journey to change

NHS
Tees, Esk and Wear Valleys
NHS Foundation Trust

Public – To be published on the Trust external website

Medicines – Retention of Records

PHARM-0002-013-v3

Status: Approved

Document type: Procedure

Overarching policy: Medicines Overarching Framework (PHARM-0002)

Contents

1 Introduction

This procedure supports our goal to co-create a great experience for our colleagues, by providing a workplace that is fit for purpose.

We do this by ensuring that records relating to the management of medicines in the Trust are retained for the minimum period required by law and/or guidance, according to the record type.

2 Purpose

Following this procedure will help the Trust to:-

- Comply with legislation and/or guidance regarding the minimum retention period for records relating to medicines management, while…..
- Complying with data security legislation and/or guidance regarding retention of patient identifiable information

3 Who this procedure applies to

This procedure applies to all staff involved in:

- handling of paperwork and emails relating to the approval, prescribing, ordering and supply of medicines
- providing advice to clinicians in response to queries about the use of medicines in specific patients

The procedure has been reviewed in consultation with the Pharmacy Leadership Team

The procedure aligns to the Trust value of RESPONSIBILITY, in terms of complying with legislation and guidance relating to retention of information.

4 Related documents

This procedure describes what you need to do to implement the retention of records section of the Medicines Overarching Framework

The Medicines Overarching Framework defines the compliance requirements for safe, secure and appropriate handling of medicine which you must read, understand and be trained in before carrying out the procedures described in this document.

5 Retention of records

Records relating to medicines must be retained for the **minimum** periods detailed below. These retention periods reflect the importance of this information for legal, audit and business purposes

Type of record	Retention Period (Years)	Place of record retention
Ward/Dept stock top up sheets and stock orders	2 years from date of last entry	Ward / Dept / Pharmacy
Delivery notes	2 years from date of delivery	Ward / Dept /
Non-stock requisition forms	2 years from date of ordering	Ward / Dept / Pharmacy
Copies of individualised prescription orders / leave & discharge prescriptions / outpatient prescriptions	2 years from date of last entry	Ward / Department
Controlled drugs order books	2 years from date of last entry	Ward or Dept
Controlled drugs registers (includes destruction records)	7 years from date of last entry	Ward or Dept
Controlled drugs transport/delivery notes	2 years from date of delivery	Ward or Dept/ Pharmacy
Drug prescription and administration record (including all chart variations)	8 years minimum	Patient's medical notes
MI enquires relating to patients	Minimum 8 years Minimum 25 years for paediatric, obstetric and Mental Health enquires Electronic database (MI Databank) records should be kept permanently	Pharmacy
FP10 usage and issue sheets	5 years	Pharmacy
Recalls and Drug alerts	5 years	Pharmacy
Individual named patient request forms (single application form)	As per MI enquiry	Pharmacy
Drug & Therapeutics Committee agendas, letters, minutes, drug submissions etc.	20 years	Pharmacy (electronic)

5.1 Retention of prescriptions in the medical notes

Where inpatient, discharge and outpatient prescriptions are held within the patient's medical notes, these must be retained for a minimum of 8 years after the conclusion of treatment. However, this retention period increases as follows if the prescriptions relate to the treatment of:

Children and young people	Records must be retained until the patient's 25th birthday or 26th if young person was 17 at conclusion of treatment, or for 8 years after patient's death if death occurred before 18th birthday.
Mental disorders	Records must be retained for 20 years after no further treatment is considered necessary, or 8 years after the patient's death if the patient died whilst still receiving treatment.

5.2 Storage of pharmacy records

All pharmacy records must be retained in a secure location.

5.3 Destruction of pharmacy records

Pharmacy records must be treated as controlled stationery and destroyed in a confidential manner by shredding.

6 Definitions

Term	Definition
Controlled drugs	• Medicines / products which are subject to the Misuse of Drugs Act and Regulations in relation to supply, possession and safe custody
FP10	• NHS prescription form used by community teams to prescribe medication for community patients, and by inpatient wards to obtain urgent supplies of medication outside the normal process
MI	• Medicines Information

7 How this procedure will be implemented

- This procedure will be published on the Trust's intranet and external website.
- Line managers will disseminate this procedure to all Trust employees to whom it is relevant through a line management briefing.

7.1 Training needs analysis

Staff/Professional Group	Type of Training	Duration	Frequency of Training
Nil			

8 How the implementation of this procedure will be monitored

Auditable Standard/Key Performance Indicators		Frequency/Method/Person Responsible	Where results and any Associate Action Plan will be reported to, implemented and monitored; (this will usually be via the relevant Governance Group).
1	All records retained for the minimum period	Ad-hoc checks in dispensaries by lead pharmacy assistant	PLT

9 References

This document refers to the following policy: SPS East of England recommendations for retention of pharmacy records 2020-2021

Publications used to provide the source for the recommendations:

- Records Management Code of Practice for Health & Social Care, Jul 2016
- Misuse of Drugs Regulations 2001
- A guide to good practice in the management of controlled drugs in primary care (England) v3.1, updated 1 Oct 2010.
- Guidance for the safe custody of controlled drugs and drug precursors in transit, Home Office Sept 2013
- Safer management of controlled drugs: a guide to good practice in secondary care (England). Dept of Health, October 2007.
- PSI IDTS 2010/45
- Good Distribution Guide
- Medicines (pharmacies/responsible pharmacist) Regulations 2008 (SI 2008/2789).
- Limitation Act 1980
- EU Guide on Good Distribution Practice (part of the Orange Guide).
- Duthie report 2005
- Safe management of healthcare waste (version 2.0), Dept of Health & Environment Agency, 2012.
- Article 9 of Directive 2003/94/EC.
- Article 17 of Directive 2005/28/EC for Clinical trials
- Wholesaler Dealers EU Guide on Good Distribution Practice
- RSPGB ethics guide
- Guidance note 14
- HSC 1999/053
- Article 51 (3) of Directive 2001/83
- HTM02-01, Part B, Chapter 6
- The Human Medicines Regulations 2012 (regulation 253 (5))
- Veterinary medicines regulations 2009 (SI 2297).
- The Human Medicines Regulations 2012 (regulation 170).
- Terms of service of Pharmacists – Schedule 4, part 2, para 18 (b) to regulation 11(1)(a)(i) of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.
- The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 Direction 5(1)(l); 7(1)(n); 10(2)(d) and 12(5)(e).
- Clinical Standards Committee, Faculty of Sexual and Reproductive Healthcare (FSRH) of the Royal College of Obstetricians and Gynaecologists.
- VAT regulations 2005 for invoices

10 Document control (external)

To be recorded on the policy register by Policy Coordinator

Date of approval:	22 July 2021 (publishing delayed – published 05 January 2022)	
Next review date:	01 August 2024	
This document replaces:	PHARM-0002-013-v2	
This document was approved by:	Name of committee/group	Date
	Drug & Therapeutics Committee	22 July 2021
This document was ratified by:	Name of committee/group	Date
	n/a	
An equality analysis was completed on this document on:	22 July 2021	
Document type	Public	
FOI Clause (Private documents only)	n/a	

Change record

Version	Date	Amendment details	Status
3	22 Jul 2021	Full scheduled review – minor changes only (e.g. removal of reference to faxes). Checked against national guidance. Transferred to new template	Approved

Appendix 1 - Equality Analysis Screening Form

Please note; The Equality Analysis Policy and Equality Analysis Guidance can be found on the policy pages of the intranet

Name of Service area, Directorate/Department i.e. substance misuse, corporate, finance etc.	Pharmacy					
Policy (document/service) name	Medicines – retention of records					
Is the area being assessed a…	Policy/Strategy		Service/Business plan		Project	
	Procedure/Guidance			X	Code of practice	
	Other – Please state					
Geographical area covered	Trustwide					
Aims and objectives	To ensure that records relating to medicines management in the Trust are retained for the minimum period required by law & guidance					
Start date of Equality Analysis Screening (This is the date you are asked to write or review the document/service etc.)	22nd July 2021					
End date of Equality Analysis Screening (This is when you have completed the equality analysis and it is ready to go to EMT to be approved)	22nd July 2021					

You must contact the EDHR team if you identify a negative impact - email tewv.eandd@nhs.net

1. Who does the Policy, Service, Function, Strategy, Code of practice, Guidance, Project or Business plan benefit?

Patients – retention of their treatment records for the minimum period required by law/guidance
Pharmacy services – retention of medicines ordering/supply/advice records for the minimum period required by law/guidance

2. Will the Policy, Service, Function, Strategy, Code of practice, Guidance, Project or Business plan impact negatively on any of the protected characteristic groups below?

Race (including Gypsy and Traveller)	No	**Disability** (includes physical, learning, mental health, sensory and medical disabilities)	No	**Sex** (Men, women and gender neutral etc.)	No
Gender reassignment (Transgender and gender identity)	No	**Sexual Orientation** (Lesbian, Gay, Bisexual and Heterosexual etc.)	No	**Age** (includes, young people, older people – people of all ages)	No
Religion or Belief (includes faith groups, atheism and philosophical belief's)	No	**Pregnancy and Maternity** (includes pregnancy, women who are breastfeeding and women on maternity leave)	No	**Marriage and Civil Partnership** (includes opposite and same sex couples who are married or civil partners)	No

Yes – Please describe anticipated negative impact/s
No – Please describe any positive impacts/s

3. Have you considered other sources of information such as; legislation, codes of practice, best practice, nice guidelines, CQC reports or feedback etc.? **If 'No', why not?**	**Yes**	**X**	**No**	

Sources of Information may include: • Feedback from equality bodies, Care Quality Commission, Equality and Human Rights Commission, etc. • Investigation findings • Trust Strategic Direction • Data collection/analysis • National Guidance/Reports		• Staff grievances • Media • Community Consultation/Consultation Groups • Internal Consultation • Research • Other (Please state below)

4. Have you engaged or consulted with service users, carers, staff and other stakeholders including people from the following protected groups?: Race, Disability, Sex, Gender reassignment (Trans), Sexual Orientation (LGB), Religion or Belief, Age, Pregnancy and Maternity or Marriage and Civil Partnership

Yes – Please describe the engagement and involvement that has taken place

Patient rep and carer rep sit on Drug & Therapeutics Committee

No – Please describe future plans that you may have to engage and involve people from different groups

5. As part of this equality analysis have any training needs/service needs been identified?					
No	Please describe the identified training needs/service needs below				
A training need has been identified for;					
Trust staff	No	Service users	No	Contractors or other outside agencies	No
Make sure that you have checked the information and that you are comfortable that additional evidence can provided if you are required to do so					

Appendix 2 – Approval checklist

	Title of document being reviewed:	Yes/No/ Not applicable	Comments
1.	**Title**		
	Is the title clear and unambiguous?	Y	
	Is it clear whether the document is a guideline, policy, protocol or standard?	Y	
2.	**Rationale**		
	Are reasons for development of the document stated?	Y	
3.	**Development Process**		
	Are people involved in the development identified?	Y	
	Has relevant expertise has been sought/used?	Y	
	Is there evidence of consultation with stakeholders and users?	Y	
	Have any related documents or documents that are impacted by this change been identified and updated?	Y	
4.	**Content**		
	Is the objective of the document clear?	Y	
	Is the target population clear and unambiguous?	Y	
	Are the intended outcomes described?	Y	
	Are the statements clear and unambiguous?	Y	
5.	**Evidence Base**		
	Is the type of evidence to support the document identified explicitly?	Y	
	Are key references cited?	Y	
	Are supporting documents referenced?	Y	
6.	**Training**		
	Have training needs been considered?	Y	
	Are training needs included in the document?	NO	Training needs – nil
7.	**Implementation and monitoring**		

	Title of document being reviewed:	Yes/No/ Not applicable	Comments
	Does the document identify how it will be implemented and monitored?	Y	
8.	**Equality analysis**		
	Has an equality analysis been completed for the document?	Y	
	Have Equality and Diversity reviewed and approved the equality analysis?	Y	
9.	**Approval**		
	Does the document identify which committee/group will approve it?	Y	
10.	**Publication**		
	Has the document been reviewed for harm?	Y	
	Does the document identify whether it is private or public?	Y	public
	If private, does the document identify which clause of the Freedom of Information Act 2000 applies?	n/a	