

Recommendations for the Retention of Pharmacy Records (England) 2019

	Record	Unique record	Reason for keeping	Recommended minimum period	Derivation of recommendation and comments
RECORDS THAT PERTAIN TO ALL PHARMACY SETTINGS					
Clinical governance	Competency/training records	Yes	Reference	Clinical training: until 75 th 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]
	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 10yrs after death of patient	Entries should be recorded directly in the patient notes / PMR.
Controlled drugs (CD)	CD register (pharmacy, ward, theatre)	Yes	Legal	2 yrs from date of last entry but if it contains records of destruction of CDs (including patient returns and out of date stock) then keep for 7 yrs	Misuse of Drugs Regulations 2001 [2] A guide to good practice in the management of controlled drugs in primary care (England) [3] Safer management of controlled drugs: a guide to good practice in secondary care (England) [4] 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])
	Hospital CD prescriptions (out-patient and TTA / TTO)	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)
	Destruction of patient's own CDs	Yes	Legal	7 yrs	Controlled drugs: safe use and management [5] Professional guidance on the safe and secure handling of medicines [9]:

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					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.
	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 Rx: 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]
	Policies, strategies, standard operating procedures (SOPs)	No	Reference	Life of organization plus 6 yrs	RMCoP 2016 [1]

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	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 25 th birthday or for 8 yrs after a child's death	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.
	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)	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]
COMMUNITY PHARMACY SPECIFIC RECORDS					
Dispensing	Patient Medical Record	Yes	Legal	For 10 yrs after the death of the patient	RMCoP 2016 [1]
	Private prescriptions (excluding private CD prescriptions – see Controlled Drugs)	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.
EPS2	Patient pharmacy nomination	Yes	Audit	6 mths after the last prescription the collected	Best practice. This also applies to patient authorisations for managed repeat systems.
Specials and unlicensed medicines	Extemporaneously prepared on the premises with <u>internal</u> quality control.	Yes	Legal	5 yrs	Human Medicines Regulations 2012 (regulation 170) [22] See note 6.
	Extemporaneously prepared by	No	Legal	5 yrs	Human Medicines Regulations 2012 (regulation 170) [22]

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	another pharmacy/company with external quality control				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	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]. We record on PharmOutcomes
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. Recorded on PharmOutcomes
Enhanced	Sexual Health service forms	Yes	Audit	Aged 18 yrs and over: 8 yrs	RMCOP 2016 [1]

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services, locally commissioned services or private services See Note 7				(10 yrs in cases of implant or device insertion). <u>For a child:</u> until the 25 th birthday or 26 th 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.	Service standards for record keeping [36] NB The longest licence period for a contraceptive device is 10 years. Recorded on PharmOutcomes
		No	Reference	Where individual patient records are kept by a sexual health team and a 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. Recorded on PharmOutcomes
	Immunisation and vaccination records	Yes	Audit	<u>For adults aged 18 yrs and over:</u> 8 yrs. <u>For a child:</u> until the 25 th birthday or 26 th 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]
	NHS health check	Yes**	Audit	2 yrs	Best practice [**Where results are not forwarded to the GP]
Invoices and consent forms	Substance misuse service forms	Yes	Audit	2 yrs	Best practice
	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. PMR entries should be kept permanently.

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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.

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)
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 <u>11 years</u> (10 years as part of CPA + 1 year best practice safety margin) Paediatric patients If a child suffers from a medication, they've got: <ul style="list-style-type: none"> 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 25 th birthday (26 th 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 <u>25 years</u> .
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).

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