YORKSHIRE & HUMBER NHS PHARMACEUTICALS PURCHASING CONSORTIUM

Document 8 - Specification

Framework Agreement for Low/Mid Tech Homecare Medicines Services

# General

## Introduction

Please read Document 2 Terms of Offer.

The Low Mid Tech Homecare Medicines Services Tender Pack contains the following:

* Standard Selection Questionnaire (SSQ) - (complete in Atamis)
* Document 1 Invitation to Offer Cover letter
* Document 2 Terms of Offer - (complete in Atamis)
* Document 3 Certificate of Bona Fide Offer and Non-Canvassing - (complete in Atamis)
* Document 4 Commercially Sensitive Information Schedule - (complete and return if

applicable)

* Document 5 Terms and Conditions NHS Framework Agreement for the Supply of Goods

and the Provision of Services - Framework (Homecare Medicines) including

Appendix A Call Off Terms and Conditions

* Document 5a Example Data Protection Protocol Homecare Medicines Services
* Document 5b NHS T&C Schedule 7 Annex A - Order Form
* Document 6 *Intentionally omitted*
* Document 7 List of Member and Eligible Participating Authorities
* Document 8 Specification - (this document)
* Document 8a Tender Response - (complete and return)
* Document 8b Commercial Schedule - (complete and return)
* Document 8c Award Criteria and Methodology

## Scope

This procurement exercise concerns the conclusion of a multiple provider unranked framework agreement for the supply of Low & Mid Tech Homecare Medicines Services, as made available under the Public Contracts Regulations 2015 Open Procedure. One or more successful Offerors will be appointed to supply goods and/or services on the terms agreed to such of the customers participating in the agreement as may place orders for such goods and/or services from time to time.

The following service Lots are included in this Framework Agreement.

Lot 1 - Short Turn Around Homecare Medicine Services

Lot 2 - Standard Turn Around Homecare Medicines Services

Lot 3 - Controlled Collection

Lot 4 - Clinical Services

Lot 5 - Immunoglobulin Homecare Medicine Services

There is no limit to the number of Lots a Supplier can offer against, and Suppliers are not required to bid for more than one Lot.

Any volume estimates provided to Suppliers by the Authority are statements of opinion, provided in good faith and based on past experience and market knowledge, but they should not be relied upon by Suppliers in formulating their offers.

Participating Authorities within the YHPPC may have other arrangements and contracts in place for low and mid tech homecare medicines services. This framework agreement and subsequent Call of Contracts are intended to replace these local agreements. Implementation will be agreed between Participating Authorities and Suppliers following Award.

## Abbreviations

|  |  |
| --- | --- |
| ABPI | Association of the British Pharmaceutical Industry |
| BGMA | British Generic Manufacturers Association |
| CCG | Clinical Commissioning Group |
| cGCP | current Good Clinical Practice guidelines issued by MHRA. |
| cGDP | current Good Distribution Practice guidelines issued by MHRA. |
| cGMP | current Good Manufacturing Practice guidelines issued by MHRA. |
| CMU | NHS England Commercial Medicines Unit |
| CPD | Continuous Professional Development |
| CRG | NHS England Clinical Reference Group |
| DBS | Disclosure and Barring Service |
| DHSC | Department of Health and Social Care |
| DTAC | Digital Technical Assessment Criteria as defined by NHS X - https://www.nhsx.nhs.uk/key-tools-and-info/digital-technology-assessment-criteria-dtac/ |
| FHIR | Fast Healthcare Interoperability Resources (FHIR) is the global industry standard for passing healthcare data between systems. |
| GPhC | General Pharmaceutical Council |
| HCP | Health Care Professional |
| ICH | The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use https://www.ich.org/ is the organisation that produces guidance on good clinical practice (GCP or cGCP) |
| LFPSE | Learning From Patient Safety Events (previously called the patient safety incident management system – PSIMS – during development) is replacing the current National Reporting and Learning System (NRLS) and Strategic Executive Information System (StEIS), to offer better support for staff from all health and care sectors. |
| MHRA | Medicines and Healthcare Products Regulatory Agency |
| NCHA | National Clinical Homecare Association |
| NHMC | National Homecare Medicines Committee |
| NHS | National Health Service |
| NHSX | now part of the NHS Transformation Directorate |
| NMC | Nursing and Midwifery Council |
| NPSA | National Patient Safety Agency |
| 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). |
| PIL | Patient Information Leaflet |
| PVG | Protection of vulnerable groups scheme. Scottish equivalent of DBS |
| RCN | Royal College of Nursing |
| RPS | Royal Pharmaceutical Society |

## 4.Definitions

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| AccessNI | Northern Ireland equivalent of DBS |
| Activity Data | management information dataset pertaining to financial activity (individual line items invoiced by the Supplier) during the reporting period. |
| 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. |
| Agreement | means the framework agreement or contract document(s) including it's terms and conditions. |
| Ancillary List | means any document so named and provided with this specification. |
| Authorised Person | means an individual with sufficient authority and/or qualification within an organisation to formally represent that organisation. |
| Bank Holiday | means the UK nationally recognised Bank Holidays |
| Buffer Stock | Safety stock of ancillaries, medicines and equipment held in home as backup for emergency use. |
| Business Days | Monday - Friday excluding Bank Holidays |
| Caldicott principles | Principles for sharing of patient information. Caldicott review: information governance in the health and care system - a report published by Department of Health 26 April 2013. Following a request from the Secretary of State for Health, Dame Fiona Caldicott carried out this independent review of information sharing to ensure that there is an appropriate balance between the protection of patient information and the use and sharing of information to improve patient care. |
| Call-off Contract | means an agreement between the Supplier and the Participating Authority in accordance with the terms of an overarching framework agreement. |
| Certification | means a relevant and auditable guarantee that an action has been undertaken. |
| Chief Pharmacist or equivalent | for the purposes of this specification 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 Pathway | is a collection of Clinical Service Protocols and relevant Standard Operating Procedures that together make up the Clinical Service that is expected from the Homecare Service that is being contracted. (would need to include a summary) |
| 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.  Please refer to page 16 and 17 of the "Handbook for Homecare Services in England, May 2014" |
| 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 | As defined in the RPS Homecare handbook appendix 19 |
| Consignment | means appropriately packaged Products delivery |
| Delivery | Delivery to patient’s normal place of residence or other community location. |
| Digital Solutions | A series of solution delivered through digital technology to improve the homecare service processes for staff involved and enhance the service experience and treatment outcome for patients. The solutions can be provided for web, desktop, mobile applications and other cloud-based devices/platforms. |
| Equipment List | means any document so named and provided with this specification. |
| Home | means patient's domicile or normal place of residence. |
| Homecare pharmacist | a pharmacist with appropriate competence in provision and administration of homecare services. |
| 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. Please refer to page 14 of the "Handbook for Homecare Services in England, May 2014" |
| Key Performance Indicators (KPI's) | Key Performance Indicators are quantifiable measurements, agreed to beforehand, that reflect the critical success factors of an organisation.  Please refer to page 24 and 25 of the "Handbook for Homecare Services in England, May 2014" This refers to Appendix 10. |
| Management Information | regular reports requested by the contracting authority or Participating Authority for the purpose of monitoring the performance of the service. Including but not limited to Key Performance Indicators (KPIs) and Activity Data. |
| Manufacturing Licence (MLA) | A manufacturing license agreement (MLA) is an agreement between an inventor and a manufacturer. The agreement allows a third party to produce and use the inventor's product for payment in royalties or a specific lump sum. There are no specific regulations regarding MLAs. |
| Marketing Authorisation | Medicinal products must be the subject of a marketing authorisation (MA) from the MHRA before being placed on the market, unless they are exempt (see Unlicensed Medicines). Medicines with a MA carry a PLGB number. Licensed medicines manufactured prior to EU exit may bear a EU or PL number. |
| 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 Homecare 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.  Please refer to the "Handbook for Homecare Services in England, May 2014", and the example at Appendix 6. |
| 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. |
| 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. |
| Normal Service Hours | As specified under each activity e.g. Patient service helpline, delivery, clinical service protocol, home visit protocol. |
| Normal Working Hours | As specified in the General Section for Homecare Administration Staff |
| Off label use | use of a licensed medicine outside the terms of its marketing authorisation (product licence) |
| Out of hours | Any time not specified as normal service hours for the relevant activity |
| Parties | relates to the collective of the Supplier, Contracting Authority and Participating Authority to the extent relevant and applicable to the specific context. |
| Patient | means the individual receiving the homecare service and/or as applicable their carer or parent/guardian. |
| 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 specification, this definition is extended to also cover non-NHS funded healthcare received as part of homecare services in England. |
| Patient’s home | the patient’s normal place of residence or other community location. |
| Pick-up | Collection of Products supplied by the Supplier from specific controlled collection sites. |
| Prescription | means any document so named and compliant with requirements set out in law. |
| Product List | means any document so named and provided with this specification. |
| Products | means any one, or combination of, medicines, ancillaries and equipment supplied to the Patient by the Supplier. |
| Participating Authority | the framework agreement owner (as applicable) or organisation letting the contract in the event of a standalone contract.  the Trust or other organisation that is Participating 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 Activation including service re-activation | means the point at which all valid registration details have been received by the Supplier and first attempt to contact the patient to make the supply of Products is complete |
| Service Level Agreement | means an agreement between the Supplier and the Participating Authority in accordance with the terms of an overarching framework agreement. |
| Service Level Summary | document outlining the services and service levels a Supplier has agreed to provide for a Participating authority during a formal tender process. This document is for information only and does not form part of the contractual relationship between the parties. |
| Services | means the services outlined in this specification including non-clinical and clinical. |
| Shared Care | for the purposes of this specification 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 healthcare professional with clinical responsibility for the patient is defined, normally within the Individual Patient Care Plan, and understood by each healthcare professional 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 healthcare professionals and using that information to inform their professional decisions about the patient’s care. |
| Socially Clean | clean to a socially acceptable standard for personal hygiene purposes but not disinfected nor sterilised. |
| Specified Medicines Ancillaries and Equipment | Any product included in the relevant medicines, ancillary or equipment lists |
| Supplier | the primary contractor who enters into an agreement with the Participating authority to supply goods and/or services. |
| Unlicensed medicine (Specials) | Medicines that are exempt from the requirement to hold a marketing authorisation under Regulation 167 of the Human Medicines Regulations 2012 are referred to as Specials. The manufacturer or assembler of Specials must hold a Manufacturer’s “Specials” Licence granted by the MHRA. https://www.gov.uk/government/publications/supply-unlicensed-medicinal-products-specials |
| Unspecified Medicines Ancillaries and Equipment | Any product not included in the relevant medicines, ancillary or equipment lists |
| Wholesale Dealers Licence | Any company or individual wishing to wholesale deal (defined as selling, supplying or procuring to anyone other than the end-user) medicinal products within GB must hold a wholesale dealer's licence (WDA(H)). |

# General

## Overall Service

### The requirements detailed in this specification are in addition to the NHS Framework Agreement for the Supply of Goods and the Provision of Services - Framework (Homecare Medicines - YHPPC)

### The Medicines Homecare Pathway(s) will be provided by Participating Authorities at point of Contract implementation.

### Suppliers will work in partnership with the Participating Authority to ensure:

* Patient safety
* Best possible clinical outcomes
* Patient satisfaction
* Minimal additional costs to the Participating Authority as a publicly funded body.

### In addition prescribed treatments are delivered in accordance with:

* the Medicines Homecare Pathway
* Individual Patient Care Plan and Equality and Diversity policy if special needs have been identified
* any written instructions from the clinician responsible for the patient's treatment.

### The Supplier's normal working hours (hours of service provision) must match or exceed Monday to Friday 09:00hrs - 17:30hrs excluding bank holidays.

### The frequency of deliveries depends on the treatment and individual patient in accordance with the Medicines Homecare Pathway. Delivery frequencies available under this framework will be provided in the commercial schedule. The delivery cycle required will be specified on the prescription. Should deliveries be required more or less frequently, the Supplier will be notified by the Participating Authority.

### Deliveries should be arranged at times acceptable to the patients and with minimum disruption to the patient work/life balance.

### As specified in the Agreement where sub-contractors are used either routinely or for contingencies for the provision of products and service, all requirements within this specification will be extended to the sub-contractor's organisation and staff. It is the responsibility of the Supplier to provide evidence that all sub-contractors meet these requirements and to inform the Participating Authority of any and all intended subcontracted parts of the service. Suppliers must maintain the list of applicable sub-contractors provided in response to the Standard Selection Questionnaire (SSQ). The list of sub-contractors is subject to change control provisions of this specification including gaining approval from the Participating Authority for any changes.

### Suppliers must have KPI's in place with all subcontractors. These should be regularly reviewed and available if requested by Authority or Participating Authority.

## Quality Guidelines and Regulatory Compliance

### The Participating Authority and Supplier will comply with the current Royal Pharmaceutical Society (RPS) Professional Standards for Homecare Services in England and Wales. To the extent applicable, the Supplier and Participating Authority shall comply with all requirements of relevant regulatory bodies e.g. General Pharmaceutical Council, Medicines and Health Regulatory Agency, Care Quality Commission and Nursing and Midwifery Council. Suppliers should make use of all applicable national standard, and all NHMC approved, documentation / guidance where available.

### The Supplier will carry out self-inspections of their quality system at regular intervals and record the results and raise corrective and preventative actions for any non-conformances found.

### The Participating Authority retains the right to audit in accordance with the Agreement. The Supplier will be given an opportunity to respond to any issues raised by a Compliance Audit. A Summary of results of Compliance Audits including the Supplier's responses may be shared with other relevant NHS Participating Authorities.

## Selection, Registration of Patients and Service Activation

### Patient selection is the responsibility of the Participating Authority. An initial patient suitability and needs assessment will be carried out by a competent member of staff appointed by the Participating Authority. The Participating Authority will explain the patient's responsibilities and confirm the patient’s motivation and suitability for the homecare service. This will include appropriate assessment of the patient’s home environment or other location where the services will be delivered and identify any special needs in an individual patient care plan.

### Further to the initial patient suitability and needs assessment carried out by the Participating Authority, the Supplier is responsible for confirming the patient's suitability for the homecare services*.* Assessment of the patient's home environment is the responsibility of the Supplier and should be undertaken within 3 business days of a request being made (this is after the 5 business days registration period). Remote assessments of the care environment should be validated at the first appropriate visit of Supplier staff to deliver the homecare service. Any issues or additional special needs identified by the Supplier must be notified to the Participating Authority within 2 business days.

### The Participating Authority will securely transmit to the supplier the specified registration information including, where applicable, details of an individual care plan. Where applicable, the registration information will include a date where product and/or service is first required. The registration form will give the confirmed or expected activation date for the Homecare Service.

### Where a registration form is used the NHMC approved template will be used unless otherwise specified in the Order Form. The NHMC template can be found on the RPS Website Homecare Handbook Appendices.

### On receipt of valid registration information, the Supplier will log the patient onto their systems. Any special needs identified in the individual patient care plan, or otherwise identified by the Supplier will be considered by the Supplier and any safety concerns or additional costs for product or service items not included in this specification raised with the Participating Authority before the patient is designated as ready for service activation. The Supplier has the right to decline to accept patients with additional special needs onto the homecare service. The patient's details should be recorded on the Supplier's systems and Service Activation completed within 5 business days subject to the timely receipt of the initial prescription and purchase order as detailed in the specification.

### The Participating Authority will complete and securely transmit to the Supplier an initial legally valid prescription for medicines, ancillaries and equipment as required for the first treatment period, plus a specified quantity of buffer stock and its associated purchase order.

### Prescriptions templates used for these services should be based on the NHMC approved template unless otherwise specified in the Order Form. The NHMC template can be found on the RPS Website Homecare Handbook Appendices.

### Training Patients to self-administer medicines will be the responsibility of the Participating Authority unless specified as a Clinical Service to be provided by the Supplier (see Clinical Service and Home Visit Sections), or as detailed in the agreed Individual Patient Care Plan.

### Patients who are self-administering medicines at home must be assessed as competent to self-administer on initiation of the service and at 12 month intervals thereafter. Competency assessments of the patients following training is the responsibility of the Participating Authority unless specified as a Clinical Service to be provided by the Supplier or as detailed in the agreed Individual Patient Care Plan. Competency documentation for a patient self-administering medicines will be held in the patient record and shared with the other party on request.

### The Participating Authority will re-assess the patient’s suitability for homecare periodically. The Supplier must inform the Participating Authority of any concerns regarding patients’, or their home environment’s, suitability for receipt of the requested homecare medicines service.

### The Supplier will notify the Participating Authority of any issue preventing the service activation for a patient on the confirmed activation date, or any patient for whom an expected service activation date has not been confirmed.

## Communication with the Patient

### Communication with the patient should be initiated by the Supplier only as needed to deliver the homecare service.

### Good communication is needed between all parties. Suppliers should be able to have effective and prompt communication with patient and Participating Authorities.

### The Participating Authority will provide information of the service to the patient prior to referral to the Supplier.

### The Supplier will make the 1st attempt to contact the patient within 5 business days of receipt of valid registration and/or prescription.

### The Supplier will provide patient information in accordance with the specified service and the data protection protocol no later than the first delivery. Any patient information provided to patients by Suppliers shall be subject to change control provisions within this specification.

### The patient information will detail useful and helpful information for patients and carers, this should include:

* Welcome to the service
* The roles of any of the Supplier's staff they will encounter during the service
* Therapy information – description of service, deliveries, equipment, visits and their responsibilities as appropriate to their Medicines Homecare Pathway
* How to arrange deliveries of medicines, ancillaries or equipment or other visits
* How to handle and store medicines, e.g. use equipment provided
* How to access patient support services provided
* Patient Services opening hours, out of hours and emergency contacts
* Who to contact if... e.g. running short of medicines or ancillaries
* What to do if... e.g. clinical adverse event occurs, equipment fails
* How their confidentiality will be maintained, and personal data used
* How to complain about the homecare service
* Provide an opportunity for a patient to request an alternative and/or additional delivery address in the local vicinity e.g.: work place.
* Privacy notice
* Travel service

### The supplier must provide an inbound patient queries and complaints service during hours of service provision offering timely response to patient queries with the following attributes preferred;

* Available between 08:00hrs and 18:00hrs weekdays and 09:00 to 12:00 on Saturdays with answer phone outside those hours
* Free phone number (from landline)
* Alternative Standard phone number for Mobiles to call
* Dedicated Nurse on call phone number for clinical emergencies

### Communication / information in relation to the homecare service will be in English. Should a patient not be fluent in English, information will be provided in their own language. Where appropriate this must also be available in pictorial format, and large print.

### All contact between the Supplier and the patient must be logged and records made available to the Participating Authority on request.

## Stock Management in the Home

### It is expected that patients will maintain buffer stock in the home. This will be agreed between Supplier and Participating Authority and documented within the Schedule 7 - Order Form of the Agreement.

### Where there are patients unsuitable for buffer stock arrangements this will be communicated to the Supplier by the Participating Authority to be recorded on the patient notes.

### The Supplier will check, and record patient reported stock levels prior to arrangement of the next delivery. Where able (depending on service type) and subject to the consent of patient, Supplier's staff will undertake a stock check of medicines, ancillaries and equipment in the patient’s home (or location of service provision) at the time of nurse visits or at the time of medication deliveries or annually or every 3 months. Evidence of suspected over or under use must be reported to the Participating Authority within 2 business days.

### The Supplier will work with patients to ensure an appropriate stock level within the patients home as agreed by the Participating Authority. Stock should not be allowed to exceed this agreed level due to risk of loss given a fridge failure or waste of ancillaries.

### Subject to the patients or carers consent, stock identified as past its expiry date or unusable for any other reason must be removed from the patient’s home at the earliest opportunity to ensure patient safety. The Supplier must log such events as incidents and report to the Participating Authority as agreed in this specification.

## Clinical Waste Management

### The Supplier will be responsible for the safe disposal of the patient’s clinical waste generated through the provision of the Service at intervals agreed with the Participating Authority and will provide approved sharps disposal boxes and appropriate clinical waste containers. All current UK law and regulations on clinical waste must be adhered to by the Supplier including the collection, transportation and disposal of clinical waste. Suppliers or their approved sub-contractor must have a waste collection license which covers the relevant waste collection activity and must make this available on request.

### Returned medicines which have been outside the control of the Supplier or an approved sub-contractor (e.g. delivered to a patient) must not be reissued to another patient by the Supplier.

## Care Away from Home / Travel Service - General

### There will continue to be a range of situations where it is appropriate to arrange short notice delivery to addresses other than the patient's home address (e.g. patient's being re-admitted to hospital at short notice).

### Suppliers may be asked to deliver to different UK addresses in term time compared to holiday time. e.g. students with home and term time addresses.

### The Supplier will be required in exceptional circumstances to provide additional supplies to cover patient holidays and travel away from home to any address in the UK mainland including islands accessible by road plus the Isle of Wight and the Isles of Scilly; or England and its Islands.

### The holiday service should include delivery of all medicines, ancillaries and equipment and clinical services; return of equipment, ancillaries and excess medicines; and disposal of clinical waste as appropriate.

### Patient Information will advise that Patients are required to provide at least 4 week’s notice of travel plans within the UK in order that the Supplier can make necessary arrangements for service delivery. If patients are planning to travel abroad, and notify the Supplier, the Supplier must notify the Participating Authority at least 4 weeks in advance of the departure date. Arrangements to administer the therapy whilst abroad are the responsibility of the specialist nursing team at the referring hospital. The Supplier may be asked to supply letters for international travel or to arrange cold chain deliveries in some circumstances (translated into other languages as required). They may also be asked to provide advice/assistance with the packaging of drug for transportation or to deliver to UK airports and ports on request.

### Any holiday services that include provision of clinical services in alternative locations must be subject to a Suitability and Needs Assessment and arranged with the full knowledge and support of the clinical team responsible for the patient’s treatment. The patient is responsible for obtaining appropriate medical insurance which will allow them to obtain appropriate medical advice and treatment locally and to cover any unplanned events. The Supplier may be contacted to provide assistance, however there is no responsibility to get medicines or ancillaries to the patient should the patient not be able to return home as planned.

## Amendment, Interruption and Termination of a Patients Homecare Service

### The Supplier must have processes in place to manage amendment, interruption or cessation of the homecare service for an individual patient on notification from the Participating Authority. The Participating Authority may request the Supplier to collect medicines, ancillaries and equipment and dispose or recycle them as appropriate. In the event of a patient’s death the process described will be carried out with particular sensitivity at a time convenient to the patient’s family or carer.

### Any instruction from the Participating Authority to amend, interrupt or cease the homecare service for an individual patient must be implemented within 2 business days. The Participating Authority will not be responsible for any costs or losses incurred by the Supplier for products or services (excluding equipment see below) provided later than the 2nd business day after notification of interruption or termination of service. Confirmation must be provided in writing by the Participating Authority if initial instruction is verbal. Service re-activation will be in accordance with the Service Activation provisions within the Selection, Registration of Patients and Service Activation section of the specification.

### All equipment, ancillaries and unwanted medicines must be collected by the Supplier within 10 business days of the termination of the homecare service or as agreed with the patient. Equipment rental will not be charged beyond 10 business days.

## Communication with Participating Authority

### The Supplier must ensure robust communication processes are in place to support the provision of the homecare service.

### The Supplier and Participating Authority will provide and maintain an up to date, comprehensive contact matrix relevant to the service including named individuals (where appropriate), role, telephone number and email address.

### Supplier to provide a service for resolution of service queries, complaints and contract management. The following attributes are preferred or the minimum requirements

* available by telephone between 08:00hrs and 18:00hrs weekdays and 09:00 to 12:00 on Saturdays with answer phone outside those hours
* Standard line number - not a Premium rate line
* secure e-mail for exchange of patient identifiable information
* named contract manager and deputy

### All contact between the Supplier and the Participating Authority must be logged and records made available to the Participating Authority on request.

### The Supplier will use the patient's NHS number or the Participating Authority's local patient identifier as set out in the registration information to identify each patient once the registration has been accepted.

### The Supplier maybe requested to use clinic number or other form or anonymised patient identifier(e.g. GUM number) as set out in the registration information to identify each patient once the registration has been accepted.

## Performance Monitoring and Management Information

### The Supplier and Participating Authority are responsible for managing the quality of the homecare services. This is managed via the collection of management Information and regular supplier review meetings. Management Information is to be delivered to the Participating Authority as specified.

### Monthly Management Information report templates should be completed for the previous calendar month by the 10th business day of the next calendar month.

### Current monthly report templates are provided in Appendix A

* Activity Report
* Key Performance Indicator Report
* Complaint and Incident Report

### The Supplier is required to submit dispensing information to the Purchasing Authority using the form which can be found in Appendix A. The data fields may change throughout the life of the Framework and in future the Supplier may be asked to send/upload the information directly to MDSAS.

### Suppliers should use the national templates for monthly management reports where available. The Authority may share Participating Authority level information within the YHPPC members.

### Requests for backing data in reference to the standard monthly Management Information may be requested by the Participating Authority and/or Authority. The data requested will be provided by the Supplier within 5 Business days of the request unless otherwise agreed.

### The Supplier will comply with all reasonable requests for management data (including supporting data for Monthly Management Information reports and dispensing information to support national recording of product information).

### In addition to the standard Monthly Management information the Supplier will comply with all reasonable requests by the Department of Health and Social Care, Commercial Medicines Unit (CMU), the Participating Authority, Integrated Care Boards (ICB) and NHS England (or any future organisations they become part of) for Management Information to be provided in respect of the products and services supplied under this Framework. This information is to be provided within 10 business days for ad hoc requests or at a time agreed between the parties. This information should be anonymised unless approval is gained from the Participating Authorities to confirm otherwise.

### Supplier Review meetings will be held by the Participating Authority with the Supplier at agreed intervals.

### Contract monitoring meetings/regional service review meetings will be held in addition to local service review meetings between the awarded Suppliers and the Authority.

### The Supplier will have an annual routine patient satisfaction survey cycle in order to ascertain the quality of the level of service and review the patient experience. Suppliers must request and receive confirmation from Participating Authorities to issue this survey to their patients. The Supplier will ensure the patient satisfaction survey is provided to each active patient on the homecare service free of charge, including providing pre paid envelopes for responses if required.

### The published RPS guidance will be used including any service specific questions in order to facilitate contract management, benchmarking and sharing of best practice. This process can be found on the RPS Website Homecare Handbook Appendices.

## Change Management

### Any changes to Agreement documents, pricing / commercial arrangements or other changes which may reasonably be expected to impact the service or compliance with this specification must be raised with and approved by all parties as far in advance as reasonably possible and in any case at least 28 calendar days prior to the change occurring.

### Where either Party requests approval for any change, approval is not to be unreasonably withheld or delayed by the other party.

### Documents, including but not limited to those listed below, will be subject to formal approval by the Supplier, Authority and Participating Authority and are subject to the change control provisions of this specification unless agreed otherwise by both parties:

* Service specification
* Commercial Schedule
* Registration Form
* Prescription Form
* Nurse Training Manuals
* Clinical service protocols
* Home visit protocols
* Patient Information / communications
* Proof of product / service delivery
* Invoice
* Patient suitability assessment form
* Patient support programme materials (where applicable)
* Equipment List
* Ancillary List
* Approved Sub Contractor List
* Order Form Template
* Monthly Management Templates

### Where a patient's homecare services is transferred between different Suppliers, the Supplier should follow the RPS guidance procedure for change management.

### The Supplier and the Participating Authority are jointly responsible for ensuring a smooth transition onto the service for new patients or from one Supplier to another.

## Provision of Services Outside this Specification

### The Supplier and Participating Authority recognise that there may be a need for additional or specialised services for individual patients, such services will be agreed between the parties and the responsibilities of each of the parties documented in the Individual Patient Care Plan.

### The Parties will work together in partnership to ensure patient safety, patient satisfaction and best possible clinical outcomes and to minimise any additional costs to the Participating Authority. Where urgent or emergency services that are outside the terms of this specification are provided by the Supplier to meet the above requirement the Supplier will make its best efforts to contact and agree its actions in advance with the Participating Authority.

# Prescribing and Dispensing

## The Prescribing Process

### The Participating Authority will provide, via any method approved by the Parties, a valid, legal and unambiguous prescription to the Supplier, which is signed by an authorised prescriber, clinically validated, and appropriately annotated with specific brand (as required), purchase order number and unlicensed/off-label flags.

### Further to "General - Amendment, interruption and termination of a patient's homecare service", The Participating Authority will notify the Supplier of changes in prescribed medications and/or dosages for existing patients. The Supplier will act on these notifications without undue delay.

### The Supplier will provide a proactive prescription management service where repeat prescriptions will be requested from the Participating Authority at least 4 weeks prior to the next scheduled delivery date.

### The prescription template will be agreed by the Supplier and Participating Authority and will be based on the current National Template.

## The Dispensing Process

### The Supplier must:

* only dispense legally valid prescriptions that have been clinically validated by the Participating Authority
* have measures in place to identify any unexpected deviations from the above prescribing process and interrupt the dispensing process for affected prescriptions until resolved.
* not dispense unlicensed medicines unless prescribed or otherwise authorised by the Participating Authority.
* supply all Products with a shelf life appropriate to the duration of treatment supply being made
* dispense and label Products in accordance with the prescription, current legislation and best practice standards.
* include full patient specific administration instructions on the dispensing label.
* supply medicines with their Patient Information Leaflets (PILs) in English with the exception of Unlicensed Compounded/Extemporaneous Prepared Medicines.

### The Supplier must have procedures in place to ensure a clinical check/validation is done by a pharmacist on the prescription on receipt in accordance with current legislation and GPhC standards (usually classified as Level 1 due to the information available at the dispensing pharmacy).

### In the event of a manufacturing or supply problem beyond the control of the Supplier, the Supplier will notify the Participating Authority as soon as reasonably practical and vice versa, the Parties will work together, in accordance with relevant national guidance, to minimise disruption and additional costs to the Participating Authority whilst maintaining patient safety.

### In the event of a supply problem within the Suppliers control (e.g. stock control), the Supplier will notify the Participating Authority as soon as reasonably practical. Parties will work together to minimise disruption and additional costs to the Participating Authority whilst maintaining patient safety. Additional costs (e.g. additional delivery fees) must be reviewed and agreed by both parties as to the responsibility of the costs.

### In the event that the Supplier cannot supply in full or in part the patient’s requirements, which will impact patient treatment/care, the Supplier should notify the Participating Authority. Where the Supplier considers patient treatment/care will not be adversely impacted by a part delivery (i.e. the Supplier can fulfil the remainder of the delivery/service very quickly) the Participating Authority need not be contacted.

### Where requested, the Suppler must supply medication in an agreed monitored dosage system or compliance aid if requested to do so by the Participating Authority.

### The Supplier should dispense Commercial Medicines Unit, Yorkshire & Humber Regional, or other Authority contract lines wherever access is sought, see Section 46.

## Outer Packaging

### Outer packaging of homecare deliveries will comply with the General Pharmaceutical Council (GPhC) Standards for home delivery of medicines and medical devices including special storage and health and safety requirements for special handling. Outer packaging should not have any unnecessary markings likely to indicate the nature of the delivery in order to maintain patient confidentiality.

### Outer packaging will ensure the integrity of the products are maintained throughout the delivery process. This will include, but is not limited to maintaining appropriate temperatures, protection from light and contamination, reasonable protection from mechanical damage.

### The Supplier will ensure that Medicines are packed in a way that does not put the person delivering or unpacking products at risk from exposure to hazardous products if the delivery is subject to mechanical damage.

### Under sections 3 and 6 of the Health and Safety at Work Act 1974 there is a duty to protect people not in a company's employment who may be affected by handling loads they have supplied. Therefore, it is good practice for manufacturers and suppliers to mark weights (and, if relevant, information about the heaviest side) on loads if this can be done easily. Please see: http://www.hse.gov.uk/msd/labellingloads.htm

### The Supplier must comply with all relevant packaging and labelling regulations and outer packaging must be sealed.

# Delivery

## Routine Delivery Scheduling

### Deliveries must be at the clinically appropriate frequency as specified in the Medicines Homecare Pathway, Individual Care Plan or on the prescription.

### The Products and Services are to be delivered at a place convenient to, and agreed with, the patient. This may be their home or other suitable setting (e.g. workplace, friend or relative's address, day care centre) and patient must have confirmed that appropriate storage is available.

### Deliveries will be scheduled to take place between no less than 08:00hrs and 18:00hrs Monday to Friday and 08:00 - 12:00hrs on Saturday. Wherever possible the scheduled delivery should be convenient to the patient at acceptable times and with minimum disruption to the patient work/life balance. The Supplier will agree, via positive confirmation, the delivery date and time window with the Patient. If the patient's routine delivery would be due on a Bank Holiday the delivery date should be scheduled to take place prior to the Bank Holiday to maintain buffer stock.

### The Supplier will remind the Patient of the agreed delivery date / time (including a 2-hour delivery window) the day before the scheduled delivery unless otherwise agreed with the patient. Additional reminders in the days preceding the scheduled delivery including early notification of 2-hour delivery windows may be beneficial.

### When the Supplier becomes aware that the confirmed delivery date and time will not be met, they must contact the patient at the earliest opportunity to advise them of the new anticipated time of arrival and/or arrange an alternative delivery date and time.

### Patient choice of innovative communication methods above standard phone call (such as text reminders and online tracking) are considered acceptable however if changes to already agreed delivery schedules are being notified via these routes positive confirmation required from Patients.

### Where required, the Parties shall agree compressed timescales for the provision of the Service.

### The Supplier will implement procedures to ensure the patient receives deliveries containing quantities of medicines and ancillaries for the expected treatment duration in accordance with the medicines pathway and/or administration instructions detailed on the patient's prescription.

### The Participating Authority will not be responsible for any additional service costs if medicines, ancillaries or equipment that could not be provided in line with the patient’s delivery cycles due to Supplier inadequate stock control.

## Preparing for the Delivery

### The delivery vehicle must not bear any markings which would indicate the nature of the delivery.

### The Supplier must ensure that all product and/or medicine are stored, transported and delivered in a clean condition.

### All deliveries must be made under appropriately controlled conditions to suit the nature of the Products being delivered. Suitable delivery methods include

* via suitably trained and competent homecare delivery drivers (Note: this is essential if the driver enters the patient's home as a standard element of the homecare service)
* specialist pharmaceutical delivery network holding an MHRA Wholesale Dealer's Licence
* vehicles with validated temperature-controlled chamber(s) or validated cold chain packaging (for more information see Cold Chain tab)
* via a healthcare professional as part of the clinical service.
* via hub and spoke controlled pick-up model (prior approval from Participating Authority required)

### Delivery networks which minimise the risk of product loss and provide audit trail of pharmaceutical storage conditions being maintained throughout are preferred.

### Alternative delivery methods may be agreed in advance with the Participating Authority and Procedures should be available on request - See "General - Change Management"

## Making the Delivery

### The delivery service is to be is to be provided in a courteous, helpful and confidential manner. The delivery personnel will carry photographic identification, to be shown and/or visible at all times, be of smart appearance, fully conversant with the delivery system, their job role and respectful of patients' needs.

### Consignments must only be delivered to the agreed address and receipted by a designated person approved by the Patient. Consignments must not be left unattended.

### No member of the Supplier’s delivery personnel is required nor expected to enter into the patient's home to provide the homecare service.

### No member of the Supplier's delivery staff may enter into the patient's home to provide the homecare service without asking the patient or carer if they are happy for the service to continue on this occasion. Delivery staff must deliver the consignment to the agreed location within the patient’s home as directed by the patient and/or carer. If requested delivery staff will unpack the delivery, rotate any existing stock ensuring a first in, first out basis, check storage conditions are appropriate and record the details of storage conditions. The Supplier must provide appropriate support and guidance for delivery staff who are unable to complete the service in accordance with their instructions. Any issues must be recorded by the Supplier and reported to the Participating Authority in accordance with this specification.

### The Patient reserves the right to refuse to accept Consignments which are found, on receipt, to be damaged, faulty and/or otherwise incorrect. Such events will be recorded by the Supplier and reported to the Participating Authority.

### The delivery personnel must remove all outer delivery packaging if requested to do so by the patient or carer.

## Failed Deliveries, Collections and Returns

### The Supplier must arrange with the patient to re-deliver or return failed deliveries and ensure the patient receives replacement Product in a timely manner, where appropriate. The Supplier will notify the Participating Authority in the event of multiple delivery failures by an individual patient.

### Collections of returned items should be made at the same time as a scheduled product delivery.

### If the collection is not taking place at the same time as the delivery, the Supplier must agree a convenient collection time with the Patient mirroring the specified delivery service level.

## Urgent and Out-of-Hours Deliveries

### The Supplier will operate an out of hours service and an urgent delivery service whereby delivery will be made within 24 hours of the request being made by the Participating Authority.

# Controlled Collection Model

## General

### Supply via Controlled Collection Model will be permitted subject to agreement from the Participating Authority in accordance the terms of the Agreement.

### To the extent applicable, all provisions of this Specification will apply to supplies made via the Controlled Collection model.

### The Supplier will maintain an up to date list of available collection points and provide to the Authority and Participating Authority.

### The Supplier must remain responsible for Products until collected by the Patient.

## Communicating with the patient

### In addition to the provisions set out in "General Section - Communicating with the Patient".

### The Supplier must direct the patient to their inbound patient queries and complaints service in the event of any queries relating to the Products or Service.

## Scheduling a delivery

### In addition to the provisions set out in "Delivery Section - Routine Delivery Scheduling".

### The Supplier must confirm the agreed pick up location and date/time pick up will be available from for each consignment.

### The Supplier must take reasonable efforts to contact the Patient 3 business days after the agreed delivery date to remind them to pick up from the agreed location.

### The Supplier must retain Products available for pick up by the Patient at the agreed pick up point for no less than 10 business days.

## Enabling pick up

### In addition to the provisions set out in "Delivery Section - Making the Delivery".

### The Supplier must ensure that Products are only delivered to the agreed pick up point and picked up by a designated person approved by the Patient.

## Failed deliveries, collections and returns

### In addition to "Delivery Section - Failed deliveries, collections and returns"

### In the event of non-pick up by the Patient, the Supplier will recover the Products from the pick-up point and notify the Patient and Participating Authority accordingly.

### The Supplier will be responsible for the safe disposal of the patient’s clinical waste generated through the provision of the Service returned to the collection point. All current UK law and regulations on clinical waste must be adhered to by the Supplier including the collection, transportation and disposal of clinical waste. Suppliers or their approved sub-contractor must have a waste collection license which covers the relevant waste collection activity and must make this available on request.

## Finance

### In addition to the provisions set out in "Finance Section".

### The Participating Authority will not be responsible for cost of Medicines, Ancillaries or Equipment from uncollected deliveries.

### The appropriate evidence of service delivery will pertain to Products being duly received by the Patient following pick up.

# Cold Chain, Controlled Drugs and Hazardous Medicines

## Special Handling

### The Participating Authority is responsible for assessing the risks associated with the storage, handling, delivery and administration of medicines products in accordance with their SmPC or Specials manufacturer's instructions.

### Equipment and/or ancillaries identified as necessary to manage risks are specified in the Equipment and Ancillaries List within the Order Form along with any restrictions to be applied when supplying equipment to an individual patient. The Supplier must be able to implement the risk control measures specified by the Participating Authority.

### Risk control measures to be implemented for specified categories of products are in the sections below.

* cold chain
* controlled drugs
* hazardous medicines

### Any medicinal product requiring special handling to meet the requirements of their SmPC or Specials manufacturer's instructions is identified in the relevant product list and where applicable in the individual product dossier.

## Cold chain medicines requiring storage between 2-8oC

### Where the Participating Authority requests supply of temperature controlled medicines, appropriate risk control measures must be established and agreed by both parties and detailed in the Order Form in accordance with the Homecare Guidance for Storage and Handling of temperature controlled medicines in the patient's home, copy provided in Appendix B.

### Unless risk control measures have been specified, storage of homecare medicines in the patient’s own domestic refrigerator will be sufficient to give assurance that the medicine will be fit for purpose at the point of administration. Where risk control measures have been specified, the requirements have been specified in the Equipment and/or Product List.

### Cold Chain in the Patient's Home; Each Participating Authority will determine the storage requirements for their patient population, this may include; use of patient own fridges with no additional monitoring, use of patient fridges with additional monitoring or the request for the Supplier to provide a pharmaceutical grade refrigerator. Pharmaceutical grade refrigerator specification is contained within Appendix B

### The Supplier will be responsible for training the patient or carer to undertake daily monitoring of the temperature of the refrigerator, knowledge of the minimum and maximum temperatures, and the action to take if found out of range.

### Maintenance, PAT testing and calibration of all refrigeration and temperature monitoring equipment will be the responsibility of the Supplier (refer to Equipment and Ancillaries section).

### Repairs and or replacement of faulty fridges must be carried out within 6 working hours of the fault being reported at no charge to the Participating Authority. Records of equipment failure, the actions taken and time period for resolution must be kept by the Supplier and supplied to the Participating Authority on a yearly basis or more frequently on request.

### The Supplier operates a validated cold chain from receipt of deliveries or manufacture through to delivery to the patient.

### Where a temperature deviation occurs a decision about suitability of the affected product for use will be made in conjunction with the Participating Authority and documented by the Supplier.

### Where a temperature deviation may result in product being wasted and/or any interruption of treatment the Participating Authority will be notified without delay.

## Cytotoxic and other hazardous medicines

### Where the Participating Authority requests supply of cytotoxic or other hazardous medicines/materials, appropriate risk control measures must be established and agreed by both parties and detailed in the Order Form.

## Controlled drugs

### Where the Participating Authority requests supply of controlled medicines, appropriate risk control measures must be established and agreed by both parties and detailed in the Order Form.

# Equipment and Ancillaries

## Equipment

### The equipment that can be provided as part of the service(s) is listed in Document 8c - Commercial Schedule. A generic specification (where required) for each different type of equipment is provided in the Call Off Contract (Order Forms) which includes quantity to be supplied plus any backup equipment, maintenance and response times.

### All fridges will be supplied with a fridge monitoring chart or equivalent monitoring ability.

### Where there is choice of equipment as detailed in the Equipment List, processes must be in place to ensure patients understand the choices open to them; the benefits and constraints associated with each type of equipment and the patient's preference is implemented wherever reasonably practical. Any case where the patient's preference cannot be accommodated or is subject to an adverse risk assessment by the Supplier, the equipment to be supplied will be agreed with the Participating Authority.

### The Supplier should maintain safety stocks of critical equipment to ensure continuity of patient treatment and/or allow new patient to be referred to the service in accordance with the timescales in the specification.

### The Supplier will provide an installation visit for equipment.

### An installation visit report must be provided to the Participating Authority for any installation of equipment. This visit report must highlight any issues that were encountered.

### The Supplier must provide the patient with appropriate information and training regarding the use and maintenance of equipment.

### Patients have responsibility to use equipment in accordance with the instructions provided. The Supplier should provide patient information in an accessible format that includes step by step instructions on how to use the equipment. A telephone helpline number should be provided. We would welcome the use of innovative formats, to suit the requirements of the individual patient and carers.

### The Supplier must maintain an asset register and maintenance records for all equipment. Equipment records for individual patients are to be made available to the Participating Authority on request.

### The Supplier will inform the Participating Authority where latex is present in equipment.

### Patients will be responsible for keeping refrigerators socially clean, but maintenance will be the responsibility of the Supplier (refer to Equipment and Ancillaries section).

### The Supplier must have robust processes to manage requests from the Participating Authority and/or Patient for equipment not on the specified Equipment lists. Direct Patient requests for exceptional supply of equipment must be referred to the Participating Authority.

## Maintenance and Servicing

### The Supplier must service and maintain all equipment supplied within the Homecare Service in accordance with the recommendations of the manufacturer of the equipment.

### A visit report must be provided to the Participating Authority for any service, maintenance or calibration of equipment which takes place in the patient's home. This visit report must highlight any issues that were encountered.

### The Supplier must keep records of equipment failure, the actions taken and time period for resolution and a summary supplied to the Participating Authority on request.

## Ancillaries

### The ancillaries to be provided as part of the service are listed in Document 8b - Commercial Schedule and are to be agreed by Parties and documented on the Order Form.

### The Supplier may offer alternative ancillaries as a 'counter offer' for items documented on the Ancillary List. Such alternatives to be detailed in the Commercial Schedule, agreed by the Participating Authority and documented on the Order Form.

### The Supplier should maintain safety stocks of critical ancillaries to ensure continuity of patient treatment and/or allow new patient to be referred to the service in accordance with the timescales in this specification.

### The Supplier will deliver ancillaries at the same time as product wherever possible. No additional delivery cost will be paid for separate ancillary deliveries, unless there are exceptional circumstances, and it has been agreed by the Participating Authority.

### The Supplier will check Patient stock levels, as a minimum prior to every routine delivery, either physically or remotely and replenish ancillaries on a regular basis. Suppliers should have Procedures in place detailing the processes followed to ensure stock levels are checked and can be provided on request, and that all appropriate staff are trained and competent in these Procedures.

### The Supplier will inform the Participating Authority if a patient's ancillary usage deviates from the expected usage level.

### The Supplier will have robust processes in place to manage requests from the Participating Authority and/or Patient for ancillaries not on the specified Ancillary List or for additional requests to the anticipated quantity required. In these circumstances Patient requests will be referred to the Participating Authority for approval.

### The Participating Authority will regularly review the ancillaries used for each patient to ensure they are appropriate and usage is within an acceptable range.

### The Supplier will inform the Participating Authority where latex is present in an ancillary.

# Home visits

## Non-Clinical Home Visits for installation, maintenance and servicing of equipment

### The Supplier will only undertake non-clinical Home visits where necessary to meet the terms of this specification.

### The Supplier will provide non-clinical home visits Monday to Friday 8am to 6pm and 8am - 12pm on a Saturday and ensure escalation contacts are available during these times. If the patient's routine delivery would be due on a Bank Holiday the delivery date must be scheduled to take place prior to the Bank Holiday to maintain buffer stock.

### All staff visiting a patient's home will carry photographic identification which will be shown on arrival.

### All staff visiting the patient at home will be courteous, helpful and maintain patient confidentiality. Visiting staff are to respect patients' and carers' needs and will comply with any reasonable conditions of entry laid down by the patient. Visiting staff will be dressed appropriately.

### Supplier's staff must check the patient continues to consent to the visit and actions to be taken by the staff on each occasion they enter the patient's home. Staff must respect any patient's wishes if they withdraw consent they have previously given.

### The Supplier is responsible for scheduling non-clinical visits at a time convenient for the patient. The Supplier will give as much notice as reasonably practicable if for any reason they are unable to meet the agreed visit.

### The Supplier will inform the Participating Authority within 2 business days of the non-clinical visit if it could not be undertaken as agreed with the patient.

### Any new or changed risks identified during a home visit will be recorded and the Individual Patient Care Plan updated with new or changed risk control measures.

### A summary report or log for non-clinical home visits must be available for each individual patient on request of the Participating Authority.

# Clinical Services

## Clinical Services

### The clinical services to be provided are as specified in the Clinical Service Pathway, Individual Patient Care Plan and/or Registration Form.

### Suppliers will work in partnership with the Participating Authority to ensure that prescribed treatments are delivered in accordance with their Clinical Service Pathway and written instructions from the clinician responsible for the patient's treatment, if special needs have been identified.

### The Participating Authority is responsible for assessing the risks associated with clinical services. Also see Risk Management section on the Governance Section.

### The Supplier and Participating Authority will agree the Clinical Service Protocols as well as the internal escalation procedure for deviations from the clinical service protocols during the service implementation period. To include but not inclusive of competencies listed below and specialist training requirements e.g. Nurses providing paediatric services must hold either RN: Children’s Level 1 or RNC: Children’s Nurse Level 1, Sub part 1.

Phlebotomy

Cannulation

Intravenous therapy in line with RCN and NMC guidelines including management of intravenous indwelling device

Management and awareness of venous access difficulties

Anaphylaxis management/ basic life-support relevant to area of clinical practice

Practical use of relevant equipment management maintenance and troubleshooting issues

Aseptic No Touch Technique (ANTT)

Infection Control

Side effect management, including the management of all types of infusion related reactions

### Where appropriate and relevant, the Clinical Service Pathway should include reference to remote consultations and interactions whether planned or unplanned. Remote consultation protocols must comply with NHS recommendations and legislative requirements. Suppliers should not offer patients remote consultations without the prior agreement of the Participating Authority.

### The Participating Authority will specify the clinical services to be provided for each patient at point of registration.

### Clinical Services will be available Monday to Friday 8am to 6pm excluding Bank Holidays. The Participating Authority will ensure clinical escalation contacts are available at all times clinical services are being provided.

### The Supplier will provide 24 hour/365 days a year manned telephone or call-back helpline service to support patients receiving the Clinical Services.

### The Supplier must ensure that the Healthcare Professional providing the clinical service has visibility of the appropriate prescription at the point of product administration.

### The Supplier is responsible for scheduling clinical services in accordance with the prescription and clinical service protocol. The Supplier will give as much notice as reasonably practicable if for any reason they are unable to meet the agreed service level. Wherever possible the Supplier will maintain continuity of staffing for an individual patient.

### When the Supplier becomes aware that the confirmed clinical service date and time will not be met, they must contact the patient at the earliest opportunity to advise them of the new anticipated date and time and/or arrange an alternative date and time.

### Where specification point 35.11 could lead to a patients delayed treatment the Participating Authority must be informed in an appropriate timeframe based on the nature of the clinical risk.

### The Supplier must have a process for accepting patients for the clinical service, assigning the appropriate healthcare professional and assurance of continuity and consistency of patient care.

### The Supplier must be able to provide a report to the Participating Authority within 2 business days of any episode of clinical service.

### A summary report or log for clinical services and clinical interventions must be available for each individual patient at the request of the Participating Authority.

## Training and Education of Patients

### Training of Patients to self-administer medicines will be the responsibility of the Participating Authority unless specified as a Clinical Service to be provided by the Supplier or as detailed in the agreed Individual Patient Care Plan.

### Competency documentation for a Patient self-administering medicines will be held in the patient record and shared by the Supplier with the Participating Authority within 2 Business Days completion.

### Patients who are self-administering medicines at home must be assessed as competent to self-administer on initiation of the service and at 12 month intervals thereafter. Competency assessments of the patients following training is the responsibility of the Participating Authority unless specified as a Clinical Service to be provided by the Supplier or as detailed in the agreed Individual Patient Care Plan.

### Competency documentation for a patient or carer self-administering medicines will be held in the patient record and shared with the other party on request.

### Where the Supplier provides the training, the Supplier will assess the patient's competency to self-manage and provide written evidence to the Participating Authority via a competency check-list or equivalent.

### The Supplier and Participating Authority will agree appropriate patient training materials prior to service commencement.

### Further to the initial patient suitability and needs assessment, the Supplier is responsible for confirming the patient's suitability for the clinical services and reporting any exceptions within 1 business day. A copy of the completed detailed patient suitability and needs assessment must be provided to the Participating Authority on request.

# Governance

## Governance Framework and Quality Systems

### The Participating Authority and Supplier will comply with the current Royal Pharmaceutical Society (RPS) Professional Standards for Homecare Services in England. To the extent applicable, the Supplier and Participating Authority will comply with all requirements of relevant regulatory bodies, examples include but are not inclusive to; General Pharmaceutical Council, Medicines and Health Regulatory Agency, Care Quality Commission and Nurse and Midwifery Council.

### Suppliers must have a robust quality system in place which includes policies on the following and must ensure that all staff comply with them. Where relevant national guidelines are in place it is mandatory that these are adopted. Where national guidelines are not in place or if the Supplier is unsure, then the Supplier will liaise with the Participating Authority to confirm mutually acceptable guidelines.

* Health and safety Policy
* Environmental Policy
* Bribery Policy
* Complaints and Incidents Policy
* Safeguarding Policy
* Equality & Diversity Policy
* Lone Worker Policy
* Medicines Policy
* Privacy Policy
* Records Management Policy
* Social Value Policy
* Transition Policy (Paediatric to adult care)
* Zero Tolerance and Policy for the Withdrawal of Care
* Risk Management Policy.

### Where Services include clinical home visits, Suppliers must have policies on the following and must ensure that all clinical staff providing clinical services involving medication administration are trained and monitored for compliance.

* Anaphylaxis Management Guidelines
* Infection Control Manual
* Resuscitation Policy and Guidelines

### The Supplier will carry out self-inspections of their quality system at regular intervals and record the results and raise corrective and preventative actions for any non-conformances found. This record and improvement plan may be reviewed at supplier review meetings.

### The Authority and/or Participating Authority reserve the right to audit the Supplier in accordance with schedule 2 clause 24 NHS Framework Agreement for the Supply of Goods and the Provision or Services (Homecare Medicines). The Supplier will be given an opportunity to respond to any issues raised by an NHS Audit. A Summary of results of NHS Audit including the Supplier's responses, resolution to any actions raised within the audit report produced may be shared with other relevant NHS Participating Authorities. Suppliers will be given a minimum of 28 calendar days notice of an audit unless deemed urgent due to potential patient safety risk.

### As specified in the Agreement where sub-contractors are used either routinely or for contingencies for the provision of products and service, all requirements within this specification will be extended to the sub-contractor's organisation and staff. It is the responsibility of the Supplier to provide evidence that all sub-contractors meet these requirements and to inform the Participating Authority of any and all intended subcontracted parts of the service.

### Suppliers shall maintain the list of applicable sub-contractors. The list of sub-contractors is subject to change control provisions of this specification including gaining approval from the Authority and Participating Authority for any changes.

## Clinical Governance

### The Participating Authority retains clinical responsibility for the patient's care and their treatment. The Supplier must carry an appropriate duty of care to patients receiving the Services.

### The Participating Authority is responsible for ensuring all relevant and appropriate diagnostic tests and other interventions including those specified in the Medicines Homecare Pathway are performed and for monitoring of patient outcomes with respect to efficacy and toxicity.

### The Supplier will communicate with the Participating Authority in the event of any clinically relevant issues that could be reasonably expected to impact on patient safety or continuity of patient treatment and will work in partnership to minimise additional costs to the Participating Authority whilst maintaining patient safety. Notification to the Participating Authority should be as soon as the Supplier is made aware of the issue.

### The Supplier and Participating Authority must ensure all their staff involved in the provision of the homecare service have knowledge of clinical governance and be committed to clinical supervision, customer care and resolution of complaints and concerns.

### The Participating Authority will provide appropriate clinical escalation contacts and ensure that an appropriate and suitably qualified clinician be available for the Supplier's staff to contact at all times whilst they are involved in delivery of a clinical intervention.

### The Supplier must ensure that their staff know how to escalate clinical concerns and how to contact the clinical escalation contacts for each Participating Authority at all times.

### Transition from paediatric to adult care will take place at a mutually agreed time between the ages of 16-18 and be initiated by the Participating Authority, following consultation with the patient and family. Where provided, the Supplier must adhere to the relevant Transition Policy employed by the Participating Authority.

### A separate instruction manual and training programme for children should be available from Suppliers if requested by Participating Authorities.

## Complaints and Concerns - to include defects, recalls, patient safety incidents, Adverse Drug Events (ADE), Adverse Drug Reactions (ADR)

### Suppliers will work in partnership with the Participating Authority to ensure; patient safety, patient satisfaction, best possible clinical outcomes and to minimise any additional costs to the Participating Authority.

### In accordance with the professional standards - RPS Handbook for Homecare Services - Appendix 19 - Further Guidance for Managing Complaints and Incidents in Homecare Services the Authority and Supplier must have a complaints and incidents policy and procedures that differentiates patient safety incidents from other types of complaints, incidents or concerns.

### The details of any complaints regarding the delivery or service, received from Patients will be forwarded in writing to secondary investigators, or primary investigator status formally transferred within 2 business days.

### Any defective medicine or device that is reported by a patient to the Supplier must be replaced free of charge in a timely manner to ensure that the patient does not experience an unavoidable delay in receiving treatment, preferably without the need for the Participating Authority to supply a new prescription.

### The Supplier must operate a system of product and batch traceability to facilitate recall of medicines, sterile ancillaries and critical equipment to patient level

### The Supplier shall not charge the Participating Authority with any costs associated with MHRA led product recalls and it is the responsibility of the Supplier to recover expenses associated with MHRA led product recalls from the manufacturer or marketing authorisation holder.

## Information Governance

### The Participating Authority will ensure all patients are informed that their personal information will be shared with the Supplier and other healthcare professionals and may be used to support clinical audit for the purpose of assuring and monitoring the quality of their treatment. In line with the RPS Professional Standards for Homecare Services.

### As detailed in Schedule 3 of the Agreement all requirements of the Data Protection Act 2018, UK General Data Protection Regulation (GDPR) and any subsequent regulations must be met in full.

### Data Protection Protocols will need to be agreed and signed between Supplier and Participating Authority at service set up. It is expected that the template Document 5a - Example DPP Homecare Medicines Services is utilised.

### To aid Data Protection compliance, Suppliers should confirm they are able to provide at no additional cost a method of secure transfer of documents from Participating Authorities to Supplier. Options may include prepaid envelopes, secure guaranteed 1pm next day delivery envelope and/or an agreed collection service.

## Risk Management

### The Participating Authority and the Supplier must have a Risk Management Policy. Risks must be deemed to be of an acceptable risk score. If the Parties disagree with a risk assessment, both Parties will work together to reach a consensus view.

### The Supplier may refuse to provide services which it deems to be unsafe or which represent unacceptable risk to patient safety under its Risk Management Policy. Where appropriate, the Supplier will work with the Participating Authority to find an acceptable alternative to facilitate the patient's care.

## Business Continuity and Contingency Planning

### The Supplier must hold and maintain an appropriate Business Continuity Plan (BPC) in accordance with Schedule 2 of the Agreement including major incident and emergency planning. Suppliers should test its BCP at reasonable intervals, and in any event no less than once every 12 months.

### Suppliers BCP should be available on request throughout the life of the Agreement.

### The Supplier will have contingency plans in place for credible threats including but not limited to vehicle breakdown, adverse weather, pandemic, Cyber-attacks, IT system failures and shortfall in the supply of medicines, ancillaries or equipment. The Authority and the Supplier will work in good faith to manage any stock shortages or other unexpected event in accordance with applicable national guidance and procedures.

### The Supplier will provide adequate facilities and resources to provide the services to the level described within the specification.

### The Supplier will represent accurately and honestly their capability to deliver a homecare service at all times during the tendering process and throughout the life of the Agreement.

### The Supplier will communicate with the Participating Authority and Authority if it is unable to fulfil any contracted or otherwise agreed duties in a timely manner to reduce risk to the contracted service.

### Suppliers are required to advise the Participating Authority and Authority as soon as they become aware of any circumstances which have the potential to have a detrimental effect on the homecare service or compliance with this specification.

## Safe Guarding

### The Supplier must ensure that all relevant staff, including all sub-contractors have undergone England and Wales Disclosure and Barring Service (DBS) for Scotland Protecting Vulnerable Groups Scheme (PVG) for Northern Ireland Access NI clearance in accordance with the prevailing regulations. Suppliers will bear the cost of carrying out these checks.

### Where relevant, the Participating Authority requires that all Supplier's Staff who have direct contact with vulnerable patients have undertaken mandatory safeguarding training, relevant to their role and undertake regular refresher training. The Supplier will provide the Participating Authority with details including the name of the organisation that delivers the training and a description of the training programme and the frequency of refresher training on request. The Participating Authority may audit training records to ensure compliance with this provision.

## Training and Competence of all Supplier's staff including non-clinical staff

### The Supplier must ensure all staff are trained and competent to perform the activities requested of them. All staff must have

* job specifications
* orientation and induction
* knowledge of relevant organisation policies
* evidence of training to perform the activities in their job specification
* training in their individual responsibility towards health & safety, safeguarding and information governance.

### The training plans and training programmes will be reviewed and updated on a regular basis to ensure they are based on current good practice.

### Suppliers must ensure that all relevant staff have an appropriate level of knowledge and expertise on the medicines, ancillaries and equipment used in the clinical specialities relevant to the Service. For example

* relevant equipment management
* evidence based clinical decision making
* side effect management
* disease awareness
* specific therapies, as prescribed.
* drug cost awareness
* reconstitution of drug awareness e.g. Myozyme –protein strands are produced if not reconstituted according to guidelines/policy
* ICH/cGCP

### The Supplier must ensure the clinical staff providing Intravenous infusion services have achieved the following additional competencies. Where staff are in training, it is anticipated that they will be supervised until they have been formally assessed as competent.

* Phlebotomy
* Cannulations
* Intravenous therapy in line with RCN and NMC guidelines including management of intravenous indwelling device
* Anaphylaxis management/ basic life-support relevant to area of clinical practice
* Practical use of relevant equipment management maintenance and troubleshooting issues
* Aseptic No Touch Technique (ANTT)
* Side effect management, including the management of all types of infusion related reactions
* Detailed knowledge of prescribed therapies including special instructions for use and learning from patient safety incidents and near misses.
* Extravasation
* Totally Implantable Vascular Access Device (TIVAD) blockage and how to deal with them
* Management and awareness of venous access difficulties

### Suppliers should be able to provide copies of any Procedure, training plans, training programmes and competency assessments if requested by Participating Authorities throughout the Agreement.

### Where regional or national training is available this should be utilised unless otherwise agreed by Parties.

### Suppliers must ensure any new staff or staff moving between roles are trained accordingly prior to taking responsibility for delivery of the Service. Where staff are in training, it is anticipated that they will be supervised until they have been formally assessed and deemed competent.

### The Supplier must facilitate Continual Professional Development (CPD) for all professional staff as required by their respective professional body. The Supplier must have a robust mechanism to ensure that relevant professional registrations are maintained.

### All Suppliers Nurse employees must be registered with the NMC.

# Finance

## Purchase Orders

### The Participating Authority will generate a unique Purchase Order Number linked to each prescription and provide it to the Supplier.

### Suppliers should be able to receive orders transmitted electronically in accordance with nationally approved standards.

## Purchasing of medicines by the supplier

### Products (including medicines, ancillaries and equipment) to be supplied with the Service and associated pricing must be set out in a Product List within the Order Form and agreed by both parties prior to service commencement. The Supplier will make reasonable efforts to secure products and prices as set out in the Product List and the Participating Authority will provide every assistance possible to ensure the Supplier is successful in gaining that agreement.

### Changes to the Product List must be in accordance with the Change Management provisions set out in this specification. In the event of short notice of change to product / price, the Supplier will undertake all reasonable endeavours to action the change in the compressed timeframe.

### The Supplier will use all reasonable endeavours to source all unspecified medicines, ancillaries and equipment at cost effective prices and any mark-up applied by the Supplier must be proportional to the additional costs incurred by the Supplier in sourcing those products.

### Product and/or medicine provided by manufacturers or wholesalers to the Supplier for the use by patients of the Participating Authority under this Agreement are not for resale by the Supplier to any third party.

### In addition to the Section on confidentiality in the Agreement, where the Supplier is given access to NHS contract price information from the Participating Authority in order to procure medicines on behalf of the NHS, this information is commercially confidential. Suppliers will not pass prices on to any third party including other companies within their group without the express permission of the Participating Authority. Under no circumstances will the Supplier purchase for the purpose of onward selling or use by an NHS Trust outside of the region(s) awarded the NHS contract price.

### The Participating Authority will aim to give 28 calendar days notice to the Supplier of any new or changed contract or framework pricing that they may have been granted access to use on behalf of the NHS to deliver the service.

### In the event of short notice of change to product / price, the Supplier shall undertake all reasonable endeavours to action the change in the compressed timeframe.

### The Supplier will be responsible for the ordering, receipt, control and payment for all medicinal products and ancillaries and will be responsible for the maintenance of adequate stock levels to satisfactorily meet the requirements of this Framework.

## Invoicing

### The Supplier will generate an accurate and valid invoice linked to each Purchase Order Number and where required contain patient unique identifier. The Supplier will use best endeavours to provide it to the Authority within 4 weeks of service delivery in line with the invoice terms in the NHS Framework Agreement for the Supply of Goods and the Provision of Services - Framework (Homecare Medicines Version). The Authority and Supplier will use best endeavours to receive or transmit invoices electronically in accordance with nationally approved standards.

### The content of the invoice and transmission process of those invoices will be agreed with both parties and documented in the Order Form. Some Participating Authorities may require patient details; if this is the case then this must be compliant with the Data Security and Protection Toolkit Standards (DSPT) or documented and controlled via data processing or data sharing agreement between parties. https://www.dsptoolkit.nhs.uk/

### All invoices must be supported by appropriate evidence showing that:-

* Goods have been duly received, are in accordance with specification and the prices are correct
* Services rendered have been satisfactorily carried out in accordance with the order and the charges are correct.

### Such evidence of service delivery will be made available for audit purposes and by exception only if there is reasonable doubt that the service has not been received.

### Evidence of service delivery and when it should be provided (e.g. with the invoice) will be agreed between parties and document on the Order Form.

### Where nursing services are used, the Supplier should ensure that proof of nursing visits are provided to the Participating Authority. These can be in either paper format or digital device. The length of the time spent with the patient should be recorded.

### In exceptional cases where the original evidence is lost, damaged or unavailable for some other substantive reason the Supplier may provide appropriate alternative evidence including the following information. The Suppliers declaration must be made by an authorised person and such declarations found to be false will be considered as a breach of this agreement.

* dispensing & despatch date
* delivery date and route or carrier information and evidence
* how the delivery was confirmed, by who, and when.

### In accordance with the provisions set out in General Section - Provision of services outside this specification the Participating Authority will reimburse reasonable additional costs incurred by the Supplier.

## Statement of Accounts and Payments

### The Supplier will provide the statement of accounts to the Participating Authority on a monthly basis.

### The Participating Authority will pay undisputed invoices 30 calendar days from the date of receipt in line with the payment terms in the NHS Framework Agreement for the Supply of Goods and the Provision of Services - Framework Version (Homecare Medicines-YHPPC).

## Risk, Liability and Insurance

### Where medicines or ancillaries or equipment are unusable due to action or inaction of the Supplier, the unusable items will be collected and replaced at no expense to the Participating Authority or, if resupply is not clinically appropriate a credit note will be raised against the invoice for those unusable items. Where medicines or ancillaries or equipment are unusable due to the Patient’s negligence, misuse, or failure to observe any instructions or training concerning the use of the equipment, the Supplier will have the right to recover the cost of replacement (or where applicable repair) from the Participating Authority, provided that such negligence, misuse or failure was not caused or contributed to by any action of or failure to take action by the Supplier. Unusable items may only be resupplied (or where applicable) repaired at the cost of the Participating Authority when prior approval has been given by the Participating Authority.

# Digital

## Digital Solution Requirement

### Digital Solutions must not be offered to patients without prior approval from the Participating Authority for its use within their Patient cohort.

### Any Digital Solutions developed must meet the RPS output-based specifications (OBS), as updated from time to time, for system-wide delivery of medicines in homecare as a minimum.

### Mobile Apps or other applicable Digital Solutions for patient’s access must be free of charge, without any in-app purchase.

### Any patient facing Apps or other applicable Digital Solutions must undergo baseline assessment by NHSE Transformation Directorate as a minimum.

### For any digital solutions,

* if the solution (or part of) is not classified as a medical device then the developer/Supplier of the digital solution has applied clinical risk management as required under "DCB0129: Clinical Risk Management: its Application in the Manufacture of Health IT Systems" during the development of the product. The Supplier should also be able to provide assistance to the Participating Authority in the application of clinical risk management as required under "DCB0160: Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems" during the deployment of the digital solution.
* if the solution (or part of) is classified as a medical device the solution must comply with the medical device directives.

### The Supplier's proposed solution must be compatible with relevant national standards and interoperable with systems commonly used by the NHS.

### The Supplier should commit to migrating to Fast Healthcare Interoperability Resources 1(FHIR) standard and other technical standards if that becomes mandated in the future.

# Net Zero and Social Value

## Net Zero and Social Value

### The Authority shall be incorporating evaluation of social value policy elements relevant to the procurement in accordance with government advice.

* High level info/context: <https://www.gov.uk/government/publications/social-value-act-information-and-resources/social-value-act-information-and-resources>
* Procurement Policy Notice: <https://www.gov.uk/government/publications/procurement-policy-note-0620-taking-account-of-social-value-in-the-award-of-central-government-contracts>
* Direct link to the quick reference table: <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/940828/Social-Value-Model-Quick-Reference-Table-Edn-1.1-3-Dec-20.pdf>

# Appendix A - Monthly Management Report Templates

Expenditure Report Template

*Note: will need to include ABI information for non-member organisations*



KPI Report Template



CAI Report Template



Dispensing Information Report Template



# Appendix B - Cold Chain Guidance and Refrigerator Specification



**Pharmaceutical Grade Refrigerator Specification**

* Must be a pharmacy medicines fridge
* Constructed of impervious, cleanable materials both internally and externally
* Single cooler panel without a freezer box
* Maintains the temperature between 2ºC and 8ºC
* Temperature distribution – maintain the required range across its entire load area
* Capacity – at least one third greater than required to allow for circulation of cooled air
* Suitable indicator/visual alarm to alert if temperature exceeds parameters (for length of time) or door left open
* Automatic defrost
* Grille-type shelving
* Integral air circulating fan
* Permanent external easy to read display of current fridge temperature shown on outside of fridge
* Calibrated to proven standard
* Child resistant closure and/or lockable with removable key
* Maximum operating noise <50 decibels