

Appendix 6 - PHM-SOP-98

Clinical Services	Document No:	PHM-SOP-98	Version	05
	Date Written	07.11.2023	Review Date	As Per Q-Pulse
Department of Pharmacy NHS Grampian	Author	CD Team	Approved by	Lyn Robertson
	QA Approver	Andrew Wilson	Date Uploaded	

Purpose: The purpose of this SOP is to define the system to be used by Pharmacy staff when carrying out controlled drug checks in a ward/department.

Scope: All wards and departments with a controlled drug cabinet containing controlled drugs within NHSG.

Responsible Personnel: Pharmacists, Band 4, 5 and 6 pharmacy technicians, foundation trainee pharmacists, CD inspectors and registered nurses/ midwives/ ODPs. (Note in community hospitals only, a 3rd year student nurse may witness a CD check).

Information:

A check of all controlled drugs (CDs) stocked within wards and departments must be completed as agreed following risk assessment but a minimum of every 4 months by Pharmacy staff in conjunction with nursing staff. A check of patients' own CDs should be carried out at the same time. These CD assurance checks may be carried out by pharmacists, pharmacy technicians, foundation trainee pharmacists or CD Inspectors, and must be witnessed by a suitable registered professional (for the purpose of this document this is defined as a registered nurse, midwife or operating department practitioner). (In community hospitals this may be a 3rd year student nurse). To ensure availability of nursing staff to complete actual count of CDs, an appointment should be arranged in advance with a member of nursing staff. In certain circumstances the check may be witnessed by a second member of pharmacy staff (refer to Guidance Notes on Carrying out CD Assurance Checks in Wards/Departments/Community Hospitals by Pharmacists/Pharmacy Technicians/CD Inspectors in NHS Grampian Section 5). Newly appointed pharmacists, pharmacy technicians and foundation trainee pharmacists should only carry out a CD assurance check after carrying out a minimum of one supervised check, in addition to reading and signing up to this SOP (for further clarification see guidance notes). CD assurance checks in wards, departments and community hospitals should be undertaken safely and consistently in accordance with legislation (Safer management of controlled drugs: A guide to good practice in secondary care (Scotland) CEL 7 (2008)).

Procedure:

1. Pharmacy staff performing a CD assurance check should note the following points:

- 1.1. Carry appropriate identification (NHSG ID card) and identify yourself to the registered professional in charge of the ward or department or operational department manager.
- 1.2. Identify a suitable registered professional from the ward to carry out the check and countersign the CD book. If it is not possible to have a member of the ward staff present, then in exceptional circumstances a second member of pharmacy staff may countersign the checks. Pharmacy staff must never undertake CD checks alone.
- 1.3. Ensure that you have the appropriate documentation and equipment required for the CD check:
 - 1.3.1. **Controlled Drugs pharmacy check record form**
 - 1.3.2. **CD balance discrepancy report form – stock**
 - 1.3.3. **CD balance discrepancy report form – patients' own drugs**
 - 1.3.4. **Clinical governance reporting form – controlled drugs**
 - 1.3.5 **A measuring cylinder.**

2. General Checks and Security Checks

- 2.1 Complete the general and security checks by answering the questions in section 1 of the pharmacy check record form and action log.
- 2.2 The Misuse of Drugs (Safe Custody) Regulations 1973, lays out the statutory specificities of controlled drugs storage receptacles. Controlled drugs cabinets which are identified as satisfying BS2881 are constructed and maintained to prevent unauthorised access. Points to consider include if the cabinet is sufficiently robust and the lock cannot be tampered with, the key to the CD cabinet should be unique to that cabinet only.
- 2.3 Note any additional comments as relevant.

Clinical Services	Document No:	PHM-SOP-98	Version	05
	Date Written	07.11.2023	Review Date	As Per Q-Pulse
Department of Pharmacy NHS Grampian	Author	CD Team	Approved by	Lyn Robertson
	QA Approver	Andrew Wilson	Date Uploaded	

3. Physical Balance and Expiry Date check

- 3.1. Complete the physical stock check (as described below) and complete section 2 in the pharmacy check record form and action log.
- 3.2. Remove all stock from CD cabinet (provided space and security allows).
- 3.3. Perform the check in a structured order by starting at the index page and methodically working through each entry as it appears until the end of the record book is reached. All pages of the CD record book need to be checked to ensure that CDs omitted from the index are still verified.
- 3.4. Inspect each drug in conjunction with an examination of the corresponding entry in the CD record book; ensure the page number stating the running balance corresponds with the page number recorded in the index.
- 3.5. Check the CD's name, formulation, strength, batch number and expiry date correspond to the information on the outer packaging.
- 3.6. The contents of broken packs must be checked individually i.e. for ampoules and strips of tablets/capsules/sachets; check name, batch number and expiry date. It is not necessary to open packs which have tamper evident seals intact. The balance of open bottles of liquids should be measured with a measuring cylinder.
- 3.7. For each item in the CD record book, check the quantity in stock matches the balance in the CD record book by checking the stock against the CD record book, NOT the CD record book against the stock.
- 3.8. Return each item to the CD cabinet after it is checked.
- 3.9. If there are any discrepancies note these on the pharmacy check record form and record any follow-up action on the action log. Also complete a CD balance discrepancy report form, (see point 7 - discrepancies).
- 3.10. Once a CD has been checked, the following should be documented on the appropriate page on the line immediately below the last recorded transaction:
 - 3.10.1. The date and time
 - 3.10.2. "Checked and balance found to be correct".
 - 3.10.3. Pharmacy staff name followed by GPhC number, or foundation trainee pharmacist number if applicable.
 - 3.10.4. The balance.
- 3.11. The entry must be independently checked and countersigned by a member of ward/departmental nursing staff or in exceptional circumstances by another member of pharmacy staff.
- 3.12. Note any additional comments as relevant
- 3.13. Repeat sections 3.2 to 3.11 for all the patients' own CDs.

4. Order book check and CD Record book stock receipt entry

- 4.1. Complete section 3 & 4 in the Controlled Drugs pharmacy check record form (order book check and CD record book stock receipt entry) as described below.
- 4.2. Select at least 5 orders placed since the previous CD assurance check (see Guidance notes).
- 4.3. For each order check that the information detailed on the check form (section 3) has been recorded correctly in the order book and that the ordering is appropriate e.g. staff on authorised signatory list, designated order day?

Clinical Services	Document No:	PHM-SOP-98	Version	05
	Date Written	07.11.2023	Review Date	As Per Q-Pulse
Department of Pharmacy NHS Grampian	Author	CD Team	Approved by	Lyn Robertson
	QA Approver	Andrew Wilson	Date Uploaded	

- 4.4. For each order check that the information detailed on the check form (section 4) has been recorded correctly in the CD record book.
- 4.5. Consider if the CD order book is in good condition and that all pages are present
- 4.6. Note any additional comments as relevant
- 4.7. When the order checks have been completed, sign and date the reverse side of the most recent order.

5. CD Record book administration entries

- 5.1. Review every page of the CD record book (since the previous assurance check) and look for:
 - 5.1.1. Repeated occurrences of broken ampoules.
 - 5.1.2. Repeated dropped, discarded or refused oral medicines.
 - 5.1.3. Multiple mistakes by same staff.
 - 5.1.4. Repeated transferring to other clinical areas.
 - 5.1.5. Similar handwriting for administration and witness.
 - 5.1.6. Inappropriate correction such as scoring out or use of correction fluid.
 - 5.1.7. Discarded amounts not witnessed or time of discard omitted
 - 5.1.8. Evidence of unused items returned to stock
 - 5.1.9. Is the CD record book in good condition, and all pages present
- 5.2. Whilst reviewing, select at least 8 administrations of CDs made since the previous CD assurance check; include different pages, drugs and dates.
- 5.3. For the 8 administrations check that the information detailed in section 5 of the check record form has been recorded correctly in the CD record book.
- 5.4. If staff are consistently making errors in recording the same information make a comment in the comments box on the check record form. It is not necessary to highlight or comment on single mistakes.
- 5.5. Note any additional comments as relevant

6. CD Record book patients' own

- 6.1. A dedicated page/section of the CD record book or a separate CD record book should be used for patients' own CDs.
- 6.2. Review every page containing patients' own CDs in the CD record book (since the previous check).
- 6.3. Whilst reviewing, select at least 8 entries of patients' own CDs from the CD record book (made since the previous check), include different pages and dates.
- 6.4. For each entry check that the information detailed in section 6a and b on the check record form has been recorded correctly in the CD record book.
- 6.5. If patients' own CDs are not used on the ward, a line should be left below the entry to allow for an entry showing when the CDs were returned to the patient or sent to pharmacy for destruction. If patients' own CDs are used on the ward then each item should be recorded on a separate page.
- 6.6. Where patients' own CDs are used on the ward, check the information in 6c to 6o on the check record form has been recorded correctly for the 8 entries selected.
- 6.7. Note any additional comments as relevant

Clinical Services	Document No:	PHM-SOP-98	Version	05
	Date Written	07.11.2023	Review Date	As Per Q-Pulse
Department of Pharmacy NHS Grampian	Author	CD Team	Approved by	Lyn Robertson
	QA Approver	Andrew Wilson	Date Uploaded	

7. Discrepancies

- 7.1. Any discrepancies MUST be brought to the attention of the registered professional in charge and they must investigate the issue.
- 7.2. Minor discrepancies do not need to be brought to the attention of the AO/CD team. For example - liquids (<5% of the volume of the bottle or 5ml whichever is smaller), addition errors which are clearly such.
- 7.3. Note minor discrepancies in the comments box on the check form and adjust CD record book.
- 7.4. If a discrepancy can be clearly identified to be an incorrect entry then brackets should be placed around the wrong entry, initialled and a dated footnote must be made to reflect the correction.
- 7.5. The CD record book should be amended "balance adjusted and now correct" and signed by 2 people as above.
- 7.6. Major discrepancies and any which cannot be resolved must ALWAYS be brought to the attention of the AO/CD team. The registered professional in charge and ward clinical pharmacist must also be made aware.
- 7.7. Complete the documentation CD balance discrepancy report form, leave the original form with the registered professional in charge and send a copy to the AO/CD team.
- 7.8. The Clinical governance reporting form or DATIX may be used if necessary and sent to AO/CD team.

8. Other points

- 8.1. The persons completing the CD check MUST sign the *Controlled Drugs Pharmacy Check Form*. A copy of the form and action log should be given to the registered professional in charge on the ward and also sent to the CD Team. The original form and action log should be held in a secure designated area within the pharmacy department. A contact within pharmacy should be identified to work with the ward/departmental team to ensure the actions are completed according to timescales stated.
- 8.2. Where the check has been completed by two pharmacy staff members an appointment must be made as soon as possible to discuss an issues/discrepancies with the registered professional in charge,
- 8.3. If any issues (such as poor record keeping) are identified they should be discussed with a pharmacist, the registered professional in charge and consider completion of clinical governance reporting form (See Guidance notes on carrying out Controlled Drug (CD) checks in wards/departments/community hospitals by pharmacist/technicians/CD Inspectors in NHS Grampian).

NHS Grampian Policy and Procedure for the Safe Management of Controlled Drugs in Hospitals and Clinics.

Referenced Guides / SOPs:

[NHS Grampian Policy and Procedure for the Safe Management of Controlled Drugs in Hospitals and Clinics](#)

Guidance notes on carrying out CD assurance checks in wards/ departments/ community hospitals (controlled drugs team NHS Grampian).

PHM-FORM-189 Controlled Drugs pharmacy check record form

Authors: CD Team

Contact list: