



# **SAFER MANAGEMENT OF CONTROLLED DRUGS:**

## **GUIDANCE ON STANDARD OPERATING PROCEDURES FOR CONTROLLED DRUGS**

**Department of Health  
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## DH INFORMATION READER BOX

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<b>For Recipient's Use</b>			

## **Guidance on Standard Operating Procedures (SOPs) for Controlled Drugs (CDs)**

### **INTRODUCTION**

- 1 The purpose of this guidance is to promote the safe, secure and effective use of all controlled drugs. Controlled drugs (CDs) are subject to special legislative controls because there is a potential for them to be abused or diverted, causing possible harm. The Government has introduced strengthened measures to make sure controlled drugs are managed safely. These governance arrangements need to be implemented in a way that supports professionals, and encourages good practice around the management and use of these important medicines when clinically required by patients.
- 2 The Government has introduced new monitoring and inspection arrangements for controlled drugs in the Health Act 2006. These will work within and alongside existing governance systems and should be seen as an integral part of the overall drive to improve quality in healthcare. Regulations made under the Health Act 2006 will require each healthcare organisation to appoint an Accountable Officer, responsible for the safe and effective use of controlled drugs in their organisation. The Regulations also introduce standard operating procedures (SOPs) for the use and management of controlled drugs. These are one of the practical measures that will help to ensure good practice throughout the health and social care system.
- 3 The 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 relation to the use of controlled drugs.
- 4 The standard operating procedures must in particular cover the following matters:
  - ordering and receipt of CDs;
  - assigning responsibilities;
  - where the controlled drugs are stored;
  - who has access to the controlled drugs;
  - record keeping;
  - who should be alerted if complications arise.

### **Definition**

- 5 An SOP is an unambiguous document, describing the responsibilities and the procedures, including audit, necessary to safely and accountably manage any set of processes, in this case around the total management of CDs. An SOP is a working document detailing the current agreed working practice that takes account of all the areas that are applicable to the management of CDs in an individual setting.
- 6 This guidance is intended to provide base line advice on the areas that might be considered for inclusion in the SOP. Different health and social care settings may have practice areas in addition to those outlined below.

## PRINCIPLES

### 7 Why are SOPs needed for CDs?

- To improve governance of controlled drugs within the organisation
- To provide clarity and consistency for all staff handling controlled drugs
- To define accountability and responsibilities and clarify where responsibility can be delegated
- To ensure practice is in line with the regulatory frameworks
- As a training tool for new and existing staff.

### Validation within the organisation

- 8 A large organisation will require an overarching policy for SOPs, and smaller organisations such as GP practices will need to have an appropriate process in place to agree and adopt SOPs for use.
- 9 SOPs will need to be agreed at a senior level on behalf of the organisation, usually through the
- Accountable Officer for designated organisations (as defined in the Health Act Regulations but likely to include PCTs, NHS Trusts, NHS Foundation Trusts and independent hospitals)
  - And/or involve other relevant stakeholders such as Senior Practitioner, senior partner, senior pharmacists, superintendent pharmacist, Clinical Governance Lead as appropriate to the organisation
- 10 The SOP policy should take account of:
- Training considerations for new and existing staff including ownership and awareness training
  - The review criteria, for example:
    - after a given time period
    - following a critical incident, to include the learning from such incidents, significant change in legislation or best practice
    - where a specific named person is included in a SOP then the SOP will need to be changed if personnel circumstances change.
  - Cascade mechanism of changes to all staff
  - Staff responsibilities – requirement to notify variation / inability to follow SOP. Opportunity to comment and be part of review process
- 11 **A common template needs to consider inclusion of the following :**
- Organisation / Area/ Service to which the SOP applies  
Objective / purpose  
Scope  
Stages of the process for example other committees that need to agree such a document  
Responsibilities  
Other useful information such as interaction with other SOPs, what to do if circumstances change  
Validation by organisation and Date  
Review period, e.g. one, two or three years.  
Lead author and named people contributing to the SOP

**SOPs should cover every aspect of the controlled drugs journey – from procurement, administration or dispensing to disposal**

- 12 SOPs are needed for every stage of the CD journey from procurement (ordering, receipt, transport), safe storage, supply, administration, destruction and guidance for dealing with an incident.  
Most will require multidisciplinary collaboration.
- 13 The organisation will need to decide how much to include in a single SOP and may need specific SOPs for specific areas.
- 14 The following table is to assist in identifying the steps in handling CDs that need to be considered in the SOP and what is appropriate for each organisation
- 15 SOPs need to be accessible to staff at all times.

## AREAS TO CONSIDER

<b>Receiving Into organisation / unit</b>		<b>Comment</b>
Ordering	Is a Home Office licence needed to hold stock?	Link to Home office website
	Record Keeping of order including descriptions of forms and other stationery to be used	
	Named person(s) (consider deputy / locum) with Authority to order	
	Organisational tendering processes – purchasing for safety	
Transport	Particularly if not from wholesaler / manufacturer	
Receipt	Personnel authorised to receive	
	Record keeping of receipt	
	Security on receipt	
Storage	Security and key/code security Personnel with access	
	Appropriateness for product e.g. temperature	
	Out of hours access	
	Contingency for extended closure	
Register entry		
Arrangements for Controlled Stationery		
Action to take if any discrepancies		
Regular (need to specify when) check / audit		
Process for reconciliation when necessary		

<b>Transfer within organisation</b>		
Request	Prescription (need to expand)	
	Signed order (correct stationery) by known signatory	
	Checking authority to order	Supplier able to check against specimen signature
Assembly and supply	Who	
	Responsible person	
	Label	
	Register entry	
Hand over	Record Keeping	
Transport	Authorised personnel	
	Audit trail on leaving department	
	Security	
Audit trail by receiving unit	handing over to persons authorised to receive – record keeping	
	(back to 'receipt' as for receiving into organisation)	

**Transport** Some organisations may require specific SOPs relating to transport arrangements

<b>Prescribing</b>	Link to legal position of who can prescribe which CDs
Authority to prescribe	supplementary prescriber status, existing and new independent prescribers, private or NHS
Prescription stationery	Hospital charts
	FP10 types
Private prescribing	
Local restrictions	

<b>Administration</b>		
Authority to prescribe	supplementary prescriber status, existing and new independent prescribers	
Authority to administer	PGD considerations, Legal and clinical check	
Assembly	Removal from cupboard/store	
	Manipulation	
Patient	Checking right patient, etc	
Register entry		
Patient specific documentation		
Disposal / recording arrangements for any unused portion		

**Register** Some organisations may want to consider specific SOPs relating to register keeping  
 Record document management  
 Retention of hard copies/back-up of e-records

<b>Individual patient supplies</b>		
	Legal and clinical check of prescription	
Assembly	Removal from cupboard	
	Manipulation	
Patient / representative	Checking right patient, etc	
	ID arrangements	
Register entry		
Prescription forms	Arrangements for sending to relevant NHS Authority eg NHSBSA	

<b>Disposal –</b> needs to include agreed Record keeping requirements		
Unused portions		
Out of date stock		
Excess	Disposal	
	Legal return to main store	
Individually prescribed		
Patient Own		

Denaturing		
Authorised witnesses if required		
Disposal		

**Illicit substances**

Local guidance on removal, storage, recording, reporting

**Incidents**

Reporting mechanisms  
Review procedures

<b><u>Audit</u></b>	
By whom	
Format	
Frequency	
Reporting route	
Record Management	



**Sharing best practice:**

The following people played a key part in developing the SOP guidance and have good practice in their fields. You may wish to share examples of good practice or experience with your peers.

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