The Regulation and Quality Improvement Authority

Guidance on Standard Operating Procedures for the Safer Management of Controlled Drugs in Registered Facilities

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informing and improving health and social care
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Introduction:

This guidance sets out strengthened governance arrangements required in care homes for the management and use of controlled drugs as a result of the Fourth Report of the Shipman Inquiry. Section 17 and 18 of The Health Act 2006 apply in Northern Ireland and provide the basis for the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009. These identify (in regulation 9) the requirement of those using controlled drugs to have Standard Operating Procedures (SOPs) in place. These are one of the practical measures that will help to ensure good practice in the management of controlled drugs throughout the health and social care system.

Legislative framework:

- The Health Act 2006
- The Misuse of Drugs (Safe Custody) Regulations 1973
- The Nursing Homes Regulations (Northern Ireland) 2005
- The Residential Care Homes Regulations (Northern Ireland) 2005
- The Children's Homes Regulations (Northern Ireland) 2005
- The Controlled Drugs (Supervision of Management and Use) Regulations (NI) 2009

Guidelines:

Department for Health, Social Services and Public Safety (2006). The Use and Control of Medicines.
Department for Health, Social Services and Public Safety (2010). Safer Management of Controlled Drugs - A guide to good practice in primary care (Northern Ireland).

Resources:

www.rqia.org.uk
www.dhsspsni.gov.uk (follow the links to the pharmaceutical advice and services page on the right hand side and then the accountable officer link on the left hand side and guidance link on the left hand side.)

Regulation 13 of the Nursing Homes Regulations (Northern Ireland) 2005 and Regulation 13 of the Residential Care Homes Regulations (Northern Ireland) 2005 require registered providers to make suitable arrangements for the ordering; storage; recording; handling; safekeeping; safe administration and disposal of medicines used in or for the purposes of the home. Regulation 20 of the Children's Homes Regulations (Northern Ireland) 2005 requires registered providers to arrange for the recording; handling; safekeeping; safe administration; and disposal of any medicines received into the children's home. These regulations apply to all medicines including controlled drugs.

Background:

In 2009, the Department of Health Social Services and Public Safety (DHSSPS) produced a guidance document; Safer Management of Controlled Drugs, Guidance on Standard Operating Procedures for Northern Ireland.

This document details which areas of the management of controlled drugs must be covered by Standard Operating Procedures, including:

- who has access to controlled drugs
- where controlled drugs are stored
- security arrangements for controlled drugs
- disposal of controlled drugs
- management of complications
- record keeping

Definition:

A standard operating procedure (SOP) is a step-by-step description of the way things are done in a particular setting. Written SOPs help to ensure the quality and consistency of the management of controlled drugs in each registered facility. They can help to identify and minimise risks and to trace the cause of any errors.

This guidance document has been produced by the Regulation and Quality Improvement Authority to help you write standard operating procedures for the management of controlled drugs in your setting. An example of a SOP has been included for information, and a list of the other SOPs that need to be implemented for the management of controlled drugs is included for guidance.

Written SOPs should be available in your setting for the management of controlled drugs to:

- improve your governance arrangements
- ensure your practice is in line with the regulatory frameworks
- improve clarity and consistency for all staff handling controlled drugs
- define accountability and responsibilities and clarify where responsibility can be delegated
- act as a training and competency assessment tool for new and existing staff

Scope of SOPs

Each registered facility should have SOPs which cover the following areas of the management of controlled drugs:

- ordering, transport and receipt
- safe storage
- administration
- disposal
- record keeping
- management of errors and incidents

EXAMPLE

Ordering Supplies of Controlled Drugs SOP Number: CD01

Prepared by/date:	Approved by/date:	Review Date:
Previous version/master copy endorsed as superseded, dated and archived: Sign: Date:	All paper copies of previous version in circulation destroyed: Sign: Date:	

Objective: To ensure that the procedure for ordering controlled drugs is robust.

Responsibility: The registered manager must ensure that the SOP is adhered to and updated when necessary.
All staff who are trained and deemed competent in the management of medicines.

Scope: This SOP must be read in conjunction with the home's policies and procedures for the management of medicines and other SOPs for the management of controlled drugs.

Process:

1 Orders for controlled drugs should be made in writing to the prescriber using the home's usual ordering process and paperwork. Orders for controlled drugs may not be made through the repeat dispensing scheme.

2 A copy of the order should be retained in the home.

3 Excessive quantities of controlled drugs should not be ordered for individual patients. Prescribers will normally provide a 28 day supply of a controlled drug on each prescription.

Signature list of staff that have read
SOP 01 - Ordering supplies of controlled drugs

I have read and understood the above SOP

Print Staff Name	Staff signature when SOP read	Date

When drafting SOPs homes should make reference to the documents Safer Management of Controlled Drugs: A Guide to Good Practice in Primary Care (Northern Ireland) 2010 and Safer Management of Controlled Drugs: Guidance on Standard Operating Procedures for Northern Ireland October 2009.

SOPs are needed for every stage of the controlled drugs journey including procurement (ordering, receipt and transport); safe storage; supply; administration; destruction and guidance for dealing with an incident. Some may require multidisciplinary collaboration.

The organisation will need to decide how much to include in a single SOP and may need specific SOPs for specific areas.

The input of designated members of staff should be encouraged when drafting SOPs. All designated members of staff should be asked to read the SOPs and should be given training on their implementation. Staff should be asked to sign the respective SOP to show that they have understood the procedures.

SOPs are working documents and should therefore be reviewed and updated on a regular basis. SOPs need to be accessible to staff at all times.

Areas to consider

ACTIVITY	DETAIL	COMMENT
Ordering	Details of staff with authority to order controlled drugs	
	Details of paperwork system used in the home	
Transport	Arrangements for obtaining prescription forms from the prescriber	It is considered good practice for the home to collect prescription forms and check them against their order before forwarding them to the pharmacy for dispensing.
	Arrangements for the transport of supplies of controlled drugs from the pharmacy to the home	Some pharmacies will deliver supplies of controlled drugs to the home. The SOP should detail the delivery arrangements and the management of delivery dockets for controlled drugs.
Receipt	Personnel authorised to receive CDs	
	Checking procedure	Medicines checked against order and record of receipt maintained, by a competent member of staff. Any discrepancies reported to the registered manager.
	Storage and management of delivery dockets	
	Security of medicines on receipt	The staff member responsible for the receipt of medicines is also responsible for the security of medicines on receipt.

ACTIVITY	DETAIL	COMMENT
Storage	Specifications of CD cabinet	Refer to Safe Custody Regulations
	Location of CD cabinet	
	Access	
	Key control	The registered manager must ensure that key control is appropriate.
	Temperature	
Record keeping	Entries in controlled drugs record book made in accordance with legislation and minimum standards and best practice guidance.	The name; date; time; and route of administration and dose given, should be recorded in the controlled drug record book immediately after the medication dose has been administered. The nurse/trained carer and the witness should also verify and record the remaining stock balance and sign the controlled drug record book.
	Details of staff authorised to make entries.	In nursing homes, if only one member of nursing staff is on duty - care staff should be trained to countersign records.
	Receipt, administration and disposal of all controlled drugs recorded.	
	Retention of records	Refer to appropriate legislation

ACTIVITY	DETAIL	COMMENT
Administration	Authority to administer	
	Assembly	Removal from cupboard/store Preparation of dose
	Patient	Verification of patient/treatment/ personal medication record
	Administration	Witnessed
	CD record book entry	
	Medication administration record entry	The entry should be made at the time of administration by the staff member administering the medicine. It is considered good practice for the member of staff witnessing the administration to also sign the administration record
Disposal/ Transfer	Disposal	Transport and destination
	Record keeping	Record signed by staff member and recipient of medicine.
	Home leave	
	Discharge of patient	
	Unused portions (e.g. ampoules, syringe driver)	The entry should be made at the time of disposal by the staff member disposing of the medicines and the member of staff witnessing the disposal.

ACTIVITY	DETAIL	COMMENT
Self-administration	Competency assessment of patient	
	Storage	
	Record keeping	
	Monitoring and review	
Monitoring and audit arrangements	Reconciliation of Schedule 2 & 3 controlled drugs by the staff members involved at each handover of responsibility.	Records of checks maintained
Errors and incidents	Discrepancy	The registered manager must be informed if a discrepancy is noted and an investigation must be undertaken.
	Administration error	
	Record keeping error	
	Reporting of errors/incidents	The registered manager must inform the relevant authorities of the outcome of the investigation, in a timely manner.
	Review procedures	The registered manager is responsible for the review of procedures to ensure that the risk of incidents in the future is reduced and that the learning points taken from the incident are communicated with all staff in an appropriate manner.
Audit of SOP	SOPs up to date and accurate	Periodic review