



ROYAL
PHARMACEUTICAL
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Professional Standards for Homecare Services in England

September 2013



Foreword

The Royal Pharmaceutical Society is delighted to publish these professional standards for homecare services. These professional standards provide a broad framework which will support all members of the pharmacy team involved in homecare services to deliver quality patient care.

In 2011 the Department of Health commissioned the report Homecare Medicines – Towards a Vision for the Future. The report made a list of recommendations to improve the financial and clinical governance arrangements for patients receiving medicines via the homecare route. In 2012, the Department of Health established a steering board chaired by the report's author, Mark Hackett, to oversee the implementation of the recommendations with a range of work streams including development of a framework of standards for homecare medicines.

The Professional Standards for Homecare Services, developed by the Homecare Standards Workgroup, overseen by the Department of Health Homecare Strategy Board, and hosted and published by the RPS closely reflect the RPS Professional Standards for Hospital Pharmacy Services, and aim to ensure that patients receive safe, effective care from homecare services.

A handwritten signature in black ink that reads "D Branford". The signature is written in a cursive style with a large, stylized 'D'.

David Branford FRPharmS
Chair
English Pharmacy Board

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Purpose of the professional standards

One of the roles of a professional body is to develop professional standards that are supportive, enabling and professionally challenging. These overarching developmental standards give a broad framework which will support teams providing and commissioning homecare services to improve services continually and to shape future services and pharmacy roles to deliver quality patient care. Ultimately, these standards will help patients experience a consistent quality of homecare services, irrespective of homecare provider, that will protect them from incidents of avoidable harm and help them to get the best outcomes from their medicines.

The development of the professional standards for homecare services has been led by the Homecare Standards Workgroup, overseen by the Department of Health Homecare Strategy Board, and hosted and published by the RPS. These professional standards will support ongoing work across homecare services and enable the continual improvement of homecare services.

Scope of the professional standards

They represent quality pharmacy led services across the full range of homecare services. The standards underpin patient experience and the safe, effective management of medicines across homecare services. The standards are designed to be used in addition to relevant legal frameworks and the standards required by regulators, the NHS Litigation Authority, and, for Controlled Drugs, the Home Office. Regulators include but are not limited to

- General Pharmaceutical Council (GPhC)
- Nursing and Midwifery Council (NMC)
- General Medical Council (GMC)
- Care Quality Commission (CQC)
- Medicines and Healthcare Products Regulatory Agency (MHRA)
- Information Commissioners Office (ICO)
- National Institute for Health and Care Excellence (NICE)
- Monitor

Many homecare medicines are subject to enhanced adverse drug event reporting requirements under the pharmacovigilance regulations including drug exposure during pregnancy. Some homecare medicines have specific reporting requirements associated with MHRA and/or NICE approved Patient Access Schemes.

Figure 1 illustrates where the professional standards sit.



FIGURE 1 WHERE THE RPS PROFESSIONAL STANDARDS 'SIT'

It is recognised that homecare services involve the whole pharmacy team and wider pharmacy workforce and therefore these standards apply to all pharmacists and all members of the pharmacy team involved in homecare services.

These standards will also be useful to other health care professionals who may be involved in the provision of the homecare services including, but not limited to:

- Medical practitioners
- Nurses
- Physiotherapists, Occupational Therapists, Speech Therapists
- Caldicott Guardians
- Safeguarding Leads
- Child Protection Officers
- Senior Information Risk Officers (SIRO) and Information asset owners

These standards should be considered as part of a “just culture”, which promotes fairer accountability and a necessary learning culture. A “just culture” is a culture which is based on fairness and is achieved when attitudes, behaviours and practices are in accordance with what is fair and right.

Responsibility and accountability

With regard to homecare services the homecare organisation commissioning the homecare service maintains overall responsibility for the service through a cascade of delegated accountability for actions, ensuring that within each level there is a pharmacist responsible for homecare and that the definitions of responsibility and accountability are documented and clearly understood by all parties. The pharmacist with responsibility for homecare also includes responsibility for other disciplines, as relating to homecare services, working to support but not provide professional oversight of other healthcare professionals.

Within this document the term “Chief Pharmacist or equivalent” is used to describe the pharmacist with responsibility for homecare. There should be one pharmacist in each organisation who is responsible for all homecare services related to medicines and the robust integration of their homecare services with all other

relevant organisations involved in the provision of the homecare service or other elements of the medication pathway including commissioners, subcontractors and other service providers.

Uses of the professional standards

The professional standards will be used both within the profession and more widely. They will give

- The public and patients – a recognised standard of care that they should expect when they experience homecare services
- Commissioners or contractors of homecare services – a framework for quality that will help to inform and support commissioning of or contracting for homecare services
- Pharmacists – a consistent set of standards against which they can be held accountable and use as a framework to continually develop their professional practice, improve services and innovate in their own organisations and with partners who deliver homecare services
- The pharmacy team – a framework of standards that allows them to recognise, develop and deliver the best possible outcomes for patients from homecare services

Structure of the professional standards

There are ten high level standards. The ten standards are grouped into three domains, as illustrated by Figure 1 - The ten standards for homecare services.

Each standard is defined by dimensions and sub-dimensions. For each dimension and sub-dimension, statements describe what a quality homecare service should deliver.

Definitions

Homecare service - a homecare medicine delivery service can be described as being a service that delivers ongoing medicine supplies and, where necessary, associated care, initiated by the hospital prescriber, direct to the patient's home with their consent. The purpose of the homecare medicines service is to improve patient care and choice of their clinical treatment.

Medicines pathway – the expected treatment to be provided within the homecare service including diagnosis, referral, dosage routes and frequencies, routine tests, decision points, treatment end points and interventions and service options available at the different stages of the medicines pathway.

The medicines pathway should indicate

- routes of delivery for each stage of the treatment e.g. inpatient, outpatient, homecare, nurse led clinic
- choices that are available to patients
- which organisation will provide each element of the treatment and/or service
- key homecare team members and their responsibilities
- where the clinical responsibility rests at each stage of the pathway
- controls in place for hand-over points
- clinical escalation process to ensure timely decisions with regard to expected treatment

Individual care plan - the medicines pathway defined for a specific individual patient giving chosen options from the medicines pathway and additional tests, reviews and services to be provided.

Homecare team – multidisciplinary and cross-organisational team involved in the management and delivery of a homecare service.

Homecare organisation – any organisation providing homecare services e.g. company or legal entity providing homecare service, pharmaceutical manufacturers, NHS Foundation Trust, Health Board, nursing agency, social enterprise, NHS England, Clinical Commissioning Group (CCG), other clinical commissioner and equivalents in devolved nations.

The Chief Pharmacist or equivalent - for the purposes of these standards this term is used to describe the senior pharmacist responsible for the provision of professional pharmacy services within the homecare organisation for example the Chief Pharmacist of an NHS Foundation Trust, or the Superintendent Pharmacist in a third party homecare service provider, or the lead Pharmacist in a commissioning organisation.

Homecare pharmacist is a pharmacist with appropriate competence in provision and administration of homecare services.

Off label use is where a licensed medicinal product is prescribed, dispensed or administered not in accordance with the Summary of Product Characteristics.

Unlicensed product is a medicinal product that does not hold a valid licence for supply to the UK market.

cGDP – current Good Distribution Practice guidelines issued by MHRA.

cGMP – current Good Manufacturing Practice guidelines issued by MHRA.

Definitions of homecare service types

Homecare services can be divided into low tech, mid tech or high tech. The complexity of services and therefore the associated competencies required to provide the services increase from low to mid to high tech. The most complex service type definition applies to the overall service. For example: an individual service defined as mid tech may include low tech service elements but not vice versa. Elements of complex homecare may be provided alongside low, mid or high tech homecare services to which this standard refers. Professional standards for provision of complex homecare are outside the scope of this standard.

Low tech homecare service

Activities include

- self-administration of oral therapy or medicinal products for external use only excluding oral oncology
- products are licensed medicines or uncomplicated medical devices
- product storage conditions are 15-25°C and/or 2 -8°C suitable for storage in the patient's own fridge
- self-administration of medicines is usually in accordance with the Summary of Product Characteristics, occasional off-label use
- homecare team members are expected to identify and report obvious misuse of medicines and non-compliance

Mid tech homecare service

Activities include

- products that are unlicensed medicines
- therapy that requires significant clinical support or diagnostic testing such as blood level monitoring as part of the homecare service e.g. oral oncology
- patient training and competency assessment relating to self-administration
- self-administration needing basic aseptic technique and standard ancillaries e.g. pre filled syringes

- medications with special storage requirements
- provision of refrigeration equipment
- compliance and/or concordance programmes including specified interventions

High tech homecare service

Activities include

- intravenous infusion
- self-administration needing advanced aseptic technique and / or portable equipment / specialist ancillaries
- products that are compounded aseptic medicines
- administration by healthcare professional
- clinical decisions taken within approved clinical protocol with escalation of out-of-limit findings to the clinically responsible person

Complex homecare service

Activities include

- provision of bespoke homecare solutions for individual patients not covered by national standards
- permanent or semi-permanent adaptation of the home environment required as part of the service
- permanent or semi-permanent installation of equipment in the home
- clinical responsibility delegated to a third party
- clinical trials including homecare services

Box 1: Putting the standards into practice

1. The ten standards are linked, so there may be overlap between the different sections. To ensure that the standards are used to fully reflect a quality homecare service, we recommend that all ten standards are reviewed.
2. The overarching standards are relevant to the breadth of homecare organisations, however, some of the underpinning dimensions and statements may be more relevant to some services than others. You should expect to spend some time thinking about how the standards apply to the context of your service.
3. Similarly, there may be variation in the evidence used to assure the delivery of the standards, and the processes used to measure the achievement of the standards, in different organisations.
4. Use the Homecare Standards Implementation Handbook (currently under development, expected publication late 2013) to support implementation of these standards in practice.

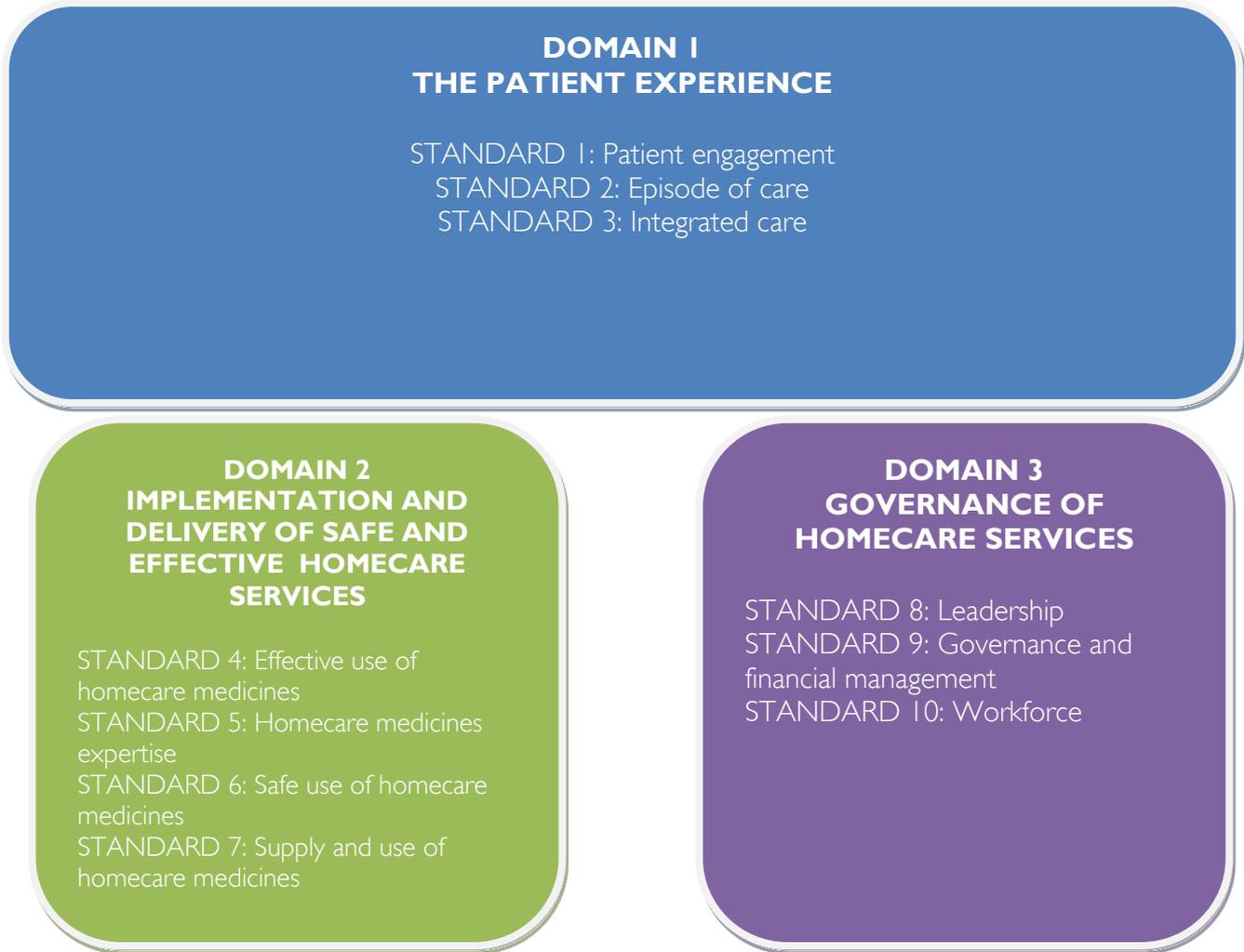


Figure 1 Ten standards for homecare pharmacy services

DOMAIN I
THE PATIENT EXPERIENCE

STANDARD 1
Patient Engagement

1.1 Informed Choice

1.2 Information about Homecare Services

1.3 Adherence to Medicines Pathway

1.4 Patient Needs and Responsibilities

STANDARD 2
Episode of Care

2.1 On Referral to Homecare Services

2.2 Ongoing Care of Homecare Patients

2.3 Monitoring Patients' Outcomes

STANDARD 3
Integrated Care

3.1 Effective Communication and
Continuity of Professional Duty of Care

3.2 Working with Other Professions

3.3 Working Within Multiple Regulatory
Frameworks

STANDARD I PATIENT ENGAGEMENT

Patients (and/or carers) are supported in their decision-making about homecare medicines.

I.1 Informed choice

Communication and the involvement of patients and carers is an integral component of effective homecare services.

- I.1.1 Homecare services provided for NHS patients comply with the NHS Homecare Patient Charter¹.
- I.1.2 Patients are informed about their medicines pathway including expected outcomes, potential risks and the role homecare service plays in the medicines pathway.
- I.1.3 Criteria for suitability of patient cohorts for homecare services are defined and approved and patients participate wherever possible in the assessment of their suitability for the homecare service.
- I.1.4 Patients and their carers are treated with dignity and respect at all times and patient confidentiality is maintained by members of the homecare team.
- I.1.5 The views of patients and carers are actively sought to inform the development and delivery of homecare services.
- I.1.6 Patients are provided with clear information about how their personal information will be shared with and between homecare organisations and the homecare service and there is no delivery of a homecare service without the informed consent of the patient.
- I.1.7 Patients understand their responsibilities to comply with their medicines pathway and provisions of their homecare service and particularly the need to immediately report any adverse clinical events.

I.2 Information about homecare services

Patients (and/or carers) have access to information and support in order to make informed choices and consent to the use of homecare services.

- I.2.1 The Chief Pharmacist or equivalent, with support of other members of the homecare team, provides leadership, systems support and expertise to enable the homecare organisation to:
 - Provide patients with information about medicines and their unwanted effects, in a form that they can understand.
 - Give patients the opportunity to discuss medicines with an appropriate healthcare professional.
 - Provide patients with information about the benefits and risks of the homecare service in a form they understand.
 - Ensure patients who believe they have received an unsatisfactory or unsafe service, know how to complain and ensure that each complaint receives a considered response.
 - Ensure patients understand how their personal data will be shared and used to provide the homecare service.
 - Ensure patients have given informed consent to receive the homecare service and this consent is updated if there are significant changes to the service.
 - Ensure patients understand their right to withdraw consent to homecare at any time, and understand how to do this.*
- I.2.2 Members of the homecare team support the provision of clear, understandable information about the homecare service across the organisations.

¹ Publication expected in 2013

- I.2.3 Patients (and/or carers) can ask to see a homecare team member or call a help line to discuss their homecare service at times which are appropriate to the homecare service.
- I.2.4 Patients are given clear information about who to contact for each type of query. All specified patient contact points are able to signpost the patient to the appropriate contact if they are unable to answer the query or resolve the issue raised themselves.

*When patients lack capacity, information about homecare is provided to a carer/next of kin to enable them to contribute to decisions about care following approved local safeguarding procedures.

I.3 Adherence to medicines pathway

Systems are in place to identify patients who may need support adhering to their medicine pathway and/or individual care plan, or to allow patients to request additional support.

- I.3.1 Patients' motivation and ability to comply with the provisions of the homecare services and to adhere to their medicines pathway is routinely assessed by healthcare professionals. Where difficulties are identified further specialist input is provided by the homecare team at the earliest available opportunity or in accordance with the patient's individual care plan.
- I.3.2 Medicines pathways and homecare services are simplified as far as possible and/or appropriate aids, reminders and charts are made available to support patients.
- I.3.3 Patients and/or carers are trained and assessed by a healthcare professional as being competent to self administer their medication including use of any equipment or ancillaries provided as part of the homecare service unless suitable alternative arrangements have been made to support delivery of the medicine pathway to the patient in their home or other appropriate community setting.
- I.3.4 Liaison with other healthcare professions or agencies is undertaken where ongoing support or help to comply with the homecare medicines pathway is needed and multi-disciplinary team care plans put in place as required.

I.4 Patient needs and responsibilities

Systems are in place to identify cohorts of patients who may be suitable for the homecare service.

- I.4.1 Patients are counseled by an appropriate healthcare professional to ensure they understand their responsibilities for adhering to the medicine pathway and provisions of the homecare service e.g. attending clinic appointments; taking required diagnostic tests; being available to receive deliveries and/or visits as scheduled; following medicines storage instructions; reporting adverse clinical events and agreeing to reasonable requests from the relevant homecare organisation to ensure continuity of their treatment if for any reason the normal service cannot be provided.
- I.4.2 Patients understand that errors can happen and if they have any concerns about their treatment or the service, the patient should raise these at the earliest opportunity so that any issues can be resolved efficiently and treatment continuity and patient safety are maintained.
- I.4.3 Systems are in place to ensure that each patient's suitability for the service is assessed against agreed criteria under the responsibility of the patients lead clinician.
- I.4.4 The Chief Pharmacist or equivalent takes the lead in ensuring the homecare teams have the skills and experience necessary to make suitability assessments and provide an escalation mechanism for resolution of issues.

STANDARD 2 EPISODE OF CARE

Patients' medicines requirements are regularly assessed and responded to in order to optimise outcomes from homecare services.

2.1 On referral to homecare services

Patients have their medicines history and proposed medicines pathway reviewed by a homecare pharmacist and, where appropriate, a specialist clinical pharmacist to ensure that homecare services are appropriate, and to optimise patient outcomes from the medicines pathway.

- 2.1.1 Patients referred for homecare services have their needs assessed and documented in a referral form and/or individual care plan which forms part of the patient record. Needs assessments include an individual risk assessment and identification of risk mitigation measures to be implemented within or alongside the homecare service.
- 2.1.2 Clinical assessment includes a check of compliance with the medicines pathway including clinic attendances and clinical and diagnostic test results.
- 2.1.3 Patients receive appropriate medicines counselling and are competent to self-administer their medicines in accordance with the medicines pathway unless other suitable arrangements have been made.
- 2.1.4 Members of the homecare team have timely access to pharmacy expertise and support from the homecare pharmacist when needed.
- 2.1.5 The patient's General Practitioner is provided with appropriate information about their patients including the medicines pathway, individual care plan and homecare services.

2.2 Ongoing care of homecare patients

Patients who are receiving medicines through a homecare service have continuity of treatment in accordance with the medicines pathway and their individual care plan.

- 2.2.1 Patients have their clinical status and suitability for the homecare service reviewed on a regular basis at appropriate intervals in accordance with their medicines pathway and/or care plan.
- 2.2.2 Any changes to dosage, medication or service are planned to ensure continuity of care and maintain patient safety, whilst minimising medicines wastage and minimising the impact of the change on the patient.
- 2.2.3 Systems are in place to receive, record and follow up, in a timely manner, reports of changes in patient circumstances which may impact on their suitability for the homecare service.
- 2.2.4 Communications processes are in place to ensure all relevant members of the homecare team and other healthcare professionals involved in the care of the patient are informed of any changes in the patient's treatment or condition in a timely manner.
- 2.2.5 Contingency plans are in place and regularly reviewed to ensure individual patients receiving homecare services have continuity of treatment and ensure patient safety issues do not arise from service failures whatever the cause.
- 2.2.6 Systems are in place to ensure administration and other clinical records are shared in a timely manner with relevant healthcare professionals involved with the patient's care to ensure continuity of care and patients safety.
- 2.2.7 If administration is withheld or any other clinically significant observations are made, a report is made without delay in accordance with the homecare service protocol

2.3 Monitoring patients' outcomes

Patients' outcomes from and experiences of treatment with homecare services are documented, monitored and reviewed.

- 2.5.1 As part of a homecare service, homecare team members monitor:
- Patients' responses to their medicines
 - Compliance with the medicines pathway
 - Unwanted effects of medicines
 - Complaints
- 2.5.2 Appropriate action is taken where problems (potential and actual) are identified.
- 2.5.3 The homecare team documents any patient safety, information governance or safeguarding incident and reports it to the service commissioner and external agencies where appropriate.
- 2.5.4 Wherever possible, the homecare team uses their experience to add to the body of published evidence to show the costs and benefits of homecare services.
- 2.5.5 Regular patient satisfaction surveys are performed to monitor and guide improvement in homecare services.

STANDARD 3 INTEGRATED CARE

3.1 Effective communication and continuity of professional duty of care

Good information processes drive strong integrated care

- 3.1.1 Responsibilities are clearly defined for each aspect of the service and for handovers between people and organisations to ensure there are no gaps.
- 3.1.2 All members of the homecare team are able to access necessary information to be able to discharge their duty of care.
- 3.1.3 Homecare services are regularly reviewed to ensure robust communication processes are in place and working effectively.
- 3.1.4 Clinical and service notes are complete, accurate and up-to-date.
- 3.1.5 Information is shared to ensure continuity of service and robust transfer of duty of care whilst maintaining patient confidentiality.
- 3.1.6 Procedures and systems are in place to ensure appropriate reporting, follow-up and escalation where necessary, of actual or suspected harm from medication and other errors.
- 3.1.7 Risk assessments include handover of care and are regularly reviewed. All relevant members of the homecare team are able to access risk assessments and are able to implement agreed risk mitigation actions.
- 3.1.8 Safeguarding escalation procedures are in place to manage incidents of actual or suspected patient harm.

3.2 Working with other professions

Homecare services are provided by multi-disciplinary teams who understand and respect each other's professional standards and work within their competence.

- 3.2.1 In NHS organisations, The Medical Director and Nursing Director are involved with the Chief Pharmacist in setting homecare strategy and risk assessment of services.
- 3.2.2 There is a robust complaints and incidents reporting system ensuring that all relevant professionals are involved, at the earliest opportunity, in the investigation and root cause analysis.

3.3 Working within multiple regulatory frameworks

- 3.3.1 The Chief Pharmacist or equivalent maintains a working knowledge of all current regulations and standards applicable to homecare services. Regional differences between England, Scotland, Wales, Northern Ireland, Channel Islands and Isle of Man are considered in the design of any services that cross borders.

DOMAIN 2
IMPLEMENTATION AND DELIVERY OF SAFE AND EFFECTIVE
HEMOCARE SERVICES

STANDARD 4
Effective Use of Homecare
Medicines

4.1 Homecare Policy

4.2 Homecare Services Procurement

4.3 Sourcing and Purchasing of Homecare Medicines

4.4 Custom Made Homecare Medicines

4.5 Imported Unlicensed Homecare Medicines

4.6 Equipment and Ancillaries

STANDARD 5
Homecare Medicines
Expertise

5.1 Expertise and Competence of the Homecare Team

5.2 Expertise for Patient Care

STANDARD 6
Safe Use of Homecare
Medicines

6.1 Safe Systems

6.2 Safety Culture

6.3 Clinical Governance

STANDARD 7
Supply and Use of
Homecare Medicines

7.1 Patient Services

7.2 Clinical Checking of Homecare Prescriptions

7.3 Dispensing

7.4 Labelling and Patient Information

7.5 Distribution and Storage

7.6 Medicines Administration and Compliance Services

STANDARD 4 EFFECTIVE USE OF HOMECARE MEDICINES

Homecare services are chosen to maximise safety, effectiveness and adherence to treatment.

4.1 Homecare policy

The homecare team support an integrated approach to the choice of safe and clinically effective homecare services for patients.

- 4.1.1 A multidisciplinary medicines management group provides a focal point for the development of medicines policy, procedures and guidance within the organisation, within appropriate resources.
- 4.1.2 A specialist homecare pharmacist is appointed to oversee the administration of homecare services within each homecare organisation.
- 4.1.3 The homecare pharmacist leads processes that ensure homecare prescribing has patient safety at its heart and is evidence-based, consistent with commissioning arrangements, and linked to treatment guidelines, protocols and local patient pathways.
- 4.1.4 The homecare policy identifies a strategy for supporting optimisation of the outcome of treatment with the homecare medicines.
- 4.1.5 Regular review of a documented homecare strategy agreed by a multidisciplinary medicines management group takes place to enable early discussions with clinicians, local partners and commissioners/purchasers about the financial and service implications of the introduction of new medicines, or new therapeutic practices.
- 4.1.6 Regular risk assessments are an integral part of the review of homecare service and additional risk assessments are made to support the introduction of new services and changes to existing homecare services for example, change of homecare services provider or introduction of new medicines or additional clinical services.
- 4.1.7 The homecare team works with healthcare professionals throughout the local health economy to provide seamless homecare service for patients.
- 4.1.8 Opportunities for collaboration and sharing best practice across healthcare organisations are identified and exploited, for example through joint posts for regional activities or meetings between senior homecare team members in different organisations.
- 4.1.9 Pharmacists within the homecare team work closely with patients and other health professionals to reach a joint decision on which treatment option best suits an individual patient's needs. This is based on the risks and benefits of each option and supported by high quality information that includes the licensed status of the chosen treatment.
- 4.1.10 Governance arrangements are in place for management of all medicines, including licensed medicines, off-label use of licensed medicines, unlicensed medicines and Investigational Medicinal Products (IMPs, Clinical Trial medicines) and are consistent with the MHRA position on unlicensed medicines.
- 4.1.11 Medicines are used in accordance with their marketing authorisations wherever possible. Selection between different licensed options for individual patients is guided by considerations of safe use, effectiveness, tolerability and value.
- 4.1.12 If individual clinical need cannot be addressed safely or appropriately by a licensed option, the off label use of a licensed medicine is chosen in preference to use of an unlicensed medicine. Unlicensed medicines are used only where licensed or off-label medicines are inappropriate for an individual patient's needs.

4.2 Homecare services procurement

Homecare service procurement is managed by pharmacy in a transparent and professional way and overseen by the Chief Pharmacist or equivalent. Quality assured homecare services are procured through robust and appropriate processes.

- 4.2.1 Procurement decisions are informed by clinical practice and formulary systems to ensure that homecare services meet the needs of patients and the members of the homecare team.
- 4.2.2 Homecare procurement takes into account nationally, regionally or locally negotiated contracts and the quality and safety of the products.
- 4.2.3 Commissioners and providers take appropriate steps to ensure availability of product supplies and contract prices via the proposed homecare service routes.
- 4.2.4 Contingency plans are included within the service specification to manage product recalls, service interruptions and shortages of medicines.
- 4.2.5 Homecare organisations ensure that medicines are procured and manufactured to the same specifications and quality standards when manufacture, packing or supply is sub-contracted.
- 4.2.6 The contract between the service commissioner and the homecare provider ensures explicit arrangements are in place to ensure continuity of supply and consistent quality of care.
- 4.2.7 Organisations that provide homecare services ensure the responsibilities of any sub-contractors are clearly defined and understood by all relevant parties.
- 4.2.8 Organisations that provide homecare services regularly audit and performance manage their sub-contracted services to ensure consistency of service against technical agreements.

4.3 Sourcing and purchasing of homecare medicines

Homecare medicines procurement is managed by pharmacy in a transparent and professional way. Quality assured medicines are procured through robust and appropriate processes.

- 4.3.1 Homecare organisations work in partnership with manufacturers of medicines to ensure continuity of supplies for homecare patients.
- 4.3.2 Commissioners and providers take appropriate steps to ensure availability of product supplies via the proposed homecare service routes before initiating the homecare service for a patient. Full account is taken of the provisions of any applicable patient access scheme.
- 4.3.3 Commissioners and providers take appropriate steps to ensure availability of product supplies and contract prices via the proposed homecare service routes.
- 4.3.4 Homecare organisations do not act or fail to act in any way that might compromise of continuity of supply of medicines for UK patients.

4.4 Custom-made homecare medicines

Any medicines custom-made by, or for, the homecare organisation are quality assured and appropriate for their intended use.

- 4.4.1 Use of compounded, extemporaneously prepared, aseptically prepared, repacked and over-labelled medicines is consistent with the principles of risk reduction and using licensed medicines wherever possible.
- 4.4.2 Aseptic preparation facilities (internal or outsourced) are subject to routine internal and external audit.
- 4.4.3 Robust operator and patient safety systems are in place for the production of high risk medicines, for example, chemotherapy, radiopharmaceuticals, parenteral nutrition.
- 4.4.4 Appropriate quality assurance and control systems support selection, management and use of all custom-made medicines whether produced internally or outsourced.

4.5 Imported unlicensed homecare medicines

Robust risk management arrangements are in place for the use of imported unlicensed medicines in line with MHRA guidance.

- 4.5.1 Imported unlicensed medicines are only used where there is no licensed alternative.
- 4.5.2 The use of all unlicensed imported medicines is approved by the pharmacist responsible for the homecare service.
- 4.5.3 Unlicensed imported medicines are risk assessed for quality and medication error potential prior to supply and are fit for the intended purpose.

4.6 Equipment and ancillaries

Equipment and ancillaries provided are suitable for their intended purpose

- 4.6.1 Equipment and ancillaries are designed to suit the intended purpose in terms of function, accuracy, safety, cleanliness and ease of use for patients and/or carers and inspection and maintenance processes are implemented as needed.
- 4.6.2 Appropriate risk assessments are in place and regularly reviewed to ensure equipment and ancillaries are suitable for use in the home environment.
- 4.6.3 Instructions and training are provided for patients and/or carers in the use of all equipment and ancillaries in the home.
- 4.6.4 Patients and carers know what action to take to obtain further supplies of ancillaries or in the event of equipment failure.
- 4.6.5 Equipment for use by members of the homecare team is maintained and operated only by appropriately trained and competent people.

STANDARD 5 HOMECARE MEDICINES EXPERTISE

Members of the homecare team provide expertise and advice to support the safe and effective use of homecare services by patients.

5.1 Expertise and competence of the homecare team

The homecare team have relevant, up-to-date, evidence-based information and expertise available to them.

- 5.1.1 The pharmacy team provide support to ensure other healthcare professionals prescribing, administering and monitoring the effects of medicines have relevant, up-to-date, evidence-based information and pharmaceutical expertise available to them at the point of care
- The pharmacy team supports induction, and ongoing training and education in the best practice use of medicines for relevant clinical and support staff across their organisation.
 - Pharmacists are accessible in (or to) clinical areas to provide advice for other healthcare professionals on the choice and use of medicines.
 - A pharmacist-led medicines information and query-answering service is available to healthcare teams, working to national standards for medicine information.
 - The pharmacy team works to ensure that prescribers are supported in their everyday activities by readily-accessible information and guidance e.g. the British National Formulary, electronic guidance to support formulary choices and decision making, prescribing guidelines and medicines treatment pathways.
- 5.1.2 All staff involved in the provision of the homecare services are appropriately trained and competent.
- 5.1.3 Members of the homecare team work within their capabilities and engage in continuous professional development to expand their knowledge of homecare.
- 5.1.4 Members of the homecare team who work remotely with patients in the community receive specific training related to their safety and security and that of other members of the homecare team and patients.
- 5.1.5 Members of the homecare team, including specialist homecare delivery drivers, are subject to safeguarding controls e.g. DBS check in accordance with the prevailing regulations.

5.2 Expertise for patient care

Homecare services are provided by multi-disciplinary teams who each play their part in ensuring a seamless and high quality service is provided to patients.

- 5.2.1 Each member of the homecare team understands and works within their level of competence and experience and is able to refer to more senior colleagues or seek appropriate advice from external experts as required.
- 5.2.2 Each member of the homecare team recognises and respects the professional duties and responsibilities of other members of the homecare team and ensures they are consulted and informed as appropriate.
- 5.2.3 Change control processes are in place to ensure changes that impact on the area of professional responsibility of other members of the homecare team are appropriately reviewed and approved.

STANDARD 6 SAFE USE OF HOMECARE MEDICINES

The homecare team ensures that safe medication practices are embedded in the homecare service.

6.1 Safe systems

The Chief Pharmacist or equivalent, in liaison with the nursing and medical director, leads on ensuring that all aspects of the homecare service are safe. Homecare services are subject to regular risk assessment and appropriate actions put in place to mitigate identified risks.

- 6.1.1 Homecare pharmacists are involved in the design and updating of prescription and other homecare service documentation and systems (paper or electronic).
- 6.1.2 Homecare pharmacists record when they have seen a prescription and assessed it as clinically appropriate for the patient and ensure that record is available to the dispensing pharmacist.
- 6.1.3 The homecare pharmacist supports the implementation of relevant national therapeutic guidance and national patient safety alerts related to medicines.
- 6.1.4 Processes are in place within the homecare organisation to ensure appropriate responses to MHRA and supplier led defective medicines and device alerts and recalls including communication to all relevant stakeholders.
- 6.1.5 Robust operator and patient safety systems are in place for the manipulation, administration and disposal of high hazard medicines (e.g. chemotherapy) in the patient's home.
- 6.1.6 Robust complaints and incidents processes are in place which ensures that information about untoward events and near misses are captured, investigation and root cause analysis is undertaken. Particular care is taken to ensure processes cover all relevant homecare organisations and sub-contractors. Corrective and preventive actions are identified and implemented as appropriate.
- 6.1.7 Lessons learned from investigation of complaints and incidents are shared widely to improve patient safety.
- 6.1.8 Robust reporting mechanisms are in place using nationally recognised systems where appropriate.

6.2 Safety culture

The Chief Pharmacist or equivalent leads on promoting a “just” culture in which medication safety has a high profile across organisations.

- 6.2.1 The Chief Pharmacist or equivalent has representation on all high level medicines safety and governance groups in the organisation.
- 6.2.2 The Chief Pharmacist or equivalent leads on management of Patient Safety Incidents (PSIs) involving medicines.
- 6.2.3 Patient safety, information governance and safeguarding incidents are identified, recorded, monitored, reported and investigated.
- 6.2.4 Learning from patient safety incidents in homecare services and systems failures related to medicines is shared with the multidisciplinary team and the whole organisation if appropriate, and acted upon to improve practice.
- 6.2.5 Shared learning is reviewed and reported at board level on a regular basis across organisations and at national level.
- 6.2.6 Whistle-blowing processes are in place to ensure reports of poor practice are managed robustly and without adverse consequences for the reporter.
- 6.2.7 A culture of continuous learning and professional development is embedded in the homecare organisation.

6.3 Clinical governance

The Chief Pharmacist or equivalent leads on ensuring assurance of high clinical governance standards for homecare services.

- 6.3.1 The Chief Pharmacist or equivalent ensures engagement with appropriate specialists to ensure governance and safeguarding standards are implemented within the homecare service.
- 6.3.2 Clinical risk assessment is integrated into the development of all homecare services and appropriate measures are implemented to mitigate identified risks.
- 6.3.3 Homecare services are subject to regular clinical audit of expected vs. actual outcome and patient safety incidents
- 6.3.4 Evidence of good clinical practices are maintained and available for clinical audit including hand-over of duty of care between members of the homecare team, and between homecare organisations.
- 6.3.5 Assurance of the quality of services and evidence of maintenance of good clinical governance is maintained where any homecare services or part thereof is sub-contracted to another homecare organisation.

STANDARD 7 SUPPLY AND USE OF HOMECARE MEDICINES

Homecare medicines are stored, dispensed, distributed, administered and if necessary disposed of in a legal, safe and timely way.

7.1 Patient services

Suitable resources are in place to administer and co-ordinate the homecare services. There is a central team which co-ordinates the homecare service and is available to support patients, prescribers and other members of the homecare team.

- 7.1.1 A help line or other support mechanism is available to members of the homecare team, healthcare professionals and patients at times when homecare services are actively provided.
- 7.1.2 The patient help line is able to deal with queries and/or signpost patients to appropriate sources of information.

7.2 Clinical checking of homecare prescriptions

Each homecare prescription is independently checked to ensure it is legally valid, in accordance with the patient's care plan and is clinically appropriate.

- 7.2.1 A clinical checking procedure is in place within the organisation that prescribes the medication and has clinical responsibility for the patient's treatment unless otherwise agreed by both the prescribing, checking and dispensing organisations.
- 7.2.2 Homecare prescriptions are reviewed for clinical appropriateness by a pharmacist with the appropriate skills and access to the patient record. The clinical check is recorded as part of the patient record.
- 7.2.3 Roles and responsibilities for performing the clinical check are clearly documented.
- 7.2.4 The person performing the clinical check on the homecare prescription takes reasonable steps to check that it is clinically and pharmaceutically appropriate in the context of other prescribed treatment and other medicines or supplements the patient is taking e.g. G.P. prescribed medicines, OTC medicines.
- 7.2.5 Records of clinical checks are clearly documented and communicated.

7.3 Dispensing

Homecare medicines are dispensed or prepared accurately, and delivered in accordance with the agreed service levels.

- 7.3.1 Before dispensing or preparation, prescriptions are reviewed by a pharmacist to ensure they are legally valid and unambiguous.
- 7.3.2 Systems are in place to ensure that any doubt as to the prescriber's intention is clarified before dispensing.
- 7.3.3 Systems are in place to prioritise dispensing in order to minimise the risks of omitted and delayed doses of critical homecare medicines or of delayed discharge.
- 7.3.4 Dispensing processes make appropriate use of technology, efficient ways of working and skill mix, for example, automated systems, near patient dispensing, accredited checking pharmacy technicians.
- 7.3.5 Systems are in place to identify, record and review dispensing errors and near misses along with their causes, to minimise the future risk of them recurring.

7.4 Labelling and patient information

Homecare medicines dispensed or prepared are labelled for safety in line with legal requirements.

- 7.4.1 Dispensaries have standards for labelling that ensure consistency and safe labelling practice.
- 7.4.2 Labelling takes into account the diversity of patients accessing homecare medicines, for example, age and disability.
- 7.4.3 Patient information leaflets are provided with each homecare delivery.

7.5 Distribution and storage

Dispensed homecare medicines are safely and securely distributed from a pharmacy and stored in a secure and suitable environment

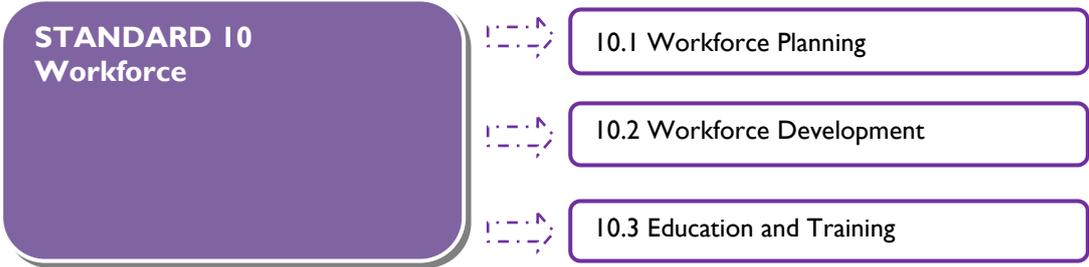
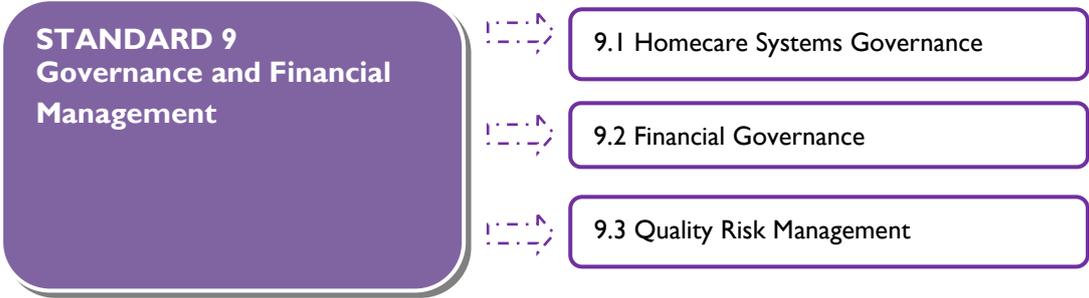
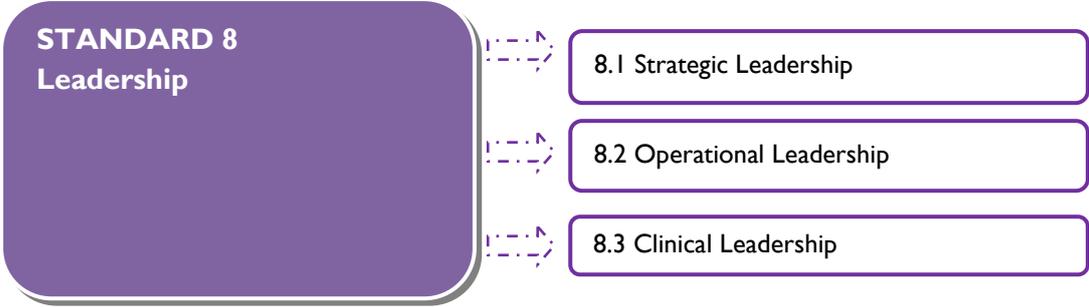
- 7.5.1 Storage, packaging and delivery processes are subject to risk assessment and risk mitigation measures where appropriate to ensure
 - medicines and their associated ancillaries and equipment are suitable for use in a homecare setting
 - medicines and other items are protected from damage by normal handling
 - patient are safeguarded and patient confidentiality is maintained
 - the health and safety of homecare staff, delivery drivers and patients is considered.
- 7.5.2 Supply systems ensure that patients have timely access to homecare medicines needed routinely.
- 7.5.3 Audit trails and governance processes are in place to underpin the supply, storage and distribution of homecare medicines and ensure product quality and integrity up to the point of administration.
- 7.5.4 Patients and/or carers are informed of the correct storage conditions for their medicines and where appropriate additional storage facilities/equipment is provided to patients as part of the service.
- 7.5.5 Where homecare medicines are delivered to patients via a community pharmacy, G.P. Surgery or clinic, procedures are in place to ensure healthcare professionals who handle the consignment are able to fulfil their professional obligations and discharge their duty of care to the patient.
- 7.5.6 Procedures are in place to ensure the appropriate management of waste disposal of ancillaries and returned homecare medicines.
- 7.5.7 Where pharmacists or healthcare professional(s) other than the dispensing pharmacist are involved in the onward supply or administration of the homecare medicine to the patient, each is fully aware of their professional responsibilities.

7.6 Medicines administration and compliance services

Provisions are made within the homecare service for medicines to be self-administered or administered by an appropriately trained and competent person.

- 7.6.1 Patients and/or carers are trained and assessed by a healthcare professional as being competent to self administer their medication including use of any equipment or ancillaries provided as part of the homecare service unless suitable alternative arrangements have been made to support delivery of the medicine pathway to the patient in their home or other appropriate community setting.
- 7.6.2 Processes are in place to perform initial and continued assessment of patients who are self-administering, recognising and acting upon changes which may impact the safety of the patient and others.
- 7.6.3 Where the homecare service includes administration of the homecare medicines by member(s) of the homecare team, they follow approved protocols, have a copy of the prescription and/or follow the clear dosage and administration directions provided on the dispensing label and keep appropriate records.
- 7.6.4 When administering or supervising the administration of the homecare medicine, the member of the homecare team exercises their professional responsibility and accountability in the best interest of the patient.

DOMAIN 3
GOVERNANCE OF HOMECARE SERVICES



STANDARD 8 LEADERSHIP

Pharmacy has strong leadership, a clear strategic vision and the governance and controls assurance necessary to ensure patients get the best from their homecare services.

8.1 Strategic leadership

The Chief Pharmacist or equivalent ensures that the organisation maintains a clear vision for homecare services, optimal use of homecare medicines and sharing best practices across homecare organisations.

- 8.1.1 The Chief Pharmacist or equivalent is responsible for ensuring that the homecare organisation has a homecare policy in place. This policy provides strategic direction for provision of homecare services and is compliant with the RPS Professional Standards for Homecare Services.
- 8.1.2 The Chief Pharmacist or equivalent is accountable for the quality of medicines used and the standard of homecare services across the organisation irrespective of whether they are sub-contracted or managed in-house.
- 8.1.3 Where the service or elements of the service are sub-contracted agreements are in place to define the responsibilities and the sub-contractor is subject to regular audit to ensure compliance with agreed standards.
- 8.1.4 The Chief Pharmacist or equivalent reports to a designated Executive Board member.
- 8.1.5 The Chief Pharmacist or equivalent provides, on a regular basis, assurance to the Board about the safe and secure handling of medicines within the organisation with robust financial governance and compliance with these professional standards.
- 8.1.6 The homecare policy identifies a strategy for supporting optimisation of the outcome of treatment with the homecare medicines.
- 8.1.7 The Chief Pharmacist or equivalent encourages improvement and innovation in the delivery of homecare services to better meet patients' needs, including the adoption of national initiatives and guidance.

8.2 Operational leadership

Homecare services are patient centred and aligned with stakeholder priorities.

- 8.2.1 The type and level of resources required to deliver safe and effective homecare services and to support the safe and secure handling of medicines are identified and available to the Chief Pharmacist or equivalent. The homecare organisation makes available sufficient resources to enable homecare services to be delivered safely and efficiently.
- 8.2.2 Agreed key performance indicators (KPIs) are in place to enable internal and external assessment of the operational and financial performance of homecare services.
- 8.2.3 Homecare services are performance managed through Service Level Agreements (SLA) and/or contract quality monitoring.
- 8.2.4 Professional and organisational responsibilities of all parties are clearly defined and regularly reviewed.
- 8.2.5 Feedback from patients, service users and colleagues inform the development of homecare services.
- 8.2.6 Operational performance is benchmarked against other relevant organisations.
- 8.2.7 Any changes to service provision or medicines specifications are subject to good systems of change management.
- 8.2.8 Systems are in place to ensure all sub-contracted services are quality assured and controlled including
 - assessing the suitability and competence of sub-contractors to carry out the activity
 - a written agreement between contract giver and acceptor defining the responsibilities and communication processes for quality related activities of the involved parties

- monitoring and review of the performance of the contract acceptor and identification and implementation of any required improvements

8.3 Clinical leadership

The pharmacy team is recognised as leading on medicines issues in the homecare organisation.

- 8.3.1 The pharmacy team provides leadership, advice, support and education to other clinicians and support staff about homecare medicines usage.
- 8.3.2 The Chief Pharmacist or equivalent leads the establishment and ongoing monitoring of all homecare services.
- 8.3.3 Homecare pharmacists support the development of integrated care pathways which involve medicines as a treatment option.
- 8.3.4 Members of the homecare team participate in relevant research and clinical audit activities within the organisation.

STANDARD 9 GOVERNANCE AND FINANCIAL MANAGEMENT

Safe systems of work are established and homecare services have sound financial management.

9.1 Homecare systems governance

Systems of work are established that are safe, productive, support continuous quality improvement, are regularly audited and comply with relevant regulations.

- 9.1.1 Homecare service specifications include provisions for continuity of patient treatment in case of foreseeable service delays or minor stock shortages and management structures for planning and mitigation of unforeseen or prolonged service disruption.
- 9.1.2 Documented and approved processes and procedures are in place for the delivery of all homecare medicines management and homecare services across the organisations.
- 9.1.3 Processes and procedures are controlled, regularly reviewed and updated.
- 9.1.4 A programme of audit informs the continuous improvement and development of systems.
- 9.1.5 Care contributions are documented and audited to demonstrate the impact of the homecare service on patient outcomes and to help target resources.
- 9.1.6 Controlled Drugs are managed in line with the requirements of the Misuse of Drugs legislation and governance requirements.
- 9.1.7 Information governance processes in line with legislation are in place to safeguard patient identifiable information used to provide the homecare services.
- 9.1.8 Homecare working environments are subject to risk assessment in line with Health and Safety and CQC requirements, GPhC and other relevant professional best practice standards. Appropriate steps are taken to mitigate identified risks and specifically to protect lone and remote workers.
- 9.1.9 Technical and Information systems capabilities are progressive and fit for purpose.

9.2 Financial governance

Robust business planning, financial planning and reporting are undertaken.

- 9.2.1 A business plan for homecare services, incorporating finance, service and workforce plans, linked to both organisations corporate plans is devised, implemented and monitored through agreed KPIs.
- 9.2.2 National, regional and local initiatives and guidance relating to homecare medicines and services are incorporated into business and financial planning activities including, where appropriate, adherence to NHS Standing Financial Instructions (SFIs)
- 9.2.3 Medicines utilisation reports are produced that support budget management and monitoring of homecare services. Members of the homecare team discuss these with other clinicians and managers to maintain or improve homecare outcomes.
- 9.2.4 Homecare pharmacists work collaboratively with commissioners/purchasers and primary care clinicians to ensure prescribing delivers value from the investment in medicines across the health community.
- 9.2.5 The Chief Pharmacist or equivalent assures themselves that any sub-contractor is financially stable and that any payments due to that contractor under the homecare service are not unreasonably withheld or delayed.
- 9.2.6 The Chief Pharmacist or equivalent ensures that within any sub-contract relationship product access and contract pricing is in accordance with their service specification.
- 9.2.7 The Chief Pharmacist or equivalent represents accurately and honestly their capability to deliver a homecare service or their authority to commission a homecare service.

9.3 Quality risk management

A risk management approach is taken to safeguarding the quality and provision of services to patients incorporating the principles of quality risk management into all aspects of homecare services in accordance with Quality Risk Management (ICH Q9).

- 9.3.1 A risk assessment is performed for each service and for each patient prior to initiating a homecare service, including the identification, analysis and evaluation of risks.
- 9.3.2 There is a process for the identification of risk reduction and control measures and for acceptance or rejection of risks by all relevant homecare organisations and, where relevant, by patient groups or individual patients.
- 9.3.3 Risk control measures are appropriate to the type of homecare service. It can be expected that the level of risk will increase for high tech services compared to mid tech and low tech services. Any element of complex care is considered high risk and therefore subject to a high degree of risk management.
- 9.3.4 There is a robust communication of risks and risk control measures to all stakeholders.
- 9.3.5 There is regular review of the effectiveness of risk control measures.
- 9.3.6 Systems are in place to ensure all sub-contracted services are quality assured and controlled. This will include:
- assessing the suitability and competence of sub-contractors to carry out the activity (e.g. by audit, material evaluation, qualification).
 - defining the responsibilities and communication processes for quality related activities of the involved parties. (This is included in written agreement between contract giver and acceptor).
 - monitoring and review of the performance of the contract acceptor and identification and implementation of any required improvements.
- 9.3.7 The Chief Pharmacist or equivalent ensures that a risk register is maintained for each homecare service in conjunction with relevant stakeholders.

STANDARD 10 WORKFORCE

The homecare team have the right skill mix and the capability and capacity to develop and provide quality homecare services to patients.

10.1 Workforce planning

The homecare workforce is planned and appropriately resourced in order to support homecare service quality, productivity and safety.

- 10.1.1 There is a plan for reviewing, developing and funding a homecare workforce that optimises skill mix and meets the changing needs of the homecare service.
- 10.1.2 Where deficiencies or shortfalls in the homecare workforce are identified a corrective plan is put in place.
- 10.1.3 Contingency plans for the homecare service include provisions to ensure continuity of treatment for homecare patients if key members of the homecare team are not available.
- 10.1.4 Succession planning arrangements are in place and are linked to homecare workforce training and personal development plans.
- 10.1.5 The homecare service benchmarks its workforce and skill mix against other relevant organisations.
- 10.1.6 The Chief Pharmacist or equivalent engages with workforce planners and education commissioners at an appropriate level.
- 10.1.7 Members of the homecare team, including specialist homecare delivery drivers, are subject to safeguarding controls in accordance with the relevant regulations.

10.2 Workforce development

Homecare organisations have an effective performance management and personal development planning process linked to workforce planning.

- 10.2.1 Members of the homecare team have roles and responsibilities clearly defined in job descriptions and are performance managed through appraisal and other regular means of engagement.
- 10.2.2 All members of the homecare team are aware of their own level of competency and see how they can develop in their roles and careers. Processes are in place to identify and manage team members who fail to reach minimum competency or performance standards.
- 10.2.3 Where they exist, recognised development frameworks and assessment tools are used for all grades of staff.
- 10.2.4 Planning is in place to ensure that competency is maintained and developed to meet changing service needs, patient expectations and the introduction of new healthcare medicines and technologies.
- 10.2.5 The transfer of skills and experience within cross-organisational teams is encouraged by job exchanges, secondments or other appropriate means to facilitate the gaining of experience within other organisations involved in providing the homecare service.

10.3 Education and training

Induction and ongoing learning and development are provided for all members of the homecare team.

- 10.3.1 All training programmes used are reviewed regularly and adapted to ensure that they remain fit for purpose.
- 10.3.2 Training records are maintained for mandatory and role related training. Regular competency assessment is in place, revalidation and refresher training provided if necessary.

- 10.3.3** Trainees receive support, facilitation and supervision from appropriate educational and practice supervisors.
- 10.3.4** The homecare team has the opportunity to undertake further learning and development that delivers improvements in patient care.

Appendix I Acknowledgements

The names of the organisations and individuals who have contributed to the project are listed below, their input and support is gratefully acknowledged.

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Chris Theaker
Sheela Upadhyaya

Homecare Standards Workgroup

Ray Fitzpatrick (Chair)
Carol McCall (Co-Chair)
Steve Cooke
Michael Dickson
Catherine Duggan
Sharon Hart-Davies
Mark Jackson
Alan Karr
Cheryl Perry
John Persaud

RPS Project Team

Catherine Duggan
Katie Griffiths
Ruth Wakeman

Review Group

Members of the National Homecare Medicines Committee (NHMC)
Members of the Pharmaceutical Market Support Group (PMSG)
Chief Pharmacists Group
Board and Members of the National Clinical Homecare Association (NCHA)
Association of the British Pharmaceutical Industry – Homecare Group (ABPI)

Other Contributors

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