

Homecare Medicines and Services Template Specification

Version 2.0

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Guidance Note: This document was created for ease for Purchasing authorities who use word or PDF version of the specification as part of their tender pack. The template is provided in a generic format which may be adapted to suit local tender documents. To the extent possible, section order and numbering should be retained.

# General

## Overall Service

### The Medicines Homecare Pathway(s) is/are shown in [insert name of tab/document/appendix]

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

* Patient safety
* Best possible clinical outcomes

Patient satisfaction

* Minimal additional costs to the Purchasing Authority as a publicly funded body.
* As well as that 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 regime in accordance with the Medicines Homecare Pathway and the stability of product in accordance with the commercial schedule. Should deliveries be required more or less frequently, the Supplier will be notified by the Purchasing Authority

### 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 Purchasing 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 Selection Questionnaire (SQ). The list of sub-contractors is subject to change control provisions of this specification including gaining approval from the Purchasing Authority for any changes.

## Quality Guidelines and Regulatory Compliance

### The Purchasing 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 Purchasing 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 Purchasing 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 Purchasing Authorities.

## Selection, Registration of Patients and Service Activation

### Patient election is the responsibility of the Purchasing Authority. An initial patient suitability and needs assessment will be carried out by a competent member of staff appointed by the Purchasing Authority. The Purchasing 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.

### The Purchasing 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 service is first required.

### 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 Purchasing 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] working days subject to the timely receipt of the initial prescription and purchase order as detailed in the specification.

### The Purchasing Authority will complete and securely transmit to the Supplier an initial 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.

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

### Patients/carers 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 and carers following training is the responsibility of the Purchasing 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.

### The Purchasing Authority will re-assess the patient’s suitability for homecare periodically. The Supplier must inform the Purchasing 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 Purchasing 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

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

(See RPS Handbook for Homecare Services Appendix 2 - <https://www.rpharms.com/recognition/setting-professional-standards/professional-standards-for-homecare-services/homecare-handbook-appendices>) The Supplier will make the 1st attempt to contact the patient within 5 working days of receipt of valid registration and 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 either party 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 answer phone outside those hours. This must include a telephone helpline at a local rate or freephone.

### Communication / information in relation to the homecare service will be in English. Should a patient and/or carer 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. Patient information is to be readily available in the following languages:- [Please insert list of languages required] Welsh – Please note that in Wales the Welsh language should be treated no less favourably than the English language. Homecare providers should note the requirement in Wales to comply with the Welsh Language Standards (No.7) Regulations 2018.

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

## Stock Management in the Home

### It is expected that patients will maintain buffer stock in the home sufficient for [14 days] treatment in addition to that calculated as normal as designated within the Medicine Pathway.

### The Supplier will check and record patient reported stock levels every 3 months. [or Subject to the consent of patient or carer, 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 Purchasing Authority within 2 working days.

### 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 Purchasing Authority as agreed in this specification.

## Returns and 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 Purchasing 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.

### It is preferable that all collections of returned items are 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 or carer.

## 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 Purchasing 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 Purchasing Authority. The Purchasing 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 Purchasing Authority to amend, interrupt or cease the homecare service for an individual patient must be implemented within [2] working days. The Purchasing 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 working day after notification of interruption or termination of service. Confirmation must be provided in writing by the Purchasing 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] working days of the termination of the homecare service or as agreed with the patient or carer. Equipment rental will not be charged beyond 10 working days.

## Communication with Purchasing Authority

### The Supplier and Purchasing 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 Purchasing Authority must be logged and records made available to the Purchasing Authority on request.

### The Supplier will use the patient's NHS number or the Purchasing Authority's local patient identifier 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 Purchasing 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 Purchasing Authority as specified. (Insert requirement)

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

Monthly Report templates are provided:- • Activity Report • Key Performance Indicator Report

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

### The Supplier will comply with all reasonable requests for management data (including supporting data for Monthly Management Information reports)

### The Supplier shall undertake patient satisfaction surveys and provide related reports to the Purchasing Authority in accordance with the RPS published guidance (link).

<https://www.rpharms.com/resources/professional-standards/professional-standards-for-homecare-services>

## 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 the other party 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 and Purchasing Authority and are subject to the change control provisions of this specification unless agreed otherwise by both parties:

* Service specification
* Commercial Schedule
* Product List
* Registration Form
* Prescription Form
* 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
* Sub Contractors

### 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 Purchasing 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 Purchasing 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 Purchasing Authority. Where urgent or emergency services that are outside the terms 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 Purchasing Authority.

# Prescribing and Dispensing

## The Prescribing Process

### The Purchasing 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, for products in the Product List and appropriately annotated with specific brand requirements, purchase order number and unlicensed/off-label flags.

### Further to "General - Amendment, interruption and termination of a patient's homecare service", The Purchasing 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 Purchasing Authority at least [4] weeks prior to the next scheduled delivery date.

## The Dispensing Process

### The Supplier must:

* 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 Purchasing Authority.
* supply all Products in the Product List 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.

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

### 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 Purchasing 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 very quickly) the Purchasing 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 Purchasing Authority.

## 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. The Supplier will agree 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 4-hour delivery window) the day before the scheduled delivery unless otherwise agreed with the patient. Additional reminders in the days preceding the scheduled delivery 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.

### Where required, the Parties shall agree compressed timescales for the provision of the Service. E.g. Chemotherapy homecare medicines services.

## 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

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 Purchasing Authority - 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 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.

### 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 Purchasing 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 where appropriate. The Supplier will notify the Purchasing Authority in the event of multiple delivery failures by an individual patient.

### It is preferable that all collections of returned items are 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 working hours of the request being made by the Purchasing Authority.

# Controlled Collection Model

## General

### Supply via Controlled Collection Model will be permitted subject to agreement from the Purchasing 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 provide to the Authority and maintain up to date a list of available collection points.

### 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 tab - 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 tab - 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 tab - 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 tab - Failed deliveries, collections and returns": In the event of non-pick up by the Patient following , the Supplier will recover the Products from the pick-up point and notify the Patient accordingly.

## Finance

In addition to the provisions set out in "Finance tab": - the appropriate evidence of service delivery will pertain to Products being duly received by the Patient following pick up.

# Custom Made Medicines (Specials)

### Technical Agreements must be in place between the Supplier and all sub-contractors or contingency partners for: - manufacturing - distribution of compounded medicines. Suppliers must provide a copy of their technical and service agreements with each compounding sub-contractor and contingency partner.

# Manufacturing Sites (Specials)

## GMP compliance details

### From the point of tender submission and during the life of the contract, Suppliers agree to provide the Purchasing Authority with:

* the dates of forthcoming MHRA inspections, as soon as they are known to the Supplier
* details of any critical deficiencies- details of any referral to IAG or CMT including evidence of progress having been made to correct the identified deficiencies
* the MHRA inspection report (or make the report available)- evidence of closure of all MHRA inspections
* the anticipated date of the next planed MHRA inspection as indicated by the inspection report.
* Suppliers will engage with stakeholders and will provide details of any identified issues, production restrictions applied and their turnaround plans.

### Suppliers must seek approval from the Purchasing Authority (and inform the Regional Homecare Specialist) for any proposed changes (permanent or temporary) that may have impact on the product supplied (specifications, products, preparation processes, packaging and labelling). This includes changes made by compounding and logistics sub-contractors.

N.B. In exceptional circumstances changes may need to be made to ensure continuity of supply. In this case the Purchasing Authorities must be notified without delay.

## Quality culture and technical capacity

### Suppliers must be able to provide documentary evidence of a robust quality culture and the technical capability to provide ready to administer compounded injectable medicines. The evidence required is detailed in the specification points below.

### Provide a brief description of how quality incidents are investigated and managed. This should include

* - deviations (non-conformances) and errors
* - complaints
* - recalls
* - investigations
* - root cause analysis
* - risk assessment
* - CAPA
* - trending of deviations and complaints.
* Provide the relevant SOPs and policies that provide evidence of all of the above.

### The Supplier's approach to assigning shelf lives aseptically compounded medicines should confirm to the current relevant Standard Protocol for derivation and assessment of stability published by the NHS Pharmaceutical QA Committee.

# Cold Chain – Controlled Drugs- Hazardous Medicines

## Special Handling

### The Purchasing 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 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 Purchasing 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 between2-8oC

### Where the Purchasing Authority requests supply of temperature controlled medicines, appropriate risk control measures must be established and agreed by both parties and detailed in the call-off contract and service level agreement in accordance with the Homecare Guidance for Storage and Handling of temperature controlled medicines in the patient's home.

### 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.

## Cytotoxic and other hazardous medicines

### Where the Purchasing 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 call-off contract and service level agreement

## Controlled drugs

### Where the Purchasing Authority requests supply of controlled medicines, appropriate risk control measures must be established and agreed by both parties and detailed in the call-off contract and service level agreement

# Equipment and Ancillaries

## Equipment

### The equipment to be provided as part of the service is listed [insert name of tab/document/appendix] in the Equipment List. A generic specification for each different type of equipment is provided in [insert name of tab/document/appendix] which includes quantity to be supplied plus any backup equipment, maintenance and response times.

### 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 Purchasing Authority.

### If specified within the Equipment List the Supplier will provide an installation visit for equipment.

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

### 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 Purchasing Authority on request.

### The Supplier will inform the Purchasing 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)

## 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.

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

## Ancillaries

### The ancillaries to be provided as part of the service is listed in [insert name of tab/document/appendix] the Ancillary List. A specification for each different type of ancillary is provided in [insert name of tab/document/appendix] which includes quantity to be supplied

### The Supplier may offer alternative ancillaries as a 'counter offer' for items documented on the Ancillary List. Such alternatives to be agreed by the Purchasing Authority.

### 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 Purchasing Authority.

### The Supplier will check stock levels either physically or remotely and replenish ancillaries on a regular basis

### The Supplier will have robust processes to manage requests from the Purchasing Authority and/or Patient for ancillaries not on the specified Ancillary List. Direct Patient requests for exceptional supply of ancillaries will be referred to the Purchasing Authority.

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

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

# 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. 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.

### 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 Purchasing Authority within 2 business days of the non-clinical visit if it could not be undertaken as agreed with the patient.

# Clinical Services

## Clinical Services

### The Clinical Services to be provided are as specified in the Clinical Service Pathway including escalation procedures [named tab/document/appendix] and Individual Patient Care Plan .

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

### The Supplier and Purchasing 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 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. Where required, clinical service protocol should include remote consultation (e.g. criteria for remote clinical service and the processes involved). No service should switch from patient contact to remote consultation without the prior agreement of the Purchasing Authority.

### Clinical Services will be available Monday to Friday 8am to 6pm excluding Bank Holidays. The Purchasing 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.

### 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 Purchasing Authority within 2 business days of any episode of clinical service.

## Training and Education of Patients

### Training of Patients to self-administer medicines will be the responsibility of the Purchasing Authority unless specified as a Clinical Service to be provided by the Supplier (see Clinical Service and Home visit tab), 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 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 Purchasing 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 Purchasing Authority via a competency check-list or equivalent.

### The Supplier and Purchasing 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. A copy of the completed detailed patient suitability and needs assessment must be provided to the Purchasing Authority on request.

# Governance

## Governance Framework and Quality Systems

### Suppliers must have a robust quality system in place which includes policies on the following and must ensure that all staff comply with them.

* 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 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 Purchasing Authority to confirm mutually acceptable guidelines.

### 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.

## Clinical Governance

### The Purchasing 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 Purchasing 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 Purchasing 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 Purchasing Authority whilst maintaining patient safety.

### The Purchasing 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 Purchasing 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 Purchasing 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 Purchasing Authority, following consultation with the patient and family. Where provided, the Supplier must adhere to the relevant Transition Policy employed by the Purchasing Authority.

## Complaints and Concerns

### 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 working days.

## Information Governance

### The Purchasing 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.

## Risk Management

### The Purchasing 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 Purchasing 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 in accordance with schedule 2 of the Agreement including major incident and emergency planning.

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

### 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.

## 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 Purchasing 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 Purchasing 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 Purchasing 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
* eidence 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

### 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.

# Finance

## Purchase Orders

### The Purchasing 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 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 Purchasing 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 Purchasing 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 Purchasing 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 Purchasing Authority.

## Invoicing

### The Supplier will generate an accurate and valid invoice linked to each Purchase Order Number and use best endeavours to provide it to the Authority within 4 weeks of service delivery. The Authority and Supplier will use best endeavours to receive or transmit invoices electronically in accordance with nationally approved standards.

All invoices must be supported by appropriate evidence 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.

### 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:

* dispensing & despatch date
* delivery date and route or carrier information and evidence
* how the delivery was confirmed, by who, and when.
* the Supplier's declaration must be made by an authorised person nominated by the Supplier.

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

## Statement of Accounts and Payments

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

### The Purchasing Authority will pay in accordance with the payment terms set out in NHS T&C's Schedule 2 general terms and conditions of the Agreement.

## 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 Purchasing 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 Purchasing 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 Purchasing Authority when prior approval has been given by the Purchasing Authority.

# Digital

## Digital Solution Requirement

### 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 previously NHSX 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 Purchasing 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 FHIR standard and other technical standards if that becomes mandated in the future.

# Net Zero and Social Value

## 53. Net Zero and Social Value

### 53.1 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>

###  53.2 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>

###  53.3 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>

###  53.4 Briefly describe how the Supplier will support the Purchasing Authority to support and improve Social Value relating to this specification.