Guidance on Retention and Secure Storage of Pharmacy Records (England) 2020-21

Introduction

This document is a collation of information on legal requirements and national guidance for retention of pharmacy records. It is intended as a comprehensive but concise first point of reference for pharmacy professionals and as an aid to local decision making. In some circumstances more than one piece of legislation is relevant to a specific record or situation and requirements of each may appear to conflict with one another. Where no relevant legal requirement or national guidance has been identified, a 'best practice' recommendation may be given. If you are in any doubt as to the interpretation of any of the requirements or recommendations in this document, consult the original document from which it was obtained. Organisations may also have their own local policy, recommendations or requirements.

In all circumstances the final decision about the most appropriate course of action to take over retention and storage of pharmacy and medicines-related records rests with the Chief Pharmacist of the organisations concerned.

2. Scope

This guidance is applicable to pharmacy departments and services commissioned by or contracted by the NHS. It applies to both paper and electronic records. In most cases requirements which apply to England also apply to the Devolved Administrations but there are also some differences such as for Patient Group Directions.

3. Guidance

This document is aligned to the DHSC Records Management, NHS Code of Practice 2016(1) and also refers to a number of other pharmacy records and retention requirements/good practice recommendations.

3.1. Trusts should consider the following key good practice points:

- The retention periods shown are minimum requirements and a longer period may be required according to local policy.
- There are specific requirements covering certain groups of patients e.g. Maternity, Children and Young People, Mental Health, and Oncology.
- Paper records may be stored in a designated secondary facility, covered by appropriate procedures for archiving and subsequent disposal (see Appendix 1)

- Paper records may be scanned provided the correct procedures are followed in committing the record to digital image (see Appendix 1)
- Electronic records must supported by audit trails, which record details of all additions, changes, and deletions.
- Procedures should be in place to cover disposal of any records to ensure compliance with Freedom of Information Legislation.
- Confidentiality should be ensured at every stage of the documentation cycle, including its destruction.

4. Storage of records: approved Places of Deposit

3.3.1. Paper records

NHS organisations considering the deposit of records selected for permanent preservation are advised to contact the National Advisory Services at the National Archives for guidance on this process and up to date information concerning relevant Places of Deposit. The list of contact addresses for Places of Deposit for public records appointed to hold NHS records can be found by contacting the National Advisory Services, The National Archives, Kew, Richmond, Surrey TW9 4DU, nas@nationalarchives.gov.uk

3.3.2. Scanned records

Paper records may be scanned provided the correct procedures are followed in committing the record to digital image. Such records must be correctly labelled and archived, records kept of the destruction of the original paper record, and the scanned copy legally admissible in a court of law if necessary.

Further information can be found at Records Management Code of Practice for Health and Social Care 2016

http://webarchive.nationalarchives.gov.uk/20160729133355/http://systems.hscic.gov.uk/infogov/iga/rmcop16718.pdf and here

BSI BIP 0008 Legal Admissibility and Record Retention www.thecabinetoffice.co.uk/page28.html

3.3.3. Electronic records

Electronic records must be backed up appropriately. In practice, retention of these records is indefinite because they are electronic.

4. Relevant legislation and published guidance.

	Record	Unique record	Reason for keeping	Recommended minimum period	Derivation of recommendation and comments
RECORDS RELEVANT TO ALL PHARMACY SETTINGS					
Clinical governance	Competency/training records	Yes	Reference	Clinical training: until 75th birthday or duration of employment plus 6 yrs whichever is longer. Statutory/mandatory training: 10yrs after training completed Other training: 6 yrs after training completed.	Records Management Code of Practice for Health and Social Care. July 2016 (RMCoP 2016) [1]
	Clinical audit	Yes	Reference	5 yrs	RMCoP 2016 [1]
	External quality control records	Yes	Audit	12 yrs	RMCoP 2016 [1]

	Record	Unique record	Reason for keeping	Recommended minimum period	Derivation of recommendation and comments
	Patient surveys	Yes	Audit	5 yrs	RMCoP 2016 [1]
	Patient complaints	Yes	Audit	10 yrs	RMCoP 2016 [1] Where a legal action has commenced, keep as advised by legal representative.
Clinical interventions	Minor clinical interventions	Yes	Audit	2 yrs	Best practice. Two part paper form recommended, original to be added to the patient record, duplicate kept for 2 yrs. Entries made on an electronic database should be reviewed after 2 yrs, if no longer needed, destroy or permanently delete record.
	Significant clinical interventions	Yes	Audit	For 10 yrs after the death of the patient	Entries should be recorded directly in the patient notes / PMR.
	Medicines Reconciliation (MR) documentation	Yes	Audit	2 yrs	See note 5.
Controlled drugs (CD)	CD register (pharmacy, ward, theatre)	Yes	Legal	2 yrs from date of last entry.	Misuse of Drugs Regulations 2001 [2] Controlled drugs: safe use and management [5] Electronic CD register - see note 2. In Secure Environments Schedule 3 CDs are also recorded in CD registers (PSI IDTS 2010/45 [6]; Professional Standards for optimizing medicines for people in secure environments [7])
	CD prescriptions for NHS patients (incl out-patient and TTA / TTO and those for patients treated under any NHS-commissioned care service)	Yes	Legal	2 yrs	Misuse of Drugs Regulations 2001 [2]: All CD prescriptions should be kept for 2 yrs. (Secure Environments see Note 9).
	Private CD prescriptions	Yes	Legal	Send to NHSBSA	The Misuse of Drugs (Amendment No. 2) Regulations 2006 [8]: Private prescriptions for Schedule 2 and 2 CDs must be sent to the relevant agency. Relevant agency - NHS Business Services Authority (NHSBSA)
	Record of destruction of patient's own CDs	Yes	Good practice	7 yrs	Controlled drugs: safe use and management [5] Professional guidance on the safe and secure handling of medicines [9]: Patient's own drugs can be removed and/or disposed of with the agreement of the patient or in the interest of the patient/general safety.
	CD ward orders or requisitions	No	Legal	2 yrs	Misuse of Drugs Regulations 2001 [2] All CD prescriptions should be kept for 2 yrs. Keep in original paper form or computerised form.
	Copy of signature for CD ward order or requisition	Yes	Validation	Duration of employment	Safer management of controlled drugs: a guide to good practice in secondary care (England) [4] Copy of signature of each authorized signatory should be available in the pharmacy department.
	Requisitions, orders, order books, delivery note or other record of receipt	No	Legal	2 yrs or 2 years from date of last entry for record books.	Misuse of Drugs Regulations 2001 [2]: All CD prescriptions should be kept for 2 yrs. Includes hospice requisitions, health and justice services & others not sent to NHSBSA. See note 3.
	Invoices	Yes	Legal	6 yrs	Controlled drugs: safe use and management [5] Limitation Act 1980 [10]: 6 complete tax years.

	Record	Unique record	Reason for keeping	Recommended minimum period	Derivation of recommendation and comments
	CD transportation by road vehicle	Yes	Audit	Driver ID: 3 mths. Recipients' signature: 6 mths in original form; then up to 18 mths in reproducible form. Orders, signed orders, requisitions, private prescriptions: 2 yrs.	Guidance for the safe custody of controlled drugs and drug precursors in transit [11]
	Extemporaneous CD preparation worksheets	Yes	GMP	5 yrs	5 years under GMP, but consider keeping for longer due to consumer liability legislation – see note 6.
	Aseptic CD worksheets - adult paediatric	Yes Yes	GMP GMP	5 yrs 5 yrs	5 years under GMP, but consider keeping for longer due to consumer liability legislation – see note 6.
	CD clinical trials information	Yes	GMP	5 yrs	This may be longer for some trials.
Patient safety incidents	Dispensing error records/incidents & associated stats (not serious incidents)	Yes	Audit	10 yrs for minor harm incidents, 1 yr plus current for no harm incidents	RMCoP 2016 [1] and best practice. Recommendations only apply to paper records; entries made on electronic databases should be kept permanently.
	Dispensing incidents resulting in disability or death (serious incidents)	Yes	Legal	20 yrs	RMCoP 2016 [1]
Recalls/drug alerts	Recall documentation	Yes	Audit	5 yrs	Recommendations from the Good Distribution Guide - especially for those with wholesale dealers licence.
Responsible pharmacist	Responsible pharmacist records/log book	Yes	Legal	At least 5 yrs	Medicines (pharmacies/responsible pharmacist) Regulations 2008 [12] Can be in hard copy or electronic.
Superseded documents	Clinical protocols	No	Reference	25 yrs	RMCoP 2016 [1]
	Departmental & organisational Policies, strategies, standard operating procedures (SOPs)	No	Reference	Life of organization plus 6 yrs	RMCoP 2016 [1]
	Patient Group Directions (PGDs)	No	Reference	For adults aged 18 yrs and over: 8 yrs (10 yrs in cases of implant insertion). For a child: until the 25th birthday or for 8 yrs after a child's death or 10 years in the case of implant insertion	Retaining PGD documentation [13]
Stock handling and transfer	Picking tickets/delivery notes	Yes	Reference	3 months	A "reasonable" period of time - for verification of order only.
	Old order books	No	Audit	2 yrs	Current financial yr plus 1.
	Invoices	Yes	Legal	6 complete tax yrs	Limitation Act 1980 [10]. See note 4.

	Record	Unique record	Reason for keeping	Recommended minimum period	Derivation of recommendation and comments
	Wholesale dealing records	Yes	GDP	5 yrs	EU Guide on Good Distribution Practice (part of the Orange Guide).
Fridge	Fridge temperature	Yes	GMP/GDP	1 yr or longer for sites holding a Wholesale Dealers Licence	Refrigerator records to be kept for the life of any product stored therein – particularly vaccines. For sites subject to GDP inspection (licensed wholesaler) records should be kept for 5 years as with other GDP records. SOPs detailing actions required in the event of fridge failure should also be available.
Waste medicines	Destruction of patients' own drugs (excluding controlled drugs) [See Note 10]	Yes	Audit	6 months	Professional guidance on the safe and secure handling of medicines [9]: Patient's own drugs can be removed and/or disposed of with the agreement of the patient or in the interest of the patient/general safety.
	Waste - Non-hazardous Transfer notes	Yes	Legal	2 yrs	Safe management of healthcare waste [14]
	Waste - hazardous Consignment notes	Yes	Legal	3 yrs	Safe management of healthcare waste [14]
HOSPITAL PHARMACY-SPECIFIC RECORDS (also applicable to Secure Environments - see Note 8)					
Clinical Trial	IMP batch production records	Yes	GMP/GCP	5 yrs after end of the trial	Article 9 of Directive 2003/94/EC [15] UK implementing directive: The Medicines for Human Use (Clinical Trials) Regulations 2004 [16]
	Protocols	Yes	Reference	5 yrs after end of the trial	See note 1.
	Dispensing records	Yes	Reference	5 yrs after end of the trial	-
	Destruction records	Yes	GMP	5 yrs after end of the trial	The sponsor of the trial is responsible for the destruction of unused and/or returned trial material. Therefore any destruction must be authorized in writing and a dated destruction certificate supplied to the sponsor.
	Preparation or dispensing of ATMPs	Yes	Reference	30 yrs	ATMP = Advanced Therapeutic Medicinal Products. Detailed guidelines on good clinical practice specific to advanced therapy medicinal products [17]
	CD clinical trials information	Yes	GMP	5 yrs	This may be longer for some trials.
	Clinical drug trials or other studies out with the Clinical Trials Directive	Yes	GCP / Against future claims	5 yrs after end of the trial	For example - metabolic studies, nutritional studies. Article 17 of Directive 2005/28/EC for Clinical trials [18], otherwise good practice. UK implementing directive: The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 [19]
Medicines Information	Question asked, information search & answer	Yes	Reference and audit	8 yrs (25 yrs for child, obstetrics and mental health enquiries)	RMCoP 2016 [1] Recommendations apply to previous paper based enquiry forms. Electronic enquiry database (MIDatabank) should be kept permanently.
	Q&A documentation	Yes	Reference and audit	8 yrs (25 yrs for child, obstetrics and mental health)	RMCoP 2016 [1]
	MI audit records	Yes	Reference	5 yrs or 2 audit cycles, whichever is longer	RMCoP 2016 [1] and best practice. To ensure the previous two audit reports are available to inform any recommendations of a current audit.
	Peer review records	Yes	Reference	At least 1 yr	Best practice. To allow any trends to be tracked. Can also be used as a basis for "peer

	Record	Unique record	Reason for keeping	Recommended minimum period	Derivation of recommendation and comments
					discussion" for revalidation.
	Patient Information Leaflets (PILs) produced in-house	Yes	Reference	6 yrs after last use	RMCoP 2016 [1]
	Newsletters / Bulletins and other miscellaneous "news" communications	No	Reference	6 yrs after distribution	RMCoP 2016 [1]
Miscellaneous	Doctors/nurses signatures	Yes	Reference	Duration of contract + 1 yr	Destroy 1 yr after termination of employment. GDPR Principle (e): Storage limitation [20]: Do not keep personal data for longer than required.
	Self-administration records	No	Reference	8 yrs	RMCoP 2016 [1] and best practice. Keep the record in the patient's medical notes after discharge.
	Superseded IV drug administration monographs	No	Reference	10 yrs	Best practice. May provide useful background information for dealing with complaints regarding IV administration of drugs.
	Drug & Therapeutics Committee agendas, letters, minutes, drug submissions etc.	No	Reference	20 yrs	RMCoP 2016 [1]
	Medicines administered under Patient Specific Direction (PSD), Patient Group Direction (PGD) or National Protocol	Yes	Legal	The individual's clinical record is maintained for 8 years for an adult and up to the 26th birthday if given to a child under the age of 18. For implants in an adult records must be kept for 10 years).	https://www.sps.nhs.uk/articles/recommendations-for-retention-of-records-of-covid-19-vaccination-administered-under-a-patient-specific-direction-psd/
Prescriptions	To take away (TTA / TTO) prescriptions	No	Audit	2 yrs	EPR will eventually hold all details - duplication of record held in notes, see note 5.
	Out-patient prescriptions	No	Audit	2 yrs	EPR will eventually hold all details - duplication of record held in notes, see note 5.
	Private prescriptions (excluding private CD prescriptions – see Controlled Drugs	Yes	Audit	2 yrs	MEP Edition 42 July 2018 [21]. (Secure Environments see Note 8 The Human Medicines Regulations 2012 (regulation 253 (5)) [22]
	Unlicensed medicines dispensing record	Yes	Legal	5 yrs	The supply of unlicensed medicinal products ("specials") [23] The Human Medicines Regulations 2012 (regulation 170 (1)) [22] Record of the batch number should also be kept.
	Parenteral nutrition (PN)	No	Audit	2 yrs	Original valid prescription should be kept in patient's notes.
	Chemotherapy prescriptions	No	Reference	2 yrs after last treatment	EPR will eventually hold all details - duplication of record held in notes.
	Clinical drugs trials or other studies out with the Clinical Trials Directive	Yes	GCP / Against future claims	5 yrs after end of the trial	For example - metabolic studies, nutritional studies. Article 17 of Directive 2005/28/EC for Clinical trials [18], otherwise good practice. UK implementing directive: The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 [19]
	Immunoglobulins/blood products	Yes	Reference	30 yrs	RMCoP 2016 [1]:

	Record	Unique record	Reason for keeping	Recommended minimum period	Derivation of recommendation and comments
					Blood Bank Register should be kept for 30 years; although there is no specific recommendation for immunoglobulins and other blood products not supplied via Blood Bank, it seems reasonable to require the same retention time. To allow full traceability of all blood products used.
	Pads of FP10s usage & issue sheets	Yes	Legal	3 yrs	Security of prescription forms guidance [24] Note: The referenced document has been superseded. However, the current document (Management and control of prescription forms: a guide for prescribers and health organisations [25]), does not include the relevant information.
Purchase Orders	Order & delivery notes	No	Audit/GDP	2 yrs or 5yrs	Current financial yr plus 1. See note 4. Wholesaler Dealers EU Guide on Good Distribution Practice requires retention of all records for 5yrs.
	Ward stock order sheets	Yes	Audit	2 yrs	Current financial yr plus 1.
	Ward pharmacy requests	No	Reference	1 yr	Record of what was requested by ward pharmacist - unlikely benefit after 12 mths.
	Ad hoc forms (e.g. dispensing request forms to stores)	No	Reference	3 months	Reasonable period and current practice.
Stock Control	Stock check lists	Yes	Audit	18 months	Records Management NHS Code of Practice [26] Note: Although the referenced document has been withdrawn, the up to date version (RMCoP 2016 [1]) does not include the relevant information.
Technical services	Any Quality Control (QC) documentation including certificates of analysis	Yes	GMP	5 yrs or 1 yr after expiry date of batch	Whichever is longer. Article 51(3) of Directive 2001/83/EC [27] UK implementing legislation: Human Medicines Regulations 2012 (regulation 170 (1)) [22]
	Environmental monitoring results	Yes	GMP	1 yr after expiry dates of products	RMCoP 2016 [1] If an electronic record, keep for 10 yrs then review & destroy if no longer needed.
	Validation/training of operators	Yes	GMP	Duration of employment + 5 yrs after leaving	Keep in personal portfolios.
	Paediatric products worksheets	Yes	GMP	5 yrs	5 years under GMP, but consider keeping for longer due to consumer liability legislation – see note 6.
	Chemo/aseptic worksheets	Yes	GMP	5 yrs	5 years under GMP, but consider keeping for longer due to consumer liability legislation – see note 6.
	PN worksheets	No	GMP	5 yrs	5 years under GMP, but consider keeping for longer due to consumer liability legislation – see note.
	Resuscitation box worksheet	Yes	GMP	1 yr after expiry of longest dated item	If sold or supplied across a legal boundary, 5 yrs or 1 yr after expiry date of batch as per GMP, whichever is longer.
	Batch production records	Yes	GMP	5 yrs	5 years under GMP, but consider keeping for longer due to consumer liability legislation – see note 6.
	Extemporaneous dispensing records	Yes	GMP	5 yrs	5 years under GMP, but consider keeping for longer due to consumer liability legislation – see note 6.
	Raw material request; packaging and control forms	Yes	GMP	At least 5 yrs	Part of batch record, 5 years under GMP, but consider keeping for longer due to consumer liability legislation – see note 6.
	Validation of equipment & maintenance logs	Yes	GMP	11 yrs	RMCoP 2016 [1] Starts after decommissioning of the equipment.

	Record	Unique record	Reason for keeping	Recommended minimum period	Derivation of recommendation and comments
	Cleaning logs	Yes	Reference	1 yr	Best practice.
	Medical gas pipeline systems – High hazard permits to work	Yes	Reference	For the lifetime of the pipeline system	Health Technical Memorandum 02-01: Medical gas pipeline systems [28]
Unlicensed medicines	Any purchased unlicensed medicines (ULM) documentation	Yes	Legal/Against future claims	5 yrs	Record of the batch number should also be kept. The supply of unlicensed medicinal products ("specials") [23] The Human Medicines Regulations 2012 (regulation 170 (1)) [22]
COMMUNITY PHARMACY-SPECIFIC RECORDS					
Dispensing	Patient Medical Record (Patient Medication Record)	Yes	Legal	For 10 yrs after the death of the patient	RMCoP 2016 [1]
	Private prescriptions (excluding private CD prescriptions – see Controlled Drugs) or any non-FP10 prescriptions for patients being treated under an NHS-commissioned care service	Yes	Legal	2 yrs	MEP Edition 42 July 2018 [21] Human Medicines Regulations 2012 (regulation 253 (5)) [22]
	POM register	No	Legal	2 yrs from last entry	Human Medicines Regulations 2012 (regulation 253 (5)) [22]
	POM-V & POM-VPS records of receipt and supply	Yes	Legal	At least 5 yrs	Veterinary medicines regulations 2009 [29] Must keep all documents relating to the transaction. Specific requirements for what information must be included.
ERDS	Any service for which patient nomination of a pharmacy remains a requirement [See note 11]	Yes	Audit	6 mths after the last prescription the collected	Best practice.
Specials and unlicensed medicines	Extemporaneously prepared on the premises with internal quality control.	Yes	Legal	5 yrs	Human Medicines Regulations 2012 (regulation 170) [22] See note 6.
	Extemporaneously prepared by another pharmacy/company with external quality control	No	Legal	5 yrs	Human Medicines Regulations 2012 (regulation 170) [22] Should have the certificate of conformity including the source of the product; to whom, and the date on which the product was sold or supplied; the prescriber's details; the quantity of each sale or supply; the batch number of the product; details of any adverse reactions to the product sold or supplied. See note 4.
	Unlicensed imports	No	Legal	5 yrs	
Equality Act	Record of assessment and outcome of patients' needs in respect of medicines	Yes	Reference	For as long as the assessment remains valid, plus 1 yr	Best practice Assessment should be repeated if patient circumstances change.
Public Health Campaigns	Evidence of participation in local public health campaigns	Yes	Reference	2 yrs	Where requested by the commissioner to do so, records should be kept to demonstrate compliance with Terms of service of NHS Pharmacists (Schedule 4, part 2, paragraph 18(b)) to regulation 11(1)(a)(i) of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 [30].

	Record	Unique record	Reason for keeping	Recommended minimum period	Derivation of recommendation and comments
Advanced services	Medicines Use Review (MUR)	Yes	Legal	2 yrs	Records can be kept electronically or in hard copy. The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 [31]: Keep records for at least two years after the date on which the consultation to which the record relates is carried out (Direction 5(1)(l)).
	New Medicine Service (NMS)	Yes	Legal	2 yrs	Records can be kept electronically or in hard copy. The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 [31]: Keep records for at least two years after the date on which the service intervention is completed or discontinued (Direction 7(1)(n)).
	Stoma appliance customisation	Yes	Legal	12 months	Records can be kept electronically or in hard copy. The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 [31]: Keep records for at least 12 months or such longer period as the commissioner may reasonably require (Direction 10(2)(d)).
	Appliance use review	Yes	Legal	12 months	Records can be kept in electronically or in hard copy. The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 [31]: Keep records for at least 12 months or such longer period as the commissioner may reasonably require (Direction 12(5)(e)).
	Community Pharmacy Seasonal Influenza Vaccination Advanced Service (CPSIVAS)	Yes	Legal	8 yrs for adults aged 18 yrs and over (2 yrs for consent forms for post payment verification)	Records can be kept in electronically or in hard copy. The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 consolidated directions and subsequent amendments [32] Service Specification: Community pharmacy seasonal influenza vaccination advanced service [33]: All relevant paperwork must be managed in line with RMCoP 2016 [1] Pharmacy Influenza Vaccination PGD [34]: Keep records for audit purposes and post payment verification.
	NHS Community Pharmacy Consultation Service	Yes	Interim best practice recommendation	2 yrs	Records can be kept in electronically or in hard copy. All relevant records must be managed in line with RMCoP [1]
Enhanced services, locally commissioned services or private services **See Note 7**	Sexual Health service forms	Yes	Audit	<u>For adults aged 18 yrs and over</u>: 8 yrs (10 yrs in cases of implant or device insertion). <u>For a child</u>: until the 25th birthday or 26th birthday if the patient was 17 yrs when treatment finished. In cases of implant or device insertion, keep the record as above or for 10 years, whichever is longer.	RMCoP 2016 [1] Service standards for record keeping [36] NB The longest licence period for a contraceptive device is 10 years.
		No	Reference	Where individual patient records are kept by a sexual health team and a	

	Record	Unique record	Reason for keeping	Recommended minimum period	Derivation of recommendation and comments
				shorter minimum period for retaining records may be stated in the service level agreement.	
	Smoking cessation service	Yes	Audit	2 yrs	RMCoP 2016 [1]
	Supply of Smoking cessation therapy e.g. NRT not via FP10 or via PGD	Yes	Audit	2 yrs	RMCoP 2016 [1]
	Minor ailments service	Yes	Audit	2 yrs	Recommended best practice.
	Immunisation and vaccination records	Yes	Legal	For adults aged 18 yrs and over: 8 yrs. For a child: until the 25th birthday or 26th birthday if the patient was 17 yrs when treatment finished.	RMCoP 2016 [1]
	NHS health check	No*	Audit	2 yrs	Best practice [*If the results are forwarded to the patients GP]
		Yes**	Audit	2 yrs	Best practice [**Where results are not forwarded to the GP]
	Substance misuse service forms	Yes	Audit	2 yrs	Best practice
	Medicines administered under Patient Specific Direction (PSD), Patient Group Direction (PGD) or National Protocol	Yes	Reference	The individual's clinical record is maintained for 8 years for an adult and up to the 26th birthday if given to a child under the age of 18.	https://www.sps.nhs.uk/articles/recommendations-for-retention-of-records-of-covid-19-vaccination-administered-under-a-patient-specific-direction-psd/
Invoices and consent forms	All payment claims, invoices and patient consent forms relating to any advanced or enhanced service	Yes	Audit	6 complete tax years	VAT regulations 2005 [37] for invoices. Individual signed consent forms support the invoiced claim. NOTE: Enhanced service consent forms represent consent at the point in time the service is provided and are not proof of ongoing consent.
Other records	Any other records pertaining to individual patient care in community pharmacy not covered elsewhere in this document.	Yes	Audit	2yrs	Best practice. This recommendation only applies for paper records. It is accepted that, where appropriate, records relating to patient care (e.g. self-care, signposting, telephone queries) should be entered on the PMR, either directly or transferred from paper records. Entries made on the PMR should be kept permanently. For further guidance see Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet [Internet]. General Pharmaceutical Council; 2019 [38]

KEY
GMP = good manufacturing practice; GDP = good distribution practice; GCP = good clinical practice; MR = medicines reconciliation; MUR = medicines use review
Where GMP is given as the reason for keeping the record, this would be legally enforceable for all unlicensed medicines and for any manufacturing of medicines under an MHRA licence. Any reason for keeping other than 'legal' can be regarded as best practice.

Topic-specific Notes	
Note 1	The sponsor of the trial is responsible under current legislation for keeping trial records. All clinical trial records should be retained for a longer (up to 15 years) if required by the applicable regulatory requirement(s) or if needed by the Sponsor as per Annex 1 to Directive 2001/83/EC and GCP requirements EMA/CHMP/ICH/135/1995. Note: The provisions of Directive 2001/83/EC are brought into UK law by the Human Medicines Regulations 2012.The HMR 2012 do not, however, reproduce the detail of the 2001 directive, so the original directive text should be referred to.
Note 2	Once electronic CD registers are in widespread use, the Government intends to require anyone required to keep secure copies of a CD register for up to 11 years. (Department of Health. Safer management of CDs: Changes to the record keeping requirements, guidance for England only. Last revised February 2008)
Note 3	Every requisition, order or private prescription on which a CD is supplied must be preserved by the pharmacy department for a minimum of 2 years from the date on which the last delivery under it was made. Although the mandatory period for keeping requisitions is 2 years, health care organizations may wish to store them for longer periods, as cases often come to court at a much later date. Future regulations may increase the period of time for the storage of records. (Department of Health/RPSGB, Safer management of controlled drugs – a guide to good practice in secondary care. (England) Oct 2007). In secure environments that do not have an in-house dispensing pharmacy, HO advice is that CD requisitions are still required where the requisitioning organisation is a different legal entity to the supplier. The national CD requisition can be used but is not mandatory. HJ providers must ensure that a Practitioner (i.e. a medical Doctor) signs the requisition where this is needed to comply with the regulation.
Note 4	The 6-tax-years limit relates to disputes over simple contract (Limitation Act 1980). Manufacturers, and sometimes others involved in a product's supply chain, are liable for their products under the Consumer Protection Act 1987. Therefore, it is recommended to keep delivery notes or invoices for 11 years as product liability records – see note 6.
Note 5	Where the electronic system has the capacity to destroy records in line with the retention schedule, and where a metadata stub can remain demonstrating that a record has been destroyed, then the Records Management Code should be followed in the same way for electronic records as for paper records with a log being kept of the records destroyed. If the system does not have this capacity, then once the records have reached the end of their retention periods they should be inaccessible to users of the system and upon decommissioning, the system (along with audit trails) should be retained for the retention period of the last entry related to the schedule. (Records Management Code of Practice for Health & Social Care, Jul 2016)
Note 6	Consumer Protection Act (CPA) 1987 allows patients to claim for injury due to a defective product (medicine) up to 10 years after a medicine has been administered. Records of manufactured products (e.g. worksheets) can prove that the product was / was not defective. The prescription / other clinical records will only indicate that the patient was prescribed / dispensed an item but will not give any indication how the product was made and from what ingredients. If the problem is a contaminated ingredient, it is possible to partially pass the responsibility to the supplier of the defective ingredient. **Adult patients** (18 years and over) Keep manufacturing records for 11 years (10 years as part of CPA + 1 year best practice safety margin) **Paediatric patients** If a child suffers from a medications, they've got: • any time up to 3 years after their 18th birthday to sue in negligence (up until they're 21 years) • 10 years from taking the medicine to sue under CPA RMCoP 2016 states that records relating to children should be kept until the child's 25th birthday (26th birthday if 17 years old at time of treatment), unless there are other factors which indicate the record should be kept for longer. Therefore, in line with RMCoP recommendation, keep all paediatric manufacturing records for 25 years.
Note 7	For locally negotiated services, if the minimum retention period stated in the contractual arrangement of the service level agreement (SLA) exceeds the recommendations of this document contractors must adhere to the SLA.
Note 8	NHS England directly commissions healthcare in all residential Secure Environments (prisons, Immigration Removal Centres and Secure Training Centres). Prescriptions generated in these settings are therefore NHS prescriptions and not private prescriptions. The expectations for prescriptions and other record retention for these settings are in the main as for hospital settings. A wing or treatment room is considered equivalent to a hospital ward. Health and justice (HJ) prescriptions are all now held on the HJIS EPR system and thus retention of the actual hand signed prescription can be reduced to 3 months (please also see the RPS Professional Standards for optimizing medicines for people in secure environments 2017). The community pharmacy section of this document is also relevant where dispensing takes place in-house and where advanced services or additional enhanced services are delivered.
Note 9	In addition to retaining the CD prescription a copy of the current CD prescription (i.e. Schedule 2 and 3) for a patient should be available on patient transfer to another secure setting. To achieve this either a scanned e-copy or a hard copy transferred with the patient is needed. This is essential for enabling continuity of supply on transfer until the prescription is reviewed. (PSI IDTS 2010/45 and RPS Professional Standards for optimizing medicines for people in secure environments, Feb 2017).

Note 10	The T28 exemption from the Environment agency allows pharmacies and similar places to denature controlled drugs to comply with Misuse of Drugs Regulations 2001. https://www.gov.uk/guidance/waste-exemption-t28-sort-and-denature-controlled-drugs-for-disposal. NHSE&I may require evidence of valid exemption from some pharmacy contactors from whom they commission services.
Note 11	Patient nomination was previously required for EPS but is no longer under EPS4.
Note 12	For general information about data protection see Guide to Data Protection, ICO. https://ico.org.uk/for-organisations/guide-to-data-protection/

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If you have a specific question about any aspect of record retention or storage, please contact your local or Regional Pharmacy Medicines Information Service.

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