness signs for administration of CDs
- Ensure that administration of CDs is signed for both on the MAR and in the CD register
- Reconcile the physical stocks of CDs with the running balance in the register on a regular basis e.g., weekly
- Ensure that any stock returned to the pharmacy for destruction or transferred to another setting, including the residents home, are recorded in the register and the balance is recalculated.
- Ensure wherever practical transfers of stock are witnessed by a second member of staff or pharmacy representative, when returning CDs to the pharmacy (residential homes only)
- Report any discrepancies found immediately to the care home manager or deputy who should investigate promptly

DO NOT:

- Order more than one month's supply at a time
- Cross out, change or 'Tippex' entries made in the CD register; if a mistake is made, an amendment should be signed and dated in an appropriate part of the register
- Store any items other than CDs in the CD cupboard
- Record more than one type or strength of drug on each page in the CD register
- Record more than one residents CDs on each page in the register

Appendix I

Controlled Drugs Schedules

SCHEDULE 2

* strength dependant, e.g. codeine inj 60mg/ml schedule 2 , codeine tabs 30 mg no schedule

Abstral
Actiq
Alfentanil
Amphetamine
Amineptine
Cocaine
Codeine Phosphate injection*
Concerta XL
Cyclimorph
Dexamfetamine
Dextromoramide
Diamorphine
Dihydrocodeine*
Dihydromorphine
Diphenoxylate*
Dipipanone
Dipipanone and Cyclizine tablets
Dronabinol
Durogesic DTrans
Effentora
Equasym XL
Fencino
Fentora
Fentalis
Fentanyl
Filnarine
Heroin
Hydrocodone
Hydromorphone
Instanyl
Lisdexamphetamine
Matrifen
Medikinet
Medikinet XL
Methadone
Methadose
Metharose
Methylamphetamine
Methylphenidate
Mezolar
Minijet Morphine
Morphgesic
Morphine*
MST Continus
MXL
Nabilone
Oramorph conc solution
Osmanil
Oxycodone
Oxycontin
OxyNorm
Palexia SR
Palladone
Palladone SR
Pamergan P100
PecFent
Pethidine
Phenazocine
Phenoperidine
Pholcodine*
Physeptone
Quinalbarbitone
Rapifen
Remifentanil
Ritalin
Secobarbital
Sevredol
Sublimaze
Synastone
Tapentadol
Targinact
Tilofyl

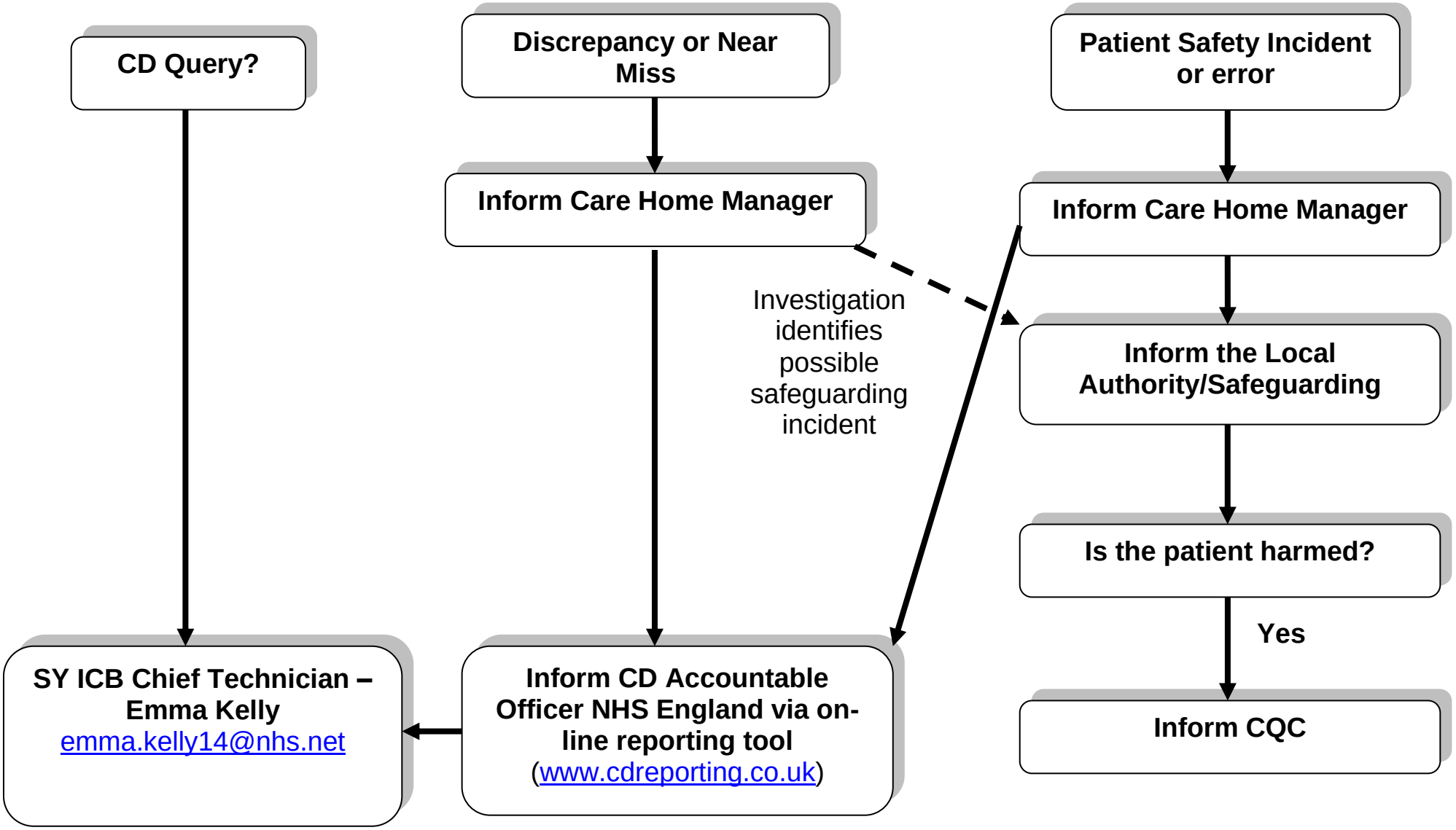
Ultiva
Victanyl
Zomorph

SCHEDULE 3

Amobarbital/Amylobarbitone
Buccolam
Buprenorphine
Butobarbital
Phentermine
Phenobarbital
Subutex
Butrans
Diethylpropion
Flunitrazepam
Hypnovel
Suboxone
Temgesic
Temazepam
Mazindol
Meprobamate/Methylbarbitone
Midazolam
Pentazocine
Transtec
Tramadol

This list is not exhaustive, reference should also be made to the Home Office's Controlled Drug List, the Misuse of Drugs Act 1971 (and amendments) and the Misuse of Drugs regulations 2001 (and amendments Jun 14)

Appendix II - Reporting of CD Incidents in Care Homes Pathway



Appendix III

Checklist - Prescription Requirements for Controlled Drugs

It is an offence for a practitioner to issue a prescription for a Schedule 2 or 3 controlled drug or for a pharmacist to dispense it, unless it is written in ink or is otherwise indelible (e.g. typed or computer generated) and contains the following information:

- The full name and address of the resident (or “no fixed abode”), and the age of the resident where appropriate.
- The name of the preparation.
- The form of the preparation, even if only one form exists.
- The strength of the preparation, where appropriate.
- The dose to be taken. Note that “***Take as directed***” or “***to be taken as required***” is not acceptable. However, a dosage of “***One to be taken as directed***” or “***One to be taken when required***” is acceptable.
- Either the total quantity (in both words and figures) of the preparation or the number (in both words and figures) of dosage units to be supplied e.g. for tablets, capsules, suppositories 10 (ten) would be acceptable. It is advised that quantities of liquid preparations should be written in millilitres
- The address of the prescriber
- Be signed by the person issuing it with their usual signature and dated by them (note that the date does not have to be handwritten, it can be a stamp or computer generated).
- If issued by a dentist, the words “for dental treatment only”.