
# SAFER MANAGEMENT OF CONTROLLED DRUGS:

# GUIDANCE ON STANDARD OPERATING PROCEDURES FOR CONTROLLED DRUGS

**Department of Health**
**Gateway Reference: 7585**

**January 2007**

## DH INFORMATION READER BOX

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|---|---|
| Policy | Estates |
| HR / Workforce | Performance |
| **Management** | IM & T |
| Planning | Finance |
| Clinical | Partnership Working |

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| **Document Purpose** | Best Practice Guidance | | |
| **ROCR Ref:** | | **Gateway Ref:** | 7585 |
| **Title** | Safer management of controlled drugs: Guidance on standard operating procedures for controlled drugs | | |
| **Author** | Department of Health | | |
| **Publication Date** | January 2007 | | |
| **Target Audience** | PCT CEs, NHS Trust CEs, SHA CEs, Care Trust CEs, Foundation Trust CEs , Medical Directors, Directors of Nursing, Allied Health Professionals, GPs | | |
| **Circulation List** | | | |
| **Description** | Best practice guidance on standard operating procedures for the use and management of controlled drugs | | |
| **Cross Ref** | n/a | | |
| **Superseded Docs** | n/a | | |
| **Action Required** | n/a | | |
| **Timing** | **n/a** | | |
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| **For Recipient's Use** | | | |

## 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 Heath 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**

| **Receiving Into organisation / unit** | | **Comment** |
|---|---|---|
| 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<br>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 | | |

| **Transfer within organisation** | | |
|---|---|---|
| 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) | |

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

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| **Prescribing** | 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 | |

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|---|---|---|
| **Administration** | | |
| 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 | | |

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

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|---|---|---|
| **Individual patient supplies** | | |
| | 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 | |

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

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| Denaturing | | |
| Authorised witnesses if required | | |
| Disposal | | |

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| **Illicit substances**<br>Local guidance on removal, storage, recording, reporting |

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| **Incidents**<br>Reporting mechanisms<br>Review procedures |

| **Audit** | |
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| 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.

| Sector | Name | Title | E-mail | Address | Telephone |
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| Acute Care | Pippa Roberts | Director of Pharmacy and Medicines Management | pippa.roberts@whnt.nhs.uk PA : Debra.Jones@whnt.nhs.uk | Wirral Hospital NHS Trust, Arrowe Park Road, upton, Wirral CH49 5PE | 0151 604 7476 Internal ext 2058 |
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| Primary Care | Heather Gray | Primary Care Contracting | heather.gray@seherts-pct.nhs.uk | South East Herts PCT , 1-4 Limes Court, conduit Lane, Hoddesdon, Herts, EN11 8EP | 01992 706120 |
| Primary Care | Iben Altman | Community Health Services Pharmacist | Iben.altman@esbh.nhs.uk | Sussex Downs and Weald PCT, PCT headquarters, 36-28 Frairs Wlak, lewes, East sussex BN7 2PB | 01273403523 |

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