

Section 4: Documentation and Record Keeping

Date Commenced		Name		Role	
<h3>Review of Pharmacy Documentation and Record Keeping</h3> <p>The purpose of this section is to review whether appropriate records are in place, and these are accurately maintained and regularly reviewed.</p>					

Controlled Drugs (CD) Register							
1	Is the CD register retained at the pharmacy for 2 years (from the date of the last entry)?				Yes	No	
2	Select three schedule 2 CDs that are recorded in the CD Register:						
	Page Number	Schedule 2 CD	Stock Balance in CD Register	Stock Balance in CD Safe	Balance Verified as correct?		
		1.			Yes	No	
		2.			Yes	No	
		3.			Yes	No	
If any discrepancy was noted, record the steps taken to (i) investigate and (ii) rectify the discrepancy:							
3	How often are stock balances recorded in the CD register checked against the physical stock of controlled drugs in the CD safe?						
<p>Note: The frequency of balance checks may vary depending on the frequency of CDs dispensed, methadone dispensing, previous stock balance discrepancies etc.</p> <p>Frequency _____</p>							

4	Using the same three schedule 2 controlled drugs selected, review the entries in the CD Register for these schedule 2 controlled drugs for the past three months:						
		1: _____		2: _____		3: _____	
	Are all entries made on the day to which they relate (or the following day)?	Yes	No	Yes	No	Yes	No
	Are all entries made in chronological order?	Yes	No	Yes	No	Yes	No
	Are running stock balances accurately maintained for all entries?	Yes	No	Yes	No	Yes	No
	Is a date recorded for every entry made?	Yes	No	Yes	No	Yes	No
	Is the patient's name and address recorded for every supply made?	Yes	No	Yes	No	Yes	No
	Is the prescriber's name recorded for every supply made?	Yes	No	Yes	No	Yes	No
	Is the quantity received / supplied recorded for every entry made?	Yes	No	Yes	No	Yes	No
	Is the wholesaler's name and address recorded for every supply received?	Yes	No	Yes	No	Yes	No
Are all errors corrected by a marginal / footnote which is dated and signed by the pharmacist?	Yes	No	Yes	No	Yes	No	
If any discrepancies or omissions were noted, please record details:							
5	Are records of the witnessed destruction of all date-expired schedule 2 controlled drugs available at the pharmacy?					Yes	No

Review of Prescription Register (Daily Audit / Dispensing Report)		
6	Review the last two weeks of prescription registers available at the pharmacy:	
	Is there a prescription register available for every day the pharmacy was open?	Yes No
	Where the prescription register is maintained as a computer print-out, is it printed, signed and dated by a pharmacist on the day to which it relates, or within 24 hours?	Yes No
	For the same two week period, review entries in the prescription registers and check to see if the following required details are recorded for the entries reviewed:	
	Date on which product was supplied	Yes No
	Name / quantity / form / strength of product supplied	Yes No
	Name of prescriber (and address, if not known to pharmacist)	Yes No
	Name and address of patient	Yes No
	Date written on prescription	Yes No
	If Emergency Supply at request of patient:	
	– Reason for the emergency supply	Yes No
	– Previous prescriber (and address, if not known to pharmacist)	Yes No
	– Previous supplying pharmacy (where applicable)	Yes No
	If any discrepancies or omissions were noted, please record details:	
7	Is the prescription register retained at the pharmacy for 2 years (from the date of last entry or date of printing)?	Yes No

Medication Error Management (including Near Misses)		
8	Are all members of staff familiar with the pharmacy's medication error management system?	Yes No
9	Are records of all medication errors (i.e. errors which reach the patient) systematically recorded and maintained in the pharmacy?	Yes No
10	How regularly are medication error records reviewed by the supervising pharmacist? Frequency: _____ Record details of reviews carried out:	
11	Are errors reported to the supervising and superintendent pharmacist(s)?	Yes No
12	Select one error Record for Review	
	What actions are taken to ensure that the impact to the patient, of any error, is minimised?	
	a) does the record clearly outline the detail of the error that occurred, including any contributing factors	Yes No
	b) does the record clearly outline the corrective actions taken to ensure that the impact to the patient is minimised?	Yes No
	c) does the record clearly outline the preventative actions identified and implemented to prevent recurrence of errors?	Yes No
	d) have all the actions identified been completed?	Yes No
	How are preventative actions identified and implemented to prevent recurrence of errors?	
	a) does the record clearly outline the detail of the error that occurred, including any contributing factors	Yes No
	b) does the record clearly outline the corrective actions taken to ensure that the impact to the patient is minimised?	Yes No
	c) does the record clearly outline the preventative actions identified and implemented to prevent recurrence of errors?	Yes No
	d) have all the actions identified been completed?	Yes No
13	Are records of 'near misses' (i.e. medication errors which do not reach the patient) systematically recorded and maintained in the pharmacy?	Yes No
14	Are records of 'near misses' regularly reviewed by the supervising pharmacist? Frequency:	Yes No

15	<p>How are lessons learnt, corrective actions and preventative actions from errors and near misses communicated with the whole pharmacy team?</p> <p>Record details:</p>
-----------	--

Expiry Date Management (including Management of Waste Medicines)		
16	<p>How often are expiry dates of medicines checked at the pharmacy?</p> <p>Note: all areas of the pharmacy where medicines are stored must be included in expiry date checks e.g dispensary, fridge, medicines counter, storage areas and CD safe etc.</p> <p>Frequency: _____</p> <p>Date of last check: _____</p>	
17	Are records of expiry date checks maintained at the pharmacy?	Yes No
18	<p>Are out of date medicines segregated from 'live' stock?</p> <p>Segregated storage location: _____</p>	Yes No
19	<p>Are patient-returned medicines segregated from 'live' stock?</p> <p>Segregated storage location: _____</p>	Yes No
20	<p>How are out of date and patient returned medicines disposed of?</p> <p>Waste management company: _____</p> <p>Date of last collection: _____</p>	

Confidentiality			
21	Do you have a confidentiality policy in place?	Yes	No
22	Are all staff trained in the policy, and are records of this maintained?	Yes	No
23	Does the pharmacy have arrangements in place to manage confidential waste?	Yes	No

Delivery (only complete this section if your pharmacy provides a delivery service)			
24	For each delivery of medicines made to a patient using a delivery system, does the pharmacist first assess whether the request for delivery is appropriate?	Yes	No
25	For each delivery of medicines made to a patient using a delivery system, does the pharmacist first assess whether or not the necessary review, including patient contact and counselling, can be achieved without face to face contact with the patient / carer?	Yes	No
26	When delivering medicines to patients on foot of a prescription are you, as supervising pharmacist, satisfied that the delivery system ensures the following:		
	Full compliance with obligations relating to a full therapeutic review carried out on each and every occasion that a prescription is delivered.	Yes	No
	The pharmacist is satisfied that the patient / carer has sufficient information on the use, storage and disposal of their medicine(s).	Yes	No
	The delivery method is secure, safe and prompt, and access to medicines and confidential information is restricted to authorised personnel only.	Yes	No
	The delivery method maintains the integrity of the medicines and prevents their deterioration while in transit.	Yes	No
	An itemised, verifiable audit trail is in place, which assures the security of the medicine from when it leaves the pharmacy until it is signed for by the patient/ carer.	Yes	No
	The delivery system incorporates the actions to be taken in the case of a failed delivery.	Yes	No
	If any of the above is not fully satisfactory, please record details of concerns / issues identified:		

Compliance Assessment – Documentation and Record Keeping

Having completed the review, please consider the statements listed below and select the level of compliance that you think best represents your pharmacy

Compliant:	
<input type="checkbox"/>	Pharmacy records, including the CD register and prescription register, are consistently maintained in accordance with legislative requirements. Regular reviews of pharmacy records support this.
<input type="checkbox"/>	All medication errors and near misses are recorded and reviewed. Corrective and preventative actions are implemented by the pharmacy team.
<input type="checkbox"/>	Clear, documented procedures for the management and destruction of medicines are in place at the pharmacy, including out of date and patient returned medicines.
<input type="checkbox"/>	The security and privacy of sensitive personal information is assured in accordance with data protection guidance.
<input type="checkbox"/>	The pharmacy's delivery service fully meets the requirements of PSI guidance.

Mostly Compliant:	
<input type="checkbox"/>	Pharmacy records are mostly maintained in accordance with legislative requirements.
<input type="checkbox"/>	Medication errors and near misses are recorded and reviewed and some corrective and preventative actions implemented.
<input type="checkbox"/>	Procedures are in place for the management and destruction of medicines at the pharmacy but are not consistently implemented.
<input type="checkbox"/>	Procedures are in place to assure the security and privacy of sensitive personal information but are not consistently implemented.
<input type="checkbox"/>	The pharmacy's delivery service mostly meets the requirements of PSI guidance.

Partially Compliant:	
<input type="checkbox"/>	Pharmacy records are partially maintained in accordance with legislative requirements.
<input type="checkbox"/>	Some medication errors and near misses are recorded but these are not consistently reviewed and corrective / preventative actions are not identified or implemented.
<input type="checkbox"/>	Procedures are in place for the management and destruction of medicines at the pharmacy but do not reflect the operation of the pharmacy.
<input type="checkbox"/>	Procedures are in place to assure the security and privacy of sensitive personal information but do not reflect the operation of the pharmacy.
<input type="checkbox"/>	The pharmacy's delivery service partially meets the requirements of PSI guidance.

Non-Compliant:	
<input type="checkbox"/>	Pharmacy records are not maintained in accordance with legislative requirements.
<input type="checkbox"/>	No medication errors and near misses are recorded or reviewed.
<input type="checkbox"/>	Procedures are not in place for the management and destruction of medicines at the pharmacy.
<input type="checkbox"/>	Procedures are not in place to assure the security and privacy of sensitive personal information.
<input type="checkbox"/>	The pharmacy's delivery service does not meet the requirements of PSI guidance.

When you have completed this, move on to the Action Plan Booklet

Notes:

The content of this document may be reproduced free of charge in any medium, as long as it is reproduced accurately and not in a misleading context. This material must be acknowledged as the Pharmaceutical Society of Ireland (PSI - The Pharmacy Regulator) copyright, and the document title specified. © PSI 2019