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Handbook for Homecare Services in England

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FOREWORD

Homecare services improve choice for patient care by providing specialist medicines and, where necessary, their associated care to patients in their homes or another community based setting. Homecare services are today provided to over 200,000 patients in the UK representing £1.5 billion of the £4 billion spent on hospital medicines. The sector has grown rapidly and continues to develop and expand to meet patient demands and NHS cost containment targets.

The increasing importance of the homecare sector led to the Chief Pharmaceutical Officer at the Department of Health asking me to undertake a review of the homecare medicines supply and associated services in England. The results of this review were published in late 2011 – 'Homecare Medicines – Towards a Vision for the Future' (Hackett Report). Following that publication, I was asked to form a Homecare Strategy Board to implement the key recommendations of my report. I am very pleased to be able to introduce this handbook and the Royal Pharmaceutical Society Professional Standards for Homecare Services that it supports as cornerstones of that implementation.

Homecare services give patients additional choice enabling them to be treated at home where it is possible to do so safely. They encompass the provision of specialist medicines and their associated services to patients in their homes or another community based setting. Homecare services range from 'low tech' delivery of specialist oral medicines for self-administration through to 'high tech' with nurse visits for intravenous infusions or training and monitoring of 'expert patients' who manage their own infusion pumps.

Whilst other healthcare professions are involved in homecare, my original report clearly put pharmacy in the driving seat and identifies the NHS Trust Chief Pharmacist as the Responsible Officer for homecare. The DH Homecare Strategy Board was delighted that the Royal Pharmaceutical Society agreed to work with us and in September 2013 the RPS Professional Standards for Homecare Services in England were launched at the British Pharmaceutical Conference and published on the RPS website www.rpharms.com.

The Homecare Strategy Board Standards Workgroup continued to work with the RPS to develop further guidance to support the implementation of the new Professional Standards for Homecare Services and high quality patient centred homecare services. This first edition of the Handbook for Homecare Services in England is the culmination of those efforts. It has been written to support organisations involved in the provision of medicines through homecare services in England to comply with the Royal Pharmaceutical Society's Professional Standards for Homecare Services and supports the implementation of the other key recommendations of the Hackett report and outputs of the DH Homecare Strategy Board Workgroups.

The Hackett report recommendations were based on a coherent set of principles and approaches which, when taken together, focus attention on the need to influence change which results in better services for patients. Homecare services designed and delivered in accordance with the RPS Standards for Homecare Services, using the best practices outlined in this handbook will enhance benefits to patients and improve outcomes. In many cases, homecare services also represent a cost effective option for the NHS avoiding costly hospital admissions and reducing the number of outpatient appointments.

I would like to thank everyone who has contributed to the development of the RPS Professional Standards for Homecare Services and this handbook and thank the RPS for embracing the DH Homecare Strategy Board's vision for professional governance of homecare services in England and establishing a process for ongoing review and updating of the documents to ensure they continue to reflect best practices in the provision of homecare medicines services.



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PURPOSE OF THE HANDBOOK FOR HOMECARE SERVICES

The purpose of this handbook is to aid implementation of the Royal Pharmaceutical Society's (RPS) Professional Standards for Homecare Services.

The Royal Pharmaceutical Society Professional Standards for Homecare Services in England aims to ensure that patients experience a consistent quality of homecare services that will protect them from incidences of avoidable harm and help them to get the best outcomes from their medicines. Homecare services have particular challenges and are, almost by definition, shared care services in which multiple different agencies must work together seamlessly to provide integrated patient care in accordance with a defined medicine pathway.

Homecare teams may already have effective local systems in place. The aim of this handbook is not to replace those existing arrangements but to share and promote best practice and facilitate shared care by promoting standardisation of working practices. The handbook will be updated at intervals and homecare teams are encouraged to use professional networks and share their practices to enable the continual improvement of homecare services.

A RPS Homecare Steering Group will be established by the RPS to oversee the ongoing review, development and updating of the RPS Professional Standards for Homecare Services and the Handbook for Homecare Services. The steering group will co-ordinate with nationally recognised bodies related to homecare including the National Homecare Medicines Committee (NHMC), the National Clinical Homecare Association (NCHA) and other stakeholders to develop further homecare guidance and promote best practice and will be the focal point for ongoing development of this handbook.

SCOPE OF THE HANDBOOK FOR HOMECARE SERVICES

The scope of the handbook is limited to the implementation of the RPS Professional Standards for Homecare Services however, it signposts to the other 'Hackett' workgroup outputs where appropriate.

The main target audience are NHS Chief Pharmacists and NHS pharmacy staff involved in the delivery of homecare in England, but will also be essential reading for NHS Commissioners, other professions involved in the delivery of homecare, and other stakeholder groups. Although this handbook does not contain specific guidance for commercial homecare providers, it is likely to be of interest to all organisations providing homecare services to patients and the term Chief Pharmacist should also be read as meaning the pharmacist responsible for the homecare services within the organisation (e.g. the Superintendent Pharmacist within the homecare service provider).

STRUCTURE OF THE HANDBOOK FOR HOMECARE SERVICES

The handbook is structured in alignment with the RPS Professional Standards for Homecare Services. It identifies currently available resources and good practice examples which may be used by homecare teams in the development of robust arrangements for compliance with the three domains identified in the RPS standards:

1. The patient experience.
2. Implementation and delivery of safe and effective homecare services.
3. Governance of homecare services.

Each section of the handbook contains information and guidance and signposts and identifies key documents that will help homecare teams manage homecare services within a clinical and financial governance framework as set out in the RPS standards. For each document the Homecare Standards Workgroup have identified documents as follows:

★★★ Documents approved for national use by multidisciplinary bodies after wide consultation.

★★ Examples from existing homecare services which are consistent with the best practices described in the RPS Professional Standards for Homecare Services and this handbook.

★ Example documents developed and used locally by homecare teams. Considered to be useful, but need to be reviewed carefully and adapted before use. They are likely to have been prepared prior to the publication of the RPS Professional Standards.

Throughout the handbook we have included links to these example documents and templates as well as further resources wherever appropriate. It is expected that nationally approved documents (marked ★★★) will be used wherever they are appropriate to the homecare service being provided. The remaining documents have been shared with the permission of the originating organisation or NHS Trusts as useful examples and templates for you to adapt to support your own homecare services.

DEVELOPMENT OF THE HANDBOOK

The need for a compendium of best practice for the delivery of homecare services was identified in 2011 and a Homecare Toolkit (version 1) was developed. The Homecare Toolkit was a compendium of best practice documents, collated by the National Homecare Medicines Committee (NHMC) with the aim of harmonising and promoting best practice. The Toolkit was distributed to interested parties and to people known to be involved in the provision of homecare services. In 2011 the Department of Health commissioned the report Homecare Medicines – Towards a Vision for the Future (also known as the 'Hackett Report'), led by Mark Hackett, formerly Chief Executive University Hospital Southampton NHS Foundation Trust. The report made a list of recommendations to improve the financial and clinical governance arrangements for patients receiving medicines via the homecare route.

In April 2012 the Department of Health established a Homecare Medicines Strategy Board, chaired by Mark Hackett, to oversee national implementation of the recommendations. The DH Homecare Strategy Board established a number of workgroups to take forward the recommendations in the Hackett report. These workgroups were:

- procurement
- gain sharing
- governance
- patients' charter
- standards and implementation handbook
- I.T. systems.

The Homecare Standards Workgroup first task was to develop national standards for homecare, these were published as the RPS Professional Standards for Homecare Services (September 2013). The Homecare Standards Workgroup then updated and expanded the Homecare Toolkit in order to align with and support the implementation of the RPS Professional Standards, to form the handbook.

The Handbook for Homecare Services has been produced in parallel with the other 'Hackett' workgroups to ensure consistency. Where appropriate the outputs of the other workgroups are included in this handbook, or signposted from this handbook.

DEFINITIONS

Abbreviations

ABPI	– Association of the British Pharmaceutical Industry
BGMA	– British Generic Manufacturers Association
CCG	– Clinical Commissioning Group
CMU	– Department of Health Commercial Medicines Unit
CRG	– NHS England Clinical Reference Group
DH	– Department of Health
MHRA	– Medicines and Healthcare Products Regulatory Agency
NCHA	– National Clinical Homecare Association
NHMC	– National Homecare Medicines Committee
NHS	– National Health Service
NPSA	– National Patient Safety Agency
RPS	– Royal Pharmaceutical Society

Definitions

Adverse Drug Reaction – is a response to a medicinal product that is noxious and unintended effects resulting not only from the authorised use of a medicinal product at normal doses, but also from medication errors and uses outside the terms of the marketing authorisation, including the misuse, off-label use and abuse of the medicinal product. The definition of Adverse Drug Reaction would also normally include incidents of noxious and unintended effects arising from unlicensed use, misuse and abuse of medicines.

cGDP – current Good Distribution Practice guidelines issued by MHRA.

cGMP – current Good Manufacturing Practice guidelines issued by MHRA.

Chief Pharmacist or equivalent – for the purposes of this handbook 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.

Clinical Outcome – an objective measure of the health, wellbeing or quality of life of a patient following a clinical intervention.

Clinical Responsibility – responsibility for a particular aspect of a patient's healthcare.

Clinical Service Protocol – the Clinical Service Protocol indicates the actions to be undertaken and the records to be kept during the provision of a clinical service and is equivalent to a Standard Operating Procedure for that clinical element of the service.

Clinically Screened – screening using clinical knowledge and professional judgement, for the purposes of this handbook the term is also used to indicate the provision of a 'second pair of eyes check' by a suitably qualified healthcare professional who has access to the patients clinical record.

Complaint – formal complaint with reference number raised and managed within the organisations complaints system.

Contractor – the primary contractor who enters into an agreement with the purchasing authority to supply goods and/or services.

Homecare organisation or provider – 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 commissioners.

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

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.

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

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 and any risk control measures or special instructions to be implemented due to the patient's individual circumstances.

Marketing Authorisation – medicines which meet the standards of safety, quality and efficacy are granted a marketing authorisation (previously a product licence), which is normally necessary before they can be prescribed or sold. This authorisation covers all the main activities associated with the marketing of a medicinal product.

Medication Errors – any Patient Safety Incident where there has been an error in the process of prescribing, preparing, dispensing, administering, monitoring or providing advice on medicines. These Patient Safety Incidents can be divided into two categories; errors of commission or errors of omission. The former include, for example, wrong medicine or wrong dose. The latter include, for example, omitted dose or a failure to monitor, such as international normalised ratio for anticoagulant therapy. The definition of medication errors would also normally include Patient Safety Incidents arising from unlicensed use, misuse and abuse of medicines.

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.

National Clinical Homecare Association (NCHA)
– represents and promotes the patient-led interests of specific organisations whose primary activity is to provide medical supplies, support and clinical services to patients in the community.

National Reporting and Learning System (NRLS)
– central database of patient safety information held by the NHS Commissioning Board Special Health Authority (the NRLS was previously developed by the National Patient Safety Agency or NPSA).

Non-clinical Home Visit Protocol – is the set of instructions describing a non-clinical activity involving entry into the patient's home equivalent to a standard operating procedure for that activity.

Off label use – use of medicines outside the terms of the licence.

Patient Safety Incidents – NRLS defines Patient Safety Incidents as any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving NHS-funded healthcare. For the purposes of this handbook, this definition is extended to also cover non-NHS funded healthcare received as part of homecare services in England.

Patient's home – patient's home or other community location where the patient has requested delivery of the service.

Purchasing Authority – the Trust or other organisation that is purchasing the homecare service for its patients.

Serious Adverse Drug Reaction – an adverse drug reaction that is fatal, life-threatening, disabling, incapacitating, result in congenital abnormalities; and results in or prolong hospitalisation.

Service Level Agreement – document defining the services and service levels a contractor has agreed to provide for a purchasing authority. This document forms part of the contractual relationship between the parties.

Service Level Summary – document outlining the services and service levels a contractor has agreed to provide for a purchasing authority during a formal tender process. This document is for information only and does not form part of the contractual relationship between the parties.

Shared Care – for the purposes of this handbook this term is used to describe the joint participation of multiple organisations in the planned delivery of care for patients informed by an enhanced information exchange over and above routine discharge and referral letters. The lead HCP with clinical responsibility for the patient is defined, normally within the Individual Patient Care Plan, and understood by each HCP involved in the provision of the shared care. Each healthcare professional involved in delivering the care has a professional duty of care to the patient. This involves taking responsibility for their own actions, ensuring relevant information arising from their actions is shared with other healthcare professionals involved in the patient's care, and ensuring they have access to relevant clinical information shared by other HCPs and using that information to inform their professional decisions about the patient's care.

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

Definitions of homecare services type

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 the RPS standards.

LOW TECH HOMECARE

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 noncompliance.

MID TECH HOMECARE

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

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 CARE 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.

DOMAIN I: THE PATIENT EXPERIENCE

Domain I of the RPS Professional Standards for Homecare Services supports teams involved in homecare services with ensuring that individual patients are informed and supported in their choice to use a homecare medicines service. The standards ensure that each patient's individual circumstances are considered when defining their Individual Care Plan and that all relevant healthcare professionals are engaged and informed about the homecare service for each individual patient. The following section gives guidance and identifies documents that will help homecare teams support patients in making informed choices in relation to homecare services.

PATIENTS' CHARTER

A national NHS Homecare Patients' Charter is a targeted output of the Homecare Patient Engagement Workgroup.

Useful example

- Appendix I National Homecare Patients' Charter (Draft) ★★.

This NHS Homecare Patient Charter has been delivered by the Patient Charter Workgroup of the Homecare Strategy Board and is recommended for approval by NHS England. When formally adopted this will supercede local patient charters for NHS Homecare Patients in England. In the meantime each organisation involved with provision of medicines via homecare should ensure that it has a relevant patients' charter in place.

This may be the overarching patients' charter of an NHS Trust or be a specific patients' charter issued only to homecare patients and carers, but it should be aligned to the principles in the NHS Constitution.

HEMOCARE SERVICE INFORMATION FOR PATIENTS AND CARERS

It is important that patients are supported in their decision making about homecare medicines service and there are robust systems in place to provide comprehensive information to patients allow informed choice.

General homecare service information for patients and carers should include:

- how to contact the homecare team (service provider and clinical team) within normal working hours and out of hours
- how to seek advice and report concerns relating to their treatment
- how the patient's confidentiality will be protected
- how the patient's data will be handled including signposting to the relevant organisation(s) Data Protection or Privacy Policy
- how to complain about the homecare service
- the need for patient informed consent to homecare treatment and the patient's right to withdraw their consent at any time during the service
- the options available should the patient wish to switch to an alternative route of care e.g. GP led, inpatient or outpatient hospital care if their clinical or personal circumstances change so the homecare service is no longer the most appropriate for them. The alternatives available will depend on the medicines pathway, individual care plan, and local commissioning arrangements that are in place with the funder of the service e.g. the patient's CCG.

It is recommended that further information is included about the treatment to be provided via the homecare services and the way the homecare services operates for example:

- patients' rights and responsibilities and/or copy of the relevant patient charter
- a summary of the benefits and risks of homecare services
- the treatment and expected outcomes
- the medicines and any potential unwanted effects including adverse drug reactions (side effects)

- details of the specific medicine pathway, diagnostic tests, reviews by the clinical team and the patient's responsibility to comply with the provisions of the medicines pathway, including what will happen if the patient does not comply e.g. does not attend their clinic appointment
- the process for delivery and storage of medicines
- the process for removal of waste medicines and clinical waste
- how nursing visits will be arranged
- what training in self-administration the patient or carer will receive, and how their competence to self-administer will be monitored
- how the patient's GP, nominated community pharmacy or other relevant healthcare professional will be informed about the homecare services provided
- how the patient's experiences of the homecare service will be monitored and how to feed back their comments
- arrangements for travel and holiday services and how to request them.

Patients will receive a copy of the manufacturer's approved Patient Information Leaflet (PIL) with each supply of licensed medicines, however, due consideration should be given as to whether additional or summary written information specific to the homecare service would be useful for patients. This is particularly important as the patient will not receive counselling at the point of dispensing as they would if collecting the medicine in person from the dispensing pharmacy.

Useful examples

- Appendix 2 is an example of a patient leaflet ★ for Homecare Medicines Services which has been shared with kind permission of Leeds Teaching Hospitals NHS Trust
- Appendix 3 is an example of a patient leaflet ★★ which has been shared with kind permission of BUPA Home Healthcare and Bristol-Myers Squibb Pharmaceuticals.

Additional specialist patient information may also be needed when supplying unlicensed medicines or to explain use and care of equipment and ancillaries including refrigerators, temperature monitors and infusion pumps in accordance with Standard 4.6 (see Section 2.2).

All information given to the patient must be suitable for their needs and written in clear language without jargon. Provision of information in other languages or in large type may be beneficial for some patients.

REGISTRATION AND CONSENT FOR NEW PATIENTS

A template combined registration and consent form approved by the NHMC is available at Appendix 4. It may be edited for a specific homecare service, or homecare teams may choose to use a form of their own design, but it is strongly recommended that all the components of the template form are retained as a minimum to ensure consistency of approach to registration of patients on homecare services.

The consent statement must be considered carefully as it will have change control implications for future transfer between providers. If the patient gives consent to the purchasing authority for the homecare services chosen by the purchasing authority, (which may vary from time to time) this may be transferable between providers. If the consent statement is specific to a homecare provider, any change of provider will trigger an administrative process to re-consent existing patients. In exceptional cases it may be possible to infer implied consent for a change of provider from existing patients so that administrative processes do not delay patient treatments or otherwise impact patient safety.

In all cases, the key element is to ensure the patient has given informed consent to the service being provided and specifically that they understand who will hold their personal data and how that data will be used.

The patient must also be informed of any change and must understand that they can, at any time, withdraw consent they have given previously. In cases of implied consent, it is important that patients are given clear information about the change and have clear guidance on what to do if they are not happy with the change. If the Chief Pharmacist has any doubt over the process for gaining informed consent the matter should be referred to the relevant Caldicott Guardian(s).

If an individual patient is not competent to make their own decisions, any actions must comply with safeguarding vulnerable adults or child protection regulations. If the Chief Pharmacist has any doubt over the process for assessing the competence of an individual patient the matter should be referred to the relevant Safeguarding Lead(s) and/or Child Protection Officer(s).

The combined registration and consent form is most useful where the form is completed by the referring healthcare professional in the clinic with the patient present. In some instances it may be appropriate to have two separate forms for consent and registration. In this case, it is important to ensure that both forms contain appropriate identification for the patient.

NHMC template

- Appendix 4 Homecare Service – patient registration and consent form †★.

PATIENT SATISFACTION QUESTIONNAIRE

A template homecare patient satisfaction questionnaire which has been approved by the NHMC can be found in Appendix 5 Using these standard questions will allow benchmarking between organisations and homecare services. Further specific questions may be added, but it is strongly recommended that the questions in the approved document are retained.

Useful example

- Appendix 5 is a ★★★ nationally approved template homecare patient satisfaction questionnaire.

MEDICINES PATHWAY

A medicines pathway should be defined for each homecare medicines service. This may be prepared by the relevant Clinical Reference Group, specialist Commissioner, Trust or by the homecare provider. There are also examples of medicines pathways being developed by medical charities and pharmaceutical companies. In any case, the medicine pathway must be appropriate for the intended cohort of patients and include the key elements of the medicine homecare service. The medicine pathway must be jointly agreed by all organisations involved in the shared care of patients. The Medicines Pathway shows the expected course of treatment, diagnostic tests, clinical reviews and other interventions for a patient group. It may be exclusively delivered via homecare, or homecare may be one of a number of options available. The Medicines Pathway should clearly state whether the options are available to all patients or only to those meeting specified criteria.

Useful examples

- Appendix 6 is an example patient pathway for outpatient parenteral antimicrobial therapy ★★ which has been shared with kind permission of BUPA Home Healthcare
- NICE pathway for nutrition support in adults <https://pathways.nice.org.uk/pathways/nutrition-support-in-adults>
- The British Lung Foundation COPD pathway <http://copdpathway.blf.org.uk> ★.

INDIVIDUAL CARE PLAN

In some cases, patients may require an individual care plan covering deviations from the standard medicines pathway where the patient has special needs or circumstances. A Trust's own standard nursing care plan could be used, although the special requirements may extend beyond the scope of the nursing care.

Examples of individual needs could include:

- special instructions related to deliveries
- assistance with unpacking and stock rotation
- keyholding (N.B. unaccompanied access to the patient's premises must only be considered in exceptional circumstances – see section on key holding for further information)
- different methods of communication for people with visual or hearing impairment.
- arrangements needed to ensure a patient with limited manual dexterity can remove medicines from the packaging
- different review frequency or additional diagnostic tests because of co-existing medical conditions
- need for communication with a lead carer rather than directly with the patient (N.B. if the patient is not competent to make their own decisions, any actions must comply with safeguarding vulnerable adults or child protection regulations).

SUITABILITY AND NEEDS ASSESSMENT FOR INDIVIDUAL PATIENTS

The assessment of whether homecare treatment is suitable for an individual patient will take into account the following:

Patient needs

- the patient's clinical condition
- the patient's willingness and ability to consent to receive treatment at home
- availability of suitable contact details in case of issue or medicine recall e.g. mobile phone
- the patient's competence to self-administer the medicine in accordance with the prescriber's instructions
- in the case of vulnerable adults or children, whether an appropriate additional care package is robust and in place
- the patient's (or carer's) ability to understand their responsibilities with regard to the treatment e.g.
 - attending appointments
 - taking required tests
 - adhering to the treatment
 - reporting any adverse reactions or side effects
 - storing the medicines appropriately
 - being available to receive deliveries
 - ensuring contact details are given to the clinical team and homecare provider and are kept up-to-date.

Suitability of home

After determining that homecare is suitable for each patient, the suitability of their home (or other location in which the patient wishes to receive treatment) will need to be assessed to ensure it is appropriate for Homecare provision.

Risk factors to be considered may include, but are not limited to:

- medicines: e.g. safe storage, storage temperature, cross contamination
- clinical: e.g. infection prevention, appropriate ancillaries, competent use of equipment
- access for delivery and nursing staff: steps, parking, street lighting
- workplace health and safety for delivery and nursing staff: slips and trips, electrical, smoking, pets

- risks to patients and carers introduced by homecare services equipment and ancillaries: e.g. needing to carry up and down stairs
- safeguarding: cultural sensitivity, disability, other occupants
- patient confidentiality: privacy, clinical records.

Making a suitability and needs assessment

Assessments of suitability must be recorded and identified risks and control measures must be shared with other relevant healthcare professionals involved in the shared care of the patient.

Useful examples

- Appendix 7 is a home suitability and needs assessment checklist ★★ has been prepared by the NHMC for 'high tech' homecare. This identifies many possible hazards, and for many homecare services this level of detail will not be required
- Appendix 8 is an example of a simplified 'Homecare Suitability and Needs Assessment' ★★.

Regardless of how it is documented, it is important that any member of staff carrying out an assessment is competent, undertakes a thoughtful identification and evaluation of potential risks and patient needs.

The responsibility for performing, recording, sharing suitability and needs assessments should be documented in the Technical Agreement between the organisations providing shared care. It may be appropriate to make the suitability and needs assessment over the telephone for low tech homecare services. For homecare services that include home visits, the findings of any suitability and needs assessment performed remotely, should be confirmed at the first visit.

Where suitability issues and/or additional needs are identified, the homecare service may still be suitable for the patient with the implementation of specific control measures (see Box 1 on the next page). These specific measures may be outside the contracted service requirements and therefore subject to separate agreement with the homecare provider.

Where specific needs are identified these should be communicated in such a way that promotes their implementation. For example, an Individual Care Plan could contain the agreed actions and responsibilities, then shared to ensure everyone involved in the shared care of the patient is aware of identified needs and agreed control measures.

There should also be periodic review to ensure that the control measures put into place have successfully met the patient's needs and controlled any risks, and to identify whether there are any new needs or risks.

BOX 1

Examples of circumstances which may require additional control measures may include:

- if the patient is under 16 years of age and registered for an adult service
- if the patient is cognitively impaired or disabled
- if the patient is receiving deliveries at their family home, but the other family members are not aware of the patient's condition
- patients living in shared houses
- patients with no fixed abode
- if the patient is receiving deliveries at work and their colleagues are not aware of the patient's condition
- if deliveries are made to secure workplaces (e.g. police stations, airports, schools) as parcels are likely to be opened by unauthorised persons to maintain security
- the patient lives in a remote geographical area or area prone to transport disruption
- if there is to be unaccompanied access to the patient's home.

CLINICAL RECORDS

In order to meet their professional requirements for maintaining records of clinical interventions, records are kept by all healthcare professionals who provide clinical care. The complete patient record containing all the key elements of the patient's treatment should be kept by the person/organisation with clinical responsibility for the patient.

Patient clinical records may be paper based or electronic. Due consideration must be given to how the records will be stored and shared to ensure all relevant healthcare professionals are informed and a complete patient record is maintained, whilst complying with information governance requirements. See section 3 Governance of Homecare Services.

In homecare, where interventions and medicines are often provided by multiple organisations, it is important to consider which clinical records will be maintained by each party and how the key elements will be shared to ensure patient safety. Whilst it may be appropriate to consolidate routine reports on a periodic basis (e.g. weekly or monthly) there must be provisions for sharing exception reports and escalating clinical concerns immediately.

There will be defined reporting structures for planned interventions (see Clinical Service Protocols and Reports and Non-Clinical Home Visit Protocols and Reports), however, due consideration must be given to recording and sharing of reports relating to unplanned events, e.g. a patient phoning the help-line with a clinical query.

CLINICAL SERVICE PROTOCOLS AND REPORTS

The Clinical Service Protocol is equivalent to the Standard Operating Procedure for that clinical element of the service. If the Clinical Service Protocol is written in the form of a checklist where staff initial to indicate compliance and spaces for patient details and comments, a completed copy may also serve as the relevant Clinical Service Report.

A Clinical Service Protocol should be in place for each discrete clinical element specific to the homecare service e.g. Home Herceptin Administration, Patient/Carer Self-Administration Training, Patient/Carer Self-administration Competency Assessment. Each Clinical Service Protocol should include escalation criteria and processes and may include details of the competencies needed by staff undertaking the actions.

Where the Clinical Service includes administration of a medicine by the healthcare professional, a copy of the relevant prescription or clear and complete instructions on the dispensing label must be available to the healthcare professional at the point of administration.

It is expected that a Clinical Service Report will contain as minimum:

- patient name and identifiers
- location/mode of service provision e.g. clinical home visit, telephone intervention, outpatient clinic
- names and contact details of care staff present
- date, start/arrival time
- confirmation of patient consent
- confirmation that special control measures as detailed in the Individual Patient Care Plan are still appropriate
- details of any patient suitability or needs issues or risks that have been newly identified, changed or are no longer relevant and any changes to special control measures
- details of any medicine administration with check initials of healthcare professional for each medicine
- details of interventions made
- post-treatment observations
- adverse drug reactions, if applicable
- any other clinically relevant information that needs to be recorded and shared
- medicines and ancillaries stock and storage issues, if applicable
- details of any written information left with the patient
- date of next visit and whether it is confirmed or planned, if applicable
- finish/departure time
- signature of patient as proof of service/treatment
- signature of lead Health Care Professional delivering the service to approve the completed record as being complete and accurate.

NON-CLINICAL HOME VISIT PROTOCOLS AND REPORTS

This section only applies to non-clinical home visits e.g. delivery and installation of equipment, delivery of high volume dialysis fluids into the patient home with stock rotation. Where a home visit includes provision of a clinical service by a healthcare professional, the details of the home visit should be included in the relevant Clinical Service Protocol and reported as above.

The Non-Clinical Home Visit Protocol is equivalent to the Standard Operating Procedure for that element of the homecare service. If the Non-Clinical Home Visit Protocol is written in the form of a checklist where staff initial to indicate compliance and spaces for patient details and comments, a completed copy may also serve as the relevant Non-Clinical Home Visit Report.

It is expected that a Non-Clinical Home Visit Report will contain as minimum:

- patient name and patient identifiers
- location of visit
- names and contact details of homecare staff present
- date, arrival time
- confirmation of patient consent to the service
- Confirmation that special control measures are appropriate
- details of any patient suitability or needs issues or risks that have been newly identified, changed or are no longer relevant and any changes to special control measures
- confirmation that service was delivered as expected or clear description of issues and actions taken
- details of any escalation of issues encountered
- details of any written information left with the patient
- departure time
- signature of recipient as proof of installation/receipt of documentation/service
- signature of lead member of staff delivering the service to approve the completed record as being complete and accurate.

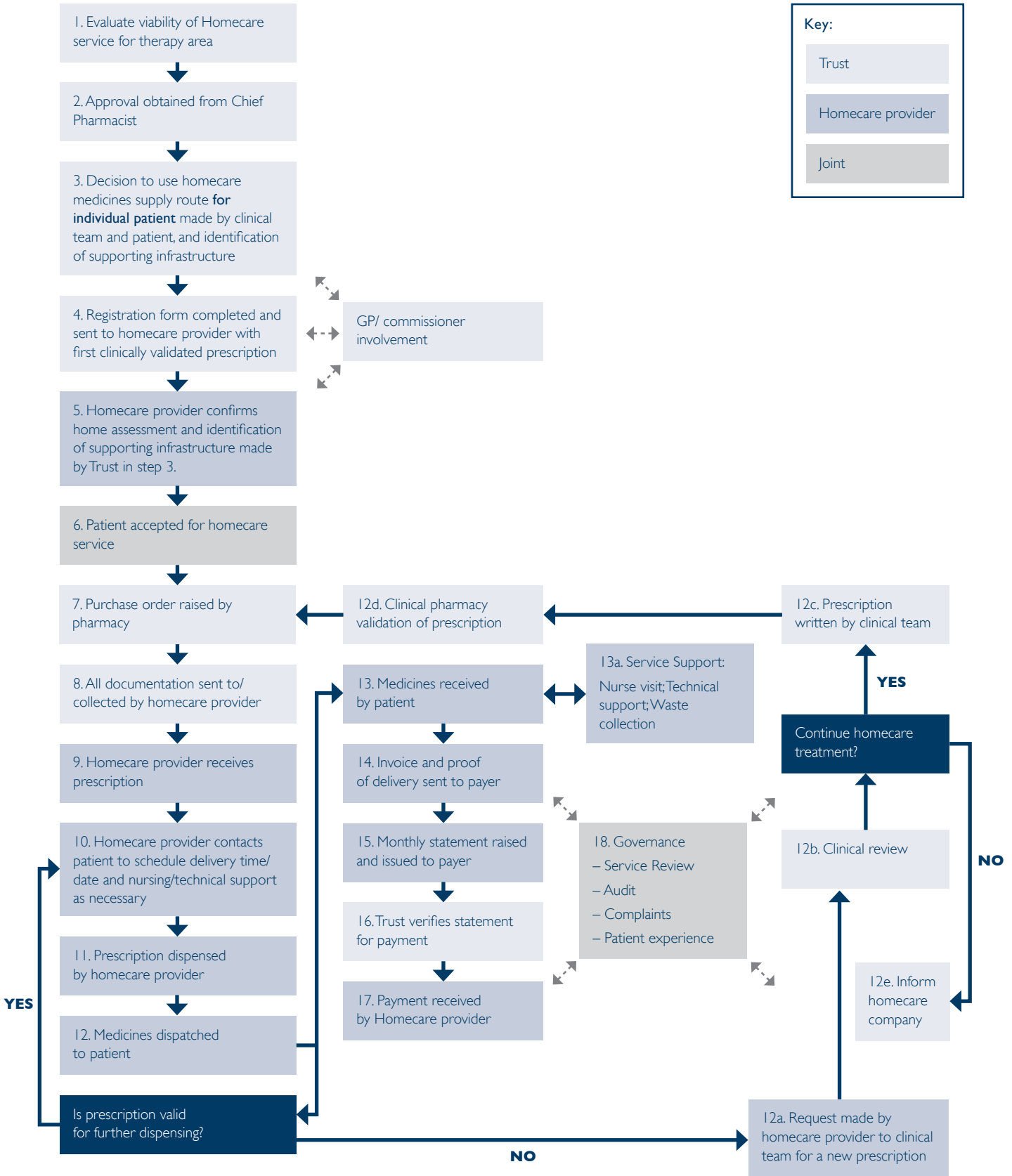
DOMAIN 2: IMPLEMENTATION AND DELIVERY OF SAFE AND EFFECTIVE HOMECARE SERVICES

Domain 2 of the RPS Professional Standards for Homecare Services describes standards for the design, setting up and delivery of a homecare service for a cohort of patients. This section of the handbook is divided into 2 sections. Section 2.1 describes the contractual framework required to set up and to manage a homecare service on an ongoing basis. Section 2.2 contains operational guidance on delivery of services by homecare teams.

The schematic overview of the process for home delivery is provided in the Homecare Process Map ★★★ in Fig. 1 on the next page.

Homecare services must be provided under the framework of a homecare policy and strategy, see Domain 3: Governance of Homecare Services for further information on this. Domain 3 also gives guidance on assessment of risks associated with the homecare service which will be needed to inform the development of the service specification.

FIG. 1 HOMECARE MEDICINES PROCESS MAP (INDIVIDUAL PATIENTS)



2.1 Contractual framework required for a homecare service

When setting up a homecare service, there is a key suite of contractual documents which taken together fully describe all aspects of the homecare service. Preparing these documents supports the design and specification and tendering of the service, and so it is essential to secure the engagement of all stakeholders including commissioners, clinical teams and patient groups.

Each of the documents builds on the one before, so they should be developed in the order shown, but at each stage it may be necessary to circle back and to review and revise the previous stage if significant new information is uncovered. It is therefore recommended that each document undergoes stakeholder review as it is developed but, wherever time permits, the suite of documents pass through the organisation's formal approval processes together when they are all finalised

- Medicine Pathway
- Homecare Service Aims and Rationale
- The Homecare Service Specification
- Tender or Proposal Documentation
 - expression of interest
 - pre-Qualification Questionnaire
 - tender Response request and adjudication criteria (Public Tender)
 - request for Proposal (RFP) and adjudication criteria (Commercial Tender)
 - tender or proposal feedback
- Service level agreement or service level specification
- Key Performance Indicators (KPI)
- Technical Agreement.

The use of these template documents in accordance with this guidance will ensure all parties involved in the service are clear as to their responsibilities, whilst ensuring consistency of service provision in compliance with the RPS Professional Standards for Homecare Services:

- the purchasing authority will specify clearly the requested service in the tender or RFP
- the providers will be clear about the criteria they are being assessed against both in adjudication of tender or RFP submissions and in the Key Performance Indicators for ongoing monitoring of service delivery.

The consistent use of this suite of documents will also avoid duplication, and therefore the risk that documents contradict each other. In turn, this will simplify the implementation process and ensure patient safety.

HOMECARE SERVICE AIMS AND RATIONALE

The Homecare Service Aims and rationale, when completed and approved, becomes the 'Aims and objectives' of the Service Specification. The aims and rationale for each service must be in line with the organisation's Homecare Policy and Homecare Strategy.

This document explains the scope of the homecare service and explains why the homecare service is being implemented. The Homecare Service Aims and Rationale can be developed as part of the Service Specification; however it may be used earlier as a stand-alone document to support approval to move to the next stage of defining the services specification.

Example aims are:

- extend homecare services to improve patient choice
- meet QIPP targets [specify]
- reduce costs by [x%]
- cap cost increases at [x%]
- give access to medicines to [x] more patients
- reduce number of outpatient appointments by [y%]
- reduce the number of hospital acquired infections by [x%]
- manage increasing patient numbers with the same staffing level
- reduce number of unplanned admissions in target patient group by [z%]
- centralise administration of homecare services
- realise planned cost savings [£x] from IT infrastructure investment.

HOMECARE SERVICE SPECIFICATION

Development of the output based service specification should be the first step when considering a new homecare service. The Service Specification is output based and describes the service that is requested by the purchasing authority. Care should be taken to avoid over-specifying elements that do not significantly impact clinical outcomes, patient satisfaction or would increase the cost of administering and/or delivering the service.

Homecare Service Specifications should:

- include 'what' elements are required to deliver the overall aims of the homecare service but not 'how' those elements should be delivered. This approach aims to promote innovation and a culture of innovation and continuous improvement
- detail the minimum acceptable standard or minimum requirement and indicate where offers of improved services would be advantageous to the patient or to the purchasing authority
- detail where an enhanced service for a specific element would be advantageous. If it is intended to give different weighting to service levels e.g. where 'minimum' and 'expected' and/or 'preferred service' levels are specified, there must be an equivalent adjudication question
- be easy to read and understand e.g. where specify higher levels of service are specified for different circumstance; consider splitting into separate specification elements rather than one complicated element
- make reference to how the service will be performance managed. It should make reference to the National Homecare KPIs. Additional KPIs should be included only where they are necessary to support the Homecare Service Aims and Rationale
- refer to NHS Standard Terms and Conditions for purchasing goods and supply of services (if the service is to be provided to NHS patients).

A standard homecare service specification and tender template is being developed by the NHMC with the support of DH's Commercial Medicines Unit (CMU) and NCHA to ensure compliance with the RPS Professional Standards for Homecare Services. This work supersedes older versions. The new template is in Excel format with worksheets relating to key parts of the homecare service. Most worksheets are to be used as standard and some are optional if those elements of service are not included in the specification e.g. cold chain, compounded products.

The template is designed to meet the needs of formal public tendering process, may also be used by pharmaceutical companies when tendering for pharmaceutical manufacturer funded homecare services for NHS patients.

Within the homecare service specification and tender template, each line item is classified as either Compliance, Specification or Adjudication Question. Line items categorised as Compliance or Specification make up the Homecare Service Specification. The role of Adjudication Questions is considered below in the following section on Tender or Request for Proposal (RFP) and Adjudication Criteria.

Compliance – These are statements of requirements. If a potential contractor is unable or unwilling to comply with the compliance elements, they are unsuitable and therefore cannot be asked to provide the services and/or are not eligible for inclusion in the next stage of the tender/proposal process. If there is a pre-qualification stage, evidence of compliance should be requested at this stage and should not be duplicated in later stages of the same tender process.

Specification – These are statement of minimum requirements. No response is needed from potential contractor unless they are unable or unwilling to provide the service meeting that minimum specification. Statements from potential contractors relating to provision of higher standards or extended or more flexible services in relation to specification line items are not relevant (see adjudication questions).

It is expected that therapy-specific homecare specifications using the nationally agreed template will be developed by the specialised commissioners, based on medicines pathways developed by the relevant Clinical Reference Group (CRG). It is therefore advisable to check what is already available with NHS England Regional Commissioners before preparing any local specifications.

The homecare service specification and tender template, described above, provides the service specification and also takes the next step to allow it to be used as a tender document and allow the purchasing authority to differentiate between responses from potential contractors as discussed below.

The homecare service specification and tender template is also designed so that Compliance and Specification line items will go on to form the basis of the Service Level Summary or Service Level Agreement.

TENDER OR REQUEST FOR PROPOSAL (RFP) AND ADJUDICATION CRITERIA

Homecare services for NHS patients are commissioned directly by an NHS organisation or are provided by the pharmaceutical company to support the distribution of their product.

Public procurement law regulates the purchasing of contracts for goods, works or services by public sector bodies like the NHS. All homecare services will be of sufficiently high value (at 1 January 2014 the threshold was £111,676 – <http://www.ojec.com/Thresholds.aspx>) to require a formal public tender as required by the European Public Contracts Directive (2004/18/EC). If a public sector organisation knows they are likely to need particular goods or services, but are unsure about exactly what they'll need or when, they may decide to set up a group of approved suppliers that they can use when necessary. This is called a 'framework agreement'. Potential contractors are invited to put themselves forward for the framework via a tender process and the purchasing authority appoints contractors to the framework. Once the framework is set up, individual contracts are made throughout the period of the agreement with one or more of the contractors appointed onto the framework. If there is more than one possible contractor on the framework, a 'mini-competition' may be held to decide who gets the contract. Each homecare organisation is likely to have its own purchasing policy and procedures which should be followed.

If a purchasing authority is delegating the tender function to another organisation or opting in under a framework tender the purchasing authority is responsible for ensuring that the tender process is/was in alignment with the RPS Professional Standards for Homecare Services.

In the case of pharmaceutical company funding, the pharmaceutical company chooses the service provider(s) and the level of service to be provided and the homecare service is included within the purchase price of the medicinal product. The definition of the service and the service levels to be provided to patients are included in the Service Level Agreement (see on next page).

General principles for homecare tenders are:

- the adjudication criteria should give a weighting to indicate which elements of the service specification are important to the overall service delivery. This means adjudication questions should be included for specification line items assigned 'critical' or 'important' to the service.

As a minimum, the adjudication question should request specific detailed evidence to show compliance.

- the adjudication criteria should cover elements of the service specification where enhanced service levels over the minimum specified would be advantageous and therefore attract a higher score in the adjudication process. The adjudication questions should begin with a statement of the benefits of the potential enhanced service and ask how the respondent could meet that need and/or propose additional service enhancements and the benefits they are anticipated to bring to the patient and/or purchasing authority
- care should be taken to ensure that new providers will not be unintentionally excluded
- if additional adjudication questions/criteria are necessary above those generated by review of the service specification this should lead to a review of the Service Specification and inclusion of additional compliance or specification element(s) against which the adjudication criteria can be assigned
- the overall adjudication assessment procedure should be reviewed to ensure it delivers the outcomes anticipated in the Homecare Service Aims and Rationale. Adjudication criteria that have no relevance to the Homecare Service Aims and Rationale should be removed and the Homecare Service Specification reviewed to remove the over-specification of related elements.

The homecare service specification and tender template described above. In addition to Compliance and Specification line items there are line items categorised as Adjudication Questions which meet the general principles for homecare tenders outlined above. Further refinement of the template is planned so it also calculates the overall score for each key part worksheet based on the pre-determined importance weightings for each Adjudication Question allowing responses from different potential contractors to be compared as follows.

Each Adjudication Question line item

- is weighted for importance to the overall service
- requires a level of evidence from the respondent (minimum = statement of intent to comply, maximum = provision of evidence of best practice and continuous improvement)
- allows responses to be objectively scored against the level of evidence requested.

SERVICE LEVEL SUMMARY (SLS) OR SERVICE LEVEL AGREEMENT (SLA)

There should be no material difference between the contents of the Service Level Summary (SLS) or Service Level Agreement (SLA). They are produced individually, one for each successful provider, including amendments according to the tender submission of that provider. This ensures significant service enhancements that were offered and were material to the adjudication are included in the contract and performance management processes. The difference between an SLS and an SLA is one of legal statuses: an SLS is for information only; an SLA forms part of the contract between the parties. Examples of whether an SLS or SLA is appropriate are given below. If there is any doubt, the organisation's purchasing specialist should be consulted. Further information and guidance may also be obtained from CMU or NHS England Regional Specialist Commissioners.

- During the public tender process submissions are binding on the provider and further contractual documentation is not needed. However, tender submissions are often difficult to navigate and it is useful for the parties to agree a Service Level Summary (SLS) to act as the working document against which service reviews are completed. The SLS must exactly mirror the tender specification; any changes may invalidate the tender processes. Whilst the SLS does not form part of the contract between the parties it is wise to include a statement that if there is any conflict between the terms and conditions set out in the SLS and its tender then the terms and conditions set out in the Contract shall prevail the tender shall prevail
- during commercial tendering Request for Proposal (RFP) responses are often submitted on a 'subject to contract' basis. In these cases a Service Level Agreement (SLA) is produced as part of the commercial and contractual agreement between the provider and Purchasing Authority.

As the main target audience for this handbook is NHS Chief Pharmacists and NHS pharmacy staff, we will use the term Service Level Summary for the remainder of this section, however, in this context the terms SLS and SLA are interchangeable.

The Service Level Summary should:

- refer to or include a copy of the Service Specification (Note: if using the homecare service specification and tender template – this means a copy of the line items classified as Compliance or Specification)

- specify exceptions where elements of the Service Specification are not to be provided as accepted within the tender and adjudication process
- specify enhanced elements offered by the provider in the Tender submission which were material in the Tender adjudication process
- define national KPI measurement criteria e.g. for KPI patient referrals processed on time, the SLS or SLA must specify the actual timings against which 'on-time' is measured.

See Box 2 below for an example.

BOX 2

Example of how an element will be managed through process and documentation:

Service Specification: Customer Services Staff available to answer patient calls between 09:00-17:00 weekdays.

Tender RFP and Adjudication Criteria: Extended hours of availability for customer services would be advantageous.

Potential Contractor's Response: Our customer service hours are 08:00-18:00 Weekdays and 09:00-12:00 Saturdays.

Service Level Summary or Agreement: Customer Services staff available to answer patient calls between 08:00-18:00 Weekdays and 09:00-12:00 Saturdays.

KPI: No specific measure required as will be captured by review of complaints.

If part of the shared care service is delivered by a third party with whom the purchasing authority has a working relationship but no contractual agreement (e.g. the homecare service provider contracted to a manufacturer to provide a wrap-around service for their product which is included in the purchase price to the purchasing authority) it is particularly important that the purchasing authority understands the specification of the service they are indirectly commissioning. There are plans for Service Level Agreements for pharmaceutical manufacturer funded homecare services to be made available to NHS purchasing authorities via the DH's Commercial Medicines Unit.

TEMPLATE TECHNICAL AGREEMENT

The technical agreement defines all parties' professional responsibilities with regard to delivery of the service. It does not contain commercial terms, which should be defined separately in the tender or commercial contract. Caution is advised where there is any element of joint responsibility – it may be better to split the activities being described into their component parts so that responsibility can be assigned to one or other of the parties to the technical agreement to avoid confusion. If part of the shared care service is delivered by a third party with whom the purchasing authority has a working relationship but no contractual relationship it is particularly important that a technical agreement is put in place to ensure patient safety by specifying the responsibilities of each party in the delivery of services to homecare patients. The technical agreement should be approved by the Chief Pharmacist or equivalent in each organisation involved in the shared care provision. Where appropriate the Technical Agreement may also be approved and countersigned by the Chief Nursing Officers of the appropriate organisations.

Useful example

- Appendix 9 an example of a technical agreement
★ ★ has been shared with kind permission of by the North East Pharmacy Procurement Group.

KPIs

The NHMC has agreed high level KPIs be used for all homecare services to monitor the performance of the entire service (see Fig 2. below).

KPIs will indicate areas of concern that impact patient safety or patient satisfaction or compliance with the SLS/SLA, irrespective of where or when they occur. The individual KPIs are linked to the critical steps in the homecare process especially at interfaces between the purchasing authority, Homecare Organisation(s) and patients. It is planned that the NHMC will collect KPI results for at least 6 months to allow resolution of reporting anomalies and inconsistencies before establishing the KPI target levels that represent good service levels for homecare services.

Review of KPIs results will allow early detection of adverse trends and assist performance management of homecare services. As the KPIs monitor performance and integration of all parties providing the homecare service, the KPI results should be transparent to all parties that are collecting data or being monitored by data collected by other parties.

FIG. 2

REF	KPI
K1	Number of correctly completed registration documents received as % of total number of new registration documents received
K2	Number of compliant prescriptions as % of total prescriptions received
K3	Number of prescriptions received with a purchase order number included as % of total prescriptions received
K4	Number of prescriptions the Trust requests that require processing quicker than required in the Specification or SLA terms as % of total number of prescriptions received
K5	Number of medicines and ancillaries deliveries not on time as % of total number of deliveries
K6	Number of medicines and ancillaries deliveries not in full as % of total number of deliveries
K7	Number of failed deliveries as % of total number of deliveries
K8	Total number of invoices remaining overdue for payment and unpaid at month end as a % of number of invoices issued
K9	Number of Credit or Debit notes as % of number of invoices issued
K10	Number of medicines errors as a % of dispensed items
K11	Number of service failures as % of number of deliveries

Useful example

- Appendix 10 The national KPI data collection template ★★★ has been produced by the DH's Commercial Medicines Unit and adopted by the NHMC as a national standard for homecare services.

Where appropriate, additional KPIs may be added to the National framework KPIs – however, any additional KPIs must not be onerous to monitor and must be justified as meaningful in terms of the Homecare Service Aims and Rationale.

Using the national KPI framework and definitions (without local amendment) will also facilitate meaningful benchmarking of performance of provider Trusts and homecare providers. Robust benchmark data will improve the overall performance of procurement and delivery of homecare services by highlighting poor performance for further investigation and allowing the identification and sharing of best practices.

Where a KPI result is below the expected level it may be appropriate to collect more detailed data to understand the root cause of the underperformance of that specific KPI. However, additional measures should be for a limited time and once the issue is corrected and overall KPIs return to expected levels, the additional data collection and monitoring should be discontinued.

The KPI report for all aspects of the service will be shared with all the parties involved on a monthly basis and reviewed during the regular Homecare Service Review Meetings. All parties will work together in good faith to identify root causes and implement appropriate corrective and preventative actions can be agreed to ensure services meet the expected standards.

2.2 Operational Guidance for Running a Homecare Service

Robust systems and supporting documentation need to be in place to support the operational implementation and delivery of the homecare service. The schematic overview of the process for home delivery is provided in the Homecare Process Map ★★★ in Fig. 1 on Page 19.

This will involve:

- ensuring homecare is suitable for the patient. This is discussed in detail in Domain 1 of this handbook
- financial approval to proceed with patient registration
- clinical review and communication of orders and prescriptions to the homecare provider
- delivery of medicines and services to the patient
- appropriate storage of medicines in patients' homes
- systems for invoicing and payment
- managing complaints
- service review.

PRESCRIPTIONS

All homecare prescriptions must be legally valid. Particular attention is needed in the design of prescriptions intended to be dispensed by a third party homecare provider as standard hospital prescriptions intended for 'internal' use may not contain all the necessary information needed by an external homecare pharmacy. The patient's address must be stated on the prescription if being dispensed by a third party. It should be noted that many hospital outpatient prescriptions do not have the patient address, therefore would not be appropriate homecare use.

Prescription formats are legal documents issued by the prescribing organisation, so homecare prescription formats and/or templates should be approved by the prescribing organisation's normal processes. The formats and/or templates must also be acceptable to the dispensing organisation. Sufficient time and priority should be allowed during the setting up of a homecare service, or transfer to a new homecare provider, to ensure prescription formats are both appropriate and approved by prescribing and dispensing organisations.

In addition, the following will support robust homecare service delivery and reduce the risk of medication errors:

- where a medicine is specified in the tender specification, it is prescribed using its description from the tender specification
- whilst hospital prescriptions are routinely written generically, where it is important for clinical or contractual reasons that the patient receives a specific manufacturer's product or presentation this must be clearly indicated on each prescription. Within a hospital pharmacy, there may be clear rules on which manufacturer's product and/or presentation is to be used, however, an external homecare pharmacy will be dealing with prescriptions from many different Trusts with many different rules, so the manufacturer and/or presentation must be stated on each and every prescription to minimise the potential for patient safety incidents
- prescriptions must consider that the patient will not receive counselling at the point of dispensing. Where it is important that specific wording is used on the dispensing label (e.g. instructions for use) the words must be reproduced in full on each and every prescription. Where patient counselling related to a specific prescription is performed, this should be recorded on the prescription and in the patient's clinical record. If patient counselling is not performed in relation to a specific prescription, processes should be in place to ensure the patient receives appropriate information and/or counselling as part of the homecare service
- if a specialist product is to be dispensed for self-administration and incorrect administration could impact patient safety – consider how the dispensing pharmacist is able to discharge their professional duty to confirm that the patient has been appropriately assessed as being 'competent' to self-administer

- if a specific manufacturer's product is to be dispensed for contract pricing reasons, this must be stated on the prescription. It may be acceptable to specify the manufacturer's product to be supplied for contract pricing purposes on an associated purchase order; however it is the purchasing authority's responsibility to ensure that procedures are in place to allow the dispensing pharmacist to have access to this information at the point of dispensing
- if the manufacturer's product or presentation dispensed is different to that intended by the prescriber but the dispensing pharmacist has dispensed in accordance with the actual prescription presented, this should be recorded as a prescribing error as the prescription was either not clear or not specific
- there may be additional requirements for specialist prescribing e.g. clinical checking and validation of prescriptions for systemic anti-cancer treatments (SACT) must be done in accordance with the British Oncology Pharmacy Association (BOPA) Prescription Verification and Prescription Management Standards. The design of the prescription should consider how the dispensing pharmacist will be able to review the approved treatment protocol
- the prescription indicates whether the treatment is new, continuing or changed – this provides useful information for the dispensing pharmacist
- formats of prescriptions for specials and compounded products must be agreed by the prescribing authority, the homecare service provider and specials manufacturer
- prescriptions for unlicensed products or for off-label use of medicines must clearly indicate to the dispensing pharmacist that the prescriber is aware that the medicine is unlicensed and the patient has given informed consent to be treated with the unlicensed product
- the name, qualifications and signature of the clinical checker and date of the check is recorded on the prescription form. Clarifications (e.g. addition of brand/presentation information) are clearly indicated as being the work of the clinical checker. Any material changes to the prescription made during clinical checking are countersigned by the prescriber.

GUIDE TO TEMPERATURE CONTROLLED STORAGE

In most cases, homecare medicines will be suitable for storage at normal room temperature or in a patient's own domestic refrigerator as is the case for medicines dispensed by a community pharmacy to a patient for use at home in accordance with prevailing guidelines from GPhC and RPS. However, some homecare medicines may be particularly unstable or present a higher than normal risk that requires additional storage control measures.

During 2011, NCHA and NHMC have recognised the disparity between tenders with regard to the management of cold chain medicines. There is therefore the need for national guidance for maintaining the cold chain within patients' homes, to ensure integrity of medicines requiring storage at 2-8°C, whilst also ensuring that costs are proportionate to the risks to patient safety. The NHMC is currently producing this guidance which will take a risk-based approach, considering factors such as:

- risk and impact of storage at higher temperatures than detailed in the Summary of Product Characteristics e.g. room temperature
- risk and impact of storage at lower temperatures than detailed in the Summary of Product Characteristics e.g. freezing
- risk and impact of other instability of the medicinal product which is known or can reasonably be inferred
- cost, ease and speed of providing a replacement product in the event of medicines being unfit for use
- the risk to patient of missing one or more doses particularly during the time needed for replacement products to be provided
- intended frequency of deliveries and therefore the length of time medicine will be stored in the home
- quantity, physical volume and value of affected medicinal products likely to be stored in the home
- safety of patients, carers and other people in the home.

CUSTOM MADE MEDICINES, AND IMPORTED MEDICINES LICENSED IN THEIR COUNTRY OF ORIGIN

Where the medicine being supplied to the patient is an unlicensed medicine (e.g. a compounded special or an imported medicine licensed in its country of origin), the purchasing authority and dispensing organisation need to be satisfied that the medicine is of an appropriate quality and meets the special needs of the patient(s). This is especially important in the case of homecare medicines, as the medicine may not be seen by the purchasing authority before it is provided to the patient.

The tendering processes should include an assessment of the suitability of suppliers of unlicensed medicines and a quality assessment of the products to be supplied. This will include an assessment of:

- the safety information available on the medicine
- GMP history and compliance
- quality system processes
- technical capability
- supply chain security
- product specifications including stability.

A product specification for all custom-made and imported unlicensed medicines should be agreed between the purchasing authority, dispensing organisation and, where appropriate the manufacturer. Any changes to the specification must be agreed between the parties before implementation.

Guidance to prescribers and purchasers of unlicensed medicines is available from the RPS and additional guidance is available from the National Prescribing Centre. The NHS Pharmaceutical QA Committee is also currently updating its guidance on the purchase and supply of unlicensed medicines in line with the RPS's Professional Standards for Hospital Pharmacy Services.

Useful example

- Appendix II an example of a product quality assessment for an unlicensed compounded antibiotic shared by kind permission of Quality Control North West ★.

KEY HOLDING GUIDELINE

The key holding guideline covers occasions when homecare staff are asked to enter the patient's home (or other community location) without supervision of the patient, carer and/or premises owner – for example to deliver medicines to the patient's home whilst the patient is at work.

- The NCHA Keyholding Service Guideline ★★★, is approved by the NHMC and should be considered as nationally approved best practice. It can be found on the NCHA website: <http://www.clinicalhomecare.co.uk/about-the-ncha/association-documents>

Unaccompanied access to private premises by any member of the homecare team is problematic in terms of:

- maintaining security and safety of the staff member
- maintaining security and safety of the premises
- risk and liability of any loss or damage that may be associated with that access.

Purchasing authorities should note that if they include a requirement for such services within their service specification, they take at least partial responsibility for any loss or damage that may occur as a result of that service.

ADVERSE WEATHER GUIDELINE

The adverse weather guideline contains useful pointers for identifying and managing the risk associated with delivery delays and its contents should be considered when designing a homecare service. It also gives practical guidance for contingency planning, anticipating and managing adverse weather situations that are commonly encountered within the UK.

- The NCHA Adverse Weather Guidelines ★★★, is approved by the NHMC and should be considered as nationally approved best practice. It can be found on the NCHA website: <http://www.clinicalhomecare.co.uk/about-the-ncha/association-documents>

HOMECARE SERVICE REVIEW MEETING AGENDA

Formal homecare service review meetings must be held regularly. These will be local, but may also be regional and/or national, depending on the service specification. It is recommended that meetings are held on a monthly basis during implementation phases. Quarterly ongoing reviews will be adequate for most established homecare services.

One meeting each year must include an annual review of trends and overall contract performance in addition to reviewing the results from the last period. Meetings should be scheduled well in advance of the meeting date to allow attendees to organise their diaries.

The agenda will include:

- apologies for absence
- review and approval of minutes of the last meeting
- matters arising from last minutes
- items for Any Other Business
- review of KPI results from last period
- review of complaints from last period
- review of patient safety incidents from the last period
- review of patient satisfaction questionnaires from the last period
- activity planning for next period
- review change requests and future service developments
- annual review of trends and contract performance (if appropriate)
- any other business
- future meeting schedule.

TRANSFERRING PATIENTS BETWEEN HOMECARE PROVIDERS

Where there are plans to transfer patients between homecare providers (e.g. after retendering of an existing homecare service), the purchasing authority must ensure arrangements are in place for seamless transition between homecare service providers to ensure patients experience no interruption in their care and that their preferences are taken into account.

Useful example

- Appendix 12 Leeds Teaching Hospitals NHS Trust has developed a procedure for transferring patients between homecare services ★★ and this has been adopted by the NHMC as national guidance.

This guideline has been in place for some years and has been used successfully to manage an orderly transfer of patients between services providers following tenders. It is now being updated by NHMC to incorporate learning from its use, however it still provides good practice example and has therefore been included in this handbook.

DOMAIN 3: GOVERNANCE OF HOMECARE SERVICES

Domain 3 of the RPS Professional Standards includes standards for leadership, governance and financial management and workforce planning and development. The standards, require that a named individual pharmacist is responsible and accountable for oversight of the homecare services provided by their organisation. The standards further outline the planning and high level control processes that should be in place to ensure safe and effective, patient centred homecare services are consistently delivered.

To underpin this, the patient's journey and the interface with other stakeholders should be considered.

HOMECARE STRATEGY

The homecare strategy for the organisation will state the high level strategic aims for the homecare services they provide. For an NHS purchasing authority, this may include elements such as:

- improve/optimize treatment outcomes
- extend patient choice or to allow patients to choose to be treated at home if it is safe to do so
- encourage patient independence and/or engagement with their treatment
- improve patient experience
- increase standardisation and consistency of homecare services
- improve governance
- improve range of homecare services offered
- improve take-up of homecare services offered
- realise time and economic savings for NHS and its patients
- financial advantages.

Each homecare service should have specific service aims and rationale that lists the expected outcomes and benefits of that specific homecare service. These could be combined and used as a basis for the organisations overall homecare strategy (see Section 2.1).

Normally the homecare strategy will include the 5-6 most important strategic aims of the organisation that are used to guide decision making and allocation of resources.

The homecare policy will normally describe the internal decision making processes that enable those strategic aims to be realised. However, each homecare organisation will have its own procedures for defining strategy and policy and these should be followed. The list of medicines pathways and/or medicines for which homecare services are provided by the organisation may be included in either the homecare strategy or the homecare policy.

Organisations' forward planning should take account of provision of homecare services to patients, and homecare should be included in annual budget planning. Homecare objectives should be included in the personal targets of the Chief Pharmacist (or equivalent) and relevant members of the homecare team.

HOMECARE POLICY

All NHS Trusts that provide homecare services to patients will need to prepare a policy for homecare.

A Homecare Policy statement will include, or refer to the key homecare processes and clearly state responsibilities of all internal parties and ensure technical agreements are in place for external parties involved in shared care. The Homecare Policy should also consider arrangements for:

- contracting and commissioning, including procurement and responsibility for managing sub-contracted services
- initiation of homecare service and professional responsibilities
- maintenance of homecare treatment including management of change
- financial management
- information governance
- clinical governance
- quality management including feedback, complaints and performance management
- risk management including contingency planning and business continuity.

Useful example

Appendix 13 University College London Hospitals NHS Trust has provided its Homecare Policy ★.

This is a comprehensive policy: individual Trusts may wish to incorporate a Homecare policy statement into the Trust's Medicines Management Policy to avoid the need for a separate Homecare Policy.

PATIENT CONFIDENTIALITY, INFORMATION SHARING AND DATA PROTECTION

The Data Protection Act makes provision for the regulation of the processing of information relating to individuals, including the obtaining, holding, use or disclosure of such information. Patient data relating to an individual's physical or mental health is considered to be sensitive personal data.

Organisations registered with the Information Commissioner's Office (ICO) under the Data Protection Act should already have a 'Data Protection' or 'Privacy' Policy that is available to all. Chief Pharmacists should check that the existing approved policy adequately covers the homecare services provided by that organisation. The Data Protection or Privacy Policy of each organisation that must be freely available or published in the public domain and homecare patients must be provided with a copy or clearly signposted to that Policy.

Under the Data Protection Act, each organisation undertakes the activities of data handler or data controller. In the provision of homecare services, organisations involved in clinical care will both be data controllers and therefore a Data Sharing Agreement is normally needed that includes a map of data flows and defining the responsibilities for record keeping.

Specific guidance as to the handling and of individual patient data was considered in the Caldicott Reviews 1997 and 2013 (see box 3 on the next page). The 1997 review gave priority to discouraging the uploading of personal information on to information technology systems outside clinical control. The issue of whether professionals shared information effectively and safely was not regarded as a problem at the time, but became more relevant during the intervening years. The 2013 review's overarching aim has been to ensure that there is an appropriate balance between the protection of the patient or user's information, and the use and sharing of such information to improve care. The burden of explicit consent is reduced under the 2013 Caldicott report. Provided the patient is informed that their information will be shared with other healthcare professionals directly involved in their care and they do not object, they are considered to have given implied consent.

- The Caldicott Report on the review of patient-identifiable information. http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationspolicyandGuidance/DH_4068403

BOX 3: REVISED CALDICOTT PRINCIPLES

The Caldicott Report set out a number of general principles that health and social care organisations should use when reviewing its use of client information and these are set out below:

- justify the purpose(s). Every proposed use or transfer of personal confidential data within or from an organisation should be clearly defined, scrutinised and documented, with continuing uses regularly reviewed, by an appropriate guardian
- don't use personal confidential data unless it is absolutely necessary. Personal confidential data items should not be included unless it is essential for the specified purpose(s) of that flow. The need for patients to be identified should be considered at each stage of satisfying the purpose(s)
- use the minimum necessary personal confidential data. Where use of personal confidential data is considered to be essential, the inclusion of each individual item of data should be considered and justified so that the minimum amount of personal confidential data is transferred or accessible as is necessary for a given function to be carried out
- access to personal confidential data should be on a strict need-to-know basis. Only those individuals who need access to personal confidential data should have access to it, and they should only have access to the data items that they need to see. This may mean introducing access controls or splitting data flows where one data flow is used for several purposes
- everyone with access to personal confidential data should be aware of their responsibilities. Action should be taken to ensure that those handling personal confidential data – both clinical and non-clinical staff – are made fully aware of their responsibilities and obligations to respect patient confidentiality
- comply with the law. Every use of personal confidential data must be lawful. Someone in each organisation handling personal confidential data should be responsible for ensuring that the organisation complies with legal requirements
- the duty to share information can be as important as the duty to protect patient confidentiality. Health and social care professionals should have the confidence to share information in the best interests of their patients within the framework set out by these principles. They should be supported by the policies of their employers, regulators and professional bodies.

Reference information: To Share Or Not To Share? The Information Governance Review
<https://www.gov.uk/government/publications/the-information-governance-review>

KEY RECOMMENDATIONS FROM DH HOMECARE STRATEGY BOARD IT WORKGROUP

The IT Workgroup of the DH Homecare Strategy Board also identified some general principles and examples of good practice in the use of existing pharmacy IT systems.

Useful example

- Appendix 14 Use of pharmacy IT systems to support homecare services ★★.

Homecare organisations will need to ensure that future development of their IT infrastructure supports the homecare service to co-ordinate communication and streamline administration. The Homecare IT workgroup has produced an Output Based Specification and

Technical Specification for homecare systems which identifies the ideal arrangements for use in the future development of homecare systems.

Useful example

- Appendix 15a Output Based Specification: System-wide Delivery of Medicines in Homecare
- Appendix 15b Technical Specification: System-wide Delivery of Medicines in Homecare.

MANAGING COMPLAINTS

Complaints should be recorded, logged and managed in line with the organisation's standard complaints procedures. NHS organisations will have local procedures

that are in line with national NHS guidance. (<http://www.nhs.uk/choiceintheNHS/Rightsandpledges/complaints/Pages/NHScomplaints.aspx>)

Homecare service providers will have their own internal complaints systems which manage complaints in line with ISO 9001 quality standard or equivalent.

As homecare is often a shared care arrangement involving multiple organisations, complaints processes which allow the sharing of complaints and co-operation in the investigation of root causes and implementation of preventative actions should be in place and integrated between the parties involved in providing the homecare services as far as possible. Complaints processes should to ensure complaints are received, recorded, investigated, acted upon and reviewed, and these processes documented in the Technical Agreement between the parties.

Any formal response to the complainant is the responsibility of the organisation receiving the complaint, unless otherwise agreed between the parties on a case by case basis.

Whilst the definitions and therefore categorisation of Complaints and Patient Safety Incidents varies slightly between organisations, the following principles should apply:

- individual events should be recorded and reported once to avoid multiple reports from different organisations and overstatement of reported error rates which cause a high administrative burden without benefit to patient safety. This generally means that ADRs, Medication Errors and Patient Safety Incidents that are reported through other national reporting systems as described in the following section should not also be reported as complaints
- service failure events that are anticipated in the service specification, i.e. where there is a Key Performance Indicator (KPI) target which is less than 100% compliance, should not normally be recorded as complaints. Where service failure events are logged as complaints due to aggravating factors, it is the aggravating factor(s) that should be logged and investigated as the complaint. The underlying service failure is managed via KPI and performance management processes

PRACTICE EXAMPLE

As an example, a patient complains about a late delivery. The complaint is recorded, however, late deliveries are anticipated in agreed service levels, so to determine if this is a justified complaint further investigation is needed to find out why the patient felt the need to complain and therefore if there were aggravating factors that would justify or validate the complaint. There could have been lack of communication from patient services or it could be the 3rd delivery failure in a row or it could be that the patient was not aware of the delivery processes. If there are no aggravating factors, whilst a complaint response (and apology) should still be sent to the patient, the complaint can be marked as 'unjustified' or 'not validated'.

- if the reporter of an incident or error requires a formal response and/or the issue to be formally recorded and subject to root cause analysis and implementation of preventative actions, the incident should be recorded as a complaint unless this would duplicate reporting e.g. in NRLS.

PATIENT SAFETY INCIDENTS AND ADVERSE DRUG REACTIONS (ADR) – REPORTING AND LEARNING

The main aim of ADR and patient safety reporting is to enhance patient safety by sharing learning for serious incidents and to identify signals and trends in events which viewed together indicate an enhanced risk to patient safety which can then be addressed. Whilst individual organisations have used existing systems to monitor patient safety incidents at local level, there has been a lack of a co-ordinated approach to patient safety reporting across homecare services and this is now being addressed. Recently issued guidance from MHRA and NHS England sought to clarify the definitions and reporting requirements for patient safety incidents to ensure the health system as a whole is able to learn from and minimise the risk of recurrence of patient safety incidents and to enable early detection of trends which might indicate a risk to patient safety and therefore require further investigation.

- Patient Safety Alerts were issued by MHRA and NHS England (<http://www.mhra.gov.uk/NewsCentre/CON395245>) in March 2014 entitled:
 - improving medication error incident reporting and learning (NHS/PSA/D/2014/005) and supporting information
 - improving medical device incident reporting and learning (NHS/PSA/D/2014/006) and supporting information.

The implementation of these Patient Safety Alerts as related to homecare is discussed below.

The Patient Safety Alert requires each homecare organisation to appoint a Medication Safety Officer and Medical Device Safety Officer to take the lead in the reporting of patient safety incidents. Where appropriate, they may be the same person. NHS Homecare organisations and large homecare provider organisations are required to participate directly in NRLS reporting and the National Medication Safety Network to share learning from NRLS reports.

See the definitions section of this handbook for the definitions for 'patient safety incident' and 'medication error'. The definition of Adverse Drug Reaction was reframed to include ADRs resulting from Medication

Errors including unlicensed use, misuse and abuse in an EU directive issued in July 2012. Since that time, there has been much debate about the need for robust reporting which ensures that ADRs meeting the extended definition are reported and learned from but that reports are not duplicated. The MHRA is developing NRLS to be integrated into the pharmacovigilance system to monitor Medication Error incidents in England. Medication Errors should be reported via NRLS. Other types of suspected ADR reports which are not the result of a medication error continue to be collected by the MHRA through the Yellow Card Scheme or by reporting direct to the marketing authorisation holder, where appropriate. Whilst the clear identification of a causal relationship between the medication and the ADR is not necessary, there should be a reasonable suspicion of a link to trigger an ADR report.

Reporting of Patient Safety Incidents under NRLS is primarily the responsibility of the organisation holding clinical responsibility for the patient, however, in accordance with the guidance, any organisation may report a Patient Safety Incident. Where the organisation reporting is not the organisation holding clinical responsibility for the patient, they should take reasonable steps to prevent duplicate reporting of the same event.

USEFUL DEFINITIONS & GUIDANCE ON CLASSIFYING EVENTS

Scenario: A homecare patient tells the homecare provider patient services team that they felt dizzy, fell over and has been injured.

Patient safety is the first concern – has the patient already consulted their GP or other HCP, is any other immediate escalation needed e.g. call an ambulance.

The fall happened yesterday and the GP has been called and will be making a house call to see the patient later today, so no immediate escalation is needed.

This is a clinically significant incident which must be reported by the homecare provider to the HCP with clinical responsibility for the homecare patient, but is it any more than that?

Could the 'event' reasonably be associated with the medicines the patient was taking? If yes, reporting should be of any Adverse Drug Reaction, not the event itself i.e. was the fall caused by dizziness or muscle weakness? Was the injury exacerbated due to decreased bone density? If this is not clear to the non-medical staff taking the report, the potential adverse drug 'event' should be handed over for further investigation to a relevant HCP who will then take on the responsibility for any ADR reporting – in this case the GP.

Unfortunately, the patient was found to have broken their hip and after treatment suffered complications and died.

The adverse drug reaction, if there is one, is the dizziness or muscle weakness or decreased bone density that is reasonably suspected to have been caused by the medication. The fall is an 'event' which the homecare provider refers on to the healthcare professional for further investigation and is not at this stage an ADR, it could just be an unfortunate accident. The broken hip and the subsequent death are 'outcomes', not ADRs.

Where Homecare Service Providers are acting as a commercial agent of the marketing authorisation (MA) holder/manufacture, the Homecare Service Provider may have an additional duty to report any ADRs and/or patient safety incidents to the MA holder/manufacture as detailed in the Technical Agreement between the parties. Where the Homecare Service Provider is not a commercial agent of the MA holder, ADR reports from homecare providers to the MA holder/manufacture are defined under the regulations as spontaneous reports from the marketplace and should be reported direct to the MHRA via the Yellow Card Scheme. Care should be taken not to duplicate ADR reports via MA holder/manufacture and Yellow Card Scheme as they do not enhance patient safety and increase the risk of false positive reports in the reporting systems.

Homecare Service Providers may also be involved in the delivery of 'Patient Support Programmes' which detail additional clinical interventions and controls that are an integral part of the 'safe' route to market approved by the MHRA. In these cases, there may be specific risk minimisation measures detailed in the risk management plan which requires specified clinical interventions and/or additional reporting to be specified in the Patient support Programme. Such Patient Support Programmes and risk controls identified in the Risk Management Plan will normally be related to pharmaceutical company funded homecare schemes and detailed in the Technical Agreement between the Homecare Service Provider and the MA holder/manufacture.

At the time of writing, the National Clinical Homecare Association is working in conjunction with the MHRA pharmacovigilance team and National Homecare Medicines Committee to prepare further nationally approved training programmes for homecare staff relating to ADR and patient safety reporting in homecare.

The responsibilities of all parties regarding reporting of patient safety incidents and adverse drug reactions should be made clear in the technical agreement (see Section 2.1) between the parties. There should be processes agreed to ensure all such events are received, recorded, investigated, acted upon and reviewed, processes should be integrated and learning shared between the parties as far as possible.

QUALITY ASSURANCE AND RISK MANAGEMENT

Systems should be in place to ensure that the homecare service is quality assured and controlled, and underpinned by the principles of quality risk management, to optimise patient outcomes.

Risk assessments should be performed on all homecare services including shared care arrangements across homecare organisations. Needs and suitability assessments should be performed for individual patients. Risk management processes must ensure that all identified risks are managed. This will involve:

- identification of hazards
- assessment and evaluation of risks
- control of risks
- acceptance of residual risks by the homecare team and by patients
- registration of inadequately controlled risks onto the organisation's Risk Register
- communication with relevant parties and stakeholders, including patients
- on-going review.

AUDIT OF COMPLIANCE WITH THE RPS PROFESSIONAL STANDARDS FOR HOMECARE SERVICES

Homecare organisations should ensure that their services are compliant with the RPS Professional Standards for Homecare Services by establishing a programme of quality review and audit. This programme should include all sub-contractors and contingency partners. A self-audit template is available on the RPS website for teams to use for a self assessment review of their services against the standards. <http://www.rpharms.com/unsecure-support-resources/professional-standards-for-homecare-services.asp>

CLINICAL TRIALS

The homecare route is sometimes utilised within the context of Clinical Trials. Relevant stakeholders including Clinical Trials Pharmacist, Chief Investigators, research and development departments, study sponsors, pharmacy homecare teams and homecare providers should be fully engaged in the governance aspects of provision of homecare services for all relevant clinical trials. National guidance relating to homecare should be followed and there should be clear accountability within all stakeholder organisations. All Clinical Trial activities contracted out by NHS Trusts/Sponsors to third parties including homecare providers should be described in detail in a technical agreement. This should define responsibilities, standards of service and record keeping/retention¹.

Clinical Trials are regulated by the Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments²⁻³ and must be conducted according to principles of GCP. These are outlined in articles 2 to 5 in the EU Directive 2005/28/EC⁴

For advice on any aspect of Clinical Trials involving medicines contact local stakeholders including Chief Pharmacist and Research and Development Lead.

Useful links:

- National Institute of Health Clinical Research Network – including access to GCP on line training for teams involved in setting up and delivering clinical research studies <http://www.crnc.nihr.ac.uk/>
- National Pharmacy Clinical Trials Advisory Group <http://www.rpharms.com/clinical-and-pharmacy-practice/clinical-trials-network---npctag.asp>
- National Research Ethics Service. www.nres.nhs.uk

WORKFORCE PLANNING AND DEVELOPMENT

The RPS Professional Standards for Homecare Services states that homecare teams will have the right skill mix and the capability and capacity to develop and provide quality homecare services to patients. To ensure this, it will be necessary to:

- secure resources and develop contingency and capacity plans
- develop the workforce and manage performance
- provide ongoing education and training.

JOB DESCRIPTIONS

Responsibility for homecare services should be clearly defined in job descriptions. The Chief Pharmacist's job description should be aligned with the Homecare Policy and will include:

- their overall responsibility for homecare services
- responsibility for liaison with Nursing Director and Medical Director as appropriate
- responsibility for ensuring policies, risk management and document approval procedures are implemented with respect to homecare services.

Useful examples

- Appendix 16 An example job description for a Homecare Pharmacist ★★ which has been shared with kind permission of Royal Wolverhampton Hospitals Foundation Trust. This was compiled in 2013 and takes into account the RPS Professional Standards for Homecare Services.
- Appendix 17 An example job description for a Homecare Pharmacy Technician ★ which has been shared by kind permission of the Leeds Teaching Hospital NHS Trust. This pre-dates the publication of the Homecare RPS Professional Standards for Homecare Services.
- Appendix 18 An example job description for a Homecare Medicines Administrator ★ which has been shared by kind permission of Chelsea and Westminster Healthcare NHS Foundation Trust.

¹ Good Clinical Practice Guide (MHRA) 14 Sep 2012

² The Medicines for Human Use (Clinical Trials) Regulations 2004. Statutory Instrument SI 2004/1031

³ The Medicines for Human Use (Clinical Trials) Amendment Regulations. Statutory Instrument SI 2006/1928, SI 2006/2984 and SI 2008/941

⁴ The Commission of the European Communities (2005) Directive 2005/28/EU

REGULATION AND EXTERNAL ACCREDITATION

The following is a list of the regulation, legislation, standards and guidance that might apply to a given circumstance, please note this list is not exhaustive.

REGULATORY FRAMEWORK

- Good Manufacturing Practice for Medicinal Products for Human use (2003/94/EC), and updating
- EU Directive 2001/83/EC relating to medicinal products for human use as amended by 2004/27/EC, and updating
- EU Directive 93/42/EEC relating to medical devices, and updating
- EU Directive 2001/20/EC relating to clinical trials, and updating
- Guidelines on Good Distribution Practice of Medicinal Products for Human Use (94/C 63/03), and updating
- Home Office Misuse of Drugs Act 1971 and amendments
- The Human Medicines Regulations 2012
- The Medicines Act 1968 and Regulations made under the Act
- Safeguarding Vulnerable Adults Act 2006
- Children Act 1989 updated 2004
- The Children (Northern Ireland) Order 1995
- The Children (Scotland) Act 1995
- The Human Rights Act (1998)
- UN Convention on the Rights of the Child
- Data Protection Act 1998
- Freedom of Information Act 2000
- Bribery Act 2010
- Competition Act 1998
- Access to Medical Reports Act 1988
- Access to Health Records Act 1990
- Health and Safety (Sharp Instruments in Healthcare) Regulations 2013.

STANDARDS AND CODES OF PRACTICE

- Royal Pharmaceutical Society Professional Standards for Homecare
- National Clinical Homecare Association Code of Practice for Homecare Providers
- Nursing and Midwifery Council Code of Conduct
- General Medical Council Code of Conduct
- Medicines Ethics and Practice
- General Pharmaceutical Council Standards.

REGISTRATION, AUDIT AND MONITORING

- General Pharmaceutical Council registration of pharmacy premises and pharmacists and pharmacy technicians
- Medicines and Healthcare products Regulatory Agency registration of manufacturers, wholesalers and distributors of medicinal products and medical devices
- Care Quality Commission registration of NHS Trusts and nursing agencies
- The Department of Health / NHS Connecting for Health Information Governance Toolkit registration of organisations managing NHS patient data
- Information Commissioner's Office registration under the Data Protection Act
- UKAS accredited bodies for certifying compliance with ISO 9001:2008, ISO 14000.

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- Association of the British Pharmaceutical Industry
- British Generic Manufacturer's Association
- BUPA Home Healthcare
- Chelsea and Westminster NHS Foundation Trust
- Department of Health Commercial Medicines Unit
- DH Homecare Strategy Board
- Leeds Teaching Hospitals NHS Trust
- National Clinical Homecare Association
- National Homecare Medicines Committee
- NHS England
- North Tees and Hartlepool NHS Foundation Trust
- Quality Control North West
- Royal Wolverhampton Hospitals NHS Trust
- University College London Hospitals NHS Trust.

As part of the development process the handbook was sent to a wide range of individuals and organisations for comment as part of a consultation process. We would like to thank all the individuals and organisations who responded, we are grateful for their feedback which was used to help refine the handbook.

APPENDICES

- APPENDIX 1** National Homecare Patients' Charter
<http://www.rpharms.com/homecare-appendices/1-homecare-medicines-charter-draft-3b-april-2013.docx>
- APPENDIX 2** Example patient leaflet for Homecare Medicines Services (Leeds Teaching Hospitals NHS Trust)
<http://www.rpharms.com/homecare-appendices/2-homecare-medicines-services---example-patient-leaflet-leeds.doc>
- APPENDIX 3** Example therapy-specific patient leaflet (BUPA Home Healthcare and Bristol-Myers Squibb Pharmaceuticals)
<http://www.rpharms.com/homecare-appendices/3-information-for-patients-receiving-sc-abatacept-bupa.pdf>
- APPENDIX 4** Patient registration and consent form (NHMC)
<http://www.rpharms.com/homecare-appendices/4-nhmc-patient-registration-and-consent-form.pdf>
- APPENDIX 5** Template homecare patient satisfaction questionnaire (NHMC)
<http://www.rpharms.com/homecare-appendices/5-patient-satisfaction-questionnaire.doc>
- APPENDIX 6** Example patient pathway for outpatient parenteral antimicrobial therapy (BUPA Home Healthcare)
<http://www.rpharms.com/homecare-appendices/6-opat-patient-pathway-bupa.docx>
- APPENDIX 7** Home suitability and needs assessment checklist (NHMC)
<http://www.rpharms.com/homecare-appendices/7-home-suitability-and-needs-assessment-checklist-nhmc.doc>
- APPENDIX 8** Example of a simplified 'Homecare Suitability and Needs Assessment (NHMC)
<http://www.rpharms.com/homecare-appendices/8-homecare-suitability-and-needs-assessment-form.doc>
- APPENDIX 9** Example technical agreement (North East Pharmacy Procurement Group)
<http://www.rpharms.com/homecare-appendices/9-technical-agreement-for-oral-chemo-neppg.docx>
- APPENDIX 10** National KPI data collection template (DH Commercial Medicines Unit)
<http://www.rpharms.com/homecare-appendices/10-kpi-data-collection-template---2013.xlsx>
- APPENDIX 11** Example product quality assessment for an unlicensed compounded antibiotic (Quality Control North West)
<http://www.rpharms.com/homecare-appendices/11-baxter-flucloxacillin-in-intermate.pdf>
- APPENDIX 12** Procedure for transferring patients between homecare services (Leeds Teaching Hospitals NHS Trust)
<http://www.rpharms.com/homecare-appendices/12-transferring-patients-between-homecare-providers.pdf>
- APPENDIX 13** Homecare Policy (University College London Hospitals NHS Trust)
<http://www.rpharms.com/homecare-appendices/13-homecare-policy-example-uclh.doc>
- APPENDIX 14** Use of pharmacy IT systems to support homecare services (DH Homecare Strategy Board)
<http://www.rpharms.com/homecare-appendices/14-use-of-pharmacy-it-systems-to-support-homecare-prescribing.docx>

-
- APPENDIX 15a** Output Based Specification:
System-wide Delivery of Medicines
in Homecare
(DH Homecare Strategy Board)
[http://www.rpharms.com/homecare-
appendices/15-obs-homecare-v8-post-
consultation.docx](http://www.rpharms.com/homecare-
appendices/15-obs-homecare-v8-post-
consultation.docx)
- APPENDIX 15b** Technical Specification: System-wide
Delivery of Medicines in Homecare
(DH Homecare Strategy Board)
[http://www.rpharms.com/homecare-
appendices/15b-homecare-technical-
specification.docx](http://www.rpharms.com/homecare-
appendices/15b-homecare-technical-
specification.docx)
- APPENDIX 16** Example job description
Homecare Pharmacist
(Royal Wolverhampton Hospitals
Foundation Trust)
[http://www.rpharms.com/homecare-
appendices/16-job-description-
homecare-pharmacist.docx](http://www.rpharms.com/homecare-
appendices/16-job-description-
homecare-pharmacist.docx)
- APPENDIX 17** Example job description Homecare
Pharmacy Technician
(Leeds Teaching Hospital NHS Trust)
[http://www.rpharms.com/homecare-
appendices/17-job-description-
homecare-pharmacy-technician.docx](http://www.rpharms.com/homecare-
appendices/17-job-description-
homecare-pharmacy-technician.docx)
- APPENDIX 18** Example job description Homecare
Medicines Administrator
(Chelsea and Westminster Healthcare
NHS Foundation Trust)
[http://www.rpharms.com/homecare-
appendices/18-job-description-
homecare-administrator.docx](http://www.rpharms.com/homecare-
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