Primary and Community Care Directorate
Pharmacy Division

The Scottish Government

CEL 14 (2007)

17 OCTOBER 2007

Dear Colleague

SAFER MANAGEMENT OF CONTROLLED DRUGS STANDARD OPERATING PROCEDURES:

Action

NHS Boards are asked to copy this letter and Annex to:

all general practices, all dentists and community pharmacy contractors on their lists, nurse prescribers and supplementary prescribers and to all staff involved in the management and use of controlled drugs. The guidance must also be copied to the Board's Accountable Officer

Purpose

1. The annexes to this letter provide a framework to support the development of Standard Operating Procedures (SOPs) for controlled drugs.

Background

2. The fourth report of the Shipman Inquiry "*The Regulation of Controlled Drugs in the Community*" made recommendations to strengthen and improve current systems for the management and use of controlled drugs. The UK Government's response to the report set out a programme of work to address the shortcomings identified by the Inquiry. The Health Act 2006 and Regulations made under the Act – the Controlled Drugs (Supervision of Management and Use) Regulations 2006 – introduced new governance arrangements for controlled drugs which includes a requirement that healthcare organisations holding stocks of controlled drugs must put in place and operate within SOPs. Full guidance on the new governance arrangements for controlled drugs can be found in Circular NHS HDL (2007) 12 dated 14 February 2007[1].

Addresses

For action
Chief Executives, NHS Boards
Chief Executive, Scottish Ambulance Service Board
Chief Executive, State Hospitals Board for Scotland
Chief Executive, National Waiting Times Centre Board
Medical Directors, NHS Boards
Directors of Nursing, NHS Boards
General Practitioners
Dental Practitioners
Community Pharmacists
Directors of Pharmacy, NHS Boards

For information
Chief Executive, NHS QIS
Chief Executive, NHS NSS
Chief Executive, NHS NES
Scottish Commission for the Regulation of Care
Royal Pharmaceutical Society of Great Britain, Scottish Division
SGPC
Community Pharmacy (Scotland)

Enquires to:
cdenquiries@scotland.gsi.gov.uk

Pharmacy Division
Room 1E.01
St Andrew's House
EDINBURGH
EH1 3DG
http://www.scotland.gov.uk

[1] http://www.show.scot.nhs.uk/publicationsindex.htm

3. A copy of this letter is being sent separately to Accountable Officers in the independent sector.

Yours sincerely

Bill Scott *Harry Burns*

PROFESSOR BILL SCOTT
Chief Pharmaceutical Officer

DR HARRY BURNS
Chief Medical Officer

ANNEX A

STANDARD OPERATING PROCEDURES: CONTROLLED DRUGS

Introduction

1. The UK Health Act 2006 introduced new monitoring and inspection requirements for controlled drugs. These new arrangements are designed to work within and alongside existing governance systems to promote the safe, secure and effective use of controlled drugs.

2. Regulations made under the Health Act - the Controlled Drugs (Supervision of Management and Use) Regulations 2006[2] (the Controlled Drugs Regulations) - require healthcare organisations to appoint an Accountable Officer to be accountable for the safe management and use of controlled drugs in their organisation. The Regulations also require healthcare organisations holding stocks of controlled drugs to put in place and comply with Standard Operating Procedures (SOPs) for the use and management of these drugs. This guidance is intended to support the development of SOPs and provides advice on the areas that should be considered for inclusion.

3. The Controlled Drugs Regulations require Accountable Officers to ensure that his or her organisation, or a body or person acting on behalf of or providing services under contract with his or her organisation, has "adequate and up-to-date SOPs in place in relation to the management and use of controlled drugs" (regulation 9). The SOPs must cover:

- who has access to the controlled drugs;
- where the controlled drugs are stored;
- security in relation to the storage and transportation of controlled drugs as required by misuse of drugs legislation;
- disposal and destruction of controlled drugs;
- who is to be alerted if complications arise, and
- record keeping, including –
  (i) maintaining relevant controlled drugs registers under the misuse of drugs legislation, and
  (ii) maintaining a record of the controlled drugs specified in Schedule 2 to the Misuse of Drugs Regulations 2001 (specified controlled drugs to which certain provisions of the Regulations apply) that have been returned by patients.

Definition

4. A SOP is an unambiguous document describing the responsibilities and procedures, including audit, necessary to safely and accountably manage any set of processes. In this case the SOP is a working document detailing the current agreed working practices that take account of all areas applicable to the management of controlled drugs in any individual setting.

5. This guidance is intended to provide base-line advice on the areas that should be considered for inclusion in the SOP. In general, an organisation should have an overarching policy for the use and management of controlled drugs and specific areas should develop SOPs based on that policy taking into account local circumstances and local information.

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[2] The Regulations can be accessed at www.opsi.gov.uk/si/si2006/20063148.htm

Principles

6. SOPs are required for the management and use of controlled drugs in order to:
    - improve governance of controlled drugs within the organisation;
    - provide clarity, consistency and protection for all staff handling controlled drugs;
    - define accountability and responsibilities and clarify where responsibility can be delegated;
    - ensure practice is in line with the regulatory framework;
    - as a training tool for new and existing staff.

Validation within the organisation

7. SOPs at all levels of the healthcare organisation should be developed with relevant stakeholders such as executive leads, senior practitioners, senior pharmacists, clinical governance lead, as appropriate. All SOPs must be approved using the appropriate governance and management structures on behalf of the organisation. The review of these structures is part of NHS Quality Improvement Scotland's Clinical Governance and Risk Management Standards and yearly improvement is monitored through NHS Boards' annual performance reviews.

SOP development

8. The SOP must take into account:
    - staff roles and responsibilities;
    - criteria which may instigate a review of the SOP, for example:
        - after a given time period;
        - following an incident, to include learning from such incidents;
        - change in legislation or best practice;
        - change of named personnel.
    - training requirements for new and existing staff;
    - cascade mechanism for any changes;
    - monitoring arrangements.

9. It is important that staff are able to access the SOP(s) at all times. Healthcare organisations and Accountable Officers must ensure that appropriate document control mechanisms are in place to ensure that staff have access to the most current version of the SOP(s).

10. SOPs must cover every aspect of the controlled drugs journey from procurement (ordering, receipt, transport), safe storage, supply, dispensing, administration through to disposal. Specific SOPs may be needed to cover different aspects of the CD journey.

11. In developing SOPs consideration must be given to the following areas:
    - organisation/area/service to which the SOP applies;
    - objective/purpose;
    - scope;
    - approval mechanisms, e.g. committees that need to agree the SOP;
    - roles and responsibilities;
    - other relevant information, e.g. interaction with other SOPs, what to do if circumstances change;
    - monitoring and reporting mechanisms;

- review period, e.g. one, two or three years;
- lead author and named individuals contributing to the SOP;
- key contacts for further information/advice.

12. Further guidance on the areas to consider for inclusion in a SOP is given in Annex B.

Standard Operating Procedures: Controlled Drugs

Developing SOPs: Areas to Consider

	Receiving into organisation/unit	
Legal requirements	Who can legally be in possession of a controlled drug.	
Ordering	Is a Home Office licence required to hold stock.	Information available at www.homeoffice.gov.uk
	Record keeping associated with order i.e. forms and other stationery to be used. Retention of order forms.	
	Identification of named individual(s) with the authority to order.	
	Organisation's tendering processes.	
Arrangements for CD stationery	For example, pharmacists from wholesalers/GPs from pharmacies.	
Arrangements for emergency supply to a practitioner		
Transport	In particular if not from wholesaler/manufacturer.	
Receipt	Personnel authorised to receive.	
	Record keeping associated with receipt.	
	Security on receipt.	
	Action to deal with any discrepancies.	
	Process for reconciliation, if necessary.	
Storage	Security and key/code security – personnel with access.	
	Appropriate conditions for product, e.g. temperature.	
	Out of Hours access.	
	GPs bag.	
	Contingency for extended closure.	
Register entry	Guidance on CD registers is available at www.rpsgb.org.uk	
Action to take if any discrepancies		
Process for reconciliation if necessary		
Timescales for checks/audit		

	Transfer within organisation	
Receive request	Prescribing requirements.	
	If signed order ensure on correct stationery by known signatory with authority to order.	Supplier to check against specimen signature.
Assembly & supply	Who does this.	
	Responsible person.	
	Labelling requirements	
	Register entry.	
Hand-over	Record keeping.	
Transport	Authorised personnel.	
	Audit trail on leaving department.	
	Security.	
Audit trail by receiving unit	Handing over to personnel authorised to receive – record keeping.	
	Back to receipt as for 'Receiving into organisation/Unit'	

Transport: Some organisations may require specific SOPs relating to transport arrangements and also consideration should be given to nurses working in the community.

Prescribing	
Authority to prescribe	Legal framework for health professionals eligible to prescribe.
Prescription stationery	Include hospital & community prescription stationery.
Private prescribing	Guidance given in Scotland in NHS HDL (2006)27 dated May 2006.
Local restrictions.	

Administration	
Authority to prescribe	Legal framework for health professionals eligible to prescribe.
Authority to administer	Legal framework, to include Patient Group Directions.
Assembly	Removal arrangements from cupboard/store.
	Manipulation.
Patient	Ensure right patient. Patient specific documentation.
Register entry	
Disposal/recording arrangements for any unused portion	Guidance is available at www.rpsgb.org.uk

CD Register: Some organisations may wish to develop SOPs relating specifically to record keeping. Guidance on CD Registers is available at www.rpsgb.org.uk

Individual Patient Supplies	
Authority to prescribe	Check legal framework for health professionals eligible to prescribe.
Assembly	Removal from cupboard/store.
	Manipulation.
Patient/representative	Ensure right patient. ID arrangements.
Register entry	
Prescription processing	Arrangements for submitting prescription forms to relevant NHS Organisation – in Scotland NHS National Services Scotland.

Disposal	
Record keeping	Check requirements e.g. unused portions, out of date stock, excess – disposal/return to store, individually prescribed, patients own returns, denaturing, authorised witnesses if required, disposal.

Audit requirements, for example, by whom, format, frequency, reporting route, record management, requirements for action/change where required to close audit loop.

Incidents i.e. reporting requirements, review procedures, actions taken, learning achieved for all healthcare professionals.

Illicit substances – check local guidance on removal, storage, recording, reporting.