Optum in association with
Lincolnshire Clinical Commissioning Groups

Policy on the Development of Standard Operating Procedures (SOPs) for the Safe and Secure Handling of Medicines

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Policy on the Development of Standard Operating Procedures (SOPs) for the Safe and Secure Handling of Medicines

Version Control Sheet

Version	Section/Para /Appendix	Version/Description of Amendments	Date	Author/Amended by
1			Nov 10	Sharon Hayler
2	Whole document	Minor amendments throughout to reflect change in organisations from April 2013	Nov 12	Sharon Hayler
3	P4	Updated link to website	Dec 14	Sharon Hayler
	P6	Removed bullet point referring to DSQS guidance	Dec 14	
	P8	References updated	Dec 14	
	Front page	Update logo to reflect new organisation	Jan 15	
4	Whole document	Updated to reflect new Optum MMO service	Mar 17	Sandra France Sharon Hayler
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Contents

i. Version control sheet
ii. Policy statement

Section		Page
1	Introduction	5
2	Standard Operating Procedures	5
3	Development of Standard Operating Procedures	6
4	Authorisation	7
5	Implementation	7
6	Audit	8
7	References	8
Appendices		
1	Template for Standard Operating Procedures	9

Policy on the Development of Standard Operating Procedures (SOPs) for the Safe and Secure Handling of Medicines

Policy Statement

Background	The purpose of this policy is to implement a co-ordinated and standardised approach to all Standard Operating Procedures involving medicines and their use.
Statement	This policy provides advice and guidance on the development and authorisation of Standard Operating Procedures for the safe and secure handling of medicines.
Responsibilities	Managers and service leads are responsible for ensuring that Standard Operating Procedures are in place for all clinical situations involving the handling of medicines. Standard Operating Procedures must be reviewed and updated at least once every 12 months and whenever procedures are amended.
Training	Managers and service leads are responsible for ensuring that any staff training needs are met to ensure implementation of this policy. Training should be provided to ensure that all staff working to Standard Operating Procedures are competent to do so.
Dissemination	Lincolnshire Clinical Commissioning Groups Website: http://lincolnshire-pacef.nhs.uk/lincolnshire-prescribing-and-clinical-effectiveness-forum-pacef
Resource implication	This policy has been developed in line with national and local guidance documents supporting the production of Standard Operating Procedures for the safe and secure handling of medicines.

POLICY ON THE DEVELOPMENT OF STANDARD OPERATING PROCEDURES FOR THE SAFE AND SECURE HANDLING OF MEDICINES

1. Introduction

1.1 This policy describes the process to be used for the development and authorisation of Standard Operating Procedures (SOPs) for the safe and secure handling of medicines.

1.2 Since January 2005, pharmacists working in hospital and community areas have had to develop and work to SOPs covering all aspects of work carried out in the dispensary.

1.3 General practices providing dispensing services are advised to produce SOPs which cover all areas of work undertaken in the dispensary. These SOPs should satisfy the requirements of the Dispensary Services Quality Scheme (DSQS).

1.4 To comply with clinical governance requirements, healthcare professionals are required to put processes in place for risk management and harm minimisation. The requirement for SOPs is part of the strategy to assure quality within medicines management.

1.5 Developing and working to SOPs will standardise the approach, ensure quality and provide an audit trail.

1.6 A robust and consistent approach is needed for SOP development to ensure compliance with the relevant organisational policy for the Safe and Secure Handling of Medicines.

2. Standard Operating Procedures

2.1 A Standard Operating Procedure (SOP) is a document which describes the responsibilities and the procedures, including audit, necessary to safely and accountably manage any set of processes (in this case) around the management of medicines.

2.2 A SOP defines the responsibilities, competencies, training and performance standards expected of staff involved in that activity. It provides a step-by-step guide to a procedure ensuring a consistent approach to the activity covered by the SOP.

2.3 SOPs provide a means by which medicines can be accounted for at each stage of the supply process, providing an audit trail to minimise the risk of harm to patients or staff and reduce the incidence of theft or fraud.

2.4 The benefits of SOPs include:

- Ensuring that good consistent practice is achieved at all times.

- Avoiding confusion over who does what, where and when.
- Clear statements as to the accountabilities and roles of all staff involved in the process.

2.5 In all clinical situations involving the handling of medicines there are statutory, professional or good practice requirements to have SOPs in place.

- SOPs are required in all NHS premises where Controlled Drugs (CDs) are handled and in all premises providing services under contract to the NHS (e.g. general practice and community pharmacy).
- The Optum Policy for the Safe and Secure Handling of Medicines states that in all service areas / health care settings where medicines are handled, SOPs must be in place to clearly describe the processes involved.

3. Development of Standard Operating Procedures

3.1 SOPs should be written by a member of staff who is familiar with the procedures to be covered by the SOP.

3.2 All SOPs should be written according to a standard format. A template document is attached in Appendix 1.

3.3 SOPs may take the form of an algorithm, bullet points, or as detailed information.

3.4 Some service areas may want to have a SOP for each individual task involved, whereas other service areas may find that they can have a single SOP covering several processes.

3.5 The SOP should contain the following:

- Title of the procedure
- Purpose
- Scope
- Responsibilities of the staff working to the SOPs and the manager responsible for the service in which the SOPs are to be used.
- When and how the procedure should be performed.
- Date of review (usually one year from the issue date)
- Name of author
- Reference number
- For details of what is required in a SOP for controlled drugs, see the relevant organisation's Controlled Drugs Policy.

3.6 The Optum Medicines Management Optimisation Service can be contacted for advice when a SOP is being developed involving the use of medicines.

3.7 SOPs should comply with all other relevant legislation and policies, for example:

- Health and Safety at Work Act
- COSHH regulations
- Medicines Act 1968

- Misuse of Drugs Act 1971
- Misuse of Drugs Regulations 2001

3.8 SOPs should be:

- Specifically written for the premises involved. SOPs covering the same procedures may vary within the same service or GP practice if used at different sites.
- Dependent on the competence of the staff working to the SOP
- Applicable at all times
- Available at all times

3.9 SOPs should cover all aspects of risk management and they should include audit trails for all processes covered by the SOP.

3.10 SOPs should highlight the accountabilities and roles of all staff working to the SOP.

4. Authorisation

4.1 The author of the document and the service manager who is responsible for the service/procedure for which the SOP has been devised should sign the completed SOP.

4.2 SOPs developed by independent contractors should be approved for use within their own setting.

4.3 SOPs developed within GP practices to cover the dispensing process should be authorised for use by the named GP accountable for dispensary services.

4.4 All SOPs generated by NHS organisations must be formally approved by the relevant specialist committee, in line with any organisational guidance for procedural documents.

5. Implementation

5.1 All staff involved in the procedure should sign the SOP to say they have read and understood the SOP and agree to act in accordance with its requirements.

5.2 It is the responsibility of the service manager who has approved the SOP to ensure that all staff are aware that the SOP is in place.

5.3 The service manager will arrange for any necessary training to meet the competencies required to undertake the procedures covered by the SOP.

5.4 SOPs should be used as training tools for new members of staff.

5.5 A copy of the SOP should be kept in each department or clinical area where it will be used.

5.6 All staff working within the standard operating procedure are responsible for identifying any deficiencies in the SOP and notifying their line manager/service manager.

5.7 It is the service manager's responsibility to ensure the SOP remains current with reference to national or local guidance and legislation and to review the SOP if any changes have occurred. There may also be a requirement for a review if there are changes in service delivery.

5.8 All SOPs should be reviewed and updated by the service manager/author at least once every 12 months. This review and update ensures the procedures outlined within the SOP are workable and reduces the risk of deficiencies or ambiguities which could render the process unsafe.

5.9 When a SOP is no longer required it is the service manager's responsibility to ensure all the relevant staff are informed.

6. Audit

6.1 At regular intervals the service manager should audit the use of the SOP. Following audit, the results should be used to amend the SOP, if necessary, to reflect current local practice and processes.

References

Developing and Implementing Standard Operating Procedures for Dispensing, November 2007, Royal Pharmaceutical Society.

Optum Policy for the Safe and Secure Handling of Medicines, March 2017.

Arden&GEM CSU Policy Relating to the Prescribing, Supply, Storage and Disposal of Controlled Drugs in Primary Care, March 2016.

Dispensary Services Quality Scheme. Supplementary guidance for revisions to the GMS contract 2006/07, NHS Employers and BMA. Available at: http://bma.org.uk/practical-support-at-work/gp-practices/service-provision/prescribing/dispensary-services-quality-scheme.

The Statement of Financial Entitlements (Amendment) (No 5) Directions 2006, 25 September 2006, Department of Health. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215044/dh_134302.pdf.

APPENDIX 1

Name of Standard Operating Procedure

Version:	
Approved by (Committee name):	
Date approved:	
Name of originator/author:	
Name of approving committee/responsible individual:	
Date issued:	
Review date:	
Target audience:	
Distributed via:	

Name of Standard Operating Procedure (SOP)

Version Control Sheet

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1				
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Name of Standard Operating Procedure (SOP)

Contents

iii. Version control sheet
iv. Policy statement

Section **Page**

Name of Standard Operating Procedure

SOP Statement

Background

Statement

Responsibilities

Training

Dissemination

Resource implication

STANDARD OPERATING PROCEDURE
(INSERT NAME OF SOP)

SOP comes into effect	
SOP Review date	
Purpose	In this section state the reason for developing the SOP. This must include complying with legislation and/ or national or local guidelines if applicable. Outline the purpose to be achieved by the SOP e.g. to outline the storage and supply of medicines
Scope	Outline the scope of the SOP. For example the SOP covers the storage and supply of medicines but not the administration.

Author Signature: Date:	Name: Position:
Approval Signature: Date:	Name: Position: Service manager **Has responsibility for authorising the use of the SOP and ensuring it complies with any relevant legislation that may cover the procedures detailed within.**

Responsibilities Staff	Outline the responsibilities of the staff who will operate within the SOP. **All staff working within the standard operating procedure are responsible for identifying any deficiencies in the SOP and notifying their line manager accordingly.** **All staff have a duty of care under the Health and Safety at Work Act 1974. Staff should also be familiar with the organisation's Whistle- Blowing Policy and should be able to share concerns without fear of recrimination.** **All staff have a responsibility to access, be familiar with and comply with all policies relating to this SOP.** **Staff must always practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct if applicable.** **All staff have a responsibility to report near misses, adverse incidents and serious untoward incidents as detailed in the organisation's Incident Reporting Policy.**

Responsibilities Manager	Outline the responsibilities of the manager. It may be necessary to have more than one section to cover managerial responsibility if the procedures cover more than one staff group or if there is more than one manager sharing responsibility for the service covered by the SOP. **It is the responsibility of the manager to inform their staff of the implementation of the SOP and to ensure that the necessary training has been undertaken to enable staff to carry out safely the procedures detailed in the SOP.** **It is the responsibility of the manager to ensure all staff have access to all policies that relate to their place of work and role within the organisation.**

All staff who will be working to this SOP should sign below to say they have read and understood the SOP and agree to act in accordance with its requirements.

Name	Job Title	Signature	Date

STANDARD OPERATING PROCEDURE FOR (INSERT NAME OF SOP)

Procedures

In the sections below, detail a step-by-step account of the procedure stating how and when it should be done and by whom.

N.B The examples contained below should be used as a guide as to the type of detail that is required in a SOP. It is not possible to include examples of every type of SOP that may need to be developed, but examples that may apply in general practice have been included.

For SOPs covering prescription handling:

- Patient details are checked and confirmed.
- The patient or their representative has signed the reverse of the form if required.
- Prescription charges are collected or patient exemptions are checked.
- The patient or their representative is advised of waiting times and procedures for collection if returning at a later time.
- Assembly and labelling of the required medicine.
- Accuracy checking procedure.
- Record keeping and completion of documentation.

For SOPs covering supplies made via a PGD:

- Safety and clinical effectiveness check.
- Assembly and labelling of required medicine or product. Where possible medicines should be issued in their original packs or pre packs.
- Accuracy checking procedure.
- Provision of advice to the patient.
- Transfer of the medicine or product to the patient.
- Record keeping and completion of documentation.

For SOPs for record keeping for Controlled Drugs:

- Details of who can accept deliveries of controlled drugs.
- Details of where and how the CDs are stored and whose responsibility this is.
- Details of the entry that needs to be made in the controlled drug register- date of receipt, name and address of the supplier, quantity received and name, form and strength of the drug.
- Details of the checks that will be made on this process.
- Details of regular stock checks that are carried out including details of frequency and whose responsibility this is.
- Details of the process steps that are taken if an error occurs.

For SOPs covering collection of a Controlled Drug:

- Detail of which grade of staff is able to hand over supplies of a controlled drug.
- Steps taken to confirm the identity of who is collecting the controlled drug e.g. patient, patient's representative or another health care professional.
- Details of records that are kept when a CD is collected and where these details are recorded.
- Steps taken if staff are unable to verify the identity of the person collecting the CD.
- Steps taken if the CD is not collected within a specified time period.
- Details of the appropriate information to be given to the patient or the patient's representative including details on the administration of the controlled drug, any side effects that might occur and details of any adverse events that might occur which might require contacting a doctor or another health care professional.
- Steps taken to check the understanding of the information provided.

References: