Essex County Council Medicines Standards for Providers

MEDICINES STANDARDS FOR PROVIDERS[1]	
PUBLISHING DATE	**FEBRUARY 2022**
REVIEW DATE	**JANUARY 2025**
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[1] With acknowledgement to Mid Essex CCG Medicines Management Team

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1 Introduction

The Commissioner requires that organisations establish, document and maintain an effective system to ensure that medicines are handled in a safe and secure manner.

This standards document forms part of the contract for any organisation or contractor commissioned to provide services which include pharmaceutical or medicines management activities such as handling, purchasing, storing, transporting, prescribing, dispensing, administering and disposal of medication. This is in addition to specific contracts and documents. Adherence to the standards is monitored via the Quality and Clinical Governance processes and Contract monitoring processes.

Organisations will need to develop local policies and procedures to ensure that medicines are handled safely, securely and in accordance with the legislation, professional standards and best practice guidance that applies to their activities. Links to the relevant documentation are given for convenience but they are not exhaustive and providers are responsible for ensuring that they refer to the current version.

Providers are expected to have a formal arrangement in place for access to pharmaceutical advice to ensure there are robust governance processes in place for medication management and to support them in achieving these standards – this may be from an employed pharmacist or through an agreement with an organisation or individual.

Employers have a responsibility to ensure staff have an appropriate level of knowledge and ability to undertake the work with medicines safely and competently. Staff must evidence competency by having current accredited training certificates.

Training must be sourced from accredited providers.

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2 Handling medicines

The Commissioner expects providers to meet the standards of the relevant legislation and local and national guidance for the processes of ordering, storing, transport, supply, administration and disposal of medicines, including but not limited to those in the table below. Providers should satisfy themselves that their insurance policy provides suitable indemnification for the policies and procedures that are followed.

Standards
• Human Medicines Regulations 2012 • Controlled Drugs (Supervision of Management and Use) Regulations 2013 • Misuse of Drugs Act 1971 • Misuse of Drugs Regulations 2001 • Misuse of Drugs (Safe Custody) Regulations 1973 • The Health Act 2006 • Health and Social Care Act 2008 • The Equality Act 2010 • Environment Agency T28 – Sorting and Denaturing Controlled Drugs for Disposal • Royal Pharmaceutical Society Medicines, Ethics and Practice • Royal Pharmaceutical Society Medicines Optimisation: Helping patients to make the most of medicines Good practice guidance for healthcare professionals in England May 2013 • Professional Guidance on the Administration of Medicines in Healthcare settings Jan 2019 • Good Practice in Prescribing and Managing Medicines and Devices (GMC 2013) • DH Protocol for ordering, storing and handling vaccines • Control of Substances Hazardous to Health (COSHH) Guidance • Current good practice guidance issued by organisations including RPS, GPhC, MHRA, DoH, NICE, Home Office, NHS Patient Safety etc • The Safe and Secure Handling of Medicines: a team approach (Royal Pharmaceutical Society) • CQC Standards for Medicines Management Outcome 9 • CQC Regulation 12: Safe care and treatment • A Guide to Good Practice in the Management of Controlled drugs in Primary Care (National Prescribing Centre) • Service Standards for Sexual and Reproductive Healthcare

2.1 Handling medicines – additional points

2.1.1 Purchasing 'special order' products

Contractors will consider the cost to the NHS when purchasing 'special order' products which are not listed in the Drug Tariff and:

- Advise the prescriber of the cost and discuss alternatives
- Ensure that the quantity prescribed and ordered minimises waste
- Purchase from a supplier offering best value to the NHS. Information can be available from the local Clinical Commissioning Group (CCG) Medicines Management teams

2.1.2 Dispensing

- Medication will be supplied on a named patient basis whenever possible (except where 'bulk-prescribing arrangements are in place), and patients who wish to self-administer their medication will be supported to do so when it can be done safely. Patient specific prescriptions will not be used to top up stock.
- It is up to the patient or their representative to choose where their prescription is dispensed. Health professionals may provide signposting information on services and opening times but will not direct prescriptions to a particular supplier.

2.1.3 Prescription charges

Providers who supply medication which attracts a prescription charge will meet the requirements for collecting the appropriate charges or confirming exemption. This applies to certain medication supplied via Patient Group Direction (PGD) as well as on FP10.

2.1.4 Emergency Medicines

In settings where it is recommended that medication is held in case of medical emergency, there will be procedures in place to ensure safe and secure storage and regular recorded checks on expiry dates. Staff will be trained in the use of the medication and be aware of the location. There will be protocols on the use of the medication.

2.1.5 Transfer of medicines

Ensuring patient's own medicines are always transferred with the patient supports accurate medicines reconciliation, helps highlight medicines-related problems resulting in admission, reduces delayed and omitted doses when medicines need to be continued, reduces patient confusion and reduces medicines waste and unnecessary re-dispensing.
Providers should use appropriate bags or equivalent packaging when they need to send medication anywhere with patients to identify patients own drugs, support medicines reconciliation and minimise loss.

2.1.6 Patient's own drugs in compliance aids

Providers are expected to follow guidelines from NICE which cover medicines support for adults (aged 18 and over) who are receiving social care in the community. It aims to ensure that people who receive social care are supported to take and look after their medicines effectively and safely at home. It gives advice on assessing if people need help with managing their medicines, who should provide medicines support and how health and social care staff should work together.

The use of original packs of medicines with appropriate support is the accepted method of supplying medicines to patients in the absence of a specific need requiring a Medicines Compliance Aid (MCA)[2] as an adherence intervention.
There is insufficient evidence[3] to support the benefits of MCA in improving medicines adherence in patients, or in improving patient outcomes and the available evidence does not support recommendations for the use of MCAs as a default.

[2] MCAs or monitored dosage systems (MDS) are the terms used to describe a range of medicines storage devices divided into compartments for some solid oral medication

[3] https://www.cqc.org.uk/guidance-providers/adult-social-care/using-multi-compartment-compliance-aids-mcas-care-homes
https://www.nice.org.uk/guidance/ng67
https://www.birmingham.ac.uk/Documents/college-mds/haps/projects/cfhep/psrp/finalreports/PS025CHUMS-FinalReportwithappendices.pdf

Each patient's needs must be assessed by the dispensing pharmacist on an individual basis and any intervention must be tailored to the patient's specific requirements.
Request of a MCA must only be made when an assessment by a health professional (for example, a pharmacist) has been carried out, in line with the Equality Act 2010, and a specific need has been identified to support medicines adherence.

Compliance aids which have been filled by a community pharmacist or dispensing doctor and:

- allow identification of individual products
- are fully labelled
- are assessed as suitable by a suitably trained member of staff
- do not contain schedule 2 or 3 controlled drugs

should be treated as all other patient's own medication in line with local policy.

Compliance aids which have been filled by the patient or a family member will not be fully labelled to allow identification of the medicines. They may be used for self-administration after risk assessment, but medicines from them cannot be administered by a nurse or carer.

Self-administration by patients should be encouraged where appropriate to ensure that these skills are not lost.

2.1.7 Illegal substances

Providers will have in place a procedure for dealing with potential illegal substances and prescription drugs liable to abuse brought in to their premises by service users or other visitors.

2.2 The Mental Capacity Act

Assessment of the Customer's capacity to give their consent is vital. If the Customer's capacity is being challenged, an assessment must take place under the Mental Capacity Act. People with capacity must give consent each time medication is given. The records should clearly state action to be taken if circumstances change, and any specific preferences that have been identified relating to equality and diversity.

A Customer may have certain preferences relating to equality and diversity. These should be recognised at the assessment stage, arrangements made to accommodate them and relevant details recorded in the patient/client record

2.3 The Equality Act

Providers are expected to meet the requirements of The Equality Act 2010 by assessing patients and making appropriate adjustments to their services. Where this involves the provision of medicines compliance aids by community pharmacy contractors and dispensing doctors:

- Patient assessment and the selection of appropriate compliance aids (which include monitored dosage systems, reminder charts, easy open containers and large print labels) is a

decision for the contractor who dispenses that patient's prescriptions (usually the pharmacist)

- The duration of the prescription is a decision for the prescriber and where a prescriber considers that there is a clinical risk in a patient having more than a certain amount of medication in the house at any one time, they will issue prescriptions of the appropriate duration
- The requirement is to support the patient in managing their own medication

2.4 Controlled Drugs

The Provider shall ensure it has robust arrangements for the safe and secure use and handling of controlled drugs (CDs) in line with legislation, national regulations and guidance. Additionally the provider will allow the Commissioner and the NHS England Area Team Controlled Drugs Accountable Officer (CDAO) to access premises to conduct audits, inspections and investigations.

General

- It is the legal responsibility of the provider to acquire and evidence to the commissioner and Area Team CDAO that the necessary Home Office CD Licences are in place where stocks of Controlled Drugs are held
- CDAOs and CD leads will, within the framework of the NHS England CD Local Intelligence Network, share information regarding the management of CDs
- Organisations will have procedures in place to ensure that complaints, incidents and concerns relating to Controlled Drugs are brought to the attention of the appropriate CDAO and the commissioner. For designated bodies this will be their own CDAO, for others this will be the specified NHS England Area Team CDAO
- Serious concerns about any element of the management and use of controlled drugs should be reported to the Area team CDAO, the police, the Local Intelligence Network, the local Clinical Performance or equivalent group, the commissioner and / or the relevant regulatory body
- Destruction of out of date and unwanted stock CDs will be witnessed by one of the groups listed in the regulations
- Providers who administer CDs will have a procedure in place to cover the arrangements for the disposal of any unused portion of an injection. Where possible there should be a witness to this procedure
- Providers will have procedures in place to monitor inappropriate, unusual or excessive prescribing and report this to the commissioner and Area Team CDAO
- The Area Team CDAO and commissioner will monitor inappropriate, unusual or excessive CD prescribing by prescribers (including non-practice prescribers, non-medical prescribers and private prescribers). Providers will respond promptly to requests for information or clarification and requests for self-assessments
- Providers will allow access on request to check physical arrangements for storage, record keeping and management of CDs

3 Medicines Policy

The Provider will have a medicines policy which complies with local and national standards (e.g. CQC, NMC and RPS) and NICE Guidelines. The policy will include guidance on (this list is not exhaustive):

- Confidentiality
- Transfer of medication
- Training
- Out of hours procedures
- Communication
- Data sharing
- Record keeping
- Reporting of adverse reactions
- Incident reporting including processes of investigation, learning and sharing
- Safeguarding (The process requires that any notifiable safeguarding concerns are reported to the Care Quality Commission (CQC), local safeguarding bodies and the Commissioner)
- Medicines review and reconciliation
- Storage and Disposal of medicines
- Process for prompting, assisting and administering medicines

4 Prescribing

The Commissioner expects providers to meet the standards of the relevant legislation and local and national guidance for prescribing including but not limited to those in the table below.

Standards
• Human Medicines Regulations 2012 • Controlled Drugs (Supervision of Management and Use) Regulations 2013 • Misuse of Drugs Act 1971 • Misuse of Drugs Regulations 2001 • Misuse of Drugs (Safe Custody) Regulations 1973 • The Health Act 2006 • Health and Social Care Act 2008 • The Equality Act 2010 • European Community Directive 2001/83/EC • Royal Pharmaceutical Society Medicines, Ethics and Practice 36 • Nursing & Midwifery Council Standards for Medicines Management • Good Practice in Prescribing and Managing Medicines and Devices GMC 2013 • Guide to Medication Review (National Prescribing Centre, 2008) • Current good practice guidance issued by organisations including RPS, GPhC, MHRA, DoH, NICE, Home Office, NHS Patient Safety etc • CCG prescribing policies, guidelines, formularies • BNF guidance and individual product SPCs • A Guide to Good Practice in the Management of Controlled Drugs in Primary Care (National Prescribing Centre) • CQC Standards for Medicines Management Outcome 9

Standards
• NICE PSG001 Technical patient safety solutions for medicines reconciliation on admission of adults to hospital 2007 • Drug Misuse and Dependence: UK Guidelines on Clinical Management • Handling Medicines in Social Care (Royal Pharmaceutical Society) • National Prescribing Centre. (2004). *Good Practice Guide to Quality Repeat Prescribing* • National Prescribing Centre. (2008). *Medicines Reconciliation; A Guide to Implementation*

The arrangements for prescribing to patients of each service will be defined within the contractual framework for that service. Generally, where a consultant / specialist initiates a new medication, s/he will generally provide the first prescription in accordance with local agreements.

Transfer of care, shared care and sharing information with colleagues should follow GMC Guidance.

The Provider will have a Commissioner agreed process including timescales for response and resolution for dealing with prescribing queries. It is imperative, that patient care does not suffer and is not interrupted or delayed due to insufficient / inaccurate information being communicated.

4.1 Prescription forms

- Providers who use individual prescription forms will have Standard Operating Procedures in place which ensure that prescription stationery is handled to the standards specified in "Security of Prescription Forms Guidance" .
- Providers who use prescriptions sheets (e.g. Prescription and Medication Administration Records) and charts will give consideration to the security of blank sheets.
- Providers will have a process in place to manage incidents involving lost, stolen or forged prescriptions. If there is a need to notify local pharmacies to prevent fraudulent prescriptions being dispensed, the provider will notify the NHS England area team who will issue an alert to the relevant contractors.
- Providers using FP10s are responsible for the secure destruction of any unused prescriptions when prescribers leave their organisation
- Prescriptions will be written or computer-generated in line with guidance in the current BNF, and include dose and frequency.
- Prescriptions will include contact details which allow the prescriber to be contacted by the dispensing pharmacist if necessary.
- The process for handing out prescription forms to patients, their representatives or healthcare staff will take into account prescription security and patient confidentiality.
- Legal responsibility for prescribing lies with the prescriber who signs the prescription.
- Provider clinicians and staff should only recommend or prescribe medicines from the local Essex formulary/guidelines except when variance has been agreed with the Commissioner medicines management team.
- Robust, reliable and secure communication systems should be in place to ensure accurate and timely information about an individual patient's medication is available to the appropriate professionals responsible for his/her care.

4.2 Supply arrangements

- The provider must have in place robust ordering systems to ensure continuity of supply and to avoid requesting urgent repeat prescriptions or patients unable to access medication in a timely manner

4.2.1 Patient Group Directions

- Providers who are commissioned to deliver a service using PGDs will develop and operate those PGDs in accordance with current legislation, and the NICE Good Practice Guidance
- Organisations which are listed in legislation as able to authorise their own PGDs will do so
- Those organisations which are not listed in legislation as able to authorise their own PGDs will arrange authorisation by the Commissioner. Providers will submit PGDs in draft form for review by members of the Commissioning medicines management team before final approval within their own organisation
- Supply or administration of the medication must be carried out by the professional who is operating the PGD, it cannot be delegated to another member of the team
- Providers are expected to consider the arrangements for the purchase, storage and supply of medication packs as specified in PGDs for take away medication. Packaging and labelling will meet regulatory requirements
- Providers will ensure staff who operate the PGDs are competent and trained
- Prescription charges will be collected where applicable
- Where a provider adopts a PGD written by another organisation, for example a GP practice or community pharmacy adopts a PGD written by the Commissioner, the PGD will be signed by a governance lead or manager on behalf of the contractor. That person is responsible for the governance arrangements for the use of the PGD within their organisation, and ensuring that each practitioner who operates the PGD is suitably qualified and signed up to it individually at that organisation

4.2.2 Verbal orders

- Providers who administer medication will assess the risks associated with verbal orders, issued in an emergency to authorise the administration or discontinuation of a prescribed medication, and when they are used, have a governance framework in place to manage those risks.
- Where verbal orders are used, providers will have a procedure in place to ensure that they are issued by a prescriber, and received, recorded and acted on by a designated practitioner.
- The procedure will specify the duration for which a verbal order will apply, and the process for obtaining the prescriber's written instructions
- The procedure will cover other methods of receiving remote instructions such as fax, email and text if applicable.
- Controlled drug orders should not be accepted verbally or by fax.

4.3 Medication review and Medicines Reconciliation

Medication reviews take place in many settings and providers are encouraged to work together to provide a complimentary service.

The following are examples of reviews that a patient may receive:

- Clinical medication reviews in primary care (GP practices)
- Community Pharmacy Medicines Use Review (MUR)
- Appliance Use Review (AUR) -Community Pharmacy and Dispensing Appliance Contractors
- Dispensing Review of Use of Medicines (DRUM) (Dispensing practices)
- Community Pharmacy New Medicines Service (NMS)

For all types of review there will be a procedure in place which complies with the principles of medication review outlined in the Guide to Medication Review.

The review will include considering the discontinuation of medication which is no longer effective or adhered to.

4.3.1 Medicines Reconciliation

Providers should establish communication links with other providers including, general practitioners, care homes, and community pharmacies to ensure that adequate information about a patients medicines arrangements, (including any supplies of medicines) are transferred with the patient

There should be a policy for medicines management arrangements on admission including:

- Medicines Reconciliation policy in line with NICE requirements
- Arrangements for medicines history taking and medication review
- Communication with general practice
- Arrangements for medicines supply for emergencies
- Continuity of care

4.4 Duration of treatment

Prescriptions will be written for the duration that meets the patient's need and must be in line with local, national and legal guidance.

4.5 Prescribers

4.5.1 General

- Providers will ensure that their prescribers have access to clinical supervision, Continuing Professional Development (CPD), up to date information sources, relevant information about prescribing policies and practice
- Providers will have robust governance arrangements for assuring safe and effective prescribing and a Commissioner agreed process for the Commissioner to raise concerns
- Providers will ensure that prescribers are registered as prescribers with the relevant governing body, and that any restrictions on their prescribing are adhered to
- Providers will maintain a list of current prescribers with specimen signatures (which will be provided to the Commissioner if requested)
- Prescribers are responsible for ensuring that arrangements are in place for disease and drug monitoring when required

4.5.2 Non-medical prescribers

- Providers will have a policy to cover the activities of non-medical prescribing. The policy will include (as a minimum):
    - The governance arrangements for assuring safe and effective non-medical prescribing
    - Employer liability
    - Professional indemnity
    - DBS checks
    - Prescribing for self, family and friends
    - Repeat prescriptions
    - Off-label prescribing and unlicensed medicines
    - Regular reviews of prescribing and identification of CPD needs
- Non-medical prescribers will:
    - Be registered as prescribers with the relevant governing body and comply with their code of practice
    - Act as prescribers only when formally contracted to do so
    - Only issue prescriptions bearing their own name and professional registration number
    - Agree a scope of practice with their employer and prescribe within this scope only
    - Ensure that they are remain up to date with current legislation on prescribing and the safe management of Controlled Drugs

4.6 Formulary

Organisations will ensure that staff are aware of the Commissioners formulary, policies and prescribing guidelines and that they prescribe and advise within these parameters.

4.6.1 Nice guidance

- Providers are expected to comply with NICE Technology Appraisals
- The Commissioner and provider will determine collaboratively when and how NICE Clinical Guidelines, Quality Standards and Public Health guidance with medicines implications are to be implemented

4.6.2 Shared- and continuing- care agreements

- For drugs subject to a shared- or continuing-care protocol, specialists will continue prescribing until a patient-specific agreement has been put in place with the GP
- When a shared- or continuing-care agreement is in place, specialists and GPs will undertake the responsibilities outlined in the local protocol
- The Provider shall have systems in place to ensure that patients transferred to other care settings have an uninterrupted supply of medicines, and that information is provided to the patient, their GP and their carer

4.6.3 Unlicensed products

- Unlicensed drugs, or drugs used ‘off label’, will only be included in the formulary where there is a substantial body of published evidence and support from local clinicians.

- See MHRA current guidance.

4.6.4 Prescribing for covert administration

Providers who are involved in administering medication will consider current legal and best practice frameworks and make an assessment of the capacity (Mental Capacity Act) of the patient to refuse their medication before undertaking covert administration.

4.6.5 Homely remedies

Providers of residential and domiciliary care will have a policy on the treatment of minor ailments and the use of homely remedies and self-purchased medicines by their service users in line with NHS guidance.

4.6.6 Complementary medicines

Complementary medicines, e.g. aromatherapy, herbal, homeopathic remedies, are used for therapeutic purposes and require the same safeguards as with other medicines. They will only be prescribed when included on the appropriate formulary. Providers will have in place a procedure for dealing with Complementary medicines brought in to their premises by service users or other visitors.

4.6.7 Medicines for clinical trials

Providers will seek the appropriate ethics approval before undertaking clinical trials which should be conducted according to current Good Clinical Practice standards. Any trial which may result in additional activity or change to existing pathways will be agreed in advance with the commissioner.

Informed consent should be obtained before patients are included in any trial. It is the responsibility of the trial organiser to ensure that this is obtained.

5 Advice to patients

5.1 Promotion of self-care

- Providers will offer opportunistic brief interventions whenever appropriate to advise patients and service users on lifestyle measures that will enable them to get the best from their medication

6 Governance

Providers are expected to have governance arrangements in place appropriate to the services they provide. The following governance arrangements are not specific to medicines management and are not covered in detail in these standards:

- Information governance
- Performance management
- Complaints and incidents
- Record keeping
- Mental capacity
- Business continuity
- Safeguarding

- Consent
- Whistle-blowing
- Bribery
- Fraud
- Theft
- Audit

Providers should have access to specialist pharmacy services including Education and Training, Medicines Information, Quality Assurance, Clinical Pharmacy, and Community and Primary Care, and Procurement and Purchasing.

6.1 Standard Operating Procedures

- Providers will develop Standard Operating Procedures (SOPs) to describe the processes of handling and managing medicines for the services commissioned
- SOPs will be formally approved by the provider, and reviewed at regular intervals
- SOPs will indicate who is authorised to carry out each activity, what training is necessary, and what records will be kept

6.2 Working with industry

- Providers will adhere to national guidelines on working with the Pharmaceutical Industry or their own equivalent policy.
- The policy will apply to all employees including non-medical prescribers and non-clinical staff
- Samples of medicines and appliances will not be accepted by staff or made available to patients

6.3 Near miss errors and medication incidents

- Providers will maintain an error /medication incident log
- The log will be reviewed regularly and providers will be able to provide evidence that they have identified and acted on trends and put corrective action in place to prevent recurrence of errors /medication incidents.
- Number of medication incidents, trends and action plans should be shared with the Commissioner.

6.4 Adverse reactions

- Suspected adverse reactions to medicines, particularly black triangle medicines under intensive monitoring, can be reported to the MHRA by anyone including non-clinical staff and patients.
- Reports can be made online at www.yellowcard.gov.uk or using the form in the BNF

6.5 Medicines Safety alerts

Providers will have a process for receiving, acknowledging and acting on medicines safety alerts, including drug recalls, whether national or local and provide assurance of implementation to the commissioners if requested

6.6 Audit

- Providers will have a programme of audit in line with their organisation's clinical governance framework, their professional code of conduct, individual service specifications and their contractual requirements.

7 Training

Health professionals should work to standards set by their professional body and ensure that they have the appropriate skills, knowledge and expertise in the safe use of medicines delivered within the commissioned service

7.1 Care Homes and Domiciliary Care

- Providers must ensure that designated staff administer medicines only when they have had the necessary training and are assessed as competent. Providers must ensure that staff who do not have the skills to administer medicines, despite completing the required training, are not allowed to administer medicines to residents/clients
- Providers should set up a learning and development programme so that care staff can gain the necessary skills for managing and administering medicines. The programme should meet the requirements of the regulators, the residents/clients and the training needs of care staff
- Providers should use an 'accredited learning' provider so that care staff who are responsible for managing and administering medicines can be assessed by an external assessor. Refresher training must be provided every two years as a minimum.
- Care staff must have induction training that is relevant to the type of organisation they are working in (domiciliary care, adult care homes or children's homes). All care staff (including registered nurses as part of their continuing professional development) involved in managing and administering medicines should successfully complete any training needed to fulfil the learning and development requirements for their role
- Providers should ensure that all care staff have an annual review of their knowledge, skills and competencies relating to managing and administering medicines. Providers should identify any other training needed by care staff responsible for managing and administering medicines. If there is a medicines-related safety incident, this review may need to be more frequent to identify support, learning and development needs
- Health professionals working in, or providing services to, care homes should work to standards set by their professional body and ensure that they have the appropriate skills, knowledge and expertise in the safe use of medicines