**NHS FRAMEWORK AGREEMENT FOR THE SUPPLY OF GOODS AND THE PROVISION OF SERVICES (HOMECARE MEDICINES)**

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| **The Authority** | NHS England whose principal office is at Quarry House, Quarry Hill, Leeds, LS2 7UE. |
| **The Supplier** | **AWARDED SUPPLIERS** |
| **Address** | **AWARDED SUPPLIERS** |
| **Commencement Date** | **1 July 2023** |
| **Type of Goods and Services** | NHS National Framework Agreement Home Delivery Service Lysosomal Storage Disorders in England and Scotland.  Period of framework agreement: 1st July 2023 – 30th June 2025 with an option or options to extend (at the Authority’s discretion) for a period or periods up to a total of 24 months. |
| **Contract Reference** | CM/MSR/17/5555 |

This Framework Agreement is made on the date set out above subject to the terms set out in the schedules and appendix listed below (“**Schedules**”). The Authority and the Supplier undertake to comply with the provisions of the Schedules in the performance of this Framework Agreement.

The Definitions in [Schedule 4](#_bookmark5) apply to the use of all capitalised terms in this Framework Agreement.

**Schedules**

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| **Schedule 1** | Key Provisions |
| **Schedule 2** | General Terms and Conditions |
| **Schedule 3** | Information and Data Provisions |
| **Schedule 4** | Definitions and Interpretations |
| **Schedule 5** | Specification and Tender Response Document |
| **Schedule 6** | Commercial Schedule |
| **Schedule 7** | Award Criteria |
| **Appendix A** | Call-off Terms and Conditions for the Supply of Goods and the Provision of Services **(**Homecare Medicines**)** |

**Signed by the authorised representative of THE AUTHORITY**

**Signed by the authorised representative of THE SUPPLIER**

**Schedule 1 Key Provisions**

**Standard Key Provisions**

1. **Application of the Key Provisions**
   1. The standard Key Provisions at Clauses 1 to 7 of this Schedule 1 shall apply to this Framework Agreement.
   2. The optional Key Provisions at Clauses 8 to [10](#_bookmark0) of this Schedule 1 shall only apply to this Framework Agreement where they have been checked and information completed as applicable.
   3. Extra Key Provisions shall only apply to this Framework Agreement where such provisions are set out at the end of this Schedule 1.
2. **Term**
   1. The Initial Term of this Framework Agreement shall be 2 years from the Commencement Date and may be extended in accordance with Clause 15.2 of Schedule 2 provided that the duration of this Framework Agreement shall be no longer than **4** years in total.
3. **Contract Managers**
   1. The Contract Managers at the commencement of this Framework Agreement are:
      1. for the Authority:

**Johanna Rodriguez**

* + 1. for the Supplier:

**[Awarded Supplier].**

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1. **Names and addresses for notices**
   1. Notices served under this Framework Agreement are to be delivered to:
      1. for the Authority:

**Johanna Rodriguez**

* + 1. for the Supplier:

**[Awarded Supplier].**

1. **Management levels for escalation and dispute resolution**
   1. The management levels at which a Dispute may be dealt with as referred to as part of the Dispute Resolution Procedure are as follows:

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| --- | --- | --- |
| **Level** | **Authority representative** | **Supplier representative** |
| 1 | **Contract Manager** | **[Contract Manager]** |
| ***2*** | **Category Manager** | **[Contract Manager]** |
| ***3*** | **Lead Category Manager** | **[Contract Manager]** |

1. **Order of precedence**
   1. Subject always to Clause 1.10 of Schedule 4, should there be a conflict between any other parts of this Framework Agreement the order of priority for construction purposes shall be:
      1. the provisions on the front page of this NHS Framework Agreement for the Supply of Goods and the Provision of Services;
      2. Schedule1: Key Provisions;
      3. Schedule 5: Specification and Tender Response Document (but only in respect of the Authority’s requirements);
      4. Schedule 2: General Terms and Conditions;
      5. Schedule 6: Commercial Schedule;
      6. Schedule 3: Information Governance Provisions;
      7. Schedule 4: Definitions and Interpretations;
      8. the order in which all subsequent schedules, if any, appear; and
      9. any other documentation forming part of the Framework Agreement in the date order in which such documentation was created with the more recent

documentation taking precedence over older documentation to the extent only of any conflict.

* 1. For the avoidance of doubt, the Specification and Tender Response Document shall include, without limitation, the Authority’s requirements in the form of its specification and other statements and requirements, the Supplier’s responses, proposals and/or method statements to meet those requirements, and any clarifications to the Supplier’s responses, proposals and/or method statements as included as part of Schedule 5. Should there be a conflict between these parts of the Specification and Tender Response Document, the order of priority for construction purposes shall be (1) The Authority’s requirements; (2) any clarification to the Supplier’s responses, proposals and/or method statements, and (3) the Supplier’s responses proposals and/or method statements.

1. **Participating Authorities**
   1. The following Contracting Authorities are entitled to place Orders:
      1. As defined in Document No.10 – Participating Authorities

For the avoidance of doubt, any successor bodies of any of the above entities shall be entitled to place Orders and shall be deemed Participating Authorities for the purposes of this Framework Agreement.

**Optional Key Provisions**

1. **Quality assurance standards**

The following quality assurance standards shall apply, as appropriate, to the manufacture, supply and/or installation of the Goods and/or provision of the Services within the Royal Pharmaceutical Society (RPS) Professional Standards for Homecare Services in England [https://www.rpharms.com/resources/professional-standards/professional-standards-for-](https://www.rpharms.com/resources/professional-standards/professional-standards-for-homecare-services) [homecare-services](https://www.rpharms.com/resources/professional-standards/professional-standards-for-homecare-services)

1. **Different levels and/or types of insurance**
   1. The Supplier shall put in place and maintain in force the following insurances with the following minimum cover per claim:

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| --- | --- |
| **Type of insurance required** | **Minimum cover** |
| Employer’s liability insurance | £ 5,000,000 |
| Public liability insurance | £ 5,000,000 |
| Product liability | £ 5,000,000 |
| Professional indemnity insurance | £ 5,000,000 |

1. **Guarantee (Only applicable to the Framework Agreement if this box is checked)**
   1. Promptly following the execution of this Framework Agreement, the Supplier shall, if it has not already delivered an executed deed of guarantee to the Authority, deliver the executed deed of guarantee to the Authority as required by the procurement process followed by the Authority. Failure to comply with this Key Provision shall be an irremediable breach of this Framework Agreement.
2. **Price Review Clause**
   1. The Contract Price shall remain fixed for the duration of the Initial Term.
   2. In the event that the Authority exercises its option(s) to extend this Framework Agreement pursuant to Clause 15.2 of Schedule 2 of this Framework Agreement, if in the three (3) month period prior to the date the Framework Agreement would otherwise have expired, the Supplier can demonstrate to the satisfaction of the Authority any changes to the Supplier's manufacturing, distribution and supply costs in connection with the provision of the Goods/Services, the Authority may (at its sole discretion) elect to review the Contract Price payable for the Goods/Services during the period(s) of the extension(s) (“**the Review**”). The Authority shall be entitled to increase (subject to Clause 11.9 of this Schedule 1) or decrease the Contract Price payable for the Goods/Services in the event that the current Contract Price does not in the reasonable (sole) opinion of the Authority reflect the principal underlying costs (including, but not limited to, wage costs, fuel costs and energy costs) necessarily and properly incurred by the Supplier in connection with the manufacture and distribution of the Goods and/or the delivery of the Services. For the avoidance of doubt both Parties accept and acknowledge that any changes to the Contract Price shall not have the effect of altering the overall nature of this Framework Agreement.
   3. In reviewing the Contract Price pursuant to Clause 11.2 of this Schedule 1 of this Framework Agreement, and subject always to Clauses 11.4 and 11.9 of this Schedule 1 of this Framework Agreement, the Authority may have regard to the following factors:
      1. any changes to the Supplier's manufacturing, distribution and supply costs, to the extent that such costs are necessary and properly incurred by the Supplier in the provision of the Goods/Services;
      2. the prices at which goods/services which are reasonably equivalent to the Goods/Services are supplied by other suppliers in the open market;
      3. prices payable by other health authorities and NHS Trusts for goods/services which are reasonably equivalent to the Goods/Services; and/or
      4. the volumes of Goods/Services ordered by, and supplied to, the Participating Authorities.
   4. The Supplier shall provide all such evidence to the Authority as the Authority may reasonably request. Such evidence shall be provided by the Supplier to the Authority on a transparent basis, reference publicly available sources of evidence where appropriate, and shall be sufficient to enable the Authority to verify and substantiate any changes to the costs of the Supplier in connection with the provision of the Goods/Services. In addition, the Supplier shall, on request, allow the Authority to inspect and take copies of (or extracts from) all relevant records and materials of the Supplier relating to the supply of the Goods/Services as may be reasonably required.
   5. Upon completion of the Review by the Authority, the Authority may elect to increase (subject to Clause 11.9 of this Schedule 1) or decrease the price of the Goods/Services by giving the Supplier not less than one (1) month's written notice of such increase or decrease ("**the Review Notice**") and the Review Notice shall stipulate the new prices as varied pursuant to the Review ("**the Revised Contract Price**") and the reasons for this. The Supplier shall be entitled to supply the Goods/Services at the Revised Contract Price as soon as it receives the Review Notice but otherwise the Revised Contract Price shall take effect on 1 July 2025 and shall apply for the duration of the extension period(s) (unless the Supplier serves notice to terminate under Clause 11.6 of this Schedule 1 of this Framework Agreement below in which case Clause 11.7 of this Schedule 1 of this Framework Agreement below shall apply).
   6. The Supplier may terminate this Framework Agreement following receipt of a Review Notice by issuing a Termination Notice giving to the Authority not less than three (3) months' notice in writing provided such Termination Notice is given within fourteen (14) days of its receipt of the Review Notice under Clause 11.5 of this Schedule 1 of this Framework Agreement above.
   7. For the avoidance of doubt, if the Supplier serves a Termination Notice under Clause

11.6 of this Schedule 1 of this Framework Agreement above until such notice expires, the Contract Prices shall remain fixed at the prices payable immediately preceding the Review.

* 1. For the further avoidance of doubt, if the Supplier serves a Termination Notice under Clause 11.6 of this Schedule 1 of this Framework Agreement above, the Supplier shall be obliged to supply the Goods/Services in accordance with the terms of this Framework Agreement and any Order that may be placed prior to the date of termination.
  2. For the purposes of this Clause 11.9 of this Schedule 1, "**Consumer Prices Index**" means the Consumer Prices Index as published by the Office for National Statistics from time to time, or failing such publication, such other index as the Authority (acting reasonably) shall decide most closely resembles such index. Notwithstanding any other provision of this Framework Agreement and/or the Call-Off Terms and Conditions for the Supply of Goods and the Provision of Services, the amount of any increase (as a percentage of the current Contract Price) to the Contract Price (whether pursuant to a Review or otherwise) shall not exceed the percentage increase in the Consumer Prices Index over the preceding twelve (12) months.

1. **Supplementary and/or Substitute Goods and Services**
   1. The Authority has the right, at any point during the Term, to request a proposal (a “**Supplementary and/or Substitute Goods and Services Change Proposal**”) from the Supplier to add supplementary and/or substitute goods and/or services required by the Authority and/or Participating Authorities to Schedules 5 (Specification and Tender Response) and 6 (Commercial Schedule) of this Framework Agreement if they are goods and/or services that are, or become, available from the Supplier within the same product range or service area as any Goods and/or Services already available from the Supplier under this Framework Agreement. For the avoidance of doubt, supplementary and/or substitute goods and/or services shall be deemed to be within the same product range or service area if they are aimed at the same Patient cohort and treat the same medical condition and may include third party manufactured products available from the Supplier. The Supplier shall provide such Supplementary and/or Substitute Goods and Services Change Proposal within fifteen (15) Business Days from the date it is requested by the Authority.
   2. All Supplementary and/or Substitute Goods and Services Change Proposals prepared by the Supplier shall be an offer capable of acceptance by the Authority and shall be signed by an authorised representative of the Supplier accordingly. Without limitation, each Supplementary and/or Substitute Goods and Services Change Proposal shall detail:
      1. the price for such supplementary and/or substitute goods and/or services;
      2. any amendments required to Schedules 5 (Specification and Tender Response) and 6 (Commercial Schedule) of this Framework Agreement by way of proposed new versions of such Schedules;
      3. in the case of substitutes, the transition arrangements that will apply (to include, without limitation, the date from which the Goods and/or Services that are being replaced will no longer be available and confirmation that the current supply arrangements will be maintained until that date);
      4. the period of time that the relevant Supplementary and/or Substitute Goods and Services Change Proposal is valid for acceptance by the Authority (“**Period of Validity**”), which, for the avoidance of doubt, shall be no less than thirty (30) days from the date of such Supplementary and/or Substitute Goods and Services Change Proposal.
   3. Each such Supplementary and/or Substitute Goods and Services Change Proposal shall be considered by the Authority. Following such consideration, the Authority (acting reasonably) may, if considered necessary, request by written notice that the Supplier shall resubmit any Supplementary and/or Substitute Goods and Services Change Proposal with any additional details, clarifications and/or confirming compliance with any applicable assessment processes requested by the Authority and the Supplier shall comply with such requests within five (5) Business Days from the date of such requests (or, where this is not possible, by such other time as may be agreed by the Parties in writing acting reasonably) by submitting a new Supplementary and/or Substitute Goods and Services Change Proposal in compliance with the requirements of Clause 12.2 of this Schedule 1 of this Framework Agreement above. For the avoidance of doubt, there shall be no obligation on the Authority to accept any Supplementary and/or Substitute Goods and Services Change Proposal (to include, without limitation, in circumstances where the Authority considers (at its sole discretion) that adding such goods and/or services to the Framework Agreement without further competition would breach any Laws applicable to public procurement.
   4. The Authority may accept any Supplementary and/or Substitute Goods and Services Change Proposal signed by an authorised representative of the Supplier at any point in time during its Period of Validity by arranging for the Supplementary and/or Substitute Goods and Services Change Proposal to be signed by an authorised representative of the Authority. From the date the Supplementary and/or Substitute Goods and Services Change Proposal is signed by such authorised representative of the Authority, the Supplementary and/or Substitute Goods and Services Change Proposal shall be deemed accepted and agreed by the Authority and a binding change to this Framework Agreement agreed in writing by both Parties in accordance with Clause 21.2 of Schedule 2 of this Framework Agreement. Once signed by an authorised representative of the Authority, the Authority shall return a copy the Supplementary and/or Substitute Goods and Services Change Proposal (as signed by both Parties) to the Supplier for the Supplier’s records. For the avoidance of doubt, any Supplementary and/or Substitute Goods and Services Change Proposal not signed by an authorised representative of the Authority in accordance with this Clause 12.4 of

this Schedule 1 of this Framework Agreement within its Period of Validity shall be deemed not agreed and rejected by the Authority.

**Schedule 2**

**General Terms and Conditions**

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1. **Supplier’s appointment**
   1. The Authority appoints the Supplier as a potential supplier of the Goods and Services and the Supplier shall be eligible to be considered for the award of Orders during the Term.
   2. In consideration of the Authority agreeing to appoint the Supplier to this Framework Agreement in accordance with Clause 1.1 of this Schedule 2 and the mutual exchange of promises and obligations under this Framework Agreement, the Supplier undertakes to supply the Goods and to provide the Services under Orders placed with the Supplier:
      1. of the exact quality, type and as otherwise specified in the Specification and Tender Response Document;
      2. at the Contract Price calculated in accordance with the Commercial Schedule; and
      3. in such quantities and to such extent and at such times and at such locations as may be specified in an Order.
   3. The Supplier agrees that the Call-Off Terms and Conditions for the Supply of Goods and the Provision of Services shall apply to all Goods and Services provided by the Supplier to a Participating Authority pursuant to this Framework Agreement. The Supplier agrees that it will not in its dealings with a Participating Authority seek to impose or rely on any other contractual terms which in any way vary or contradict the relevant Contract.
   4. The Supplier shall comply fully with its obligations set out in this Framework Agreement, the Specification and Tender Response Document, the Call-off Terms and Conditions for the Supply of Goods and the Provision of Services and any other provisions of Contracts entered into under and in accordance with this Framework Agreement (to include, without limitation, the KPIs and all obligations in relation to the quality, performance characteristics, supply, delivery and installation and training in relation to use of the Goods).
   5. If there are any quality, performance and/or safety related reports, notices, alerts or other communications issued by the Supplier or any regulatory or other body in relation to the Goods, the Supplier shall promptly provide the Authority with a copy of any such reports, notices, alerts or other communications.
   6. Upon receipt of any such reports, notices, alerts or other communications pursuant to Clause 1.5 of this Schedule 2, the Authority shall be entitled to request further information from the Supplier and/or a meeting with the Supplier, and the Supplier shall cooperate fully with any such request.
   7. In complying with its obligations under this Framework Agreement, the Supplier shall, and shall procure that all Staff shall, act in accordance with the NHS values as set out in the NHS Constitution from time to time.
2. **Authority commitments**
   1. Unless otherwise set out in the Commercial Schedule, the Supplier acknowledges that:
      1. there is no obligation on the Authority or on any other Participating Authority to purchase any Goods or Services from the Supplier during the Term;
      2. no undertaking or any form of statement, promise, representation or obligation has been made by the Authority and/or any other Participating Authority in respect of the total quantities or volumes or value of the Goods or Services to be ordered by them pursuant to this Framework Agreement and the Supplier acknowledges and agrees that it has not entered into this Framework Agreement on the basis of any such undertaking, statement, promise or representation;
      3. in entering this Framework Agreement, no form of exclusivity has been granted by the Authority and/or other Participating Authority; and
      4. the Authority and/or other Participating Authorities are at all times entitled to enter into other contracts and agreements with other suppliers for the provision of any or all goods or services which are the same as or similar to the Goods or Services.
3. **Ordering procedure**
   1. Any Participating Authority may enter into Contracts by placing an Order in accordance with the Ordering Procedure.
4. **Reasonable assistance**
   1. Upon the written request of any Participating Authority, the Supplier shall provide such Participating Authority with any reasonable and proportionate information that it holds about the Goods and/or Services it supplies under this Framework Agreement including, without limitation, the compatibility and interoperability of such Goods and/or Services with other products alongside other related services, to enable the Participating Authority to complete any necessary due diligence before purchasing such Goods and/or Services, or any connected or replacement Goods and/or Services.
5. **Supplier Performance and Lifescience Industry Accredited Credentialing** **Register**
   1. The Supplier shall perform all Contracts entered into under this Framework Agreement by the Authority or any other Participating Authority in accordance with:
      1. the requirements of this Framework Agreement; and
      2. the provisions of the respective Contracts.
   2. Unless otherwise confirmed by the Authority in writing, the Supplier shall ensure full compliance (to include with any implementation timelines) with any Guidance issued by the Department of Health and Social Care and/or any requirements and/or Policies issued by the Authority (to include as may be set out as part of any procurement documents leading to the award of this Framework Agreement) in relation to the adoption of, and compliance with, any scheme or schemes to verify the credentials of Supplier representatives that visit NHS premises (to include use of the Lifescience Industry Accredited Credentialing Register). Once compliance with any notified implementation timelines has been achieved by the Supplier, the Supplier shall, during the Term, maintain the required level of compliance in accordance with any such Guidance, requirements and Polices.
6. **Business continuity**
   1. Throughout the Term, the Supplier will ensure its Business Continuity Plan provides for continuity during a Business Continuity Event. The Supplier confirms and agrees such Business Continuity Plan details and will continue to detail robust arrangements that are reasonable and proportionate to:
      1. the criticality of this Framework Agreement to the Participating Authorities; and
      2. the impact of and any disruption caused by EU exit;
      3. any reasonably foreseeable risks; and
      4. the size and scope of the Supplier’s business operations,

regarding continuity of the supply of Goods and/or the provision of the Services during and following a Business Continuity Event.

* 1. The Supplier shall test its Business Continuity Plan at reasonable intervals, and in any event no less than once every twelve (12) months or such other period as may be agreed between the Parties taking into account the criticality of this Framework Agreement to Participating Authorities and the size and scope of the Supplier’s business operations. The Supplier shall promptly provide to the Authority, at the Authority’s written request, copies of its Business Continuity Plan, reasonable and proportionate documentary evidence that the Supplier tests its Business Continuity Plan in accordance with the requirements of this Clause 6.2 of this schedule 2 and reasonable and proportionate information regarding the outcome of such tests. The Supplier shall provide to the Authority a copy of any updated or revised Business Continuity Plan within fourteen (14) Business Days of any material update or revision to the Business Continuity Plan.
  2. The Authority may suggest reasonable and proportionate amendments to the Supplier regarding the Business Continuity Plan at any time. Where the Supplier, acting reasonably, deems such suggestions made by the Authority to be relevant and appropriate, the Supplier will incorporate into the Business Continuity Plan all such suggestions made by the Authority in respect of such Business Continuity Plan. Should the Supplier not incorporate any suggestion made by the Authority into such Business Continuity Plan it will explain the reasons for not doing so to the Authority.
  3. Should a Business Continuity Event occur at any time, the Supplier shall implement and comply with its Business Continuity Plan and provide regular written reports to the Authority on such implementation.
  4. During and following a Business Continuity Event, the Supplier shall use reasonable endeavours to continue to fulfil its obligations in accordance with this Framework Agreement.

1. **The Authority’s obligations**
   1. The Authority shall provide reasonable cooperation to the Supplier and shall, as appropriate, provide copies of or give the Supplier access to such of the Policies that

are relevant to the Supplier complying with its obligations under this Framework Agreement.

* 1. The Authority shall comply with the Authority’s Obligations, if any.

1. **Contract management**
   1. Each Party shall appoint and retain a Contract Manager who shall be the primary point of contact for the other Party in relation to matters arising from this Framework Agreement. Should the Contract Manager be replaced, the Party replacing the Contract Manager shall promptly inform the other Party in writing of the name and contact details for the new Contract Manager. Any Contract Manager appointed shall be of sufficient seniority and experience to be able to make decisions on the day to day operation of the Framework Agreement. The Supplier confirms and agrees that it will be expected to work closely and cooperate fully with the Authority’s Contract Manager.
   2. Each Party shall ensure that its representatives (to include, without limitation, its Contract Manager) shall attend review meetings on a regular basis to review the performance of the Supplier under this Framework Agreement and to discuss matters arising generally under this Framework Agreement. Each Party shall ensure that those attending such meetings have the authority to make decisions regarding the day to day operation of the Framework Agreement. Review meetings shall take place at the frequency specified in the Specification and Tender Response Document. Should the Specification and Tender Response Document not state the frequency, then the first such meeting shall take place on a date to be agreed on or around the end of the first month after the Commencement Date. Subsequent meetings shall take place at quarterly intervals or as may otherwise be agreed in writing between the Parties.
   3. Two weeks prior to each review meeting (or at such time and frequency as may be specified in the Specification and Tender Response Document) the Supplier shall provide a written contract management report to the Authority regarding the supply of Goods, the provision of the Services and the operation of this Framework Agreement. Unless otherwise agreed by the Parties in writing, such contract management report shall contain:
      1. details of the performance of the Supplier under this Framework Agreement and any Contracts when assessed in accordance with the KPIs, as relevant to the Framework Agreement and any Contracts, since the last such performance report;
      2. details of any complaints by Participating Authorities in relation to the supply of Goods or the provision of the Services, their nature and the way in which the Supplier has responded to such complaints since the last review meeting written report;
      3. the information specified in the Specification and Tender Response Document as being relevant to the operation of this Framework Agreement;
      4. a status report in relation to the implementation of any current Remedial Proposals by either Party; and
      5. such other information as reasonably required by the Authority.
   4. Unless specified otherwise in the Specification and Tender Response Document, the Authority shall take minutes of each review meeting and shall circulate draft minutes to the Supplier within a reasonable time following such review meeting. The Supplier shall inform the Authority in writing of any suggested amendments to the minutes within five (5) Business Days of receipt of the draft minutes. If the Supplier does not respond to the Authority within such five (5) Business Days the minutes will be deemed to be approved. Where there are any differences in interpretation of the minutes, the Parties will use their reasonable endeavours to reach agreement. If agreement cannot be reached the matter shall be referred to, and resolved in accordance with, the Dispute Resolution Procedure.
   5. The Supplier shall provide such management information as the Authority may request from time to time within seven (7) Business Days of the date of the request. The Supplier shall supply the management information to the Authority in such form as may be specified by the Authority and, where requested to do so, the Supplier shall also provide such management information to another Contracting Authority, whose role it is to analyse such management information in accordance with UK government policy (to include, without limitation, for the purposes of analysing public sector expenditure, planning future procurement activities and/or monitoring and planning healthcare) (“**Third Party Body”**). The Supplier confirms and agrees that the Authority may itself provide the Third Party Body with management information relating to the Goods and/or the Services ordered and any payments made under this Framework Agreement or any Contracts and any other information relevant to the operation of this Framework Agreement.
   6. Upon receipt of management information supplied by the Supplier to the Authority and/or the Third Party Body, or by the Authority to the Third Party Body, the Parties hereby consent to the Third Party Body and the Authority:
      1. storing and analysing the management information and producing statistics; and
      2. sharing the management information, or any statistics produced using the management information with any other Contracting Authority.
   7. If the Third Party Body and/or the Authority shares the management information or any other information provided under Clause 8.6 of this Schedule 2 , any Contracting Authority receiving the management information shall, where such management information is subject to obligations of confidence under this Framework Agreement and such management information is provided direct by the Authority to such Contracting Authority, be informed of the confidential nature of that information by the Authority and shall be requested by the Authority not to disclose it to any body that is not a Contracting Authority (unless required to do so by Law).
   8. The Authority may make changes to the type of management information which the Supplier is required to supply and shall give the Supplier at least one (1) month’s written notice of any changes.
2. **Price and payment**
   1. The Contract Price for all Contracts shall be calculated as set out in the Commercial Schedule and the payment provisions for all Contracts shall be as set out in the Call- Off Terms and Conditions for the Supply of Goods and the Provision of Services.
   2. Where any payments are to be made under this Framework Agreement by either Party in addition to any payments to be made by Participating Authorities under any Contracts, the details of such payments and the invoicing arrangements shall be set out in the Commercial Schedule.
3. **Warranties**
   1. The Supplier warrants and undertakes that:
      1. it will comply with the terms of all Contracts entered into by Participating Authorities under this Framework Agreement;
      2. it will fully and promptly respond to all requests for information and/or requests for answers to questions regarding this Framework Agreement, the Goods, the Services, any complaints, any Disputes and any Contracts at the frequency, in the timeframes and in the format as requested by the Authority from time to time (acting reasonably);
      3. all information included within the Supplier’s responses to any documents issued by the Authority as part of the procurement relating to the award of this Framework Agreement (to include, without limitation, as referred to in Specification and Tender Response Document and Commercial Schedule) and all accompanying materials is accurate;
      4. it has and shall as relevant maintain all rights, consents, authorisations, licences and accreditations required to enter into and comply with its obligations under this Framework Agreement;
      5. it has the right and authority to enter into this Framework Agreement and that it has the capability and capacity to fulfil its obligations under this Framework Agreement;
      6. it is a properly constituted entity and it is fully empowered by the terms of its constitutional documents to enter into and to carry out its obligations under this Framework Agreement and the documents referred to in this Framework Agreement;
      7. all necessary actions to authorise the execution of and performance of its obligations under this Framework Agreement have been taken before such execution;
      8. there are no pending or threatened actions or proceedings before any court or administrative agency which would materially adversely affect the financial condition, business or operations of the Supplier;
      9. there are no material agreements existing to which the Supplier is a party which prevent the Supplier from entering into or complying with this Framework Agreement;
      10. it has and will continue to have the capacity, funding and cash flow to meet all its obligations under this Framework Agreement;
      11. it has satisfied itself as to the nature and extent of the risks assumed by it under this Framework Agreement and has gathered all information

necessary to perform its obligations under this Framework Agreement and all other obligations assumed by it;

* + 1. it shall comply with all relevant Law, Guidance and provisions of the Supplier Code of Conduct and shall use Good Industry Practice to ensure that there is no slavery or human trafficking in its supply chains; and
    2. it shall at all times conduct its business in a manner that is consistent with any anti-slavery Policy of the Authority and shall provide to the Authority any reports or other information that the Authority may request as evidence of the Supplier’s compliance with this Clause [10.1.13](#_bookmark2) and/or as may be requested or otherwise required by the Authority in accordance with its anti- slavery Policy.
  1. The Supplier warrants that all information, data and other records and documents required by the Authority as set out in the Specification and Tender Response Document shall be submitted to the Authority in the format and in accordance with any timescales set out in the Specification and Tender Response Document.
  2. The Supplier warrants and undertakes to the Authority that it shall comply with any eProcurement Guidance as it may apply to the Supplier and shall carry out all reasonable acts required of the Supplier to enable the Authority to comply with such eProcurement Guidance.
  3. The Supplier warrants and undertakes to the Authority that, as at the Commencement Date, it has notified the Authority in writing of any Occasions of Tax Non-Compliance or any litigation that it is involved in that is in connection with any Occasions of Tax Non-Compliance. If, at any point during the Term, an Occasion of Tax Non-Compliance occurs, the Supplier shall:
     1. notify the Authority in writing of such fact within five (5) Business Days of its occurrence; and
     2. promptly provide to the Authority:
        1. details of the steps which the Supplier is taking to address the Occasion of Tax Non-Compliance and to prevent the same from recurring, together with any mitigating factors that it considers relevant; and
        2. such other information in relation to the Occasion of Tax Non- Compliance as the Authority may reasonably require.
  4. The Supplier further warrants and undertakes to the Authority that it will inform the Authority in writing immediately upon becoming aware that any of the warranties set out in Clause 10 of this Schedule 2 have been breached or there is a risk that any warranties may be breached.
  5. Any warranties provided under this Framework Agreement are both independent and cumulative and may be enforced independently or collectively at the sole discretion of the enforcing Party.

1. **Statutory compliance**
   1. The Supplier shall comply with all Law and Guidance relevant to its obligations under this Framework Agreement and any Contracts.
   2. Without limitation to Clause 11.1 of this Schedule 2, the Supplier shall be responsible for obtaining any statutory licences, authorisations, consents or permits required in connection with its performance of its obligations under this Framework Agreement and any Contracts.
2. **Independence of Participating Authorities**
   1. The Supplier acknowledges that each Participating Authority is independently responsible for the conduct of its award of Contracts under this Framework Agreement and that the Authority is not responsible or accountable for and shall have no liability whatsoever in relation to:
      1. the conduct of Participating Authorities other than the Authority in relation to the operation of this Framework Agreement; or
      2. the performance or non-performance of any Participating Authorities other than the Authority under any Contracts between the Supplier and such other Participating Authorities entered into under this Framework Agreement.
3. **Limitation of liability**
   1. Nothing in this Framework Agreement shall exclude or restrict the liability of either Party:
      1. for death or personal injury resulting from its negligence;
      2. for fraud or fraudulent misrepresentation;
      3. in any other circumstances where liability may not be limited or excluded under any applicable law;
      4. to make any payments agreed in accordance with Clause 9.2 of this Schedule 2; or
      5. pursuant to 2.5 of Schedule 3.
   2. Subject to Clause 13.1, 13.3 and 13.5 of this Schedule 2, the total liability of each Party to the other under or in connection with this Framework Agreement whether arising in contract, tort, negligence, breach of statutory duty or otherwise shall be limited in aggregate to five hundred thousand GBP (£500,000).
   3. There shall be no right to claim losses, damages and/or other costs and expenses under or in connection with this Framework Agreement whether arising in contract (to include, without limitation, under any relevant indemnity), tort, negligence, breach of statutory duty or otherwise to the extent that any losses, damages and/or other costs and expenses claimed are in respect of loss of production, loss of business opportunity or are in respect of indirect loss of any nature suffered or alleged.
   4. Each Party shall at all times take all reasonable steps to minimise and mitigate any loss for which that Party is entitled to bring a claim against the other pursuant to this Framework Agreement.
   5. The liability of the Supplier and any Participating Authorities under any Contracts entered into pursuant to this Framework Agreement shall be as set out in the Call-off Terms and Conditions for the Supply of Goods and the Provision of Services forming part of such Contracts.
4. **Insurance**
   1. Subject to Clauses 14.2 and 14.3 of this Schedule 2 and unless otherwise confirmed in writing by the Authority, as a minimum level of protection, the Supplier shall put in place and/or maintain in force at its own cost with a reputable commercial insurer, insurance arrangements in respect of employer’s liability, public liability and professional indemnity and product liability and clinical negligence in accordance with Good Industry Practice with the minimum cover per claim of the greater of five million pounds (£5,000,000) or any sum as required by Law unless otherwise agreed with the Authority in writing. These requirements shall not apply to the extent that the Supplier is a member and maintains membership of each of the indemnity schemes run by the NHS Litigation Authority.
   2. Without limitation to any insurance arrangements as required by Law, the Supplier shall put in place and/or maintain the different types and/or levels of indemnity arrangements explicitly required by the Authority, if specified in the Key Provisions.
   3. Provided that the Supplier maintains all indemnity arrangements required by Law, the Supplier may self-insure in order to meet other relevant requirements referred to at Clauses 14.1 and 14.2 of this Schedule 2 on condition that such self-insurance arrangements offer the appropriate levels of protection and are approved by the Authority in writing prior to the Commencement Date.
   4. The amount of any indemnity cover and/or self-insurance arrangements shall not relieve the Supplier of any liabilities under this Framework Agreement. It shall be the responsibility of the Supplier to determine the amount of indemnity and/or self- insurance cover that will be adequate to enable it to satisfy its potential liabilities under this Framework Agreement. Accordingly, the Supplier shall be liable to make good any deficiency if the proceeds of any indemnity cover and/or self-insurance arrangement is insufficient to cover the settlement of any claim.
   5. The Supplier warrants that it shall not take any action or fail to take any reasonable action or (in so far as it is reasonable and within its power) permit or allow others to take or fail to take any action, as a result of which its insurance cover may be rendered void, voidable, unenforceable, or be suspended or impaired in whole or in part, or which may otherwise render any sum paid out under such insurances repayable in whole or in part.
   6. The Supplier shall from time to time and in any event within five (5) Business Days of written demand provide documentary evidence to the Authority that insurance arrangements taken out by the Supplier pursuant to Clause 14 of this Schedule 2 and the Key Provisions are fully maintained and that any premiums on them and/or contributions in respect of them (if any) are fully paid.
   7. Upon the expiry or earlier termination of this Framework Agreement, the Supplier shall ensure that any ongoing liability it has or may have arising out of this Framework

Agreement shall continue to be the subject of appropriate indemnity arrangements for the period of twenty one (21) years from termination or expiry of this Framework Agreement or until such earlier date as that liability may reasonably be considered to have ceased to exist.

1. **Term and termination**
   1. This Framework Agreement shall commence on the Commencement Date and, unless terminated earlier in accordance with the terms of this Framework Agreement or the general law, shall continue until the end of the Term.
   2. The Authority shall be entitled to extend the Term on one or more occasions by giving the Supplier written notice no less than three (3) months prior to the date on which this Framework Agreement would otherwise have expired, provided that the duration of this Framework Agreement shall be no longer than the total term specified in the Key Provisions.
   3. In the case of a breach of any of the terms of this Framework Agreement by either Party that is capable of remedy (including any failure to pay any sums due under this Framework Agreement), the non-breaching Party may, without prejudice to its other rights and remedies under this Framework Agreement, issue a Breach Notice and shall allow the Party in breach the opportunity to remedy such breach in the first instance via a remedial proposal put forward by the Party in breach (“**Remedial Proposal**”) before exercising any right to terminate this Framework Agreement in accordance with Clause 15.4(ii) of this Schedule 2. Such Remedial Proposal must be agreed with the non-breaching Party (such agreement not to be unreasonably withheld or delayed) and must be implemented by the Party in breach in accordance with the timescales referred to in the agreed Remedial Proposal. Once agreed, any changes to a Remedial Proposal must be approved by the Parties in writing. Any failure by the Party in breach to:
      1. put forward and agree a Remedial Proposal with the non-breaching Party in relation to the relevant default or breach within a period of ten (10) Business Days (or such other period as the non-breaching Party may agree in writing) from written notification of the relevant default or breach from the non- breaching Party;
      2. comply with such Remedial Proposal (including, without limitation, as to its timescales for implementation, which shall be thirty (30) days unless otherwise agreed between the Parties); and/or
      3. remedy the default or breach notwithstanding the implementation of such Remedial Proposal in accordance with the agreed timescales for implementation,

shall be deemed, for the purposes of Clause 15.4(ii) of this Schedule 2, a material breach of this Framework Agreement by the Party in breach not remedied in accordance with an agreed Remedial Proposal.

* 1. Either Party may terminate this Framework Agreement by issuing a Termination Notice to the other Party if such other Party commits a material breach of any of the terms of this Framework Agreement which is:

1. not capable of remedy; or
2. in the case of a breach capable of remedy, which is not remedied in accordance with a Remedial Proposal.
   1. The Authority may terminate this Framework Agreement by issuing a Termination Notice to the Supplier if:
      1. the Supplier, or any third party guaranteeing the obligations of the Supplier under this Framework Agreement, ceases or threatens to cease carrying on its business; suspends making payments on any of its debts or announces an intention to do so; is, or is deemed for the purposes of any Law to be, unable to pay its debts as they fall due or insolvent; enters into or proposes any composition, assignment or arrangement with its creditors generally; takes any step or suffers any step to be taken in relation to its winding-up, dissolution, administration (whether out of court or otherwise) or reorganisation (by way of voluntary arrangement, scheme of arrangement or otherwise) otherwise than as part of, and exclusively for the purpose of, a bona fide reconstruction or amalgamation; has a liquidator, trustee in bankruptcy, judicial custodian, compulsory manager, receiver, administrative receiver, administrator or similar officer appointed (in each case, whether out of court or otherwise) in respect of it or any of its assets; has any security over any of its assets enforced; or any analogous procedure or step is taken in any jurisdiction;
      2. the Supplier undergoes a change of control within the meaning of sections 450 and 451 of the Corporation Tax Act 2010 (other than for an intra-group change of control) without the prior written consent of the Authority and the Authority shall be entitled to withhold such consent if, in the reasonable opinion of the Authority, the proposed change of control will have a material impact on the performance of this Framework Agreement or the reputation of the Authority;
      3. the Supplier purports to assign, Sub-contract, novate, create a trust in or otherwise transfer or dispose of this Framework Agreement in breach of Clause 28.1 of this Schedule 2;
      4. pursuant to and in accordance with the Key Provisions and Clauses15.6,

23.8; 25.2; 25.4 and 29.2 of this Schedule 2;

* + 1. the warranty given by the Supplier pursuant to Clause 10.4 of this Schedule 2 is materially untrue, the Supplier commits a material breach of its obligation to notify the Authority of any Occasion of Tax Non-Compliance as required by Clause 10.4 of this Schedule2, or the Supplier fails to provide details of proposed mitigating factors as required by Clause 10.4 of this Schedule2 that in the reasonable opinion of the Authority are acceptable; or
    2. at any time at its convenience by giving at least three (3) months written notice.
  1. If the Authority, acting reasonably, has good cause to believe that there has been a material deterioration in the financial circumstances of the Supplier and/or any third party guaranteeing the obligations of the Supplier under this Framework Agreement and/or any material Sub-contractor of the Supplier when compared to any information provided to and/or assessed by the Authority as part of any procurement process or

other due diligence leading to the award of this Framework Agreement to the Supplier or the entering into a Sub-contract by the Supplier, the following process shall apply:

* + 1. the Authority may (but shall not be obliged to) give notice to the Supplier requesting adequate financial or other security and/or assurances for due performance of its material obligations under this Framework Agreement on such reasonable and proportionate terms as the Authority may require within a reasonable time period as specified in such notice;
    2. a failure or refusal by the Supplier to provide the financial or other security and/or assurances requested in accordance with Clause 15.6 of this Schedule 2 in accordance with any reasonable timescales specified in any such notice issued by the Authority shall be deemed a breach of this Framework Agreement by the Supplier and shall be referred to and resolved in accordance with the Dispute Resolution Procedure; and
    3. a failure to resolve such breach in accordance with such Dispute Resolution Procedure by the end of the escalation stage of such process shall entitle, but shall not compel, the Authority to terminate this Framework Agreement in accordance with Clause 15.4(i) of this Schedule 2.

In order that the Authority may act reasonably in exercising its discretion in accordance with Clause 15.6 of this Schedule 2, the Supplier shall provide the Authority with such reasonable and proportionate up-to-date financial or other information relating to the Supplier or any relevant third party entity upon request.

* 1. The Authority may terminate this Framework Agreement by issuing a Termination Notice to the Supplier where:
     1. the Framework Agreement has been substantially amended to the extent that the Public Contracts Regulations 2015 require a new procurement procedure;
     2. the Authority has become aware that the Supplier should have been excluded under Regulation 57(1) or (2) of the Public Contracts Regulations 2015 from the procurement procedure leading to the award of this Framework Agreement;
     3. the Framework Agreement should not have been awarded to the Supplier in view of a serious infringement of obligations under European law declared by the Court of Justice of the European Union under Article 258 of the Treaty on the Functioning of the EU; or
     4. there has been a failure by the Supplier and/or one of its Sub-contractors to comply with legal obligations in the fields of environmental, social or labour law. Where the failure to comply with legal obligations in the fields of environmental, social or labour Law is a failure by one of the Supplier’s Sub- contractors, the Authority may request the replacement of such Sub- contractor and the Supplier shall comply with such request as an alternative to the Authority terminating this Framework Agreement under this Clause 15.7.4.
  2. If the Authority novates this Framework Agreement to any body that is not a Contracting Authority, from the effective date of such novation, the rights of the Authority to terminate this Framework Agreement in accordance with Clause 15.5.1 to

Clause 15.5.3 of this Schedule 2 shall be deemed mutual termination rights and the Supplier may terminate this Framework Agreement by issuing a Termination Notice to the entity assuming the position of the Authority if any of the circumstances referred to in such Clauses apply to the entity assuming the position of the Authority.

1. **Consequences of expiry or early termination of this Framework Agreement**
   1. Upon expiry or earlier termination of this Framework Agreement, the Authority and the Supplier agree that all Contracts entered into under this Framework Agreement will continue in full force and effect unless otherwise terminated under the terms and conditions of such Contracts.
   2. The Supplier shall cooperate fully with the Authority or, as the case may be, any replacement supplier during any re-procurement and handover period prior to and following the expiry or earlier termination of this Framework Agreement. This cooperation shall extend to providing access to all information relevant to the operation of this Framework Agreement, as reasonably required by the Authority to achieve a fair and transparent re-procurement and/or an effective transition without disruption to routine operational requirements. Any Personal Data Processed by the Supplier on behalf of the Authority shall be returned to the Authority or destroyed in accordance with the relevant provisions of the Data Protection Protocol.
   3. The expiry or earlier termination of this Framework Agreement for whatever reason shall not affect any rights or obligations of either Party which accrued prior to such expiry or earlier termination.
   4. The expiry or earlier termination of this Framework Agreement shall not affect any obligations which expressly or by implication are intended to come into or continue in force on or after such expiry or earlier termination.
2. **Suspension of Supplier’s appointment**
   1. Without prejudice to the Authority's rights to terminate this Framework Agreement, if a right for the Authority to terminate this Framework Agreement arises (irrespective of whether the circumstances leading to such right are capable of remedy) in accordance with Clause 15 of this Schedule 2, the Authority may suspend the Supplier's appointment to receive new Orders under this Framework Agreement by giving notice in writing to the Supplier and all Participating Authorities.
   2. If the Authority provides notice to the Supplier in accordance with Clause 17.1 of this Schedule 2, the Supplier's appointment shall be suspended for the period set out in the notice or such other period notified to the Supplier by the Authority in writing from time to time provided that such suspension shall be lifted where:
      1. the circumstances leading to the Authority’s right to terminate this Framework Agreement have been remedied;
      2. the Authority has satisfied itself that the risk and/or impact of the circumstances giving rise to the Authority’s right to terminate this Framework Agreement no longer requires such suspension; or
      3. the Authority exercises its rights to terminate this Framework Agreement in accordance with Clause 15 of this Schedule 2.
3. **Complaints**
   1. The Supplier shall notify the Authority of any notices of breach issued by any Participating Authorities relating to the Supplier’s noncompliance with any of its obligations under any Contract within ten (10) Business Days of the Supplier receiving such notice of breach.
   2. Within five (5) Business Days of a written request by the Authority, the Supplier shall provide further reasonable details of the breach to the Authority, including details of the steps being taken to progress its remedy and, following its remedy, details of how and when the breach was remedied.
4. **Sustainable development**
   1. The Supplier shall comply in all material respects with applicable environmental and social and labour Law requirements in force from time to time in relation to the Goods and Services. Where the provisions of any such Law are implemented by the use of voluntary agreements, the Supplier shall comply with such agreements as if they were incorporated into English law subject to those voluntary agreements being cited in the Specification and Tender Response Document. Without prejudice to the generality of the foregoing, the Supplier shall:
      1. comply with all Policies and/or procedures and requirements set out in the Specification and Tender Response Document in relation to any stated environmental, social and labour requirements, characteristics and impacts of the Goods and Services and the Supplier’s supply chain;
      2. maintain relevant policy statements documenting the Supplier’s significant labour, social and environmental aspects as relevant to the Goods and Services being provided and as proportionate to the nature and scale of the Supplier’s business operations; and
      3. maintain plans and procedures that support the commitments made as part of the Supplier’s significant labour, social and environmental policies, as referred to at Clause 19.1.2 of this Schedule 2.
   2. The Supplier shall meet reasonable requests by the Authority for information evidencing the Supplier’s compliance with the provisions of Clause 19 of this Schedule 2.
5. **Electronic product and services information**
   1. Where requested by the Authority, the Supplier shall provide the Authority the Product Information and the Services Information in such manner and upon such media as agreed between the Supplier and the Authority from time to time for the sole use by the Authority.
   2. The Supplier warrants that the Product Information and the Services Information is complete and accurate as at the date upon which it is delivered to the Authority and that the Product Information and/or Services Information shall not contain any data or statement which gives rise to any liability on the part of the Authority following publication of the same in accordance with Clause 20 of this Schedule 2.
   3. If the Product Information and Services Information ceases to be complete and accurate, the Supplier shall promptly notify the Authority in writing of any modification or addition to or any inaccuracy or omission in the Services Information.
   4. The Supplier grants the Authority a perpetual, non-exclusive, royalty free licence to use and exploit the Product Information and the Services Information and any Intellectual Property Rights in the Product Information and the Services Information for the purpose of illustrating the range of goods and services (including, without limitation, the Goods and Services) available pursuant to the Authority’s contracts from time to time. Subject to Clause 20.5 of this Schedule 2, no obligation to illustrate or advertise the Services Information is imposed on the Authority, as a consequence of the licence conferred by this Clause 20.4 of this Schedule 2.
   5. The Authority may reproduce for its sole use the Services Information provided by the Supplier in the Authority's product and/or services catalogue from time to time which may be made available on any NHS communications networks in electronic format and/or made available on the Authority's external website and/or made available on other digital media from time to time.
   6. Before any publication of the Product Information and the Services Information (electronic or otherwise) is made by the Authority, the Authority will submit a copy of the relevant sections of the Authority's product and/or services catalogue to the Supplier for approval, such approval not to be unreasonably withheld or delayed. For the avoidance of doubt the Supplier shall have no right to compel the Authority to exhibit the Product Information and the Services Information in any product and/or services catalogue as a result of the approval given by it pursuant to this Clause 20.6 of this Schedule 2 or otherwise under the terms of this Framework Agreement.
   7. If requested in writing by the Authority, and to the extent not already agreed as part of the Specification and Tender Response Document, the Supplier and the Authority shall discuss and seek to agree in good faith arrangements to use any Electronic Trading System.
6. **Change management**
   1. The Supplier acknowledges to the Authority that the requirements for the Goods and/or Services may change during the Term and the Supplier shall not unreasonably withhold or delay its consent to any reasonable variation or addition to the Specification and Tender Response Document, as may be requested by the Authority from time to time.
   2. Subject to Clause 21.3 of this Schedule 2, any change to the Goods and/or Services or other variation to this Framework Agreement shall only be binding once it has been agreed in writing and signed by an authorised representative of both Parties.
   3. Any change to the Data Protection Protocol shall be made in accordance with the relevant provisions of that protocol.
7. **Dispute resolution**
   1. During any Dispute, including a Dispute as to the validity of the Framework Agreement, it is agreed that the Supplier shall continue its performance of the provisions of the Framework Agreement (unless the Authority requests in writing that the Supplier does not do so).
   2. In the case of a Dispute the Supplier and the Authority shall make every reasonable effort to communicate and cooperate with each other with a view to resolving the Dispute and shall follow the procedure set out in this Clause 22 of this Schedule 2.
   3. In the event of a Dispute either Party may serve a Dispute Notice on the other Party to commence formal resolution of the Dispute. The Dispute Notice shall set out:
      1. the material particulars of the Dispute; and
      2. the reasons why the Party serving the Dispute Notice believes the Dispute has arisen.
   4. Following the service of a Dispute Notice the Parties shall first seek to resolve the Dispute by convening a meeting between the Authority’s Contract Manager and the Supplier’s Contract Manager (together the “**Contract Managers**”).
      1. The meeting of the Contract Managers must take place within five (5) Business Days of the date of the Dispute Notice (the “**Dispute Meeting**”).
      2. The Contract Managers shall be given ten (10) Business Days following the date of the Dispute Meeting to resolve the Dispute.
      3. The Contract Managers can agree to further meetings at levels 2 and/or 3 as referred to at Clause 5.1 of the Key Provisions in Schedule 1, in addition to the Dispute Meeting, but such meetings must be held within the ten (10) Business Day timetable set out in paragraph 22.4.2 of Schedule 2.
      4. If at any point it becomes clear that the timetable set out cannot be met or has passed, the Parties may (but shall be under no obligation to) agree in writing to extend the timetable. Any agreed extension to the timetable shall have the effect of delaying the start of the subsequent stages by the period agreed in the extension.
   5. If the procedure set out in Clause 22.4 of this Schedule 2 has been exhausted and fails to resolve the Dispute either party may request the Dispute be resolved by way of a binding expert determination (pursuant to Clause 22.6 of this Schedule 2). For the avoidance of doubt, the Expert shall determine all matters (including, without limitation, matters of contractual construction and interpretation) in connection with any Dispute referred to binding expert determination pursuant to Clause 22.6 of this Schedule 2.
   6. Where the Dispute is referred to binding expert determination the following process will apply:
      1. The Party wishing to refer the Dispute to expert determination shall give notice in writing to the other Party informing it of its wish to refer the Dispute to expert determination and giving brief details of its position in the Dispute.
      2. The Parties shall attempt to agree upon a single expert (who must have no connection with the Dispute unless both Parties have consented in writing) (an “**Expert**”). For the avoidance of doubt, where the Dispute relates to contractual interpretation and construction, the Expert may be Queen’s Counsel. In the event that the Parties fail to agree upon an Expert within five (5) Business Days following the date of the notice referred to in paragraph 22.6.1 of this Schedule 2 (or if the person agreed upon is unable

or unwilling to act), the Parties agree that the Expert will be nominated and confirmed to be appointed by the Centre for Effective Dispute Resolution.

* + 1. The Expert must be willing and able to complete the expert determination process within thirty (30) Business Days of the Date of Final Representations (as defined below in Clause 22.6.5 of this Schedule 2).
    2. The Expert shall act as an expert not as an arbitrator or legal advisor. There will be no formal hearing and the Expert shall regulate the procedure as she or he sees fit.
    3. The Parties shall each have the right to make written representations to the Expert and will, with reasonable promptness, provide the Expert with such assistance and documents as the Expert reasonably requires for the purpose of reaching a decision. Such representations must be made within twenty eight (28) Business Days of the Expert being appointed, or fourteen

(14) Business Days after the last documents requested by the Expert have been provided to the Expert, whichever is the later (“**Date of Final Representations**”). Any documents provided to the Expert and any correspondence to or from the Expert, including email exchanges, shall be copied to the other Party simultaneously.

* + 1. The Expert shall have the power to open up, review and revise any certificate, opinion, requisition or notice and to determine all matters in Dispute (including his jurisdiction to determine matters that have been referred to him).
    2. The Expert may take such advice and assistance from professional advisers or other third parties as he reasonably considers appropriate to enable him to reach a determination of the Dispute and may issue orders that one or both of the Parties are to pay such third party costs, stating the proportion. For the avoidance of doubt, where the Expert is not Queen’s Counsel, and the Expert requires advice or assistance on matters of contractual interpretation and construction, the Expert may take such advice and assistance from a third party Queen’s Counsel of their choosing under this Clause 22.6.7 of this Schedule 2. The Parties will pay any such third party costs incurred pursuant to this Clause 22.6.7 of this Schedule 2 in such proportions as the Expert shall order. In the absence of such order such third party costs will be paid equally.
    3. The Expert shall provide the Parties with a written determination of the Dispute (the “**Expert’s Decision**”) within thirty (30) Business Days of the Date of Final Representations, which shall, in the absence of fraud or manifest error, be final and binding on the Parties.
    4. The Expert’s Decision shall include reasons.
    5. The Parties agree to implement the Expert’s Decision within five (5) Business Days of the Expert’s Decision being provided to them or as otherwise specified as part of the Expert’s Decision.
    6. The Parties agree that the Expert shall be entitled to proceed to give his binding determination should one or both Parties fail to act in accordance with the procedural timetable set out above.
    7. The Parties will pay the Expert’s costs in such proportions as the Expert shall determine. In the absence of such determination such costs will be shared equally.
    8. The Parties agree to keep confidential all information arising out of or in connection with the expert determination, including details of the underlying Dispute, except where disclosure is required by Law.
  1. Nothing in this Framework Agreement shall prevent:
     1. the Authority taking action in any court in relation to any death or personal injury arising or allegedly arising in connection with the supply of Goods and/or the provision of Services;
     2. either Party seeking from any court any interim or provisional relief that may be necessary to protect the rights or property of that Party (including Intellectual Property Rights) or which relates to the safety of patients and other service users or the security of Confidential Information, pending the resolution of the relevant Dispute in accordance with the Dispute Resolution Procedure.
  2. Subject to Clause 22.7 of this Schedule 2, neither Party may commence legal proceedings in relation to a Dispute until the dispute resolution procedures set out in this Clause 22 have been exhausted. For the avoidance of doubt, either Party may commence legal action to enforce the Expert’s Decision.
  3. This Clause 22 of this Schedule 2 shall survive the expiry of or earlier termination of this Framework Agreement for any reason.

1. **Force majeure**
   1. Subject to Clause 23.2 of this Schedule 2 neither Party shall be liable to the other for any failure to perform all or any of its obligations under this Framework Agreement nor liable to the other Party for any loss or damage arising out of the failure to perform its obligations to the extent only that such performance is rendered impossible by a Force Majeure Event.
   2. The Supplier shall only be entitled to rely on a Force Majeure Event and the relief set out in Clause 23 of this Schedule and will not be considered to be in default or liable for breach of any obligations under this Framework Agreement if:
      1. the Supplier has fulfilled its obligations pursuant to Clause 6 of this Schedule 2;
      2. the Force Majeure Event does not arise directly or indirectly as a result of any wilful or negligent act or default of the Supplier; and
      3. the Supplier has complied with the procedural requirements set out in Clause 23 of this Schedule 2.
   3. Where a Party is (or claims to be) affected by a Force Majeure Event it shall use reasonable endeavours to mitigate the consequences of such a Force Majeure Event upon the performance of its obligations under this Framework Agreement and to resume the performance of its obligations affected by the Force Majeure Event as soon as practicable.
   4. Where the Force Majeure Event affects the Supplier’s ability to perform part of its obligations under the Framework Agreement the Supplier shall fulfil all such contractual obligations that are not so affected and shall not be relieved from its liability to do so.
   5. If either Party is prevented or delayed in the performance of its obligations under this Framework Agreement by a Force Majeure Event, that Party shall as soon as reasonably practicable serve notice in writing on the other Party specifying the nature and extent of the circumstances giving rise to its failure to perform or any anticipated delay in performance of its obligations.
   6. Subject to service of such notice, the Party affected by such circumstances shall have no liability for its failure to perform or for any delay in performance of its obligations affected by the Force Majeure Event only for so long as such circumstances continue and for such time after they cease as is necessary for that Party, using its best endeavours, to recommence its affected operations in order for it to perform its obligations.
   7. The Party claiming relief shall notify the other in writing as soon as the consequences of the Force Majeure Event have ceased and of when performance of its affected obligations can be resumed.
   8. If the Supplier is prevented from performance of its obligations as a result of a Force Majeure Event, the Authority may at any time if the Force Majeure Event subsists for thirty (30) days or more, terminate this Framework Agreement by issuing a Termination Notice to the Supplier.
   9. Following such termination in accordance with Clause 23.8 of this Schedule 2 and subject to Clause 23.10 of this Schedule 2, neither Party shall have any liability to the other.
   10. Any rights and liabilities of either Party which have accrued prior to such termination in accordance with Clause 23.8 of this Schedule 2 shall continue in full force and effect unless otherwise specified in this Framework Agreement.
2. **Records retention and right of audit**
   1. Subject to any statutory requirement and Clause 24.2 of this Schedule 2, the Supplier shall keep secure and maintain for the Term and six (6) years afterwards, or such longer period as may be agreed between the Parties, full and accurate records of all matters relating to this Framework Agreement.
   2. Where any records could be relevant to a claim for personal injury such records shall be kept secure and maintained for a period of twenty one (21) years from the date of expiry or earlier termination of this Framework Agreement.
   3. The Authority shall have the right to audit the Supplier’s compliance with this Framework Agreement. The Supplier shall permit or procure permission for the Authority or its authorised representative during normal business hours having given advance written notice of no less than five (5) Business Days, access to any premises and facilities, books and records reasonably required to audit the Supplier’s compliance with its obligations under this Framework Agreement.
   4. Should the Supplier Sub-contract any of its obligations under this Framework Agreement, the Authority shall have the right to audit and inspect such third party. The

Supplier shall procure permission for the Authority or its authorised representative during normal business hours no more than once in any twelve (12) months, having given advance written notice of no less than five (5) Business Days, access to any premises and facilities, books and records used in the performance of the Supplier’s obligations under this Framework Agreement that are Sub-contracted to such third party. The Supplier shall cooperate with such audit and inspection and accompany the Authority or its authorised representative if requested.

* 1. The Supplier shall grant to the Authority or its authorised representative, such access to those records as they may reasonably require in order to check the Supplier’s compliance with this Framework Agreement for the purposes of:
     1. the examination and certification of the Authority’s accounts; or
     2. any examination pursuant to section 6(1) of the National Audit Act 1983 of the economic efficiency and effectiveness with which the Authority has used its resources.
  2. The Comptroller and Auditor General may examine such documents as they may reasonably require which are owned, held or otherwise within the control of the Supplier and may require the Supplier to provide such oral and/or written explanations as they consider necessary. Clause 24 of this Schedule 2 does not constitute a requirement or agreement for the examination, certification or inspection of the accounts of the Supplier under sections 6(3)(d) and 6(5) of the National Audit Act 1983.
  3. The Supplier shall provide reasonable cooperation to the Authority, its representatives and any regulatory body in relation to any audit, review, investigation or enquiry carried out in relation to the subject matter of this Framework Agreement.
  4. The Supplier shall provide all reasonable information as may be reasonably requested by the Authority to evidence the Supplier’s compliance with the requirements of this Framework Agreement.

1. **Conflicts of interest and the prevention of fraud**
   1. The Supplier shall take appropriate steps to ensure that neither the Supplier nor any Staff are placed in a position where, in the reasonable opinion of the Authority, there is or may be an actual conflict, or a potential conflict, between the pecuniary or personal interests of the Supplier and the duties owed to the Authority under the provisions of this Framework Agreement. The Supplier will disclose to the Authority full particulars of any such conflict of interest which may arise.
   2. The Authority reserves the right to terminate this Framework Agreement by Issuing a Termination Notice to the Supplier and/or to take such other steps it deems necessary where, in the reasonable opinion of the Authority, there is or may be an actual conflict, or a potential conflict, between the pecuniary or personal interests of the Supplier and the duties owed to the Authority under the provisions of this Framework Agreement. The actions of the Authority pursuant to this Clause 25.2 of this [Schedule 2](#_bookmark1) shall not prejudice or affect any right of action or remedy which shall have accrued or shall subsequently accrue to the Authority.
   3. The Supplier shall take all reasonable steps to prevent Fraud by Staff and the Supplier (including its owners, members and directors). The Supplier shall notify the Authority immediately if it has reason to suspect that any Fraud has occurred or is occurring or is likely to occur.
   4. If the Supplier or its Staff commits Fraud the Authority may terminate this Framework Agreement and recover from the Supplier the amount of any direct loss suffered by the Authority resulting from the termination.
2. **Equality and human rights**
   1. The Supplier shall:
      1. ensure that: (a) it does not, whether as employer, a supplier of Goods, or as a provider of Services, engage in any act or omission that would contravene the Equality Legislation, and (b) it complies with all its obligations as an employer, a supplier of Goods, or provider of the Services and any associated services as set out in the Equality Legislation and take reasonable endeavours to ensure its Staff do not unlawfully discriminate within the meaning of the Equality Legislation;
      2. in the management of its affairs and the development of its equality and diversity policies, cooperate with the Authority in light of the Authority’s obligations to comply with its statutory equality duties whether under the Equality Act 2010 or otherwise. The Supplier shall take such reasonable and proportionate steps as the Authority considers appropriate to promote equality and diversity, including race equality, equality of opportunity for disabled people, gender equality, and equality relating to religion and belief, sexual orientation and age; and
      3. the Supplier shall impose on all its Sub-contractors and suppliers, obligations substantially similar to those imposed on the Supplier by Clause 26 of this Schedule 2.
   2. The Supplier shall meet reasonable requests by the Authority for information evidencing the Supplier’s compliance with the provisions of Clause 26 of this Schedule 2.
3. **Notice**
   1. Any notice required to be given by either Party under this Framework Agreement shall be in writing quoting the date of the Framework Agreement and shall be delivered by hand or sent by prepaid first class recorded delivery or by email to the person referred to in the Key Provisions or such other person as one Party may inform the other Party in writing from time to time.
   2. A notice shall be treated as having been received:
      1. if delivered by hand within normal business hours when so delivered or, if delivered by hand outside normal business hours, at the next start of normal business hours; or
      2. if sent by first class recorded delivery mail on a normal Business Day, at 9.00 am on the second Business Day subsequent to the day of posting, or, if the notice was not posted on a Business Day, at 9.00 am on the third Business Day subsequent to the day of posting; or
      3. if sent by email, if sent within normal business hours when so sent or, if sent outside normal business hours, at the next start of normal business hours provided the sender has either received an electronic confirmation of

delivery or has telephoned the recipient to inform the recipient that the email has been sent.

1. **Assignment, novation and Sub-contracting**
   1. The Supplier shall not assign, Sub-contract, novate, create a trust in, or in any other way dispose of the whole or any part of this Framework Agreement without the prior consent in writing of the Authority, such consent not to be unreasonably withheld or delayed. If the Supplier Sub-contracts any of its obligations under this Framework Agreement, every act or omission of the Sub-contractor shall for the purposes of this Framework Agreement be deemed to be the act or omission of the Supplier and the Supplier shall be liable to the Authority as if such act or omission had been committed or omitted by the Supplier itself.
   2. Any authority given by the Authority for the Supplier to Sub-contract any of its obligations under this Framework Agreement shall not impose any duty on the Authority to enquire as to the competency of any authorised Sub-contractor. The Supplier shall ensure that any authorised Sub-contractor has the appropriate capability and capacity to perform the relevant obligations and that the obligations carried out by such Sub-contractor are fully in accordance with this Framework Agreement.
   3. Where the Authority considers that the grounds for exclusion under Regulation 57 of the Public Contracts Regulations 2015 apply to any Sub-contractor, then:
      1. if the Authority finds there are compulsory grounds for exclusion, the Supplier shall ensure, or shall procure, that such Sub-contractor is replaced or not appointed; or
      2. if the Authority finds there are non-compulsory grounds for exclusion, the Authority may require the Supplier to ensure, or to procure, that such Sub- contractor is replaced or not appointed and the Supplier shall comply with such a requirement.
   4. The Authority shall upon written request have the right to review any Sub-contract entered into by the Supplier in respect of the provision of the Supply of Goods and/or the Services and the Supplier shall provide a certified copy of any Sub-contract within five (5) Business Days of the date of a written request from the Authority. For the avoidance of doubt, the Supplier shall have the right to redact any confidential pricing information in relation to such copies of Sub-contract.
   5. The Authority may at any time transfer, assign, novate, sub-contract or otherwise dispose of its rights and obligations under this Framework Agreement or any part of this Framework Agreement and the Supplier warrants that it will carry out all such reasonable further acts required to effect such transfer, assignment, novation, sub- contracting or disposal. If the Authority novates this Framework Agreement to any body that is not a Contracting Authority, from the effective date of such novation, the party assuming the position of the Authority shall not further transfer, assign, novate, sub- contract or otherwise dispose of its rights and obligations under this Framework Agreement or any part of this Framework Agreement without the prior written consent of the Supplier, such consent not to be unreasonably withheld or delayed by the Supplier.
2. **Prohibited Acts**
   1. The Supplier warrants and represents that:
      1. it has not committed any offence under the Bribery Act 2010 or done any of the following (“**Prohibited Acts**”):
         1. offered, given or agreed to give any officer or employee of the Authority any gift or consideration of any kind as an inducement or reward for doing or not doing or for having done or not having done any act in relation to the obtaining or performance of this or any other agreement with the Authority or for showing or not showing favour or disfavour to any person in relation to this or any other agreement with the Authority; or
         2. in connection with this Framework Agreement paid or agreed to pay any commission other than a payment, particulars of which (including the terms and conditions of the agreement for its payment) have been disclosed in writing to the Authority; and
      2. it has in place adequate procedures to prevent bribery and corruption, as contemplated by section 7 of the Bribery Act 2010.
   2. If the Supplier or its Staff (or anyone acting on its or their behalf) has done or does any of the Prohibited Acts or has committed or commits any offence under the Bribery Act 2010 with or without the knowledge of the Supplier in relation to this or any other agreement with the Authority:
      1. the Authority shall be entitled:
         1. to terminate this Framework Agreement and recover from the Supplier the amount of any loss resulting from the termination;
         2. to recover from the Supplier the amount or value of any gift, consideration or commission concerned; and
         3. to recover from the Supplier any other loss or expense sustained in consequence of the carrying out of the Prohibited Act or the commission of the offence under the Bribery Act 2010;
      2. any termination under Clause 29.2.1 of this Schedule 2 shall be without prejudice to any right or remedy that has already accrued, or subsequently accrues, to the Authority; and
      3. notwithstanding Clause 22 of this Schedule 2, any Dispute relating to:
         1. the interpretation of Clause 29 of this Schedule 2; or
         2. the amount or value of any gift, consideration or commission,

shall be determined by the Authority, acting reasonably, and the decision shall be final and conclusive.

1. **General**
   1. Each of the Parties is independent of the other and nothing contained in this Framework Agreement shall be construed to imply that there is any relationship between the Parties of partnership or of principal/agent or of employer/employee nor are the Parties hereby engaging in a joint venture and accordingly neither of the Parties

shall have any right or authority to act on behalf of the other nor to bind the other by agreement or otherwise, unless expressly permitted by the terms of this Framework Agreement.

* 1. Failure or delay by either Party to exercise an option or right conferred by this Framework Agreement shall not of itself constitute a waiver of such option or right.
  2. The delay or failure by either Party to insist upon the strict performance of any provision, term or condition of this Framework Agreement or to exercise any right or remedy consequent upon such breach shall not constitute a waiver of any such breach or any subsequent breach of such provision, term or condition.
  3. Any provision of this Framework Agreement which is held to be invalid or unenforceable in any jurisdiction shall be ineffective to the extent of such invalidity or unenforceability without invalidating or rendering unenforceable the remaining provisions of this Framework Agreement and any such invalidity or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provisions in any other jurisdiction.
  4. Each Party acknowledges and agrees that it has not relied on any representation, warranty or undertaking (whether written or oral) in relation to the subject matter of this Framework Agreement and therefore irrevocably and unconditionally waives any rights it may have to claim damages against the other Party for any misrepresentation or undertaking (whether made carelessly or not) or for breach of any warranty unless the representation, undertaking or warranty relied upon is set out in this Framework Agreement or unless such representation, undertaking or warranty was made fraudulently.
  5. Each Party shall bear its own expenses in relation to the preparation and execution of this Framework Agreement including all costs, legal fees and other expenses so incurred.
  6. The rights and remedies provided in this Framework Agreement are independent, cumulative and not exclusive of any rights or remedies provided by general law, any rights or remedies provided elsewhere under this Framework Agreement or by any other contract or document. In this Clause 30.7 of this Schedule 2, right includes any power, privilege, remedy, or proprietary or security interest.
  7. A person who is not a party to this Framework Agreement shall have no right to enforce any terms of it which confer a benefit on such person. No such person shall be entitled to object to or be required to consent to any amendment to the provisions of this Framework Agreement.
  8. This Framework Agreement, any variation in writing signed by an authorised representative of each Party and any document referred to (explicitly or by implication) in this Framework Agreement or any variation to this Framework Agreement, contain the entire understanding between the Supplier and the Authority relating to the operation of this Framework Agreement to the exclusion of all previous agreements, confirmations and understandings and there are no promises, terms, conditions or obligations whether oral or written, express or implied other than those contained or referred to in this Framework Agreement. Nothing in this Framework Agreement seeks to exclude either Party's liability for Fraud. Any tender conditions and/or disclaimers set out in the Authority’s procurement documentation leading to the award of this Framework Agreement shall form part of this Framework Agreement.
  9. This Framework Agreement, and any Dispute or claim arising out of or in connection with it or its subject matter (including any non-contractual claims), shall be governed by, and construed in accordance with, the laws of England and Wales.
  10. Subject to Clause 22 of this Schedule 2, the Parties irrevocably agree that the courts of England and Wales shall have non-exclusive jurisdiction to settle any Dispute or claim that arises out of or in connection with this Framework Agreement or its subject matter.
  11. All written and oral communications and all written material referred to under this Framework Agreement shall be in English.

**Schedule 3**

**Information and Data Provisions**

1. **Confidentiality**
   1. In respect of any Confidential Information it may receive directly or indirectly from the other Party (“**Discloser**”) and subject always to the remainder of Clause [1](#_bookmark4) of this [Schedule 3](#_bookmark3), each Party (“**Recipient**”) undertakes to keep secret and strictly confidential and shall not disclose any such Confidential Information to any third party without the Discloser’s prior written consent provided that:
      1. the Recipient shall not be prevented from using any general knowledge, experience or skills which were in its possession prior to the Commencement Date;
      2. the provisions of Clause 1 of this Schedule 3 shall not apply to any Confidential Information:
         1. which is in or enters the public domain other than by breach of this Framework Agreement or other act or omissions of the Recipient;
         2. which is obtained from a third party who is lawfully authorised to disclose such information without any obligation of confidentiality;
         3. which is authorised for disclosure by the prior written consent of the Discloser;
         4. which the Recipient can demonstrate was in its possession without any obligation of confidentiality prior to receipt of the Confidential Information from the Discloser; or
         5. which the Recipient is required to disclose purely to the extent to comply with the requirements of any relevant stock exchange.
   2. Nothing in Clause 1 of this Schedule 3 shall prevent the Recipient from disclosing Confidential Information where it is required to do so by judicial, administrative, governmental or regulatory process in connection with any action, suit, proceedings or claim or otherwise by applicable Law, including the Freedom of Information Act 2000 (“**FOIA**”), Codes of Practice on Access to Government Information, on the Discharge of Public Authorities’ Functions or on the Management of Records (“**Codes of Practice**”) or the Environmental Information Regulations 2004 (“**Environmental Regulations**”).
   3. The Authority may disclose the Supplier’s Confidential Information:
      1. on a confidential basis, to any Contracting Authority (the Parties agree that all Contracting Authorities receiving such Confidential Information shall be entitled to further disclose the Confidential Information to other Contracting Authorities on the basis that the information is confidential and is not to be disclosed to a third party which is not part of any Contracting Authority);
      2. on a confidential basis, to any consultant, contractor or other person engaged by the Authority and/or the Contracting Authority receiving such information;
      3. to any relevant party for the purpose of the examination and certification of the Authority’s accounts;
      4. to any relevant party for any examination pursuant to section 6(1) of the National Audit Act 1983 of the economy, efficiency and effectiveness with which the Authority has used its resources;
      5. to Parliament and Parliamentary Committees or if required by any Parliamentary reporting requirements; or
      6. on a confidential basis, to a proposed successor body in connection with any proposed or actual, assignment, novation or other disposal of rights, obligations, liabilities or property in connection with this Framework Agreement;

and for the purposes of this Framework Agreement, references to disclosure "on a confidential basis" shall mean the Authority making clear the confidential nature of such information and that it must not be further disclosed except in accordance with Law or this Clause 1.3 of this Schedule 3.

* 1. The Supplier may only disclose the Authority’s Confidential Information, and any other information provided to the Supplier by the Authority in relation to the operation of this Framework Agreement, to the Supplier’s Staff or professional advisors who are directly involved in the performance of or advising on the Supplier’s obligations under this Framework Agreement. The Supplier shall ensure that such Staff or professional advisors are aware of and shall comply with the obligations in Clause 1 of this Schedule 3 as to confidentiality and that all information, including Confidential Information, is held securely, protected against unauthorised use or loss and, at the Authority’s written discretion, destroyed securely or returned to the Authority when it is no longer required. The Supplier shall not, and shall ensure that the Staff do not, use any of the Authority’s Confidential Information received otherwise than for the purposes of performing the Supplier’s obligations in this Framework Agreement.
  2. For the avoidance of doubt, save as required by Law or as otherwise set out in this Schedule 3 the Supplier shall not, without the prior written consent of the Authority (such consent not to be unreasonably withheld or delayed), announce that it has entered into this Framework Agreement and/or that it has been appointed as a Supplier to the Authority and/or make any other announcements about this Framework Agreement.
  3. Clause [1](#_bookmark4) of this Schedule 3 shall remain in force:
     1. without limit in time in respect of Confidential Information which comprises Personal Data or which relates to national security; and
     2. for all other Confidential Information for a period of three (3) years after the expiry or earlier termination of this Framework Agreement unless otherwise agreed in writing by the Parties.

1. **Data protection**
   1. The Parties acknowledge their respective duties under Data Protection Legislation and shall give each other all reasonable assistance as appropriate or necessary to enable each other to comply with those duties. For the avoidance of doubt, the Supplier shall take reasonable steps to ensure it is familiar with the Data Protection Legislation and

any obligations it may have under such Data Protection Legislation and shall comply with such obligations.

* 1. Where the Supplier is Processing Personal Data under or in connection with this Framework Agreement, the Parties shall comply with the Data Protection Protocol.
  2. The Supplier and the Authority shall ensure that Personal Data is safeguarded at all times in accordance with the Law, and this obligation will include (if transferred electronically) only transferring Personal Data (a) if essential, having regard to the purpose for which the transfer is conducted; and (b) that is encrypted in accordance with any international data encryption standards for healthcare, and as otherwise required by those standards applicable to the Authority under any Law and Guidance (this includes, data transferred over wireless or wired networks, held on laptops, CDs, memory sticks and tapes).
  3. Where any Personal Data is Processed by any Sub-contractor of the Supplier in connection with this Framework Agreement, the Supplier shall procure that such Sub- contractor shall comply with the relevant obligations set out in Clause 2 of this Schedule 3, as if such Sub-contractor were the Supplier.
  4. The Supplier shall indemnify and keep the Authority indemnified against, any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings whatsoever or howsoever arising from the Supplier’s unlawful or unauthorised Processing, destruction and/or damage to Personal Data in connection with this Framework Agreement.

1. **Freedom of Information and Transparency**
   1. The Parties acknowledge the duties of Contracting Authorities under the FOIA, Codes of Practice and Environmental Regulations and shall give each other all reasonable assistance as appropriate or necessary to enable compliance with those duties.
   2. The Supplier shall assist and cooperate with the Authority to enable it to comply with its disclosure obligations under the FOIA, Codes of Practice and Environmental Regulations. The Supplier agrees:
      1. that this Framework Agreement and any recorded information held by the Supplier on the Authority’s behalf for the purposes of this Framework Agreement are subject to the obligations and commitments of the Authority under the FOIA, Codes of Practice and Environmental Regulations;
      2. that the decision on whether any exemption to the general obligations of public access to information applies to any request for information received under the FOIA, Codes of Practice and Environmental Regulations is a decision solely for the Authority;
      3. that where the Supplier receives a request for information under the FOIA, Codes of Practice and Environmental Regulations and the Supplier itself is subject to the FOIA, Codes of Practice and Environmental Regulations it will liaise with the Authority as to the contents of any response before a response to a request is issued and will promptly (and in any event within two (2) Business Days) provide a copy of the request and any response to the Authority;
      4. that where the Supplier receives a request for information under the FOIA, Codes of Practice and Environmental Regulations and the Supplier is not itself subject to the FOIA, Codes of Practice and Environmental Regulations, it will not respond to that request (unless directed to do so by the Authority) and will promptly (and in any event within two (2) Business Days) transfer the request to the Authority;
      5. that the Authority, acting in accordance with the Codes of Practice issued and revised from time to time under both section 45 of FOIA, and regulation 16 of the Environmental Regulations, may disclose information concerning the Supplier and this Framework Agreement; and
      6. to assist the Authority in responding to a request for information, by processing information or environmental information (as the same are defined in FOIA and the Environmental Regulations) in accordance with a records management system that complies with all applicable records management recommendations and codes of conduct issued under section

46 of FOIA, and providing copies of all information requested by the Authority within five (5) Business Days of that request and without charge.

* 1. The Parties acknowledge that, except for any information which is exempt from disclosure in accordance with the provisions of the FOIA, Codes of Practice and Environmental Regulations, the content of this Framework Agreement is not Confidential Information.
  2. Notwithstanding any other term of this Framework Agreement, the Supplier consents to the publication of this Framework Agreement in its entirety (including variations), subject only to the redaction of information that is exempt from disclosure in accordance with the provisions of the FOIA, Codes of Practice and Environmental Regulations.
  3. In preparing a copy of this Framework Agreement for publication under Clause 3.4 of this Schedule 3, the Authority may consult with the Supplier to inform decision making regarding any redactions but the final decision in relation to the redaction of information will be at the Authority’s absolute discretion.
  4. The Supplier shall assist and cooperate with the Authority to enable the Authority to publish this Framework Agreement.
  5. Where any information is held by any Sub-contractor of the Supplier in connection with this Framework Agreement, the Supplier shall procure that such Sub-contractor shall comply with the relevant obligations set out in Clause 3 of this Schedule 3, as if such Sub-contractor were the Supplier.

1. **Information Security**
   1. Without limitation to any other information governance requirements set out in this Schedule 3, the Supplier shall:
      1. notify the Authority forthwith of any information security breaches or near misses (including without limitation any potential or actual breaches of confidentiality or actual information security breaches) in line with the Authority’s information governance Policies; and
      2. fully cooperate with any audits or investigations relating to information security and any privacy impact assessments undertaken by the Authority and shall provide full information as may be reasonably requested by the Authority in relation to such audits, investigations and assessments.
   2. Where required in accordance with the Specification and Tender Response Document, the Supplier shall obtain and maintain certification under the HM Government Cyber Essentials Scheme at the level set out in the Specification and Tender Response Document.

**Schedule 4**

**Definitions and Interpretations**

1. **Definitions**
   1. In this Framework Agreement the following words shall have the following meanings unless the context requires otherwise, other than in relation to the Call-off Terms and Conditions for the Supply of Goods and the Provision of Services at Appendix A of this Framework Agreement. The definitions and Interpretations that apply to the Call-off Terms and Conditions for the Supply of Goods and the Provision of Services are as set out at Appendix A of this Framework Agreement.

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| **“Authority”** | means the authority named on the form of Framework Agreement on the first page unless the context dictates otherwise; |
| **“Authority’s Obligations”** | means the Authority’s further obligations, if any, referred to in the Specification and Tender Response Document; |
| **“Breach Notice”** | means a written notice of breach given by one Party to the other, notifying the Party receiving the notice of its breach of this Framework Agreement; |
| **“Business Continuity Event”** | means any event or issue that could impact on the operations of the Supplier and its ability to fulfil its obligations under this Framework Agreement including an influenza pandemic, EU Exit and any Force Majeure Event; |
| **“Business Continuity Plan”** | means the Supplier’s business continuity plan which includes its plans for continuity of the supply of Goods and provision Services during a Business Continuity Event; |
| **“Business Day”** | means any day other than Saturday, Sunday, Christmas Day, Good Friday or a statutory bank holiday in England and Wales; |
| **“Call-off Terms and Conditions for the Supply of Goods and the Provision of Services”** | means the call-off terms and conditions for Contracts as set out at Appendix A of this Framework Agreement forming part of the Contracts placed under this Framework Agreement; |
| **“Codes of Practice”** | shall have the meaning given to the term in Clause 1.2 of Schedule 3; |
| **“Commencement Date”** | means 1st July 2023 |

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| **“Commercial Schedule”** | means the document set out at Schedule 6; |
| **“Confidential Information”** | means information, data and material of any nature, which either Party may receive or obtain in connection with the conclusion and/or operation of the Framework Agreement including any procurement process which is:   1. Personal Data including without limitation which relates to any patient or other service user or his or her treatment or clinical or care history; 2. designated as confidential by either party or that ought reasonably to be considered as confidential (however it is conveyed or on whatever media it is stored); and/or 3. Policies and such other documents which the Supplier may obtain or have access to through the Authority’s intranet; |
| **“Contract”** | means any contract entered into under this Framework Agreement with the Supplier by any Participating Authority as further defined in the Call-off Terms and Conditions for the Supply of Goods and the Provision of Services; |
| **“Contracting Authority”** | means any contracting authority as defined in Regulation 3 of the Public Contracts Regulations 2015 (SI 2015/102) (as amended), other than the Authority; |
| **“Contract Manager”** | means for the Authority and for the Supplier the individuals specified in the Key Provisions or such other person notified by a Party to the other Party from time to time in accordance with Clause 8.1 of Schedule 2; |
| **“Contract Price”** | means the price exclusive of VAT that is payable to the Supplier by a Participating Authority under any Contract for the full and proper performance by the Supplier of its obligations under such Contracts (as calculated in accordance with the provisions of the Commercial Schedule) and as confirmed in the relevant Order Form relating to the particular Contract; |
| **“Controller”** | shall have the same meaning as set out in the GDPR; |
| **“Data Protection Legislation”** | means (i) the Data Protection Act 1998 or, from the date it comes into force, the Data Protection Act 2018 to the extent that it relates to processing of personal data and privacy; (ii) the GDPR, the Law Enforcement Directive (Directive (EU) 2016/680) and any applicable national implementing Law as amended from time to time; and (iii) all applicable Law about the processing of personal data and privacy; |
| **“Data Protection Protocol”** | means any document of that name as provided to the Supplier by the Authority (as amended from time to time in accordance with its terms), which shall include, without limitation, any such document appended to Schedule 3 (Information and Data Provisions) of this Framework Agreement; |

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| **“Dispute(s)”** | means any dispute, difference or question of interpretation or construction arising out of or in connection with this Framework Agreement, including any dispute, difference or question of interpretation relating to the Goods or Services, any matters of contractual construction and interpretation relating to the Framework Agreement, or any matter where this Framework Agreement directs the Parties to resolve an issue by reference to the Dispute Resolution Procedure; |
| **“Dispute Notice”** | means a written notice served by one Party to the other stating that the Party serving the notice believes there is a Dispute; |
| **“Dispute Resolution Procedure”** | means the process for resolving Disputes as set out in Clause 22 of Schedule 2; |
| **“DOTAS”** | means the Disclosure of Tax Avoidance Schemes rules which require a promoter of tax schemes to tell HM Revenue and Customs of any specified notifiable arrangements or proposals and to provide prescribed information on those arrangements or proposals within set time limits as contained in Part 7 of the Finance Act 2004 and in secondary legislation made under vires contained in Part 7 of the Finance Act 2004 and as extended to National Insurance Contributions by the National Insurance Contributions (Application of Part 7 of the Finance Act 2004) Regulations 2012, SI 2012/1868 made under s.132A Social Security Administration Act 1992; |
| **“Electronic Trading System(s)”** | means such electronic data interchange system and/or world wide web application and/or other application with such message standards and protocols as the Authority may specify from time to time; |
| **“Environmental Regulations”** | shall have the meaning given to the term in Clause 1.2 of Schedule 3; |
| **“eProcurement Guidance”** | means the NHS eProcurement Strategy available via: <http://www.gov.uk/government/collections/nhs-procurement>  together with any further Guidance issued by the Department of Health in connection with it; |
| **“Equality Legislation”** | means any and all legislation, applicable guidance and statutory codes of practice relating to equality, diversity, non- discrimination and human rights as may be in force in England and Wales from time to time including, but not limited to, the Equality Act 2010, the Part-time Workers (Prevention of Less Favourable Treatment) Regulations 2000 and the Fixed-term Employees (Prevention of Less Favourable Treatment) Regulations 2002 (SI 2002/2034) and the Human Rights Act 1998; |
| **"EU Exit"** | means the process of the UK leaving the EU pursuant to Article 50 of the Treaty on the Functioning of the European Union and |

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|  | any resulting changes in Law, customs duties and/or tariffs, and/or import/export rules or restrictions; |
| **“FOIA”** | shall have the meaning given to the term in Clause 1.2 of Schedule 3; |
| **“Force Majeure Event”** | means any event beyond the reasonable control of the Party in question to include, without limitation:   1. war including civil war (whether declared or undeclared), riot, civil commotion or armed conflict materially affecting either Party’s ability to perform its obligations under this Framework Agreement; 2. acts of terrorism; 3. flood, storm or other natural disasters; 4. fire; 5. unavailability of public utilities and/or access to transport networks to the extent no diligent supplier could reasonably have planned for such unavailability as part of its business continuity planning; 6. government requisition or impoundment to the extent such requisition or impoundment does not result from any failure by the Supplier to comply with any relevant regulations, laws or procedures (including such laws or regulations relating to the payment of any duties or taxes) and subject to the Supplier having used all reasonable legal means to resist such requisition or impoundment; 7. compliance with any local law or governmental order, rule, regulation or direction applicable outside of England and Wales that could not have been reasonably foreseen; 8. industrial action which affects the ability of the Supplier to supply the Goods and/or to provide the Services, but which is not confined to the workforce of the Supplier or the workforce of any Sub-contractor of the Supplier; and 9. a failure in the Supplier’s and/or Authority’s supply chain to the extent that such failure is due to any event suffered by a member of such supply chain, which would also qualify as a Force Majeure Event in accordance with this definition had it been suffered by one of the Parties; but excluding, for the avoidance of doubt, the withdrawal of the United Kingdom from the European Union and any related circumstances, events, changes or requirements; |
| **“Framework Agreement”** | means the form of framework agreement at the front of this document and all schedules and appendices attached to the form of framework agreement; |
| **“Fraud”** | means any offence under any law in respect of fraud in relation to this Framework Agreement or defrauding or attempting to defraud or conspiring to defraud the government, parliament or any Contracting Authority; |

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| **“GDPR”** | means the General Data Protection Regulation (Regulation (EU) 2016/679) (as it forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act of 2018); |
| **“General Anti-Abuse Rule”** | means   1. the legislation in Part 5 of the Finance Act 2013; and 2. any future legislation introduced into parliament to counteract tax advantages arising from abusive arrangements to avoid national insurance contributions; |
| **“Good Industry Practice”** | means the exercise of that degree of skill, diligence, prudence, risk management, quality management and foresight which would reasonably and ordinarily be expected from a skilled and experienced supplier and/or service provider engaged in the manufacture and/or supply of goods and/or the provision of services similar to the Goods and Services under the same or similar circumstances as those applicable to this Framework Agreement, including in accordance with any codes of practice published by relevant trade associations; |
| **“Goods”** | means all goods, materials or items that the Supplier is required to supply to Participating Authorities under Contracts placed under this Framework Agreement, details of such Goods, materials or other items being set out in the Specification and Tender Response Document and any Order; |
| **“Guidance”** | means any applicable guidance, direction or determination and any policies, advice or industry alerts which apply to the Goods and/or Services, to the extent that the same are published and publicly available or the existence or contents of them have been notified to the Supplier by the Authority and/or have been published and/or notified to the Supplier by the Department of Health, Monitor, NHS England, the Medicines and Healthcare Products Regulatory Agency, the European Medicine Agency the European Commission, the Care Quality Commission and/or any other regulator or competent body; |
| **“Halifax Abuse Principle”** | means the principle explained in the CJEU Case C-255/02 Halifax and others; |
| **"HM Government Cyber Essentials Scheme"** | means the HM Government Cyber Essentials Scheme as further defined in the documents relating to this scheme published at: https://[www.gov.uk/government/publications/cyber-essentials-](http://www.gov.uk/government/publications/cyber-essentials-) scheme-overview; |
| **“Initial Term”** | means the initial term as set out in the Key Provisions; |
| **“Intellectual Property Rights”** | means all patents, copyright, design rights, registered designs, trademarks, know-how, database rights, confidential formulae and any other intellectual property rights and the rights to apply for patents and trademarks and registered designs; |

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| **“Key Provisions”** | means the key provisions set out in Schedule 1; |
| **“KPI”** | means the key performance indicators as set out in Schedule 5; |
| **“Law”** | means any applicable legal requirements including, without limitation:   1. any applicable statute or proclamation, or any delegated or subordinate legislation or regulation as applicable in England and Wales; 2. any retained EU law (as defined by section 6(7) of the European Union (Withdrawal) Act 2018; 3. (subject to EU Exit) any applicable European Union directive, regulation, decision or law; 4. (subject to EU Exit) any enforceable community right within the meaning of section 2(1) European Communities Act 1972; 5. any applicable judgment of a relevant court of law which is a binding precedent in England and Wales; 6. requirements set by any regulatory body as applicable in England and Wales; and 7. any applicable code of practice as applicable in England and Wales; and 8. any relevant collective agreement and/or international law provisions (to include, without limitation, as referred to in (a) to (f) above); |
| **“NHS”** | means the National Health Service; |
| **“Occasion of Tax Non- Compliance”** | means:   1. any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1 October 2012 is found on or after 1 April 2013 to be incorrect as a result of:    1. a Relevant Tax Authority successfully challenging the Supplier under the General Anti-Abuse Rule or the Halifax Abuse Principle or under any tax rules or legislation that have an effect equivalent or similar to the General Anti-Abuse Rule or the Halifax Abuse Principle;    2. the failure of an avoidance scheme which the Supplier was involved in, and which was, or should have been, notified to a Relevant Tax Authority under the DOTAS or any equivalent or similar regime; and/or 2. any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1 October 2012 gives rise, on or after 1 April 2013, to a criminal conviction in any jurisdiction for tax related offences which is not spent at the Effective Date or to a civil penalty for fraud or evasion; |

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| **“Order Form”** | means the Purchase Orders and prescriptions on which Orders are to be placed, as referred to at Annex A to Schedule 5. For avoidance of doubt, the Purchase Order with the associated prescription and any ancillary documentation shall be deemed a single Order Form for these purposes; |
| **“Ordering Procedure”** | means the procedure enabling Participating Authorities to call- off Goods and/or Services and enter into Contracts under this Framework Agreement, as referred to at Annex A to Schedule 5; |
| **“Orders”** | means orders for Goods and/or Services placed under this Framework Agreement by Participating Authorities; |
| **“Participating Authority”** | means a Contracting Authority entitled to place Orders under this Framework Agreement including the Authority and any other Contracting Authority as set out in the Key Provisions; |
| **“Party”** | means the Authority or the Supplier as appropriate and Parties means both the Authority and the Supplier; |
| **“Personal Data”** | shall have the same meaning as set out in the GDPR; |
| **“Policies”** | means the policies, rules and procedures of the Authority as notified to the Supplier from time to time; |
| **“Process”** | shall have the same meaning as set out in the GDPR. Processing and Processed shall be construed accordingly; |
| **“Processor”** | shall have the same meaning as set out in the GDPR; |
| **“Product Information”** | means information concerning the Goods as may be reasonably requested by the Authority and supplied by the Supplier to the Authority in accordance with Clause 20 of Schedule 2 for inclusion in the Authority's product catalogue from time to time; |
| **“Prohibited Acts”** | has the meaning given under 29.1.1 of Schedule 2; |
| **“Relevant Tax Authority”** | means HM Revenue and Customs, or, if applicable, a tax authority in the jurisdiction in which the Supplier is established; |
| **“Remedial Proposal”** | has the meaning given under Clause 15.3 of Schedule 2; |
| **“Services”** | means the services that the Supplier is required to provide to Participating Authorities under Contracts placed under this Framework Agreement, details of such Services being set out in the Specification and Tender Response Document and any Order; |
| **“Services Information”** | means information concerning the Services as may be reasonably requested by the Authority and supplied by the Supplier to the Authority in accordance with Clause 20 of Schedule 2 for inclusion in the Authority's services catalogue from time to time; |

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| **“Specification and Tender Response Document”** | means the document set out in Schedule 5 as amended and/or updated in accordance with this Framework Agreement; |
| **“Staff”** | means all persons employed or engaged by the Supplier to perform its obligations under this Framework Agreement including any Sub-contractors and person employed or engaged by such Sub-contractors; |
| **“Sub-contract”** | means a contract between two or more suppliers, at any stage of remoteness from the Supplier in a sub-contracting chain, made wholly or substantially for the purpose of performing (or contributing to the performance of) the whole or any part of this Framework Agreement; |
| **“Sub-contractor”** | means a party to a Sub-contract other than the Supplier; |
| **“Supplier”** | means the supplier named on the form of Framework Agreement on the first page; |
| **“Supplier Code of Conduct”** | means the code of that name published by the Government Commercial Function originally dated September 2017, as may be amended, restated, updated, re-issued or re-named from time to time; |
| **“Term”** | means the Initial Term plus any extension periods; |
| **“Termination Notice”** | means a written notice of termination given by one Party to the other notifying the Party receiving the notice of the intention of the Party giving the notice to terminate this Framework Agreement on a specified date and setting out the grounds for termination; |
| **“Third Party Body”** | has the meaning given under Clause 8.5 of Schedule 2; and |
| **“VAT”** | means value added tax chargeable under the Value Added Tax Act 1994 or any similar, replacement or extra tax. |

* 1. References to any Law shall be deemed to include a reference to that Law as amended, extended, consolidated, re-enacted, restated, implemented or transposed from time to time.
  2. References to any legal entity shall include any body that takes over responsibility for the functions of such entity.
  3. References in this Framework Agreement to a “Schedule”, “Appendix”, “Paragraph” or to a “Clause” are to schedules, appendices, paragraphs and clauses of this Framework Agreement.
  4. References in this Framework Agreement to a day or to the calculation of time frames are references to a calendar day unless expressly specified as a Business Day.
  5. Unless set out in the Commercial Schedule as a chargeable item and subject to Clause

30.6 of Schedule 2, the Supplier shall bear the cost of complying with its obligations under this Framework Agreement.

* 1. The headings are for convenience only and shall not affect the interpretation of this Framework Agreement.
  2. Words denoting the singular shall include the plural and vice versa.
  3. Where a term of this Framework Agreement provides for a list of one or more items following the word “including” or “includes” then such list is not to be interpreted as an exhaustive list. Any such list shall not be treated as excluding any item that might have been included in such list having regard to the context of the contractual term in question. General words are not to be given a restrictive meaning where they are followed by examples intended to be included within the general words.
  4. Where there is a conflict between the Supplier’s responses to the Authority’s requirements (the Supplier’s responses being set out in Schedule 5) and any other part of this Framework Agreement, such other part of this Framework Agreement shall prevail.
  5. Where a document is required under this Framework Agreement, the Parties may agree in writing that this shall be in electronic format only.
  6. Any guidance notes in grey text do not form part of this Framework Agreement.
  7. Any Breach Notice issued by a Party in connection with this Framework Agreement shall not be invalid due to it containing insufficient information. A Party receiving a Breach Notice (“**Receiving Party**”) may ask the Party that issued the Breach Notice (“**Issuing Party**”) to provide any further information in relation to the subject matter of the Breach Notice that it may reasonably require to enable it to understand the Breach Notice and/or to remedy the breach. The Issuing Party shall not unreasonably withhold or delay the provision of such further information as referred to above as may be requested by the Receiving Party but no such withholding or delay shall invalidate the Breach Notice.
  8. Any terms defined as part of a Schedule or other document forming part of this Framework Agreement shall have the meaning as defined in such Schedule or document.

**Schedule 5**

**Specification and Tender Response Document**

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| **OFFICIAL SENSITIVE - COMMERCIAL** |  |  |  | OFFICIAL SENSITIVE - COMMERCIAL |
| **©NHS England 2022** | 50 |  |  |  |
| **CM/MSR/17/5555 - NHS National Framework Agreement for the Supply of Home Delivery Service - Lysosomal Storage Disorders England and Scotland** | | |  | **(\*) Please ensure Supplier Name is entered correctly; this will then appear at the top of each worksheet** |
| **Document 5a - General** | **General** |  |  |  |
| **Paragraph** | **Specification Compliance or Adjudication** | **Specification Item** | **Do you comply with Specification? Paragraph by paragraph** | **Supplier's Answer (or file reference to separate document with answer / requested documentation)** |
|  |  | **Specification Compliance Summary** |  |  |
| **5a\_c** | **Compliance Yes/No** | By complying with these specification points means that at any point during the life of the framework, a request for further information must be made accessible in an electronic format i.e. word or excel, of a procedure, policy or other evidence formats to either the Purchasing Authority or NHSE. This will enable NHSE to have a mechanism for review to support monitoring of the agreement or to support the Purchasing Authorities.  Please advise that you can comply with all specification points in this section, that do not specifically have an adjudication question attached. If there are any points that you can not comply with, please provide the point number in the answer section here, and the explanation of what you cannot comply with against the relevant point (i.e. populate the grey box currently populated with 'n/a' with your rationale) | **This Framework Has Been Redacted – Section 43 (commercial Interests)** | |
| **5a\_1** |  | **Overall Service** |  |  |
| **5a\_1.1s** | **Specification** | The Medicines Homecare Pathway(s) is/are shown in: Document No. 5a - Patient Homecare Support Pathway - Existing Patients Document No. 5b - Patient Homecare Support Pathway - New Patients. |  | N/A |
| **5a\_1.2s** | **Specification** | Suppliers will work in partnership with the Purchasing Authority to ensure: - Patient safety - Best possible clinical outcomes - Patient satisfaction - Minimal additional costs to the Participating 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. |  | N/A |
| **5a\_1.3s** | **Specification** | The Supplier's normal working hours (hours of service provision) must match or exceed Monday to Friday 09:00hrs - 17:30hrs excluding bank holidays. |  | N/A |
| **5a\_1.3aq** | **Adjudication Question** | **With reference to the Specification Point above, Suppliers should state their normal working hours for responding to queries from the Purchasing Authority.** | N/A |  |
| **5a\_1.4s** | **Specification** | 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.   The frequency of deliveries will usually be 4 weekly for patients receiving treatment via infusions, and 4, 8 or 12 weekly for patients on oral treatment. In exceptional circumstances a 'JIT' (Just in Time) delivery may be required. This must be agreed by the Purchasing Authority for individual patients, following Patient suitability and Home Suitability assessments. JIT delivery may be weekly or fortnightly depending on individual requirements. |  | N/A |
| **5a\_1.5s** | **Specification** | 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. |  | N/A |
| **5a\_2** |  | **Quality Guidelines and Regulatory Compliance** |  |  |
| **5a\_2.1c** | **Compliance Yes/No** | The Purchasing Authority and Supplier must comply with the current Royal Pharmaceutical Society (RPS) Professional Standards for Homecare Services in England and Scotland. To the extent applicable, the Supplier and Purchasing Authority must 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.  **Please indicate Yes / No as to if you comply. Please note that the inability to comply, may result in not being successful in your bid.** |  |  |
| **5a\_2.2s** | **Specification** | 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. |  | N/A |
| **5a\_2.3c** | **Compliance Yes/No** | 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.  **Please indicate Yes / No as to if you comply. Please note that the inability to comply, may result in not being successful in your bid.** |  |  |
| **5a\_3** |  | **Selection, Registration of Patients and Service Activation** |  |  |
| **5a\_3.1s** | **Specification** | Patient selection 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.  The Supplier will carry out a patient care plan and homecare risk assessment to determine suitability of the home environment or other location where the services will be delivered and identify and raise any concerns to the Purchasing Authority. |  | N/A |
| **5a\_3.2s** | **Specification** | 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. |  | N/A |
| **5a\_3.3s** | **Specification** | On receipt of valid registration information, the Supplier will log the patient onto their systems.  A patient care plan and homecare risk assessment should be undertaken to identify any specific needs or risks and to confirm the patient’s suitability for homecare. Any concerns related to safety, additional costs for products or service items outside of this specification should be raised with the Purchasing Authority before the patient is designated as ready for service activation.   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. |  | N/A |
| **5a\_3.4s** | **Specification** | The Supplier has the right to decline to accept patients following the above steps if the assessment confirms that homecare is not suitable. |  | N/A |
| **5a\_3.5s** | **Specification** | 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. |  | N/A |
| |  | | --- | | **5a\_3.6s** | | **Specification** | 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. |  | N/A |
| **5a\_3.7s** | **Specification** | 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. |  | N/A |
| **5a\_4** |  | **Communication with the Patient** |  |  |
| **5a\_4.1s** | **Specification** | The Purchasing Authority will provide the patient information of the service prior to referral to the Supplier     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 will be subject to change control provisions within this specification.  App 2 - Patient Information Guidance (rpharms.com) |  | N/A |
| **5a\_4.2s** | **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 |  | N/A |
| **5a\_4.2aq** | **Adjudication Question** | **With reference to the specification point above, please provide an example of your welcome pack, patient information.** | N/A |  |
| **5a\_4.3s** | **Specification** | 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. |  | N/A |
| **5a\_4.4s** | **Specification** | 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.   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. |  | N/A |
| **5a\_4.4aq** | **Adjudication Question** | **With reference to the Specification Point above, Suppliers should indicate which languages they are able to provide for this service for at no extra cost.** | N/A |  |
| **5a\_4.5s** | **Specification** | All contact between the Supplier and the patient must be logged and records made available to the Purchasing Authority on request. |  | N/A |
| **5a\_5** |  | **Stock Management in the Home** |  |  |
| **5a\_5.1s** | **Specification** | It is expected that patients will maintain buffer stock in the home please refer to Equipment and Ancils tab specification point 5e\_line 27. |  | N/A |
| **5a\_5.2s** | **Specification** | The Supplier will perform stock checks for independent patients reporting stock levels prior to scheduling of their next delivery.   Subject to the consent of patient or carer, The Supplier will undertake a stock check of medicines, ancillaries and equipment in the patients home (or location of service provision) at the time of nurse visits.  Discrepancies in stock levels must be reported to the Purchasing Authority within 5 working days.  Evidence of suspected over or under use must be reported to the Purchasing Authority within 2 working days. |  | N/A |
| **5a\_5.3s** | **Specification** | 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. |  | N/A |
| **5a\_5.4** |  | **Returns & Clinical Waste Management** |  |  |
| **5a\_5.5c** | **Compliance Yes/No** | 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.  **Please indicate Yes / No as to if you comply. Please note that the inability to comply may result in a bid being unsuccessful. In addition, please provide a copy of the applicable waste management licence.** |  |  |
| **5a\_5.6s** | **Specification** | 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. Unused medicines must be offered to be returned to the Purchasing Authority, as they may be of use in the laboratories for testing purposes. |  | N/A |
| **5a\_5.7s** | **Specification** | It is the expectation 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 liaise with the Purchasing Authority and agree a convenient collection time with the patient or carer. |  | N/A |
| **5a\_6** |  | **Care Away from Home / Travel Service - General** |  |  |
| **5a\_6.1s** | **Specification** | 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). |  | N/A |
| **5a\_6.2s** | **Specification** | 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. |  | N/A |
| **5a\_6.3s** | **Specification** | 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. |  | N/A |
| **5a\_6.3aq** | **Adjudication Question** | **With reference to the above specification points, please provide details of how this service to patients, when they are on holiday or travel away from home in the UK, will be managed.** | N/A |  |
| **5a\_6.4s** | **Specification** | Patient Information will advise that Patients are required to provide at least 4 weeks 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 patients 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. |  | N/A |
| **5a\_7** |  | **Amendment, interruption and termination of a patient's homecare service** |  |  |
| **5a\_7.1s** | **Specification** | 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. |  | N/A |
| **5a\_7.1aq** | **Adjudication Question** | **With reference to the above specification point, please provide details of how this process will be managed.** | N/A |  |
| **5a\_7.2s** | **Specification** | 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.  The Purchasing Authority will provide the instruction on the following forms please see Appendix E - On Hold form and Appendix F - Re-starting Treatment form |  | N/A |
| **5a\_7.3s** | **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. |  | N/A |
| **5a\_8** |  | **Communication with the Purchasing Authority** |  |  |
| **5a\_8.1s** | **Specification** | 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.  *Please complete tab 5l\_Contact Matrix within this specification* |  | N/A |
| **5a\_8.2s** | **Specification** | 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 |  | N/A |
| **5a\_8.3s** | **Specification** | All contact between the Supplier and the Purchasing Authority must be logged and records made available to the Purchasing Authority on request. |  | N/A |
| **5a\_8.4s** | **Specification** | 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. |  | N/A |
| **5a\_9** |  | **Performance Monitoring and Management Information** |  |  |
| **5a\_9.1s** | **Specification** | 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 Contracting Authority and Purchasing Authority as specified. |  | N/A |
| **5a\_9.2c** | **Compliance Yes/No** | **The Supplier will comply with all reasonable requests for management data (including supporting data for Monthly Management Information reports). 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  Please indicate Yes / No as to if you comply. Please note that the inability to comply may result in a bid being unsuccessful.** |  |  |
| **5a\_9.3s** | **Specification** | The following reports should be sent directly to the Purchasing Authority by the following timelines: • Appendix A - Missed infusion form within 2 working days (where infusion cannot be re-scheduled) • Appendix B - Monthly Homecare report (Nurse Visit Report) - by the 5th working day of the following month • Individual Patient Nurse Visit Report (for specific patients) - within 2 working days . |  | N/A |
| **5a\_9.4s** | **Specification** | Supplier Review Meetings will be held with each of the successful Suppliers a minimum of 4 times each year, at the desecration of the Purchasing Authority if require more frequent and 2 meetings at a National level with all relevant stakeholders. Framework Monitoring Meetings may be held in place of local Contract Review Meetings. |  | N/A |
| **5a\_9.5s** | **Specification** | The Supplier will undertake patient satisfaction surveys and provide related reports to the Purchasing Authority in accordance with the RPS published guidance (link).  Patient Satisfaction Survey Guidance (rpharms.com) |  | N/A |
| **5a\_10** |  | **Change Management** |  |  |
| **5a\_10.1s** | **Specification** | 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. |  | N/A |
| **5a\_10.2s** | **Specification** | Where either Party requests approval for any change, approval is not to be unreasonably withheld or delayed by the other party. |  | N/A |
| **5a\_10.3c** | **Compliance Yes/No** | **Below is a list of all documents that must be subject to formal approval by the Supplier and Purchasing Authority and are subject to the change control provisions of this specification: • Product List • Registration Form • Prescription Form • Complaints and Incidents 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 Please indicate Yes / No as to if you comply. Please note that the inability to comply, may result in not being successful in your bid.** |  |  |
| **5a\_10.4s** | **Specification** | Where a patient's homecare services is transferred between different Suppliers, the Supplier should follow the RPS guidance procedure for change management.  homecare-services-handbook.pdf (rpharms.com) |  | N/A |
| **5a\_10.5s** | **Specification** | 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.  homecare-services-handbook.pdf (rpharms.com) |  | N/A |
| **5a\_10.5aq** | **Adjudication Question** | **With reference to the above specification points, could you please provide details on how you will ensure a smooth implementation of a new service and smooth transition of existing patients.** | N/A |  |
| **5a\_11** |  | **Provision of services outside this specification** |  |  |
| **5a\_11.1s** | **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. |  | N/A |
| **5a\_11.2s** | **Specification** | 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. |  | N/A |

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| **Document 5b - Prescribing & Dispensing** | **Prescribing and Dispensing** |  |  |  |
| **Paragraph** | **Specification Compliance or Adjudication** | **Specification Item** | **Do you comply with Specification? Paragraph by paragraph** | **Supplier's Answer (or file reference to separate document with answer / requested documentation)** |
|  |  | **Specification Compliance Summary** |  |  |
| **5b\_c** | **Compliance Yes/No** | By complying with these specification points means that at any point during the life of the framework, a request for further information must be made accessible in an electronic format i.e. word or excel, of a procedure, policy or other evidence formats to either the Purchasing Authority or NHSE. This will enable NHSE to have a mechanism for review to support monitoring of the agreement or to support the Purchasing Authorities.  Please advise that you can comply with all specification points in this section, that do not specifically have an adjudication question attached. If there are any points that you can not comply with, please provide the point number in the answer section here, and the explanation of what you cannot comply with against the relevant point (i.e. populate the grey box currently populated with 'n/a' with your rationale) | **This Framework Has Been Redacted – Section 43 (commercial Interests)** | |
| **5b\_1** |  | **The prescribing process** |  |  |
| **5b\_1.1** | **Specification** | The Purchasing Authority will provide, via any method approved by the Parties, a valid, legal and unambiguous prescription in accordance with the prevailing regulations and in the agreed format 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. |  | N/A |
| **5b\_1.2** | **Specification** | 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. |  | N/A |
| **5b\_1.3s** | **Specification** | 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. |  | N/A |
| **5b\_1.3aq** | **Adjudication Question** | **With reference to the above specification point please describe the key features of your prescription management process.** | N/A |  |
| **5b\_2** | |  | | --- | |  | | **The dispensing process** |  |  |
| **5b\_2.1** | **Specification** | Wherever possible, the Purchasing Authority will provide prescriptions for products included in the Commercial Medicines Unit Framework's contract lines and prices.  Whilst prescriptions are routinely written generically, where it is important for a specific brand or manufacturer's product to be supplied the Purchasing Authority will issue a prescription detailing this.  This will be accomplished by showing the brand manufacturer for each specified item each prescription. |  | N/A |
| **5b\_2.2** | **Specification** | 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. |  | N/A |
| **5b\_2.3** | **Specification** | 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. |  | N/A |
| **5b\_2.4** | **Specification** | 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. |  | N/A |
| **5b\_3** |  | **Outer packaging** |  |  |
| **5b\_3.1** | **Specification** | 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. |  | N/A |
| **5b\_3.2** | **Specification** | 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. |  | N/A |
| **5b\_3.3** | **Specification** | 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. |  | N/A |
| **5b\_3.4** | **Specification** | 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 regulationns and outer packaging must be sealed. |  | N/A |

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| **Document 5c - Delivery** | **Delivery** |  |  |  |
| **Paragraph** | **Specification. Compliance or Adjudication** | **Specification Item** | **Do you comply with Specification? Paragraph by paragraph** | **Supplier's Answer (or file reference to separate document with answer / requested documentation)** |
|  |  | **Specification Compliance Summary** |  |  |
| **5c\_c** | **Compliance Yes/No** | By complying with these specification points means that at any point during the life of the framework, a request for further information must be made accessible in an electronic format i.e. word or excel, of a procedure, policy or other evidence formats to either the Purchasing Authority or NHSE. This will enable NHSE to have a mechanism for review to support monitoring of the agreement or to support the Purchasing Authorities.  Please advise that you can comply with all specification points in this section, that do not specifically have an adjudication question attached. If there are any points that you can not comply with, please provide the point number in the answer section here, and the explanation of what you cannot comply with against the relevant point (i.e. populate the grey box currently populated with 'n/a' with your rationale) | **This Framework Has Been Redacted – Section 43 (commercial Interests)** | |
| **5c\_1** |  | **Routine Delivery Scheduling** |  |  |
| **5c\_1.1s** | **Specification** | Deliveries must be at the clinically appropriate frequency as specified in the Medicines Homecare Pathway, Individual Care Plan or on the prescription. |  | N/A |
| **5c\_1.2s** | **Specification** | 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. |  | N/A |
| **5c\_1.3s** | **Specification** | 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 agreed 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. |  | N/A |
| **5c\_1.3aq** | **Adjudication Question** | **With reference to the specification point above please state your standard delivery days/hours, and any additional delivery days/hours routinely available (excluding those exclusively offered as part of an emergency service).** | N/A |  |
| **5c\_1.4s** | **Specification** | 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. |  | N/A |
| **5c\_1.4aq** | **Adjudication Question** | **With reference to the above specification point, please provide details of your cancellation and re-booking and how this process will be managed.** | N/A |  |
| **5c\_2** |  | **Preparing for the Delivery** |  |  |
| **5c\_2.1s** | **Specification** | The delivery vehicle must not bear any markings which would indicate the nature of the delivery. |  | N/A |
| **5c\_2.2s** | **Specification** | The Supplier must ensure that all product and/or medicine are stored, transported and delivered in a clean condition. |  | N/A |
| **5c\_2.3s** | **Specification** | 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. 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 tab - Change Management" |  | N/A |
| **5c\_2.3aq** | **Adjudication Question** | **With reference to the Specification Point above, please certify that your standard operating procedure is in place and comply with the above. You will be able to provide an example of your relevant standard operating procedure upon request.** | N/A |  |
| **5c\_3** |  | **Making the Delivery** |  |  |
| **5c\_3.1s** | **Specification** | The delivery service 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. |  | N/A |
| **5c\_3.1aq** | **Adjudication Question** | **With reference to the Specification Point above please attach images of your vehicle delivery and driver uniform.** | N/A |  |
| **5c\_3.2s** | **Specification** | 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. |  | N/A |
| **5c\_3.2aq** | **Adjudication Question** | **With reference to the Specification Point above, please provide details of how you would manage this.** | N/A |  |
| **5c\_3.3s** | **Specification** | All deliveries require a signature accompanied by the date and time of the delivery, from the person accepting the delivery as proof of delivery, unless otherwise agreed with the Purchasing Authority, i.e. if a Key Holding Service has been agreed. |  | N/A |
| **5c\_3.4s** | **Specification** | No member of the Supplier's delivery staff is required to enter into the patient's home to provide the homecare service, unless it has been agreed in advance via a patient risk assessment. This must be documented on the patient registration form, for instance the patient requires help unpacking and putting the medicines in the refrigerator. Should a member of the Supplier's Delivery Staff be invited to enter the patient's home they should only do so if essential e.g. to ensure patient safety. A record of this event must be recorded. |  | N/A |
| **5c\_3.5s** | **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 Purchasing Authority. |  | N/A |
| **5c\_3.6s** | **Specification** | The delivery personnel must remove all outer delivery packaging if requested to do so by the patient or carer. |  | N/A |
| **5c\_4.4** |  | **Failed deliveries, collections and returns** |  |  |
| **5c\_4.1s** | **Specification** | 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. |  | N/A |
| **5c\_4.2s** | **Specification** | 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. |  | N/A |
| **5c\_5** |  | **Urgent and Out-of-hours Deliveries** |  |  |
| **5c\_5.1s** | **Specification** | 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. |  | N/A |
| **5c\_5.1aq** | **Adjudication Question** | **With reference to the Specification Point above, please provide details of how you manage your out of hours and urgent delivery services.** | N/A |  |

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| **Document 5d - Cold Chain** | **Cold Chain** |  |  |  |
| **Paragraph** | **Specification. Compliance or Adjudication** | **Specification Item** | **Do you comply with Specification? Paragraph by paragraph** | **Supplier's Answer (or file reference to separate document with answer / requested documentation)** |
|  |  | **Specification Compliance Summary** |  |  |
| **5d\_c** | **Compliance Yes/No** | By complying with these specification points means that at any point during the life of the framework, a request for further information must be made accessible in an electronic format i.e. word or excel, of a procedure, policy or other evidence formats to either the Purchasing Authority or NHSE. This will enable NHSE to have a mechanism for review to support monitoring of the agreement or to support the Purchasing Authorities.  Please advise that you can comply with all specification points in this section, that do not specifically have an adjudication question attached. If there are any points that you can not comply with, please provide the point number in the answer section here, and the explanation of what you cannot comply with against the relevant point (i.e. populate the grey box currently populated with 'n/a' with your rationale) | **This Framework Has Been Redacted – Section 43 (commercial Interests)** | |
| **5d\_1** |  | **Special Handling** |  |  |
| **5d\_1.1s** | **Specification** | 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 |  | N/A |
| **5d\_1.2s** | **Specification** | 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. |  | N/A |
| **5d\_2** |  | **Cold chain Medicines requiring storage between 2-8oC** |  |  |
| **5d\_2.1s** | **Specification** | 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 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. |  | N/A |
| **5d\_2.2s** | **Specification** | 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. |  | N/A |
| **5d\_2.3c** | **Compliance Yes/No** | Please certify that you comply with the GDP and the MHRA regulations and can provide further information if requested.   Please indicate Yes / No as to if you comply. Please note that the inability to comply, may result in not being successful in your bid. |  |  |
| **5d\_2.4s** | **Specification** | **Cold Chain in the Patient's Home**  In many cases storage of homecare medicines are in the patient’s own domestic refrigerator with external temperature monitoring will be sufficient to give assurance that the medicine will be fit for purpose at the point of administration, but in some cases storage between 2°C and 8°C will need to be strictly controlled and monitored because the medicine is particularly unstable at higher temperatures, or may be damaged by freezing.  The Purchasing Authority in conjunction with the patient will determine the appropriate storage requirements for all medicines to be supplied using a risk based approach, using the product's SmPC, other data from the manufacturer, or information from the Specials manufacturer. |  | N/A |
| **5d\_2.5s** | **Specification** | The Purchasing Authority has determined that max/min thermometers should be provided and should be read and reset daily by the patient/carer or when HCP nursed service. |  | N/A |
| **5d\_2.6s** | **Specification** | In the event of any temperature deviation being reported to the homecare provider, they must inform the Purchasing Authority so that the effect on the medicine can be evaluated by the Purchasing Authority and an audit trail kept of such assessment and the decisions taken. Where a temperature deviation results in product being wasted and/or any interruption of treatment the Purchasing Authority will be notified without delay. |  | N/A |
| **5d\_2.6aq** | **Adjudication Question** | **With reference to the above specification point, please provide details of how temperature deviations are managed.** | N/A |  |
| **5d\_2.7s** | **Specification** | The Supplier may offer alternatives to specified risk control measures for storage of medicines in the patient’s home subject to acceptance by the Purchasing Authority. |  | N/A |
| **5d\_2.10s** | **Specification** | Maintenance and calibration of all refrigeration and temperature monitoring equipment will be the responsibility of the Supplier (refer to Equipment and Ancillaries section) |  | N/A |

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| **Document 5e - Equipment and Ancillary** | **Equipment and Ancills** |  |  |  |
| **Paragraph** | **Specification. Compliance or Adjudication** | **Specification Item** | **Do you comply with Specification? Paragraph by paragraph** | **Supplier's Answer (or file reference to separate document with answer / requested documentation)** |
|  |  | **Specification Compliance Summary** |  |  |
| **5e\_c** | **Compliance Yes/No** | By complying with these specification points means that at any point during the life of the framework, a request for further information must be made accessible in an electronic format i.e. word or excel, of a procedure, policy or other evidence formats to either the Purchasing Authority or NHSE. This will enable NHSE to have a mechanism for review to support monitoring of the agreement or to support the Purchasing Authorities.  Please advise that you can comply with all specification points in this section, that do not specifically have an adjudication question attached. If there are any points that you can not comply with, please provide the point number in the answer section here, and the explanation of what you cannot comply with against the relevant point (i.e. populate the grey box currently populated with 'n/a' with your rationale) | **This Framework Has Been Redacted – Section 43 (commercial Interests)** | |
| **5e\_1** |  | **Equipment** |  |  |
| **5e\_1.1s** | **Specification** | The equipment to be provided as part of the service is listed and a generic specification for each different type of equipment is provided in 5l\_Equipment List which includes quantity to be supplied plus any backup equipment, maintenance and response times. |  | N/A |
| **5e\_1.2s** | **Specification** | 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. |  | N/A |
| **5e\_1.3s** | **Specification** | If specified within the Equipment List the Supplier will provide an installation visit for equipment. |  | N/A |
| **5e\_1.4s** | **Specification** | The Supplier must provide the patient with appropriate information and training regarding the use and maintenance of equipment. |  | N/A |
| **5e\_1.5s** | **Specification** | 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. |  | N/A |
| **5e\_1.6s** | **Specification** | The Supplier will inform the Purchasing Authority where latex is present in equipment. |  | N/A |
| **5e\_1.7s** | **Specification** | Patients will be responsible for keeping refrigerators socially clean, but maintenance will be the responsibility of the Supplier. |  | N/A |
| **5e\_2** |  | **Maintenance and Servicing** |  |  |
| **5e\_2.1s** | **Specification** | The Supplier must service and maintain all equipment supplied within the Homecare Service in accordance with the recommendations of the manufacturer of the equipment. |  | N/A |
| **5e\_2.2s** | **Specification** | 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. |  | N/A |
| **5e\_2.2aq** | **Adjudication Question** | **With in reference to the above please provide an example of your maintained, servicing, pat testing records.** | N/A |  |
| **5e\_3** |  | **Ancillaries** |  |  |
| **5e\_3.1s** | **Specification** | The ancillaries to be provided as part of the service is listed and a specification for each different type of ancillary is provided in 5k\_Ancillary List which includes quantity to be supplied. |  | N/A |
| **5e\_3.2s** | **Specification** | 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. |  | N/A |
| **5e\_3.2aq** | **Adjudication Question** | **With reference to the above specification point, please advise if a suggested alternative ancillary list is being provided.** | N/A |  |
| **5e\_3.4s** | **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 Purchasing Authority. |  | N/A |
| **5e\_3.5s** | **Specification** | The Supplier will check stock levels either physically or remotely and replenish ancillaries on a regular basis. |  | N/A |
| **5e\_3.6s** | **Specification** | 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. |  | N/A |
| **5e\_3.7s** | **Specification** | The Supplier must have a robust process for managing initial supplies and replenishment of ancillaries to ensure continuity of patient treatment. It is the Supplier’s responsibility to check stock levels by contacting the patient by phone or by the attending nurse ahead of the planned delivery. There should always be 2 infusions worth of consumables available, and stock should be rotated. It is as important to avoid over stocking as it is under stocking. No delivery fee will be paid for the separate delivery of ancillaries, as these should be delivered with the relevant medicine. |  | N/A |
| **5e\_3.8s** | **Specification** | The Supplier will inform the Purchasing Authority where latex is present in an ancillary. |  | N/A |
| **5e\_3.9s** | **Specification** | The Supplier will inform the Purchasing Authority if a patient's ancillary usage deviates from the expected usage level. |  | N/A |

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| **Document 5f - Home visits & Clinical Services** | **Clinical Services and Home Visits** | |  |  |
| **Paragraph** | **Specification, Compliance or Adjudication** | **Specification Item** | **Do you comply with Specification? Paragraph by paragraph** | **Supplier's Answer (or file reference to separate document with answer / requested documentation)** |
|  |  | **Specification Compliance Summary** |  |  |
| **5f\_c** | **Compliance Yes/No** | By complying with these specification points means that at any point during the life of the framework, a request for further information must be made accessible in an electronic format i.e. word or excel, of a procedure, policy or other evidence formats to either the Purchasing Authority or NHSE. This will enable NHSE to have a mechanism for review to support monitoring of the agreement or to support the Purchasing Authorities.  Please advise that you can comply with all specification points in this section, that do not specifically have an adjudication question attached. If there are any points that you can not comply with, please provide the point number in the answer section here, and the explanation of what you cannot comply with against the relevant point (i.e. populate the grey box currently populated with 'n/a' with your rationale) | **This Framework Has Been Redacted – Section 43 (commercial Interests)** | |
| **5f\_1** |  | **Non-Clinical Home Visits for installation, maintenance and servicing of equipment** |  |  |
| **5f\_1.1s** | **Specification** | The Supplier will only undertake non-clinical Home visits where necessary to meet the terms of this specification. |  | N/A |
| **5f\_1.2s** | **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. |  | N/A |
| **5f\_1.3s** | **Specification** | Any non-clinical home visits to be provided as part of the homecare service are listed below and should be conducted between 08.00 and 18.00. Non-clinical home visits are undertaken by the Supplier only where necessary to meet the terms of this specification.   - Equipment installation visit - Delivery of heavy items into the patient home - Unattended delivery via a Key holding service  The Purchasing Authority and Supplier will work in partnership to determine patient suitability see Patient Selection section on the General Tab. The Contractor will ensure escalation contacts are available at all times during Home Visits when services are being undertaken.. |  | N/A |
| **5f\_1.4s** | **Specification** | 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. |  | N/A |
| **5f\_1.5s** | **Specification** | 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. |  | N/A |
| **5f\_1.6s** | **Specification** | 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. |  | N/A |
| **5f\_1.7s** | **Specification** | 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. |  | N/A |
| **5f\_1.8s** | **Specification** | Following a home visit, a report should be made to the Purchasing Authority within 2 working days if the planned activity could not be completed. Any new or changed risks identified during a non-clinical home visit will be recorded and the Individual Patient Care Plan updated with new or changed risk control measures.  A summary report or log including non-clinical Home Visits must be available for each individual patient on request of the Purchasing Authority. |  | N/A |
| **5f\_1.8aq** | **Adjudication Question** | **With reference to the above specification point, please detail how these reports will be recorded and communicated to the Purchasing Authority.** | N/A |  |
| **5f\_2** |  | **Scope of Nursing Requirements** |  |  |
| **5f\_2.1s** | **Specification** | The Supplier will be required to provide clinical services and home visits to any address in the UK that falls within the remit of NHS England and NHS Scotland. |  | N/A |
| **5f\_2.2s** | **Specification** | The Clinical Services to be provided are as specified in the Clinical Service Pathway including escalation procedures:  Document No. 5b - Patient Homecare Support Pathway - New Patients. Document No. 5a - Patient Homecare Support Pathway - Existing Patients |  | N/A |
| **5f\_2.3s** | **Specification** | Where nursing services are delivered in Scotland the Supplier, or sub-contractor delivering nursing services, is required to be registered with the Care Inspectorate at the point of service delivery, where deemed necessary. |  | N/A |
| **5f\_2.4s** | **Specification** | The Purchasing Authority is responsible for assessing the risks associated with clinical services. Also see Risk Management section on the Governance Tab. |  | N/A |
| **5f\_2.5s** | **Specification** | 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. |  | N/A |
| **5f\_2.6s** | **Specification** | The Supplier must ensure that the clinical service complies with clinical service protocols below (this list is by no means exhaustive) and copies of any clinical service protocols must be provided to the Purchasing Authority upon request. • Phlebotomy  • Cannulation  • 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 • Side effect management  • Managing infusion reactions |  | N/A |
| **5f\_2.7s** | **Specification** | 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.  Weekend and bank holiday would only be applicable at the agreement of the Purchasing Authority prior to the visit. |  | N/A |
| **5f\_2.8s** | **Specification** | The clinical services and nurse time banding to be provided as part of the homecare service are listed below. The Purchasing Authority will specify the clinical services and nurse time banding to be provided for each patient on the registration form.  **The categories are:** **“Full nurse support” (FNS)**  Provision of a complete infusion, whereby the patient will be cannulated/portacath accessed, infusion will be prepared and administered, observations carried out and infusion completed and venous access removed.  **“Semi-Independent” (SI)**  A homecare nurse will attend the patient’s home or alternative infusion setting (e.g. school, workplace) to obtain vascular access and/or to reconstitute infusion.  **“Fully Independent” (FI)**  The patient or an appropriate carer will obtain vascular access themselves, and prepare and administer their own infusions.  **The price banding are:** LSD Nursing Band A (5 - 15 mins) LSD Nursing Band B (0 - 60 mins) LSD Nursing Band C (0 - 120 mins) LSD Nursing Band D (121 - 180 mins) LSD Nursing Band E (181 - 240 mins) LSD Nursing Band F (241 - 360 mins) LSD Nursing Band G (> 360 mins)  **Virtual Nurse** - **(FI)** Will be only be available for the following nurse bands and must be agreed with the Purchasing Authority for patient suitability:  LSD Nursing Band A (5 - 15 mins) LSD Nursing Band B (0 - 60 mins) |  | N/A |
| **5f\_2.9s** | **Specification** | The Supplier will provide a 24 hour/365 days a year manned telephone or call-back helpline service to support patients receiving the Clinical Services. |  | N/A |
| **5f\_2.10s** | **Specification** | The Supplier must ensure that the Healthcare Professional providing the clinical service has visibility of the appropriate prescription at the point of product administration. |  | N/A |
| **5f\_2.11s** | **Specification** | 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. |  | N/A |
| **5f\_2.12s** | **Specification** | 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. |  | N/A |
| **5f\_2.13s** | **Specification** | The Supplier must be able to provide a clinical evaluation form or Nurse visit report form to the Purchasing Authority within 2 working days of any episode of clinical service. Any new or changed risks identified during a clinical home visit will be recorded and reported. Processes for recording and transmission of clinical records between the parties must be via approved methods that are IGT Level 2 compliant or otherwise specified in the Data Sharing or Data Processing agreement. A summary report or log including clinical services and clinical interventions must be available for each individual patient at the request of the Purchasing Authority. Please note that going forward, IGT Level 2 toolkit will be replaced by the Data Security Protection Toolkit.  Data Security and Protection Toolkit (dsptoolkit.nhs.uk) |  | N/A |
| **5f\_2.14s** | **Specification** | All patients referred will require an Introductory/ Welcome visit and home risk assessment regardless of level of dependence.  In order to deliver these clinical services the Supplier will be required to provide clinical service protocols that include: • venous access • drug administration • management of infusion related reactions • anaphylaxis • patient self administration training and competency assessment • safe use of equipment • adverse events • incident management • stock checking and temperature monitoring checks during visits |  | N/A |
| **5f\_2.15s** | **Specification** | The Supplier will provide a Healthcare Professional call-back service for patients between the hours of 08.00 and 22.00 hours Monday to Friday, except Bank Holidays. Outside of these hours a signposting message answer phone service will be provided.   Extended hours or enhanced services above the minimum stated are considered advantageous. |  | N/A |
| **5f\_3** |  | **Training and Education of Patients** |  |  |
| **5f\_3.1s** | **Specification** | Training of Patients to self-administer medicines will be the responsibility of the Supplier as part of a Clinical Service to be provided by the Supplier  Competency documentation for a Patient self-administering medicines will be held in the patient record and shared within 2 working Days completion. |  | N/A |
| **5f\_3.2s** | **Specification** | 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 Supplier as a Clinical Service to be provided by the Supplier   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. |  | N/A |
| **5f\_3.3s** | **Specification** | 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. |  | N/A |
| **5f\_3.4s** | **Specification** | The Supplier and Purchasing Authority will agree appropriate patient training materials prior to service commencement. |  | N/A |
| **5f\_3.4aq** | **Adjudication Question** | **With reference to the above specification point, please describe the key features of your face to face infusion clinical training service.** | N/A |  |
| **5f\_3.5s** | **Specification** | 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. |  | N/A |

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| **CM/MSR/17/5555 - NHS National Framework Agreement for the Supply of Home Delivery Service - Lysosomal Storage Disorders England and Scotland** | | |  | **(\*) Please ensure Supplier Name is entered correctly; this will then appear at the top of each worksheet** |
| **Document 5g - Governance** | **Governance** |  |  |  |
| **Paragraph** | **Specification. Compliance or Adjudication** | **Specification Item** | **Do you comply with Specification? Paragraph by paragraph** | **Supplier's Answer (or file reference to separate document with answer / requested documentation)** |
|  |  | **Specification Compliance Summary** |  |  |
| **5g\_c** | **Compliance Yes/No** | By complying with these specification points means that at any point during the life of the framework, a request for further information must be made accessible in an electronic format i.e. word or excel, of a procedure, policy or other evidence formats to either the Purchasing Authority or NHSE. This will enable NHSE to have a mechanism for review to support monitoring of the agreement or to support the Purchasing Authorities.  Please advise that you can comply with all specification points in this section, that do not specifically have an adjudication question attached. If there are any points that you can not comply with, please provide the point number in the answer section here, and the explanation of what you cannot comply with against the relevant point (i.e. populate the grey box currently populated with 'n/a' with your rationale) | **This Framework Has Been Redacted – Section 43 (commercial Interests)** | |
| **5g\_1** |  | **Governance Framework and Quality Systems** |  |  |
| **5g\_1.1s** | **Specification** | 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 • Fridge maintained 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. |  | N/A |
| **5g\_1.1aq** | **Adjudication Question** | **With reference to the Specification Point above, Please provide your Complaints and incidents policy and fridge maintenance policy for review and certify you have the above documents stating when your review cycle is for the policies and you will provide them upon request.** | N/A |  |
| **5g\_1.2s** | **Specification** | 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 |  | N/A |
| **5g\_1.2aq** | **Adjudication Question** | **With reference to the Specification Point above, please certify you have the above documents and you will provide them upon request.** | N/A |  |
| **5g\_1.3s** | **Specification** | 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. |  | N/A |
| **5g\_2** |  | **Clinical Governance** |  |  |
| **5g\_2.1s** | **Specification** | 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. |  | N/A |
| **5g\_2.2s** | **Specification** | 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. |  | N/A |
| **5g\_2.3s** | **Specification** | 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. |  | N/A |
| **5g\_2.4s** | **Specification** | 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. |  | N/A |
| **5g\_2.5s** | **Specification** | 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. |  | N/A |
| **5g\_2.6s** | **Specification** | 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. |  | N/A |
| **5g\_2.7s** | **Specification** | 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.   The Purchasing Authority and Supplier will use the following form : Appendix H - Patient transfer of centre |  | N/A |
| **5g\_2.7aq** | **Adjudication Question** | **With reference to the Specification Point above, please provide your pharmacovigilance reporting process.** | N/A |  |
| **5g\_3** |  | **Complaints & Concerns** |  |  |
| **5g\_3.1c** | **Compliance Yes/No** | 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 Purchasing Authority have provided the following appendix for use withe the service: Appendix G - Homecare complaints and incidents form  **Please indicate Yes / No as to if you comply. Please note that the inability to comply may result in a bid being unsuccessful.** |  | N/A |
| **5g\_3.2s** | **Specification** | The details of any complaints regarding the delivery or service, received from Patients will be forwarded in writing to Purchasing Authority within 2 working days. Formal response to complaint investigation to be forwarded to Purchasing Authority within 30 days. |  | N/A |
| **5g\_4** |  | **Information Governance** |  |  |
| **5g\_4.1c** | **Compliance Yes/No** | Professional Standards for Homecare Services (rpharms.com)   |  | | --- | | 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. Inline with the RPS Professional Standards for Homecare Services.     **Please indicate Yes / No as to if you comply. Please note that the inability to comply may result in a bid being unsuccessful.** | |  | N/A |
| **5g\_4.2s** | **Specification** | |  | | --- | | Patient and family confidentiality must be respected at all times. No patient or carer contact will be made, other than that required by the Supplier in the performance of their duties, or unless specifically requested to do so by the Purchasing Authority. No identifiable data will be shared with any third party including Pharmaceutical companies directly. | |  | N/A |
| **5g\_5** |  | **Risk Management** |  |  |
| **5g\_5.1s** | **Specification** | 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. |  | N/A |
| **5g\_5.2s** | **Specification** | 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. |  | N/A |
| **5g\_6** |  | **Business Continuity and Contingency Planning** |  |  |
| **5g\_6.1s** | **Specification** | The Supplier must hold and maintain an appropriate Business Continuity Plan in accordance with schedule 2 terms and conditions of the Agreement including major incident and emergency planning. |  | N/A |
| **5g\_6.2s** | **Specification** | 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. |  | N/A |
| **5g\_6.3s** | **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 Purchasing 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. |  | N/A |
| **5g\_6.3aq** | **Adjudication Question** | **With reference to the above specification point, please provide your contingency plans, detailing the types of situations they cover. Please also describe how these events would be monitored.** | N/A |  |
| **5g\_7** |  | **Safeguarding** |  |  |
| **5g\_7.1s** | **Specification** | 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. |  | N/A |
| **5g\_7.2s** | **Specification** | 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. |  | N/A |
| **5g\_8** |  | **Training and Competence of all Supplier's staff including non-clinical staff** |  |  |
| **5g\_8.1s** | **Specification** | 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. |  | N/A |
| **5g\_8.1aq** | **Adjudication Question** | **With reference to the above specification point, please describe the key features of training systems and competency assessment** | N/A |  |
| **5g\_8.2s** | **Specification** | The training plans and training programmes will be reviewed and updated on a regular basis to ensure they are based on current good practice. |  | N/A |
| **5g\_8.3s** | **Specification** | 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 |  | N/A |
| **5g\_8.4s** | **Specification** | 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. |  | N/A |
| **5g\_8.5s** | **Specification** | 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. |  | N/A |

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| **Document 5h - Finance** | **Finance** |  |  |  |
| **Paragraph** | **Specification. Compliance or Adjudication** | **Specification Item** | **Do you comply with Specification? Paragraph by paragraph** | **Supplier's Answer (or file reference to separate document with answer / requested documentation)** |
|  |  | **Specification Compliance Summary** |  |  |
| **5h\_c** | **Compliance Yes/No** | By complying with these specification points means that at any point during the life of the framework, a request for further information must be made accessible in an electronic format i.e. word or excel, of a procedure, policy or other evidence formats to either the Purchasing Authority or NHSE. This will enable NHSE to have a mechanism for review to support monitoring of the agreement or to support the Purchasing Authorities.  Please advise that you can comply with all specification points in this section, that do not specifically have an adjudication question attached. If there are any points that you can not comply with, please provide the point number in the answer section here, and the explanation of what you cannot comply with against the relevant point (i.e. populate the grey box currently populated with 'n/a' with your rationale) | **This Framework Has Been Redacted – Section 43 (commercial Interests)** | |
| **5h\_1** |  | **Purchase Orders** |  |  |
| **5h\_1.1s** | **Specification** | The Purchasing Authority will generate a unique Purchase Order Number linked to each prescription and provide it to the Supplier. |  | N/A |
| **5h\_1.2s** | **Specification** | Suppliers should be able to receive orders transmitted electronically in accordance with nationally approved standards. |  | N/A |
| **5h\_2** |  | **Purchasing of medicines by the Supplier** |  |  |
| **5h\_2.1s** | **Specification** | 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. |  | N/A |
| **5h\_2.2s** | **Specification** | 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. |  | N/A |
| **5h\_2.3s** | **Specification** | 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. |  | N/A |
| **5h\_2.4s** | **Specification** | 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. |  | N/A |
| **5h\_2.5s** | **Specification** | In addition to the Section on confidentiality in theAgreement,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. |  | N/A |
| **5h\_3** |  | **Invoicing** |  |  |
| **5h\_3.1s** | **Specification** | 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. |  | N/A |
| **5h\_3.1aq** | **Adjudication Question** | **With reference to the above specification point, please provide key features of current capability to receive or transmit invoices electronically.** | N/A |  |
| **5h\_3.2s** | **Specification** | The Supplier will ensure the collection of 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. |  | N/A |
| **5h\_3.3s** | **Specification** | 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. |  | N/A |
| **5h\_3.4s** | **Specification** | 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. |  | N/A |
| **5h\_4** |  | **Statement of Accounts & Payments** |  |  |
| **5h\_4.1s** | **Specification** | The Supplier will provide a statement of accounts to the Purchasing Authority on a monthly basis. |  | N/A |
| **5h\_4.2s** | **Specification** | The Purchasing Authority will pay in accordance with the payment terms set out in Schedule 2 general terms and conditions of the Agreement. |  | N/A |
| **5h\_5** |  | **Risk, Liability & Insurance** |  |  |
| **5h\_5.1s** | **Specification** | Where medicines, 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. |  | N/A |

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| **CM/MSR/17/5555 - NHS National Framework Agreement for the Supply of Home Delivery Service - Lysosomal Storage Disorders England and Scotland** |  |  |  | **(\*) Please ensure Supplier Name is entered correctly; this will then appear at the top of each worksheet** |
| **Document 5i - Digital** | **Digital** |  |  |  |
| **Paragraph Numbering** | **Specification. Compliance or Adjudication** | **Specification Item** | **Do you comply with Specification? Paragraph by paragraph** | **Supplier's Answer (or file reference to separate document with answer / requested documentation)** |
|  |  | **Specification Compliance Summary** |  |  |
| **5i\_c** | **Compliance Yes/No** | By complying with these specification points means that at any point during the life of the framework, a request for further information must be made accessible in an electronic format i.e. word or excel, of a procedure, policy or other evidence formats to either the Purchasing Authority or NHSE. This will enable NHSE to have a mechanism for review to support monitoring of the agreement or to support the Purchasing Authorities.  Please advise that you can comply with all specification points in this section, that do not specifically have an adjudication question attached. If there are any points that you can not comply with, please provide the point number in the answer section here, and the explanation of what you cannot comply with against the relevant point (i.e. populate the grey box currently populated with 'n/a' with your rationale) | **This Framework Has Been Redacted – Section 43 (commercial Interests)** | |
| **5i\_1** |  | **Digital Solution Requirement** |  |  |
| **5i\_1.1s** | **Specification** | 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. |  | N/A |
| **5i\_1.2s** | **Specification** | Mobile Apps or other applicable Digital Solutions for patients access must be free of charge, without any in-app purchase. |  | N/A |
| **5i\_1.3s** | **Specification** | Any patient facing Apps or other applicable Digital Solutions must undergo baseline assessment by NHSE Transformation Directorate previously NHSX as a minimum. |  | N/A |
| **5i\_1.4s** | **Specification** | For any digital solutions,  i) if the solution (or part of) is not classified as a medical device then the developer/Contractor 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.  ii) if the solution (or part of) is classified as a medical device the solution must comply with the medical device directives. |  | N/A |
| **5i\_1.5s** | **Specification** | 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. |  | N/A |
| **5i\_1.5aq** | **Adjudication Question** | **Please provide a list of digital technologies that you are offering (e.g. remote consultation platform, web portal) supported with evidence of DTAC submission where applicable** | N/A |  |

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| **CM/MSR/17/5555 - NHS National Framework Agreement for the Supply of Home Delivery Service - Lysosomal Storage Disorders England and Scotland** | | |  | **(\*) Please ensure Supplier Name is entered correctly; this will then appear at the top of each worksheet** |
| **Document 5j - Net Zero&Social Value** | **Net Zero & Social Value** |  |  |  |
| **Paragraph** | **Specification. Compliance or Adjudication** | **Specification Item** | **Do you comply with Specification? Paragraph by paragraph** | **Contractor's Answer (or file reference to separate document with answer / requested documentation)** |
| **5J\_1** |  | **Equal Opportunity** |  |  |
| **5j\_1.1aq** | **Adjudication Question** | *Using a maximum of 1,000 characters describe the commitment your organisation will make to ensure that opportunities under this framework agreement deliver the Award Criteria. Please include:* ● your ‘Method Statement’, stating how you will achieve this and how your commitment meets the Award Criteria, and ● a timed project plan and process, including how you will implement your commitment and by when. Also, how you will monitor, measure and report on your commitments and the impact of your proposals. You should include but not be limited to: ○ timed action plan ○ use of metrics ○ tools/processes used to gather data ○ reporting ○ feedback and improvement ○ transparency | N/A |  |
| **5j\_1.2aq** | **Adjudication Question** | *Using a maximum of 1,000 characters describe the commitment your organisation will make to ensure that opportunities under this framework agreement deliver the Award Criteria. Please include:* Equalities - As part of your training, do you train staff on your equality policy and does this include barring discrimination on the grounds of all nine protected characteristics: 1 Age, 2 Disability, 3 Gender Reassignment, 4 Marriage & Civil Partnership, 5 Pregnancy & Maternity, 6 Race, 7 Religion or Belief, 8 Sex and 9 Sexual Orientation. | N/A |  |
| **5j\_2** |  | **Fighting Climate Change** |  |  |
| **5j\_2.1aq** | **Adjudication Question** | NHS England has a duty to consider the Social Value Act 2012 as part of this procurement process.  *Using a maximum of 1,000 characters describe the commitment your organisation will make to ensure that opportunities under the framework deliver the outcome and Award Criteria. Please include:* ● your ‘Method Statement’, stating how you will achieve this and how your commitment meets the Award Criteria, and ● a timed project plan and process, including how you will implement your commitment and by when. Also, how you will monitor, measure and report on your commitments/the impact of your proposals. You should include but not be limited to: ○ timed action plan ○ use of metrics ○ tools/processes used to gather data ○ reporting ○ feedback and improvement ○ transparency | N/A |  |
| **5j\_2.2aq** | **Adjudication Question** | Detail how, through the delivery of the framework agreement, you will reduce the amount of single use plastic used for both packaging and products that will be provided and or service | N/A |  |
| **5j\_2.3aq** | **Adjudication Question** | Detail how, through the delivery of the contract, you plan to reduce your carbon emissions (both in your supply chain and embedded carbon within products) through the provision of the product/service | N/A |  |

# Annex A – Homecare Medicines Service: Order Process

Rx requires change

Product /Service List agreed

*(inc. pricing and specific product brand requirements)*

Product /service

list variation process

Prescription generated by Authority’s clinical team and

sent to Authority’s pharmacy homecare team

Product/service

list requires change

Pharmacy homecare team (or specialist clinical

pharmacist) undertake clinical validation of prescription(Rx) and validate Rx against Product

/service List

Pharmacy homecare team raises a purchase order in

accordance with the Rx, annotate the PO number on the prescription and send the Rx to the Supplier

Supplier validates Rx against Product / Service List

Rx processed by Supplier

Product /service delivered

# Annex B – Homecare Medicines Service: Invoice Process



**Notes:**

1. For the avoidance of doubt, the 7 day period during which a Participating Authority’s pharmacy Homecare team validates invoices is included with the 30 days for payment of a valid invoice from its receipt.
2. Subject to point (3) below, if an invoice is queried or disputed, the 30 day period for payment of a valid invoice from its receipt shall be suspended pending resolution of such query or dispute.
3. If an invoice query or invoice dispute is resolved and/or determined with the effect that the Supplier is required to submit a corrected invoice, the corrected invoice shall be treated as a new invoice and the 30 day period for payment of a valid invoice from its receipt shall restart from the point the Participating Authority receives the corrected invoice.
4. Invoice disputes shall resolve in accordance with the following process:

**Process for dealing with invoice disputes:**

Any invoice queries raised in accordance with the above process and not resolved within thirty (30) days of such query being raised shall be deemed an invoice dispute (and a “Dispute” for the purposes of the relevant Contract) and shall be referred by the Participating Authority contracting party for resolution / determination under the Dispute Resolution Process for the Contract. For the avoidance of doubt, the Participating Authority party to the Contract shall not be in breach of its payment obligations in respect of any invoice that is the subject of an invoice dispute unless such Dispute Resolution Process has been followed in respect of such invoice dispute and it has been resolved / determined that the disputed invoice amount is properly due to the Supplier party under such Contract and the Participating Authority party under such Contract has then failed to pay such sum within a reasonable period following such resolution / determination.

**Schedule 6**

**Commercial Schedule**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
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| **NHS National Framework Agreement for the Supply of Home Delivery Service - Lysosomal Storage Disorders England and Scotland  Offer reference number: CM/MSR/17/5555 Period of framework agreement: 1 July 2023 to 30 June 2025 with option(s) to extend for up to a total period of 24 months** | | | | |
| **Offer (Price) Schedule \_ Document No.6** | **This spreadsheet should incorporate ALL costs in column C.  Additional attachments relating to pricing will not be accepted as part of your offer and will not form part of the framework agreement.  Please ensure you take note of all the service elements in Column B full descriptions are provided in on the equipment and ancillary lists tabs.** | | | |
| **Supplier Name** |  | | | |
|  | **Please note: a numerical price must be entered for each line. There should be no blank fields.  JIT Section: this is the only section where submitting a price for all items is optional, please write 'no offer' if there are any lines with prices not being submitted for, so that they do not accidentally read as £0.00.** | | | |
| **Product group** | **Service** | **Offer Price** | **Frequency of Charge** | **Note** |
| Pump Rental | Pump Rental (for ONE pump, includes initial delivery of pump & back pack, maintenance, removal / replacement if required) |  | 4 weekly fee |  |
|  |  | 1 weekly fee | to be applied when a full 4 week period has not been utilised. |
| Refrigerator Rental (Pharmaceutical grade refrigerator with alarm) | Fridge Size 1 (small) (for ONE refrigerator, includes initial delivery of refrigerator, repair, replacement , removal if required) |  | 4 weekly fee | **Note:** Not all patients will require a Pharmaceutical grade fridge, Pharmaceutical grade fridges should only be supplied with the agreement of the Purchasing Authority. **Note:** If a fridge is in situ paid for under previous frameworks before rental charges or replacement commence, the authority should be consulted to see if the patient still requires a pharmaceutical grade fridge  **Note**: the 1 weekly fee is to be applied when a full 4 week period has not been utilised |
|  | Fridge Size 1 (small) (for ONE refrigerator, includes initial delivery of refrigerator, repair, replacement , removal if required) |  | 1 weekly fee |
|  | Fridge Size 2 (medium)  (for ONE refrigerator, includes initial delivery of refrigerator, repair, replacement , removal if required) |  | 4 weekly fee |
|  | Fridge Size 2 (medium)  (for ONE refrigerator, includes initial delivery of refrigerator, repair, replacement , removal if required) |  | 1 weekly fee |
|  | Fridge Size 3 (large) (for ONE refrigerator, includes initial delivery of refrigerator, repair, replacement , removal if required) |  | 4 weekly fee |
|  | Fridge Size 3 (large) (for ONE refrigerator, includes initial delivery of refrigerator, repair, replacement , removal if required) |  | 1 weekly fee |
| Elastromeric Devices | Intermate elastomeric pump devices 100mls/hr bottles  For ambulatory pump (SV100) |  | 1 | Dependent on drug and infusion rate |
| Intermate elastomeric pump devices 100mls/hr bottles  For ambulatory pump (LV100) |  | 1 | Dependent on drug and infusion rate |
| Intermate elastomeric pump devices 250mls/hr bottles  For ambulatory pump (LV250) |  | 1 | Dependent on drug and infusion rate |
| One off individual fees | Fridge temperature monitor |  | as supplied (set up or replacement) | if required |
| Folding infusion stand |  | as supplied (set up or replacement) |  |
| Tourniquet |  | as supplied (set up or replacement) | For cannulating patients |
| Clinical tray |  | as supplied (set up or replacement) | To place items on for reconstitution of drug/cannulation |
| Storage box |  | as supplied (set up or replacement) | To keep consumables clean/dry/ together ready for infusion |
| Dispense, Prescription management, Delivery, Ancills and Waste collection Cost | **Oral Drugs - delivery 4 weekly - Normal Delivery Hours** Dispense, Prescription management, Delivery, Ancills and Waste collection Cost |  | Per delivery | Deliveries may be requested to be 4 weekly at first, and then changed to 8 or 12 weekly once there is confidence that the patient can tolerate the treatment.  Dispense, Prescription management, Delivery, Ancills and Waste collection inc in your offer price |
| **Oral Drugs - delivery 4 weekly - Normal Delivery Hours Additional Patients - i.e. discounted fee for delivering to a 2nd, 3rd, 4th etc. patient at the same address, and same time.** Dispense, Prescription management, Delivery, Ancills and Waste collection Cost to multiple patients at same address |  | per delivery | Deliveries may be requested to be 4 weekly at first, and then changed to 8 or 12 weekly once there is confidence that the patient can tolerate the treatment.  Dispense, Prescription management, Delivery, Ancills and Waste collection inc in your offer price |
| **Oral Drugs - delivery 8 weekly - Normal Delivery Hours** Dispense, Prescription management, Delivery, Ancills and Waste collection Cost |  | Per delivery | Dispense, Prescription management, Delivery, Ancills and Waste collection inc in your offer price |
| **Oral Drugs - delivery 8 weekly - Normal Delivery Hours Additional Patients - i.e. discounted fee for delivering to a 2nd, 3rd, 4th etc. patient at the same address, and same time.** Dispense, Prescription management, Delivery, Ancills and Waste collection Cost to multiple patients at same address |  | Per delivery | Dispense, Prescription management, Delivery, Ancills and Waste collection inc in your offer price |
| **Oral Drugs - delivery 12 weekly - Normal Delivery Hours** Dispense, Prescription management, Delivery, Ancills and Waste collection Cost |  | Per delivery | Dispense, Prescription management, Delivery, Ancills and Waste collection inc in your offer price |
| **Oral Drugs - delivery 12 weekly - Normal Delivery Hours Additional Patients - i.e. discounted fee for delivering to a 2nd, 3rd, 4th etc. patient at the same address, and same time.** Dispense, Prescription management, Delivery, Ancills and Waste collection Cost to multiple patients at same address |  | Per delivery | Dispense, Prescription management, Delivery, Ancills and Waste collection inc in your offer price |
| **Infusions - delivery 4 weekly - Normal Delivery Hours** Dispense, Prescription management, Delivery, Ancills and Waste collection Cost |  | Per delivery | Dispense, Prescription management, Delivery, Ancills and Waste collection inc in your offer price |
| **Infusions - delivery 4 weekly - Normal Delivery Hours Additional Patients - i.e. discounted fee for delivering to a 2nd, 3rd, 4th etc. patient at the same address, and same time.** Dispense, Prescription management, Delivery, Ancills and Waste collection Cost to multiple patients at same address |  | Per delivery | Dispense, Prescription management, Delivery, Ancills and Waste collection inc in your offer price |
| **Combined Infusion and Oral delivery - 4 weekly - Normal Delivery Hours** Dispense, Prescription management, Delivery, Ancills and Waste collection Cost |  | Per delivery | Dispense, Prescription management, Delivery, Ancills and Waste collection inc in your offer price |
|  | Emergency Same Day Delivery |  | Per delivery | Emergency deliveries are only to be made with permission from the Purchasing Authority. |
| Additional Just In Time (‘JIT’) Delivery Prices | Delivery with Nurse Dispense, Prescription management, Delivery, Ancills and Waste collection Cost |  | Per delivery | JIT' deliveries are only to be made with permission from the Purchasing Authority.  **Please Note: Please submit prices for as many options as you can offer. You may however choose to quote purely for Delivery with Nurse, or purely for delivery by validated cold chain shipper. As long as one option is provided to get product to a patients 'just in time' for the nurse to administer, in agreed cases where it cannot (for whatever reason) be stored in the patients home.** |
| Weekly Shipper Delivery Dispense, Prescription management, Delivery, Ancills and Waste collection Cost |  | Per delivery |
| Fortnightly Shipper Delivery Dispense, Prescription management, Delivery, Ancills and Waste collection Cost |  | Per delivery |
| Monthly Shipper Delivery Dispense, Prescription management, Delivery, Ancills and Waste collection Cost |  | Per delivery |
| Additional Cost for Re-Delivery | Additional Cost for Re-Delivery (Monday - Friday) |  | Per delivery | Only applicable when the re-delivery is required due to the fault of patient or Purchasing Authority e.g. Patient not in at agreed delivery time slot. Purchasing Authority should be notified in advance. |
| Additional Cost for Re-Delivery (Saturdays, Sundays, Bank Holidays) |  | Per delivery |
| Nursing Service Bandings | Mon - Fri  LSD Nursing Band A 5 - 15 mins |  | Per visit | See examples of activities likely to be included in each band in Tab 'Nurse Banding Examples'.   Saturday and Bank holiday nursing - Will only be applicable if agreed by the referring centre prior to nurse visits and wont be at the request of the HCP. |
| Saturday  LSD Nursing Band A 5 - 15 mins |  | Per visit |
| Mon - Fri  LSD Nursing Band B 0 - 60 mins |  | Per visit |
| Saturday LSD Nursing Band B 0 - 60 mins |  | Per visit |
| Mon - Fri  LSD Nursing Band C 0 - 120 mins |  | Per visit |
| Saturday LSD Nursing Band C 0 - 120 mins |  | Per visit |
| Mon - Fri  LSD Nursing Band D 121 - 180 mins |  | Per visit |
| Saturday LSD Nursing Band D 0 - 120 mins |  | Per visit |
| Mon - Fri  LSD Nursing Band E 181 - 240 mins |  | Per visit |
| Saturday LSD Nursing Band E 181 - 240 mins |  | Per visit |
| Mon - Fri  LSD Nursing Band F 241 - 360 mins |  | Per visit |
| Saturday LSD Nursing Band F 241 - 360 mins |  | Per visit |
| Mon - Fri  LSD Nursing Band G > 360 mins |  | Per visit |
| Saturday LSD Nursing Band G > 360 mins |  | Per visit |
| Vritual Nurse | Nursing Band A |  | Per visit | See examples of activities likely to be included in each band in Tab 'Nurse Banding Examples'.  Mon- Fri - Fully Independent patients only and agreed by the referring centre |
| Nursing Band B |  | Per visit |

**Schedule 7 Award Criteria**

1. *the call-off terms and conditions set out at Appendix A of this Framework Agreement;*
2. *a completed Order Form;*
3. *the applicable parts of the Specification and Tender Response Document set out at* [*Schedule 5*](#_bookmark6) *of this Framework Agreement, as may be supplemented by information set out and/or referred to in the Order Form;*
4. *the applicable parts of the Commercial Schedule set out at* [*Schedule 6*](#_bookmark7) *of this Framework Agreement, as may be supplemented by information set out and/or referred to in the Order Form; and*
5. *any relevant provisions applicable to the call-off contract as set out in the Framework Agreement.*
6. *the Purchasing Authority ascertains the relevant methodology laid down in document 2a Award Criteria, local award tool and patient suitability.*

**Appendix A**

**Call-off Terms and Conditions for the Supply of Goods and the Provision of Services (Homecare Medicines)**

## Appendix A

**Call-off Terms and Conditions for the Supply of Goods and the Provision of Services (Homecare Medicines)**

Where an Order Form is issued by the Authority that refers to the Framework Agreement, the Contract is made between the Authority and the Supplier on the date of that Order Form. The Contract is subject to the terms set out in the schedules of these Call-off Terms and Conditions listed below (“**Schedules**”).

The Authority and the Supplier undertake to comply with the provisions of the Schedules in the performance of the Contract.

The Supplier shall supply to the Authority, and the Authority shall receive and pay for, the Goods and/or Services on the terms of the Contract.

For the avoidance of doubt, any actions or work undertaken by the Supplier prior to the receipt of an Order Form covering the relevant Goods and/or Services shall be undertaken at the Supplier’s risk and expense and the Supplier shall only be entitled to invoice for Goods or Services covered by a valid Order Form.

The Definitions in [Schedule 4](#_bookmark120) of these Call-off Terms and Conditions apply to the use of all capitalised terms in the Contract.

**Schedules**

|  |  |
| --- | --- |
| [Schedule 1](#_bookmark8) of these Call- off Terms and Conditions | Key Provisions |
| [Schedule 2](#_bookmark12) of these Call- off Terms and Conditions | General Terms and Conditions |
| [Schedule 3](#_bookmark114) of these Call- off Terms and Conditions | Information and Data Provisions |
| [Schedule 4](#_bookmark120) of these Call- off Terms and Conditions | Definitions and Interpretations |

**Schedule 1 Key Provisions**

**Standard Key Provisions**

1. **Application of the Key Provisions**
   1. The standard Key Provisions at Clauses [1](#_bookmark9) to [9](#_bookmark11) of this [Schedule 1](#_bookmark8) of these Call-off Terms and Conditions shall apply to this Contract.
   2. Extra Key Provisions shall only apply to this Contract where such provisions are set out as part of the Order Form.

## Term

* 1. This Contract shall commence on the Commencement Date.
  2. The Term of this Contract shall be as set out in the Order Form.
  3. The Term may be extended in accordance with Clause [15.2](#_bookmark58) of [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions provided that the duration of this Contract shall be no longer than any maximum applicable to the Contract if such maximum duration is set out in the Framework Agreement (including any options to extend).

## Contract Managers

* 1. The Contract Managers at the commencement of this Contract shall be as set out in the Order Form or as otherwise agreed between the Parties in writing.

## Names and addresses for notices

* 1. Unless otherwise agreed by the Parties in writing, notices served under this Contract are to be delivered to such persons at such addresses as referred to in the Order Form.

## Management and escalation levels for dispute resolution

* 1. Unless otherwise agreed by the Parties in writing, the management levels at which a Dispute will be dealt with as referred to as part of the Dispute Resolution Procedure are as follows:

|  |  |  |
| --- | --- | --- |
| **Level** | **Authority representative** | **Supplier representative** |
| 1 | Contract Manager | Contract Manager |
| 2 | Assistant Director or equivalent | Assistant Director or  equivalent |
| 3 | Director or equivalent | Director or equivalent |

## Order of precedence

* 1. Subject always to Clause [1.10](#_bookmark122) of [Schedule 4](#_bookmark120), should there be a conflict between any other parts of this Contract the order of priority for construction purposes shall be:
     1. the Order Form
     2. the applicable provisions of the Framework Agreement other than the Specification and Tender Response Document;
     3. the provisions on the front page of these Terms and Conditions for the Supply of Goods and the Provision of Services (Purchase Order Version);
     4. [Schedule 1 of these Call-off Terms and Conditions](#_bookmark8): Key Provisions;
     5. the Specification and Tender Response Document (but only in respect of the requirements and, for the avoidance of doubt, the order of precedence set out in Clause 6.2 of Schedule 1 of the Framework Agreement in relation to the various parts of the Specification and Tender Response Document shall apply);
     6. [Schedule 2 of these Call-off Terms and Conditions](#_bookmark12): General Terms and Conditions;
     7. [Schedule 3 of these Call-off Terms and Conditions](#_bookmark114): Information Governance Provisions;
     8. [Schedule 4 of these Call-off Terms and Conditions](#_bookmark120): Definitions and Interpretations;
     9. the order in which all subsequent schedules, if any, appear; and
     10. any other documentation forming part of the Contract in the date order in which such documentation was created with the more recent documentation taking precedence over older documentation to the extent only of any conflict.

## Application of TUPE at the commencement of the provision of Services

* 1. The Parties agree that at the commencement of the provision of Services by the Supplier, TUPE and the Cabinet Office Statement shall not apply so as to transfer the employment of any employees of the Authority or a Third Party to the Supplier.
  2. If any person who is an employee of the Authority or a Third Party claims or it is determined that their contract of employment has been transferred from the Authority or Third Party to the Supplier or a Sub-contractor pursuant to TUPE, or claims that their employment would have so transferred had they not resigned, then:
     1. the Supplier will, within seven (7) days of becoming aware of that fact, give notice in writing to the Authority;
     2. the Authority or Third Party may offer employment to such person within twenty-eight (28) days of the notification by the Supplier;
     3. if such offer of employment is accepted, the Supplier or a Sub- contractor shall immediately release the person from their employment;
     4. if after that period specified in Clause 7.2.2 of this Schedule 1 of these Call-off Terms and Conditions has elapsed, no offer of employment has been made by the Authority or Third Party, or such offer has been made by the Authority or Third Party but not accepted within a reasonable time, the Supplier or Sub-contractor shall employ that person in accordance with its obligations and duties under TUPE and shall be responsible for all liabilities arising in respect of any such person and shall (where relevant) be bound to apply Fair Deal for Staff Pensions in respect of any such person in accordance with the requirements of Part D of Schedule 7 of the NHS Terms and Conditions for the Provision of Services (Contract Version) (January 2018).

## Purchase Orders

* 1. The Authority shall issue a Purchase Order to the Supplier in respect of any Goods and/or Services to be supplied to the Authority under this Contract. The Supplier shall comply with the terms of such Purchase Order as a term of this Contract. For the avoidance of doubt, any actions or work undertaken by the Supplier under this Contract prior to the receipt of a Purchase Order covering the relevant Goods and/or Services shall be undertaken at the Supplier’s risk and expense and the Supplier shall only be entitled to invoice for Goods and/or Services covered by a valid Purchase Order.

## Liquidated damages for late delivery

* 1. If (1) the Supplier does not deliver the Goods and/or provide the Services in accordance with the timescales set out in the Specification and Tender Response Document; and (2) the Authority determines (at its sole discretion acting reasonably) that it is required to provide the Goods and/or Services itself or via a third party to ensure there is no risk to a Patient’s continued treatment, the Supplier shall pay, as liquidated damages, the following sums to Authority (plus any applicable VAT):
     1. The actual cost of delivery (by the Authority or a third party) up to a maximum of £100 per delivery;
     2. £250 to cover compounding and administration of medicines;
     3. £100 to cover the Authority’s incidental costs and expenses and any staff time; and
     4. 20% of the price (excluding VAT) paid by the Authority to any third party for the medicines dispensed.

**Schedule 2**

**General Terms and Conditions**

|  |
| --- |
| **Contents** |
| 1. Supply of Goods and the provision of Services |
| 2. Delivery of the Goods and passing of risk in and ownership of the Goods |
| 3. Inspection and recall of the Goods |
| 4. Operation of the Services |
| 5. Staff and Lifescience Industry Accredited Credentialing Register |
| 6. Business continuity |
| 7. The Authority’s obligations |
| 8. Contract management |
| 9. Price and payment |
| 10. Warranties |
| 11. Intellectual property |
| 12. Indemnity |
| 13. Limitation of liability |
| 14. Insurance |
| 15. Term and termination |
| 16. Consequences of expiry or early termination of this Contract |
| 17. Staff information and the application of TUPE at the end of the Contract |
| 18. Packaging, identification, end of use and coding requirements |
| 19. Sustainable development |
| 20. Electronic product and services information |
| 21. Change management |
| 22. Dispute resolution |
| 23. Force majeure |
| 24. Records retention and right of audit |
| 25. Conflicts of interest and the prevention of fraud |
| 26. Equality and human rights |
| 27. Notice |
| 28. Assignment, novation and Sub-contracting |

|  |
| --- |
| 29. Prohibited Acts |
| 30. General |

1. **Supply of Goods and the provision of Services**
   1. The Supplier shall supply the Goods ordered by the Authority and provide the Services ordered by the Authority, as appropriate, to the Patients and/or the Authority under this Contract:
      1. promptly and in any event within any time limits as may be set out in this Contract;
      2. in accordance with all other provisions of this Contract;
      3. with reasonable skill and care and in accordance with the provisions of the Framework Agreement as applicable and/or the provisions of the Order Form;
      4. in accordance with any quality assurance standards as set out in the Specification and Tender Response Document;
      5. in accordance with the Law and with Guidance;
      6. in accordance with Good Industry Practice;
      7. in accordance with the Policies; and
      8. in a professional and courteous manner.

In complying with its obligations under this Contract, the Supplier shall, and shall procure that all Staff shall, act in accordance with the NHS values as set out in the NHS Constitution from time to time.

* 1. The Supplier shall comply with the Implementation Requirements (if any) in accordance with any timescales as may be set out in the Specification and Tender Response Document.
  2. The Supplier shall commence:
     1. supply of the Goods on the Commencement Date; and
     2. delivery of the Services on the Commencement Date.
  3. The Supplier acknowledges that there is no obligation on the Authority to purchase any Goods or Services from the Supplier except to the extent that the Authority has issued a Purchase Order for specific Goods and/or Services in accordance with Clause [8](#_bookmark10) of [Schedule 1](#_bookmark8) of these Call-off Terms and

Conditions and Annex A: (Homecare Medicines Services: Order Process) of the Specification and Tender Response Document.

* 1. The Supplier shall comply fully with its obligations set out in the Specification and Tender Response Document and/or Order Form (to include, without limitation, the KPIs and all obligations in relation to the quality, performance characteristics, supply, delivery, installation, administration, commissioning, maintenance and training in relation to the Goods and their use).
  2. Unless otherwise agreed by the Parties in writing, the Goods shall be new, consistent with any sample, and shall comply with any applicable specification set out in this Contract (to include, without limitation, the provisions of the Authority’s requirements set out in the Specification and Tender Response Document and the Supplier’s response to such requirements) and any applicable manufacturers’ specifications.
  3. The Supplier shall ensure that all relevant consents, authorisations, licences and accreditations:
     1. required to supply the Goods are in place prior to the delivery of any Goods to the Authority; and
     2. required to provide the Services are in place at the Actual Services Commencement Date and are maintained throughout the Term.
  4. If there are any incidents that in any way relate to or involve the use of the Goods by the Authority, the Supplier shall cooperate fully with the Authority in relation to the Authority’s application of the Policies on reporting and responding to all incidents, including serious incidents requiring investigation, and shall respond promptly to any reasonable and proportionate queries, questions and/or requests for information that the Authority may have in this context in relation to the Goods.
  5. If there are any quality, performance and/or safety related reports, notices, alerts or other communications issued by the Supplier or any regulatory or other body or entity (including, without limitation, the manufacturer of the Goods) in relation to the Goods, the Supplier shall promptly provide the Authority with a copy of any such reports, notices, alerts or other communications.
  6. Upon receipt of any such reports, notices, alerts or other communications pursuant to Clause [1.8](#_bookmark13) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions, the Authority shall be entitled to request further information from the Supplier and/or a meeting with the Supplier, and the Supplier shall cooperate fully with any such request.

## Delivery of the Goods and passing of risk and ownership in the Goods

* 1. The Supplier shall deliver the Goods in accordance with any delivery timescales, delivery dates and delivery instructions (to include, without limitation, as to delivery location and delivery times) set out in the Specification and Tender Response Document, the Order Form or as otherwise agreed with the Authority in writing.
  2. Delivery shall be completed when the Goods and Services have been provided to a Patient in accordance with this Contract. Given that the Services involve providing Patients with hospital prescribed medicines and delays in receiving and/or administering such medicines could result directly in adverse health effects for such Patients, if the Supplier fails to meet any delivery dates or any home visit times in circumstances where it has not either: (i) made alternative delivery and/or home visit arrangements with that Patient; or (ii) urgently notified the Authority of any actual or anticipated failure to either deliver, make a home visit or make alternative delivery and/or home visit arrangements with that Patient (so that any risk of a Patient running out of the medicines or not taking the medicines can be managed by the Authority), this shall be deemed a critical failure by the Supplier (“**Critical Service Failure**”).
  3. Unless otherwise set out in the Specification and Tender Response Document or agreed with the Authority in writing, the Supplier shall be responsible for carriage, insurance, transport, all relevant licences, all related costs, and all other costs associated with the delivery of the Goods to the delivery location.
  4. Unless otherwise set out in the Specification and Tender Response Document and without prejudice to the Authority’s other rights and remedies under this Contract, ownership and risk in any Goods shall remain with the Supplier up to the point such Goods are delivered and/or administered to Patients in accordance with this Contract, except that the Supplier shall remain responsible for any loss or damage to the Goods following delivery to a Patient to the extent that such loss or damage is due to a negligent act or omission or breach of this Contract by the Supplier and/or its Staff.
  5. All tools, equipment and materials of the Supplier required in the performance of the Supplier’s obligations under this Contract shall be and remain at the sole risk of the Supplier, whether or not they are situated at a delivery location.

## Inspection and recall of the Goods

* 1. As relevant and proportionate to the Goods in question and subject to reasonable written notice, the Supplier shall permit any person authorised by the Authority, to inspect the storage facilities used in the storage of the Goods at all reasonable times at the Supplier’s premises or at the premises of any Sub-contractor or agent of the Supplier in order to confirm that the Goods are being stored in accordance with Good Industry Practice and in compliance the

requirements of this Contract and/or that stock holding and quality assurance processes are in accordance with the requirements of this Contract.

* 1. Where the Supplier and/or the relevant manufacturer and/or the relevant distributor of the Goods is required by Law, Guidance, and/or Good Industry Practice to order a product recall (“**Requirement to Recall**”) in respect of the Goods, the Supplier shall comply with all relevant provisions of the Specification and Tender Response Document relevant to a recall and in any event shall:
     1. promptly (taking into consideration the potential impact of the continued use of the Goods on Patients and the Authority as well as compliance by the Supplier with any regulatory requirements) notify the Authority in writing of the recall together with the circumstances giving rise to the recall;
     2. consult with the Authority as to the most efficient method of executing the recall of the Goods and use its reasonable endeavors to minimise the impact on the Authority and Patients of the recall; and
     3. indemnify and keep the Authority indemnified against any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings suffered or incurred by the Authority as a result of such Requirement to Recall.

## Operation of the Services

* 1. The Services shall be provided at such premises and at such locations within those premises, as may be set out in the Specification and Tender Response Document (to include, without limitation, at the homes of Patients) or as otherwise agreed by the Parties in writing (“**Premises and Locations**”).
  2. Subject to the Supplier and its Staff complying with all relevant Policies applicable to such Premises and Locations, the Authority shall use its reasonable endeavours to procure that Patients grant access to the Supplier and its Staff to such Premises and Locations to enable the Supplier to provide the Services.
  3. Unless otherwise set out in the Specification and Tender Response Document or otherwise agreed by the Parties in writing, any equipment or other items provided by the Authority for use by the Supplier and/or for loan to a Patient in connection with the Services:
     1. shall be provided at the Authority’s sole discretion;
     2. shall be inspected by the Supplier in order that the Supplier can confirm to its reasonable satisfaction that such equipment and/or

item is fit for its intended use and shall not be used by the Supplier until it has satisfied itself of this;

* + 1. must be returned to the Authority within any agreed timescales for such return or otherwise upon the request of the Authority; and
    2. shall be used by the Supplier at the Supplier’s risk and the Supplier shall upon written request by the Authority reimburse the Authority for any loss or damage relating to such equipment or other items caused by the Supplier (fair wear and tear exempted).

For the avoidance of doubt, any equipment or other items provided by the Authority for loan to Patients shall be repaired or replaced by the Authority at its expense to the extent that the loss or damage relating to such equipment is not caused by the Supplier but by a Patient.

* 1. If the Services, or any part of them, are regulated by any regulatory body, the Supplier shall ensure that at the Actual Services Commencement Date it has in place all relevant registrations and shall maintain such registrations during the Term. The Supplier shall notify the Authority forthwith in writing of any changes to such registration or any other matter relating to its registration that would affect the delivery or the quality of Services.
  2. The Supplier shall notify the Authority forthwith in writing:
     1. of any pending inspection of the Services, or any part of them, by a regulatory body immediately upon the Supplier becoming aware of such inspection; and
     2. of any failure of the Services, or any part of them, to meet the quality standards required by a regulatory body, promptly and in any event within two (2) Business Days of the Supplier becoming aware of any such failure. This shall include without limitation any informal feedback received during or following an inspection raising concerns of any nature regarding the provision of the Services.
  3. Following any inspection of the Services, or any part of them, by a regulatory body, the Supplier shall provide the Authority with a copy of any report or other communication published or provided by the relevant regulatory body in relation to the provision of the Services.
  4. Upon receipt of notice pursuant to Clause [4.8](#_bookmark18) of this [Schedule 2](#_bookmark12) of these Call- off Terms and Conditions or any report or communication pursuant to Clause

[4.9](#_bookmark19) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions, the Authority shall be entitled to request further information from the Supplier and/or a meeting with the Supplier, and the Supplier shall cooperate fully with any such request.

* 1. Where applicable, the Supplier shall implement and comply with the Policies on reporting and responding to all incidents and accidents, including serious incidents requiring investigation, shall complete the Authority’s incident and accident forms in accordance with the Policies and provide reasonable support and information as requested by the Authority to help the Authority deal with any incident or accident relevant to the Services. The Supplier shall ensure that its Contract Manager informs the Authority’s Contract Manager in writing forthwith upon (a) becoming aware that any serious incidents requiring investigation and/or notifiable accidents have occurred; or (b) the Supplier’s Contract Manager having reasonable cause to believe any serious incidents and/or notifiable accidents requiring investigation have occurred. The Supplier shall ensure that its Contract Manager informs the Authority’s Contract Manager in writing within forty eight (48) hours of all other incidents and/or accidents that have or may have an impact on the Services.
  2. The Supplier shall, as reasonably required by the Authority, cooperate with any other service providers to the Authority and/or any other third parties as may be relevant in the provision of the Services.
  3. To the extent relevant to the Services, the Supplier shall have in place and operate a complaints procedure which complies with the requirements of the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009.
  4. Complaints received by the Supplier from or on behalf Patients arising out of or in connection with the provision of the Services shall be managed and resolved in accordance with the relevant provisions of the Specification and Tender Response Document and in line with any relevant guidance or instructions notified in writing to the Supplier by the Authority from time to time.
  5. Should the Authority be of the view, acting reasonably, that the Supplier is unable to provide the Goods and/or Services in compliance with this Contract, then, without prejudice to the Authority’s rights and remedies under this Contract, the Authority shall be entitled to step-in (either itself or using a third party supplier) to provide the Goods and/or Services in order to ensure Patient safety.
  6. The Supplier shall be relieved from its obligations under this Contract to provide the Services to the extent that it is prevented from complying with any such obligations due to any acts, omissions or defaults of the Authority. To qualify for such relief, the Supplier must notify the Authority promptly (and in any event within five (5) Business Days) in writing of the occurrence of such act, omission, or default of the Authority together with the potential impact on the Supplier’s obligations.

## Staff and Lifescience Industry Accredited Credentialing Register

* 1. Subject to the requirements of this Contract and any Law, the Supplier shall be entirely responsible for the employment and conditions of service of Staff. The Supplier shall ensure that such conditions of employment are consistent with its obligations under this Contract.
  2. The Supplier will employ sufficient Staff to ensure that it complies with its obligations under this Contract. This will include, but not be limited to, the Supplier providing a sufficient reserve of trained and competent Staff to supply the Goods and/or provide the Services during Staff holidays or absence.
  3. The Supplier shall use reasonable endeavours to ensure the continuity of all Staff in the provision of the Services and, where any member of Staff is designated as key to the provision of the Services as set out in the Specification and Tender Response Document, the Order Form or as otherwise agreed between the Parties in writing, any redeployment and/or replacement of such member of Staff by the Supplier shall be subject to the prior written approval of the Authority, such approval not to be unreasonably withheld or delayed.
  4. The Supplier shall ensure that all Staff are aware of, and at all times comply with, the Policies.
  5. The Supplier shall:
     1. employ only those Staff who are careful, skilled and experienced in the duties required of them;
     2. ensure that every member of Staff is properly and sufficiently trained and instructed;
     3. ensure all Staff have the qualifications to carry out their duties and are covered by the Supplier’s insurance arrangements;
     4. maintain throughout the Term all appropriate licences and registrations with any relevant bodies (at the Supplier’s expense) in respect of the Staff;
     5. ensure all Staff comply with such registration, continuing professional development and training requirements or recommendations appropriate to their role including those from time to time issued by the Department of Health or any relevant regulatory body or any industry body in relation to such Staff; and
     6. comply with the Authority’s staff vetting procedures and other staff protocols, as may be relevant to this Contract and which are notified to the Supplier by the Authority in writing.
  6. The Supplier shall not deploy in the provision of the Services any person who has suffered from, has signs of, is under treatment for, or who is suffering from any medical condition which is known to, or does potentially, place the health and safety of the Authority’s staff, patients, Patients or visitors at risk unless otherwise agreed in writing with the Authority.
  7. The Supplier shall ensure that all potential Staff or persons performing any of the Services during the Term who may reasonably be expected in the course of performing any of the Services under this Contract to have access to or come into contact with children or other vulnerable persons and/or have access to or come into contact with persons receiving health care services:
     1. are questioned concerning their Convictions; and
     2. obtain appropriate disclosures from the Disclosure and Barring Service (or other appropriate body) as required by Law and/or the Policies before the Supplier engages the potential staff or persons in the provision of the Services.
  8. The Supplier shall take all necessary steps to ensure that such potential staff or persons obtain standard and enhanced disclosures from the Disclosure and Barring Service (or other appropriate body) and shall ensure all such disclosures are kept up to date. The obtaining of such disclosures shall be at the Supplier’s cost and expense.
  9. The Supplier shall ensure that no person is employed or otherwise engaged in the provision of the Services without the Authority’s prior written consent if:
     1. the person has disclosed any Convictions upon being questioned about their Convictions in accordance with Clause [5.7.1](#_bookmark21) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions of these Call-off Terms and Conditions;
     2. the person is found to have any Convictions following receipt of standard and/or enhanced disclosures from the Disclosure and Barring Service (or other appropriate body) in accordance with Clause [5.7.2](#_bookmark22) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions; or
     3. the person fails to obtain standard and/or enhanced disclosures from the Disclosure and Barring Service (or other appropriate body) upon request by the Supplier in accordance with Clause [5.7.2](#_bookmark22) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions.
  10. In addition to the requirements of Clause [5.7](#_bookmark20) to Clause [5.9](#_bookmark23) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions, where the Services are or include regulated activities as defined by the Safeguarding Vulnerable Groups Act 2006 the Supplier:
      1. warrants that it shall comply with all requirements placed on it by the Safeguarding Vulnerable Groups Act 2006;
      2. warrants that at all times it has and will have no reason to believe that any member of Staff is barred in accordance with the Safeguarding Vulnerable Groups Act 2006; and
      3. shall ensure that no person is employed or otherwise engaged in the provision of the Services if that person is barred from carrying out, or whose previous conduct or records indicate that they would not be suitable to carry out, any regulated activities as defined by the Safeguarding Vulnerable Groups Act 2006 or may present a risk to patients, Patients or any other person.
  11. The Supplier shall ensure that the Authority is kept advised at all times of any member of Staff who, subsequent to their commencement of employment as a member of Staff receives a Conviction or whose previous Convictions become known to the Supplier or whose conduct or records indicate that they are not suitable to carry out any regulated activities as defined by the Safeguarding Vulnerable Groups Act 2006 or may present a risk to patients, Patients or any other person. The Supplier shall only be entitled to continue to engage or employ such member of Staff with the Authority’s written consent and with such safeguards being put in place as the Authority may reasonably request. Should the Authority withhold consent the Supplier shall remove such member of Staff from the provision of the Services forthwith.
  12. The Supplier shall immediately provide to the Authority any information that the Authority reasonably requests to enable the Authority to satisfy itself that the obligations set out in Clause [5.7](#_bookmark20) to Clause [5.11](#_bookmark24) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions have been met.
  13. The Authority may at any time request that the Supplier remove and replace any member of Staff from the provision of the Services, provided always that the Authority will act reasonably in making such a request. Prior to making any such request the Authority shall raise with the Supplier the Authority’s concerns regarding the member of Staff in question with the aim of seeking a mutually agreeable resolution. The Authority shall be under no obligation to have such prior discussion should the Authority have concerns regarding patient or Patient safety.
  14. Unless otherwise confirmed by the Authority in writing, the Supplier shall ensure full compliance (to include with any implementation timelines) with any Guidance issued by the Department of Health and Social Care and/or any requirements and/or Policies issued by the Authority (to include as may be set out as part of any procurement documents leading to the award of this Contract) in relation to the adoption of, and compliance with, any scheme or schemes to verify the credentials of Supplier representatives that visit NHS

premises (to include use of the Lifescience Industry Accredited Credentialing Register). Once compliance with any notified implementation timelines has been achieved by the Supplier, the Supplier shall, during the Term, maintain the required level of compliance in accordance with any such Guidance, requirements and Polices.

## Business continuity

* 1. The Supplier shall also ensure that its Business Continuity Plan complies on an ongoing basis with any specific business continuity requirements, as may be set out in the Specification and Tender Response Document.
  2. Throughout the Term, the Supplier will ensure its Business Continuity Plan provides for continuity during a Business Continuity Event. The Supplier confirms and agrees such Business Continuity Plan details and will continue to detail robust arrangements that are reasonable and proportionate to:
     1. the criticality of this Contract to the Authority; and
     2. the size and scope of the Supplier’s business operations,

regarding continuity of the supply of the Goods and the provision of the Services during and following a Business Continuity Event.

* 1. The Supplier shall test its Business Continuity Plan at reasonable intervals, and in any event no less than once every twelve (12) months or such other period as may be agreed between the Parties taking into account the criticality of this Contract to the Authority and the size and scope of the Supplier’s business operations. The Supplier shall promptly provide to the Authority, at the Authority’s written request, copies of its Business Continuity Plan, reasonable and proportionate documentary evidence that the Supplier tests its Business Continuity Plan in accordance with the requirements of this Clause [6.3](#_bookmark26) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions and reasonable and proportionate information regarding the outcome of such tests. The Supplier shall provide to the Authority a copy of any updated or revised Business Continuity Plan within fourteen (14) Business Days of any material update or revision to the Business Continuity Plan.
  2. The Authority may suggest reasonable and proportionate amendments to the Supplier regarding the Business Continuity Plan at any time. Where the Supplier, acting reasonably, deems such suggestions made by the Authority to be relevant and appropriate, the Supplier will incorporate into the Business Continuity Plan all such suggestions made by the Authority in respect of such Business Continuity Plan. Should the Supplier not incorporate any suggestion made by the Authority into such Business Continuity Plan it will explain the reasons for not doing so to the Authority.
  3. Should a Business Continuity Event occur at any time, the Supplier shall implement and comply with its Business Continuity Plan and provide regular written reports to the Authority on such implementation.
  4. During and following a Business Continuity Event, the Supplier shall use reasonable endeavours to continue to supply the Goods and provide the Services in accordance with this Contract.

## The Authority’s obligations

* 1. Subject to the Supplier supplying the Goods and providing the Services in accordance with this Contract, the Authority will pay the Supplier for the Goods and/or Services in accordance with Clause [9](#_bookmark30) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions.
  2. The Authority shall, as appropriate, provide copies of or give the Supplier access to such of the Policies that are relevant to the supply of the Goods and the provision of the Services.
  3. The Authority shall comply with the Authority’s Obligations, as may be referred to in the Specification and Tender Response Document.
  4. The Authority shall provide the Supplier with any reasonable and proportionate co-operation necessary to enable the Supplier to comply with its obligations under this Contract. The Supplier shall at all times provide reasonable advance written notification to the Authority of any such cooperation necessary in circumstances where such cooperation will require the Authority to plan for and/or allocate specific resources in order to provide such cooperation.

## Contract management

* 1. Each Party shall appoint and retain a Contract Manager who shall be the primary point of contact for the other Party in relation to matters arising from this Contract. Should the Contract Manager be replaced, the Party replacing the Contract Manager shall promptly inform the other Party in writing of the name and contact details for the new Contract Manager. Any Contract Manager appointed shall be of sufficient seniority and experience to be able to make decisions on the day to day operation of the Contract. The Supplier confirms and agrees that it will be expected to work closely and cooperate fully with the Authority’s Contract Manager.
  2. Each Party shall ensure that its representatives (to include, without limitation, its Contract Manager) shall attend review meetings on a regular basis to review the performance of the Supplier under this Contract and to discuss matters arising generally under this Contract. Each Party shall ensure that those attending such meetings have the authority to make decisions regarding the day to day operation of the Contract. Review meetings shall take place at the frequency specified in the Specification and Tender Response Document.

Should the Specification and Tender Response Document not state the frequency, then the first such meeting shall take place on a date to be agreed on or around the end of the first month after the Commencement Date. Subsequent meetings shall take place at monthly intervals or as may otherwise be agreed in writing between the Parties.

* 1. Two weeks prior to each review meeting (or at such time and frequency as may be specified in the Specification and Tender Response Document) the Supplier shall provide a written contract management report to the Authority regarding the supply of the Goods, the provision of the Services and the operation of this Contract. Unless otherwise agreed by the Parties in writing, such contract management report shall contain:
     1. details of the performance of the Supplier when assessed in accordance with the KPIs since the last such performance report;
     2. details of any complaints by the Authority regarding the supply of Goods or provision of Services and any complaints from or on behalf of patients or other Patients, their nature and the way in which the Supplier has responded to such complaints since the last review meeting written report;
     3. the information specified in the Specification and Tender Response Document;
     4. a status report in relation to the implementation of any current Remedial Proposals by either Party; and
     5. such other information as reasonably required by the Authority.
  2. Unless specified otherwise in the Specification and Tender Response Document, the Authority shall take minutes of each review meeting and shall circulate draft minutes to the Supplier within a reasonable time following such review meeting. The Supplier shall inform the Authority in writing of any suggested amendments to the minutes within five (5) Business Days of receipt of the draft minutes. If the Supplier does not respond to the Authority within such five (5) Business Days the minutes will be deemed to be approved. Where there are any differences in interpretation of the minutes, the Parties will use their reasonable endeavours to reach agreement. If agreement cannot be reached the matter shall be referred to, and resolved in accordance with, the Dispute Resolution Procedure.
  3. The Supplier shall provide such management information and notifications as set out in the Specification and Tender Response Document in accordance with any specified timescales set out in such Specification and Tender Response Document and such further management information and notifications as the Authority may request from time to time within seven (7) Business Days of the date of the request. The Supplier shall supply the management information to the Authority in such form as may be specified by

the Authority and, where requested to do so, the Supplier shall also provide such management information to another Contracting Authority, whose role it is to: (a) analyse such management information in accordance with UK government policy (to include, without limitation, for the purposes of analysing public sector expenditure, planning future procurement activities, and monitoring and or planning healthcare); or (b) to manage the Framework Agreement with the Supplier (“**Third Party Body”**). The Supplier confirms and agrees that the Authority may itself provide the Third Party Body with management information relating to the Goods and Services purchased, any payments made under this Contract, and any other information relevant to the operation of this Contract.

* 1. Upon receipt of management information supplied by the Supplier to the Authority and/or the Third Party Body, or by the Authority to the Third Party Body, the Parties hereby consent to the Third Party Body and the Authority:
     1. storing and analysing the management information and producing statistics; and
     2. sharing the management information or any statistics produced using the management information with any other Contracting Authority.
  2. If the Third Party Body and/or the Authority shares the management information or any other information provided under Clause [8.6](#_bookmark29) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions, any Contracting Authority receiving the management information shall, where such management information is subject to obligations of confidence under this Contract and such management information is provided direct by the Authority to such Contracting Authority, be informed of the confidential nature of that information by the Authority and shall be requested by the Authority not to disclose it to any body that is not a Contracting Authority (unless required to do so by Law).
  3. The Authority may make changes to the type of management information which the Supplier is required to supply and shall give the Supplier at least one (1) month’s written notice of any changes.

## Price and payment

* 1. The Contract Price shall be calculated in accordance with the provisions of the Framework Agreement, as confirmed in the Order Form.
  2. Unless otherwise stated in the Framework Agreement and/or Order Form, the Contract Price:
     1. shall remain fixed during the Term; and
     2. in respect of the Goods, is the entire price payable by the Authority to the Supplier in respect of the provision of the Goods and includes, without limitation:
        1. packaging, packing materials, addressing, labelling, loading, delivery to and unloading at the delivery location, the costs of any import or export licences, all appropriate taxes (excluding VAT), duties and tariffs, any expenses arising from import and export administration, any installation costs and associated works, the costs of all associated documentation and information supplied or made accessible to the Authority in any media, and any training in relation to the use, storage, handling or operation of the Goods;
        2. any royalties, licence fees or similar expenses in respect of the making, use or exercise by the Supplier of any Intellectual Property Rights for the purposes of performing this Contract, and any licence rights granted to the Authority in accordance with Clause [11](#_bookmark43) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions; and
        3. costs and expenses in relation to supplies and materials used by the Supplier or any third party in the manufacture of the Goods, and any other costs incurred by the Supplier in association with the manufacture, supply or administration of the Goods; and
     3. in respect of the Services:
        1. shall be payable from the Actual Services Commencement Date; and
        2. is the entire price payable by the Authority to the Supplier in respect of the Services and includes, without limitation, any delivery and administration of the Goods, any royalties, licence fees, supplies and all consumables used by the Supplier, travel costs, accommodation expenses and the cost of Staff and all appropriate taxes (excluding VAT), duties and tariffs and any expenses arising from import and export administration.
  3. The invoice requirements and payment profile shall be as set out in the Specification and Tender Response Document. Each invoice shall contain such information and be addressed to such individual as the Authority may inform the Supplier from time to time.
  4. The Contract Price is exclusive of VAT, which, if properly chargeable, the Authority shall pay at the prevailing rate subject to receipt from the Supplier of

a valid and accurate VAT invoice. Such VAT invoices shall show the VAT calculations as a separate line item.

* 1. Where the Contract Price is or may become subject to any pricing requirements of any voluntary and/or statutory pricing regulation schemes, the Parties shall comply with such pricing requirements as required by Law from time to time and specifically as required by the statutory pricing regulation scheme (and any future regulation) or to the extent applicable to the Supplier from time to time as an industry member of a voluntary scheme, including any reductions in price by reason of the application of such schemes.
  2. The standard procedures relating to the submission, verification, agreement and correction of invoices (and the associated timescales) is set out at Annex B (Homecare Medicines Service: Invoicing Process) of the Specification and Tender Response Document.
  3. All invoicing queries and Disputes shall be dealt with in accordance with the relevant process for dealing with such queries as set out at Annex B (Homecare Medicines Service: Invoicing Process) of the Specification and Tender Response Document. For the avoidance of doubt, the Authority shall not be in breach of any of its payment obligations under this Contract in relation to any queried or disputed invoice sums unless the process for dealing with such queries and Disputes as set out at Annex B (Homecare Medicines Service: Invoicing Process) of the Specification and Tender Response Document has been followed and it has been resolved / determined that the queried or disputed invoice amount is properly due to the Supplier and the Authority has then failed to pay such sum within a reasonable period following such resolution / determination.
  4. The Supplier shall pay to the Authority any service credits and/or other deductions relating to a reduction in the Contract Price and/or any other sums payable to the Authority that may become due in accordance with the provisions of this Contract. For the avoidance of doubt, the Authority may invoice the Supplier for such deductions or sums at any time in the event that they have not, where relevant, automatically been credited to the Authority in accordance with the provisions of the Contract. Such invoice shall be paid by the Supplier within thirty (30) days of the date of such invoice.
  5. The Authority reserves the right to set-off:
     1. any monies due to the Supplier from the Authority as against any monies due to the Authority from the Supplier under this Contract; and
     2. any monies due to the Authority from the Supplier as against any monies due to the Supplier from the Authority under this Contract.
  6. Where the Authority is entitled to receive any sums (including without limitation any costs, charges or expenses) from the Supplier under this

Contract, the Authority may invoice the Supplier for such sums. Such invoices shall be paid by the Supplier within 30 days of the date of such invoice.

* 1. If a Party fails to pay any undisputed sum properly due to the other Party under this Contract, the Party due such sum shall have the right to charge interest on the overdue amount at the applicable rate under the Late Payment of Commercial Debts (Interest) Act 1998, accruing on a daily basis from the due date up to the date of actual payment, whether before or after judgment.

## Warranties

* 1. The Supplier warrants and undertakes that:
     1. it shall comply with the Framework Agreement and the Goods shall be suitable for the purposes and/or treatments as referred to in the Specification and Tender Response Document, be of satisfactory quality, fit for their intended purpose and shall comply with the standards and requirements set out in this Contract;
     2. unless otherwise confirmed by the Authority in writing (to include, without limitation, as part of the Specification and Tender Response Document), it will ensure that the Goods and any products purchased by the Supplier partially or wholly for the purpose of providing the Services comply with requirements five (5) to eight (8), as set out in Annex 1 of the Cabinet Office Procurement Policy Note – Implementing Article 6 of the Energy Efficiency Directive (Action Note 07/14 3rd June 2014), to the extent such requirements apply to the relevant Goods;
     3. it shall ensure that prior to actual delivery to the Authority the Goods are manufactured, stored and/or distributed using reasonable skill and care and in accordance with Good Industry Practice;
     4. without prejudice to the generality of the warranty at [10.1.3](#_bookmark33) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions, it shall ensure that, the Goods are manufactured, stored and/or distributed in accordance with good manufacturing practice and/or good warehousing practice and/or good distribution practice, as may be defined under any Law, Guidance and Good Industry Practice relevant to the Goods, and in accordance with any specific instructions of the manufacturer of the Goods;
     5. it shall ensure that all facilities used in the manufacture, storage and distribution of the Goods are kept in a state and condition necessary to enable the Supplier to comply with its obligations in accordance with this Contract;
     6. it has, or the manufacturer of the Goods has, manufacturing and warehousing capacity sufficient to comply with its obligations under this Contract;
     7. it will ensure sufficient stock levels to comply with its obligations under this Contract;
     8. it shall ensure that the transport and delivery of the Goods mean that they are delivered in good and useable condition;
     9. where the Goods are required to be stored at a certain temperature, it shall provide, or shall procure the provision of, complete and accurate temperature records for each delivery of the Goods during the period of transport and/or storage of the Goods from the point of manufacture to the point of delivery to the Authority;
     10. where there is any instruction information, including without limitation patient information leaflets, that accompany the Goods, it shall provide a sufficient number of copies to the Authority and provide updated copies should the instruction information change at any time during the Term;
     11. all Goods delivered to the Authority shall comply with any shelf life requirements set out in the Specification and Tender Response Document;
     12. it shall not make any significant changes to the Goods without the prior written consent of the Authority, such consent not to be unreasonably withheld or delayed;
     13. any equipment it uses in the manufacture, delivery, or administration of the Goods shall comply with all relevant Law and Guidance, be fit for its intended purpose and maintained fully in accordance with the manufacturer’s specification;
     14. it has and shall as relevant maintain all rights, consents, authorisations, licences and accreditations required to supply the Goods;
     15. it has, and shall ensure its Staff shall have, and shall maintain throughout the Term, all appropriate licences and registrations with the relevant bodies to fulfil its obligations under this Contract;
     16. it has all rights, consents, authorisations, licences and accreditations required to provide the Services and shall maintain such consents, authorisations, licences and accreditations throughout the Term;
     17. it has and shall maintain a properly documented system of quality controls and processes covering all aspects of its obligations under

this Contract (to include, without limitation, any such quality controls, processes or policies as may be set out in the Specification and Tender Response Document) and/or under Law and/or Guidance and shall at all times comply with, and shall procure that its Staff comply with, such quality controls, processes and policies;

* + 1. it shall not make any significant changes to its system of quality controls and processes in relation to the Goods and/or Services without notifying the Authority in writing at least twenty one (21) days in advance of such change (such notice to include the details of the consequences which follow such change being implemented);
    2. where any act of the Supplier requires the notification to and/or approval by any regulatory or other competent body in accordance with any Law and Guidance, the Supplier shall comply fully with such notification and/or approval requirements;
    3. receipt of the Goods and/or Services by or on behalf of the Authority and use of the Goods and/or deliverables or of any other item or information supplied or made available to the Authority will not infringe any third party rights, to include without limitation any Intellectual Property Rights;
    4. it will comply with all Law, Guidance, Policies and the Supplier Code of Conduct in so far as is relevant to the supply of the Goods and/or the provision of the Services;
    5. it will provide the Services using reasonable skill and care and in accordance with Good Industry Practice and shall fulfil all requirements of this Contract using appropriately skilled, trained and experienced staff;
    6. unless otherwise set out in the Specification and Tender Response Document and/or as otherwise agreed in writing by the Parties, it has and/or shall procure all resources, equipment, consumables and other items and facilities required to provide the Services;
    7. without limitation to the generality of Clause [10.1.21](#_bookmark34) of this [Schedule](#_bookmark12)

[2](#_bookmark12) of these Call-off Terms and Conditions, it shall comply with all health and safety processes, requirements safeguards, controls, and training obligations in accordance with its own operational procedures, Law, Guidance, Policies, Good Industry Practice, the requirements of the Specification and Tender Response Document and any notices or instructions given to the Supplier by the Authority and/or any competent body, as relevant to the supply of the Goods, the provision of the Services and the Supplier’s access to the Premises and Locations in accordance with this Contract;

* + 1. without prejudice to any specific notification requirements set out in this Contract, it will promptly notify the Authority of any health and safety hazard which has arisen, or the Supplier is aware may arise, in connection with the Goods and/or the performance of the Services and take such steps as are reasonably necessary to ensure the health and safety of persons likely to be affected by such hazards;
    2. any equipment it uses in the provision of the Services shall comply with all relevant Law and Guidance, be fit for its intended purpose and maintained fully in accordance with the manufacturer’s specification and shall remain the Supplier's risk and responsibility at all times;
    3. it shall use Good Industry Practice to ensure that any information and communications technology systems and/or related hardware and/or software it uses are free from corrupt data, viruses, worms and any other computer programs or code which might cause harm or disruption to the Authority's information and communications technology systems;
    4. it shall: (i) comply with all relevant Law and Guidance and shall use Good Industry Practice to ensure that there is no slavery or human trafficking in its supply chains; and (ii) notify the Authority immediately if it becomes aware of any actual or suspected incidents of slavery or human trafficking in its supply chains;
    5. it shall at all times conduct its business in a manner that is consistent with any anti-slavery Policy of the Authority and shall provide to the Authority any reports or other information that the Authority may request as evidence of the Supplier’s compliance with this Clause

[10.1.29](#_bookmark36) and/or as may be requested or otherwise required by the Authority in accordance with its anti-slavery Policy;

* + 1. will fully and promptly respond to all requests for information and/or requests for answers to questions regarding this Contract, the Goods, the provision of the Services, any complaints and any Disputes at the frequency, in the timeframes and in the format as requested by the Authority from time to time (acting reasonably);
    2. all information included within the Supplier’s responses to any documents issued by the Authority as part of the procurement relating to the award of this Contract (to include, without limitation, as referred to in the Specification and Tender Response Document and/or Order Form) and all accompanying materials is accurate it has the right and authority to enter into this Contract and that it has the capability and capacity to fulfil its obligations under this Contract;
    3. it is a properly constituted entity and it is fully empowered by the terms of its constitutional documents to enter into and to carry out its

obligations under this Contract and the documents referred to in this Contract;

* + 1. all necessary actions to authorise the execution of and performance of its obligations under this Contract have been taken before such execution;
    2. there are no pending or threatened actions or proceedings before any court or administrative agency which would materially adversely affect the financial condition, business or operations of the Supplier;
    3. there are no material agreements existing to which the Supplier is a party which prevent the Supplier from entering into or complying with this Contract;
    4. it has and will continue to have the capacity, funding and cash flow to meet all its obligations under this Contract; and
    5. it has satisfied itself as to the nature and extent of the risks assumed by it under this Contract and has gathered all information necessary to perform its obligations under this Contract and all other obligations assumed by it.
  1. Where any Relevant Activities relate to medical devices (as defined under any relevant Law and Guidance), medicinal products (as defined under any relevant Law and Guidance), products and services ancillary to medical devices and/or medicinal products or other Goods and/or Services that are subject to any requirements under Law and/or Guidance, the Supplier warrants and undertakes that it will comply with, and/or shall procure that any relevant third parties forming part of its supply chain shall comply with, such applicable Law and Guidance relating to such Relevant Activities in relation to such medical devices, medicinal products, products and services ancillary to medical devices and/or medicinal products and/or other Goods and/or Services that are subject to any requirements under Law and/or Guidance. In particular, but without limitation, the Supplier warrants that:
     1. at the point any Goods are supplied to the Authority and/or any Patient and/or are used by the Supplier in connection with the provision of the Services, that all such Goods shall, to the extent required by Law and Guidance in relation to the particular Goods, comply with all relevant authorisation, license, marking, labelling, registration, approval and documentation requirements as required under Law and Guidance relating to any Relevant Activities;
     2. without limitation to Clause [10.2.1](#_bookmark37) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions, at the point any Goods are supplied to the Authority and/or any Patient, all such Goods shall, to the extent required by Law and Guidance in relation to the particular Goods, have valid CE marking;
     3. without limitation to Clause [10.2.1](#_bookmark37) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions, at [the poi](#_bookmark37)nt any [Goods are](#_bookmark12) supplied to the Authority and/or any Patient, all such Goods shall, to the extent required by Law and Guidance in relation to the particular Goods, have a valid marketing authorisation covering the supply of the Goods to the Authority and/or Patients;
     4. at the point any Services are provided to the Authority and/or any Patient, all such Services shall, to the extent required by Law and Guidance, comply with any relevant authorisation, license, registration, approval and documentation requirements as required under Law and Guidance;
     5. it shall maintain, and no later than any due date when it would otherwise expire, obtain a renewal of, any authorisation, license, registration or approval (including without limitation CE marking and/or marketing authorisation) required in relation to the Goods and/or Services in accordance with Law and Guidance; and
     6. it shall, without limitation to the foregoing provisions of this Clause

10.2 of this Schedule 2 of these Call-off Terms and Conditions, upon written request from the Authority, make available to the Authority evidence of the grant of such required valid CE markings, valid marketing authorisations, valid licenses and evidence of any other markings, authorisations, registrations, labelling, approvals or documentation as required by Law and Guidance.

* 1. Without prejudice to any other right or remedy of the Authority, if the Supplier is in breach of Clause [10.2](#_bookmark38) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions, then:
     1. the Authority may upon written notice suspend the supply of Goods and/or provision of the Services until such breach is remedied by the Supplier;
     2. the Supplier shall, subject to Clause [13.2](#_bookmark51) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions, indemnify and keep the Authority indemnified against, any loss, damages, costs (including, without limitation, any extra costs incurred by the Authority purchasing replacement or alternative goods and/or services during any period of a suspension of the supply of the Goods and/or provision of the Services pursuant to Clause [10.3.1](#_bookmark39) of this [Schedule 2](#_bookmark12) of these Call- off Terms and Conditions), expenses (including without limitation legal costs and expenses), claims or proceedings suffered or incurred by the Authority as a result of such breach of Clause [10.2](#_bookmark38) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions and/or as a result of such suspension of the supply of Goods and/or provision of Services in accordance with Clause [10.3.1](#_bookmark39) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions; and
     3. within seven (7) days of a written request from the Authority, the Supplier shall, at the option and at the sole discretion of the Authority, provide a full refund, credit note or cancellation note to the Authority relating to the element of the Contract Price that relates to any Goods and/or Services breaching the requirements of Clause

[10.2](#_bookmark38) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions and/or which have been suspended by the Authority in accordance with Clause [10.3.1](#_bookmark39) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions.

* 1. The Supplier agrees to use reasonable endeavours to assign to the Authority upon request the benefit of any warranty, guarantee or similar right which it has against any third party manufacturer or supplier of the Goods in full or part.
  2. The Supplier warrants that all information, data and other records and documents required by the Authority as set out in the Specification and Tender Response Document shall be submitted to the Authority in the format and in accordance with any timescales set out in the Specification and Tender Response Document.
  3. Without prejudice to the generality of Clause [10.5](#_bookmark41) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions, the Supplier acknowledges that a failure by the Supplier to submit accurate invoices and other information on time to the Authority may result in the commissioner of health services, or other entity responsible for reimbursing costs to the Authority, delaying or failing to make relevant payments to the Authority. Accordingly, the Supplier warrants that it shall submit accurate invoices and other information on time to the Authority.
  4. The Supplier warrants and undertakes to the Authority that it shall comply with any eProcurement Guidance as it may apply to the Supplier and shall carry out all reasonable acts required of the Supplier to enable the Authority to comply with such eProcurement Guidance.
  5. The Supplier warrants and undertakes to the Authority that, as at the Commencement Date, it has notified the Authority in writing of any Occasions of Tax Non-Compliance or any litigation that it is involved in that is in connection with any Occasions of Tax Non Compliance. If, at any point during the Term, an Occasion of Tax Non-Compliance occurs, the Supplier shall:
     1. notify the Authority in writing of such fact within five (5) Business Days of its occurrence; and
     2. promptly provide to the Authority:
        1. details of the steps which the Supplier is taking to address the Occasion of Tax Non-Compliance and to prevent the same from recurring, together with any mitigating factors that it considers relevant; and
        2. such other information in relation to the Occasion of Tax Non-Compliance as the Authority may reasonably require.
  6. The Supplier further warrants and undertakes to the Authority that it will inform the Authority in writing immediately upon becoming aware that any of the warranties set out in Clause [10](#_bookmark31) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions have been breached or there is a risk that any warranties may be breached.
  7. Any warranties provided under this Contract are both independent and cumulative and may be enforced independently or collectively at the sole discretion of the enforcing Party.

## Intellectual property

* 1. Unless specified otherwise in the Specification and Tender Response Document, the Supplier hereby grants to the Authority, and/or shall procure that any relevant third party owner of such Intellectual Property Rights grants direct to the Authority, an irrevocable, royalty-free, non-exclusive licence of any Intellectual Property Rights required for the purposes of receiving and using, and to the extent necessary to receive and use, the Goods (to include any associated technical or other documentation and information supplied or made accessible to the Authority in any media) in accordance with this Contract.
  2. Unless specified otherwise in the Specification and Tender Response Document, the Supplier hereby grants to the Authority, for the life of the use by the Authority of any deliverables, material or any other output supplied to the Authority in any format as part of the Services, an irrevocable, royalty-free, non-exclusive licence to use, modify, adapt or enhance such items in the course of the Authority’s normal business operations. For the avoidance of doubt, unless specified otherwise in the Specification and Tender Response Document, the Authority shall have no rights to commercially exploit (e.g. by selling to third parties) any deliverables, matter or any other output supplied to the Authority in any format as part of the Services.

## Indemnity

* 1. The Supplier shall be liable to the Authority for, and shall indemnify and keep the Authority indemnified against, any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings in respect of:
     1. any injury or allegation of injury to any person, including injury resulting in death;
     2. any loss of or damage to property (whether real or personal);
     3. any breach of Clause [10.1.20](#_bookmark35) and/or Clause [11](#_bookmark43) of this [Schedule 2](#_bookmark12) of these Call-off Terms a[nd Co](#_bookmark35)nditions; and/or
     4. any failure by the Supplier to commence the delivery of the Services by the Services Commencement Date;

that arise or result from the Supplier’s negligent acts or omissions or breach of contract in connection with the performance of this Contract including the supply of Goods and provision of the Services, except to the extent that such loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings have been caused by any act or omission by, or on behalf of, or in accordance with the instructions of, the Authority.

* 1. Liability under Clauses [12.1.1](#_bookmark44), [12.1.3](#_bookmark46) and [17.13](#_bookmark75) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions and Clause [2.6](#_bookmark118) of [Schedule 3](#_bookmark114) of these Call-off Terms and Conditions shall be unlimited. Liability under Clauses [3.2.3](#_bookmark16), [10.3](#_bookmark40),

[12.1.2](#_bookmark45) and [12.1.4](#_bookmark47) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions shall be subject to the limitation of liability set out in Clause [13](#_bookmark49) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions.

* 1. In relation to all third party claims against the Authority, which are the subject of any indemnity given by the Supplier under this Contract, the Authority shall use its reasonable endeavours, upon a written request from the Supplier, to transfer the conduct of such claims to the Supplier unless restricted from doing so. Such restrictions may include, without limitation, any restrictions:
     1. relating to any legal, regulatory, governance, information governance, or confidentiality obligations on the Authority; and/or
     2. relating to the Authority’s membership of any indemnity and/or risk pooling arrangements.

Such transfer shall be subject to the Parties agreeing appropriate terms for such conduct of the third party claim by the Supplier (to include, without limitation, the right of the Authority to be informed and consulted on the ongoing conduct of the claim following such transfer and any reasonable cooperation required by the Supplier from the Authority).

1. **Limitation of liability**
   1. Nothing in this Contract shall exclude or restrict the liability of either Party:
      1. for death or personal injury resulting from its negligence;
      2. for fraud or fraudulent misrepresentation; or
      3. in any other circumstances where liability may not be limited or excluded under any applicable law.
   2. Subject to Clauses [12.2](#_bookmark48), [13.1](#_bookmark50), [13.3](#_bookmark52) and [13.5](#_bookmark53) of this [Schedule 2](#_bookmark12) of these Call- off Terms and Condi[tio](#_bookmark48)ns[, the](#_bookmark50) [total](#_bookmark52) liabil[ity of](#_bookmark53) each P[arty to the](#_bookmark12) other under or in connection with this Contract whether arising in contract, tort, negligence, breach of statutory duty or otherwise shall be limited in aggregate to the greater of: (a) five million GBP (£5,000,000); or (b) one hundred and twenty five percent (125%) of the total Contract Price paid or payable by the Authority to the Supplier for the Goods and Services.
   3. There shall be no right to claim losses, damages and/or other costs and expenses under or in connection with this Contract whether arising in contract (to include, without limitation, under any relevant indemnity), tort, negligence, breach of statutory duty or otherwise to the extent that any losses, damages and/or other costs and expenses claimed are in respect of loss of production, loss of business opportunity or are in respect of indirect loss of any nature suffered or alleged. For the avoidance of doubt, without limitation, the Parties agree that for the purposes of this Contract the following costs, expenses and/or loss of income shall be direct recoverable losses (to include under any relevant indemnity) provided such costs, expenses and/or loss of income are properly evidenced by the claiming Party:
      1. extra costs incurred purchasing replacement or alternative goods and/or services;
      2. costs incurred in relation to any product recall;
      3. costs associated with advising, screening, testing, treating, retreating or otherwise providing healthcare to patients;
      4. the costs of extra management time; and/or
      5. loss of income due to an inability to provide health care services,

in each case to the extent to which such costs, expenses and/or loss of income arise or result from the other Party’s breach of contract, negligent act or omission, breach of statutory duty, and/or other liability under or in connection with this Contract.

* 1. Each Party shall at all times take all reasonable steps to minimise and mitigate any loss for which that Party is entitled to bring a claim against the other pursuant to this Contract.
  2. If the total Contract Price paid or payable by the Authority to the Supplier over the Term:
     1. is less than or equal to one million pounds (£1,000,000), then the figure of five million pounds (£5,000,000) at Clause [13.2](#_bookmark51) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions shall be replaced with one million pounds (£1,000,000);
     2. is less than or equal to three million pounds (£3,000,000) but greater than one million pounds (£1,000,000), then the figure of five million pounds (£5,000,000) at Clause [13.2](#_bookmark51) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions shall be replaced with three million pounds (£3,000,000);
     3. is equal to, exceeds or will exceed ten million pounds (£10,000,000), but is less than fifty million pounds (£50,000,000), then the figure of five million pounds (£5,000,000) at Clause [13.2](#_bookmark51) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions of these Call-off Terms and Conditions shall be replaced with ten million pounds (£10,000,000) and the figure of one hundred and twenty five percent (125%) at Clause [13.2](#_bookmark51) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions shall be deemed to have been deleted and replaced with one hundred and fifteen percent (115%); and
     4. is equal to, exceeds or will exceed fifty million pounds (£50,000,000), then the figure of five million pounds (£5,000,000) at Clause [13.2](#_bookmark51) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions shall be replaced with fifty million pounds (£50,000,000) and the figure of one hundred and twenty five percent (125%) at Clause [13.2](#_bookmark51) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions shall be deemed to have been deleted and replaced with one hundred and five percent (105%).
  3. Clause [13](#_bookmark49) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions of these Call-off Terms and Conditions shall survive the expiry of or earlier termination of this Contract for any reason.

## Insurance

* 1. Subject to Clauses [14.2](#_bookmark56) and [14.3](#_bookmark57) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions and unless otherwise confirmed in writing by the Authority, as a minimum level of protection, the Supplier shall put in place and/or maintain in force at its own cost with a reputable commercial insurer, insurance arrangements in respect of employer’s liability, public liability, product liability and professional indemnity and clinical negligence in accordance with Good Industry Practice with the minimum cover per claim of the greater of five million pounds (£5,000,000) or any sum as required by Law unless otherwise agreed with the Authority in writing. These requirements shall not apply to the extent that the Supplier is a member and maintains membership of each of the indemnity schemes run by the NHS Litigation Authority.
  2. Without limitation to any insurance arrangements as required by Law, the Supplier shall put in place and/or maintain the different types and/or levels of indemnity arrangements specified in the Framework Agreement, if any.
  3. Provided that the Supplier maintains all indemnity arrangements required by Law, the Supplier may self insure in order to meet other relevant requirements

referred to at Clauses [14.1](#_bookmark55) and [14.2](#_bookmark56) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions on condition that such self insurance arrangements offer the appropriate levels of protection and are approved by the Authority in writing prior to the Commencement Date.

* 1. The amount of any indemnity cover and/or self insurance arrangements shall not relieve the Supplier of any liabilities under this Contract. It shall be the responsibility of the Supplier to determine the amount of indemnity and/or self insurance cover that will be adequate to enable it to satisfy its potential liabilities under this Contract. Accordingly, the Supplier shall be liable to make good any deficiency if the proceeds of any indemnity cover and/or self insurance arrangement is insufficient to cover the settlement of any claim.
  2. The Supplier warrants that it shall not take any action or fail to take any reasonable action or (in so far as it is reasonable and within its power) permit or allow others to take or fail to take any action, as a result of which its insurance cover may be rendered void, voidable, unenforceable, or be suspended or impaired in whole or in part, or which may otherwise render any sum paid out under such insurances repayable in whole or in part.
  3. The Supplier shall from time to time and in any event within five (5) Business Days of written demand provide documentary evidence to the Authority that insurance arrangements taken out by the Supplier pursuant to Clause [14](#_bookmark54) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions and the Key Provisions are fully maintained and that any premiums on them and/or contributions in respect of them (if any) are fully paid.
  4. Upon the expiry or earlier termination of this Contract, the Supplier shall ensure that any ongoing liability it has or may have arising out of this Contract shall continue to be the subject of appropriate indemnity arrangements for the period of twenty one (21) years from termination or expiry of this Contract or until such earlier date as that liability may reasonably be considered to have ceased to exist.

## Term and termination

* 1. This Contract shall commence on the Commencement Date and, unless terminated

earlier in accordance with the terms of this Contract or the general law, shall continue until the end of the Term.

* 1. The Authority:
     1. subject to Clause [15.2.2](#_bookmark59) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions, shall be entitled to extend the Term on one or more occasions by giving the Supplier written notice no less than three

(3) months prior to the date on which this Contract would otherwise

have expired, provided that the duration of this Contract shall be no longer than the total term referred to in the Key Provisions; or

* + 1. where the Term or any extension of the Term expires at a date the same as or after expiry of the Framework Agreement (including any extensions of the Framework Agreement in accordance with its terms), shall only be entitled to extend the Term with the prior written agreement of the Supplier, such agreement not to be unreasonably withheld or delayed.
  1. In the case of a breach of any of the terms of this Contract by either Party that is capable of remedy (including, without limitation any breach of any KPI and, subject to Clause [9.7](#_bookmark32) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions, any breach of any payment obligations under this Contract), the non-breaching Party may, without prejudice to its other rights and remedies under this Contract, issue a Breach Notice and shall allow the Party in breach the opportunity to remedy such breach in the first instance via a remedial proposal put forward by the Party in breach (“**Remedial Proposal**”) before exercising any right to terminate this Contract in accordance with Clause [15.4.1(ii)](#_bookmark61) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions. Such Remedial Proposal must be agreed with the non-breaching Party (such agreement not to be unreasonably withheld or delayed) and must be implemented by the Party in breach in accordance with the timescales referred to in the agreed Remedial Proposal. Once agreed, any changes to a Remedial Proposal must be approved by the Parties in writing. Any failure by the Party in breach to:
     1. put forward and agree a Remedial Proposal with the non-breaching Party in relation to the relevant default or breach within a period of ten (10) Business Days (or such other period as the non-breaching Party may agree in writing) from written notification of the relevant default or breach from the non-breaching Party;
     2. comply with such Remedial Proposal (including, without limitation, as to its timescales for implementation, which shall be thirty (30) days unless otherwise agreed between the Parties); and/or
     3. remedy the default or breach notwithstanding the implementation of such Remedial Proposal in accordance with the agreed timescales for implementation,

shall be deemed, for the purposes of Clause [15.4.1(ii)](#_bookmark61) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions, a material breach of this Contract by the Party in breach not remedied in accordance with an agreed Remedial Proposal.

* 1. Either Party may terminate this Contract by issuing a Termination Notice to the other Party if such other Party:
     1. commits a material breach of any of the terms of this Contract which is:
        1. not capable of remedy; or
        2. in the case of a breach capable of remedy, which is not remedied in accordance with a Remedial Proposal; or
     2. commits a material breach of this Contract in circumstances where it is served with a valid Breach Notice having already been served with at least two (2) previous valid Breach Notices within the last twelve (12) calendar month rolling period as a result of any previous material breaches of this Contract which are capable of remedy (whether or not the Party in breach has remedied the breach in accordance with a Remedial Proposal). The twelve (12) month rolling period is the twelve (12) months immediately preceding the date of the third Breach Notice.
  2. The Authority may terminate this Contract by issuing a Termination Notice to the Supplier:
     1. if a Critical Service Failure occurs;
     2. if the Supplier, or any third party guaranteeing the obligations of the Supplier under this Contract, ceases or threatens to cease carrying on its business; suspends making payments on any of its debts or announces an intention to do so; is, or is deemed for the purposes of any Law to be, unable to pay its debts as they fall due or insolvent; enters into or proposes any composition, assignment or arrangement with its creditors generally; takes any step or suffers any step to be taken in relation to its winding-up, dissolution, administration (whether out of court or otherwise) or reorganisation (by way of voluntary arrangement, scheme of arrangement or otherwise) otherwise than as part of, and exclusively for the purpose of, a bona fide reconstruction or amalgamation; has a liquidator, trustee in bankruptcy, judicial custodian, compulsory manager, receiver, administrative receiver, administrator or similar officer appointed (in each case, whether out of court or otherwise) in respect of it or any of its assets; has any security over any of its assets enforced; or any analogous procedure or step is taken in any jurisdiction;
     3. if the Supplier undergoes a change of control within the meaning of sections 450 and 451 of the Corporation Tax Act 2010 (other than for an intra-group change of control) without the prior written consent of

the Authority and the Authority shall be entitled to withhold such consent if, in the reasonable opinion of the Authority, the proposed change of control will have a material impact on the performance of this Contract or the reputation of the Authority;

* + 1. if the Supplier purports to assign, Sub-contract, novate, create a trust in or otherwise transfer or dispose of this Contract in breach of Clause [28.1](#_bookmark104) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions;
    2. pursuant to and in accordance Clauses [15.6](#_bookmark65), [23.8](#_bookmark97); [25.2](#_bookmark101); [25.4](#_bookmark102) and

[29.2](#_bookmark110) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions;

* + 1. if the warranty given by the Supplier pursuant to Clause [10.8](#_bookmark42) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions is materially untrue, the Supplier commits a material breach of its obligation to notify the Authority of any Occasion of Tax Non-Compliance as required by Clause [10.8](#_bookmark42) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions, or the Supplier fails to provide details of proposed mitigating factors as required by Clause [10.8](#_bookmark42) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions that in the reasonable opinion of the Authority are acceptable; or
    2. at any time at its convenience by giving at least three (3) months written notice.
  1. If the Authority, acting reasonably, has good cause to believe that there has been a material deterioration in the financial circumstances of the Supplier and/or any third party guaranteeing the obligations of the Supplier under this Contract and/or any material Sub-contractor of the Supplier when compared to any information provided to and/or assessed by the Authority as part of any procurement process or other due diligence leading to the award of this Contract to the Supplier or the entering into a Sub-contract by the Supplier, the following process shall apply:
     1. the Authority may (but shall not be obliged to) give notice to the Supplier requesting adequate financial or other security and/or assurances for due performance of its material obligations under this Contract on such reasonable and proportionate terms as the Authority may require within a reasonable time period as specified in such notice;
     2. a failure or refusal by the Supplier to provide the financial or other security and/or assurances requested in accordance with Clause

[15.6](#_bookmark65) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions in accordance with any reasonable timescales specified in any such notice issued by the Authority shall be deemed a breach of this Contract by the Supplier and shall be referred to and resolved in accordance with the Dispute Resolution Procedure; and

* + 1. a failure to resolve such breach in accordance with such Dispute Resolution Procedure by the end of the escalation stage of such process (as set out in Clause [22.4](#_bookmark88) of this [Schedule 2](#_bookmark12) of these Call- off Terms and Conditions) shall entitle, but shall not compel, the Authority to terminate this Contract in accordance with Clause [15.4.1(i)](#_bookmark62) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions.

In order that the Authority may act reasonably in exercising its discretion in accordance with Clause [15.6](#_bookmark65) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions, the Supplier shall provide the Authority with such reasonable and proportionate up-to-date financial or other information relating to the Supplier or any relevant third party entity upon request.

* 1. The Authority may terminate this Contract by issuing a Termination Notice to the Supplier where:
     1. the Contract has been substantially amended to the extent that the Public Contracts Regulations 2015 require a new procurement procedure;
     2. the Authority has become aware that the Supplier should have been excluded under Regulation 57(1) or (2) of the Public Contracts Regulations 2015 from the procurement procedure leading to the award of this Contract;
     3. the Contract should not have been awarded to the Supplier in view of a serious infringement of obligations under European law declared by the Court of Justice of the European Union under Article 258 of the Treaty on the Functioning of the EU; or
     4. there has been a failure by the Supplier and/or one of its Sub- contractors to comply with legal obligations in the fields of environmental, social or labour Law. Where the failure to comply with legal obligations in the fields of environmental, social or labour Law is a failure by one of the Supplier’s Sub-contractors, the Authority may request the replacement of such Sub-contractor and the Supplier shall comply with such request as an alternative to the Authority terminating this Contract under this Clause [15.7.4](#_bookmark66).
  2. If the Authority novates this Contract to any body that is not a Contracting Authority, from the effective date of such novation, the rights of the Authority to terminate this Contract in accordance with Clause [15.5.2](#_bookmark63) to Clause [15.5.4](#_bookmark64) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions shall be deemed mutual termination rights and the Supplier may terminate this Contract by issuing a Termination Notice to the entity assuming the position of the Authority if any of the circumstances referred to in such Clauses apply to the entity assuming the position of the Authority.

## Consequences of expiry or early termination of this Contract

* 1. Upon expiry or earlier termination of this Contract, the Authority agrees to pay the Supplier for:
     1. the Goods referred to in a Purchase Order which have been supplied by the Supplier in accordance with this Contract prior to the expiry or earlier termination of this Contract; and
     2. the Services referred to in a Purchase Order which have been completed by the Supplier in accordance with this Contract prior to expiry or earlier termination of this Contract.
  2. Immediately following expiry or earlier termination of this Contract the Parties shall comply with their respective obligations under the Specification and Tender Response Document that are expressed to apply upon the termination or earlier expiry of this Contract. Any Personal Data Processed by the Supplier on behalf of the Authority shall be returned to the Authority or destroyed in accordance with the relevant provisions of the Data Protection Protocol.
  3. The Supplier shall cooperate fully with the Authority or, as the case may be, any replacement supplier during any re-procurement and handover period prior to and following the expiry or earlier termination of this Contract. This cooperation shall extend to providing access to all information relevant to the operation of this Contract, as reasonably required by the Authority to achieve a fair and transparent re-procurement and/or an effective transition without disruption to routine operational requirements.
  4. The expiry or earlier termination of this Contract for whatever reason shall not affect any rights or obligations of either Party which accrued prior to such expiry or earlier termination.
  5. The expiry or earlier termination of this Contract shall not affect any obligations which expressly or by implication are intended to come into or continue in force on or after such expiry or earlier termination.
  6. The expiry or earlier termination of the Framework Agreement shall not affect this Contract. For the avoidance of doubt, any obligations set out in the Framework Agreement that form part of this Contract shall continue to apply for the purposes of this Contract notwithstanding any termination of the Framework Agreement.

## Staff information and the application of TUPE at the end of the Contract

* 1. Upon the day which is no greater than nine (9) months before the expiry of this Contract or as soon as the Supplier is aware of the proposed termination of the Contract, the Supplier shall, within twenty eight (28) days of receiving a written request from the Authority and to the extent permitted by Law, supply

to the Authority and keep updated all information required by the Authority as to the terms and conditions of employment and employment history of any Supplier Personnel (including all employee liability information identified in regulation 11 of TUPE) and the Supplier shall warrant such information is full, complete and accurate.

* 1. No later than twenty eight (28) days prior to the Subsequent Transfer Date, the Supplier shall or shall procure that any Sub-contractor shall provide a final list to the Successor and/or the Authority, as appropriate, containing the names of all the Subsequent Transferring Employees whom the Supplier or Sub-contractor expects will transfer to the Successor or the Authority and all employee liability information identified in regulation 11 of TUPE in relation to the Subsequent Transferring Employees.
  2. If the Supplier shall, in the reasonable opinion of the Authority, deliberately not comply with its obligations under Clauses [17.1](#_bookmark68) and [17.2](#_bookmark69) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions, the Authority may withhold payment under Clause [9](#_bookmark30) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions.
  3. The Supplier shall be liable to the Authority for, and shall indemnify and keep the Authority indemnified against, any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings that arise or result from any deficiency or inaccuracy in the information which the Supplier is required to provide under Clauses [17.1](#_bookmark68) and [17.2](#_bookmark69) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions.
  4. Subject to Clauses [17.6](#_bookmark71) and [17.7](#_bookmark72) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions, during the period of nine (9) months preceding the expiry of this Contract or after notice of termination of this Contract has been served by either Party, the Supplier shall not, and shall procure that any Sub-contractor shall not, without the prior written consent of the Authority, such consent not to be unreasonably withheld or delayed:
     1. make, propose or permit any material changes to the terms and conditions of employment or other arrangements of any of the Supplier Personnel;
     2. increase or seek to increase the emoluments (excluding cost of living increases awarded in the ordinary course of business) payable to any of the Supplier Personnel;
     3. replace any of the Supplier Personnel or increase the total number of employees providing the Services;
     4. deploy any person other than the Supplier Personnel to perform the Services;
     5. terminate or give notice to terminate the employment or arrangements of any of the Supplier Personnel;
     6. increase the proportion of working time spent on the Services by any of the Supplier Personnel; or
     7. introduce any new contractual term or customary practice concerning the making of any lump sum payment on the termination of employment of any of the Supplier Personnel.
  5. Clause [17.5](#_bookmark70) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions shall not prevent the Supplier or any Sub-contractor from taking any of the steps prohibited in that Clause in circumstances where the Supplier or Sub- contractor is required to take such a step pursuant to any changes in legislation or pursuant to a collective agreement in force at that time.
  6. Where the obligations on the Supplier under Clause [17](#_bookmark67) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions are subject to the Data Protection Legislation, the Supplier will, and shall procure that any Sub-contractor will, use its best endeavours to seek the consent of the Supplier Personnel to disclose any information covered under the Data Protection Legislation and utilise any other exemption or provision within the Data Protection Legislation which would allow such disclosure.
  7. Having as appropriate gained permission from any Sub-contractor, the Supplier hereby permits the Authority to disclose information about the Supplier Personnel to any Interested Party provided that the Authority informs the Interested Party in writing of the confidential nature of the information.
  8. The Parties agree that where a Successor or the Authority provides the Services or services which are fundamentally the same as the Services in the immediate or subsequent succession to the Supplier or Sub-contractor (in whole or in part) on expiry or early termination of this Contract (howsoever arising) TUPE, the Cabinet Office Statement and Fair Deal for Staff Pensions may apply in respect of the subsequent provision of the Services or services which are fundamentally the same as the Services. If TUPE, the Cabinet Office Statement and Fair Deal for Staff Pensions apply then Clause [17.11](#_bookmark73) to Clause [17.14](#_bookmark76) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions and (where relevant) the requirements of Clause 1.15 of Part D of Schedule 7 of the NHS Terms and Conditions for the Provision of Services (Contract Version) (January 2018) shall apply.
  9. If on the termination or at the end of the Contract TUPE does not apply, then all Employment Liabilities and any other liabilities in relation to the Supplier Personnel shall remain with the Supplier or Sub-contractor as appropriate. The Supplier will, and shall procure that any Sub-contractor shall, indemnify and keep indemnified the Authority in relation to any Employment Liabilities arising out of or in connection with any allegation or claim raised by any Supplier Personnel.
  10. In accordance with TUPE, and any other policy or arrangement applicable, the Supplier shall, and will procure that any Sub-contractor shall, comply with

its obligations to inform and consult with the appropriate representatives of any of its employees affected by the subsequent transfer of the Services or services which are fundamentally the same as the Services.

* 1. The Supplier will and shall procure that any Sub-contractor will on or before any Subsequent Transfer Date:
     1. pay all wages, salaries and other benefits of the Subsequent Transferring Employees and discharge all other financial obligations (including reimbursement of any expenses and any contributions to retirement benefit schemes) in respect of the period between the Transfer Date and the Subsequent Transfer Date;
     2. account to the proper authority for all PAYE, tax deductions and national insurance contributions payable in respect of the Subsequent Transferring Employees in the period between the Transfer Date and the Subsequent Transfer Date;
     3. pay any Successor or the Authority, as appropriate, the amount which would be payable to each of the Subsequent Transferring Employees in lieu of accrued but untaken holiday entitlement as at the Subsequent Transfer Date;
     4. pay any Successor or the Authority, as appropriate, the amount which fairly reflects the progress of each of the Subsequent Transferring Employees towards achieving any commission, bonus, profit share or other incentive payment payable after the Subsequent Transfer Date wholly or partly in respect of a period prior to the Subsequent Transfer Date; and
     5. subject to any legal requirement, provide to the Successor or the Authority, as appropriate, all personnel records relating to the Subsequent Transferring Employees including, without prejudice to the generality of the foregoing, all records relating to national insurance, PAYE and income tax. The Supplier shall for itself and any Sub-contractor warrant that such records are accurate and up to date.
  2. The Supplier will and shall procure that any Sub-contractor will indemnify and keep indemnified the Authority and/or a Successor in relation to any Employment Liabilities arising out of or in connection with any claim arising from:
     1. the Supplier’s or Sub-contractor’s failure to perform and discharge its obligations under Clause [17.12](#_bookmark74) of this [Schedule 2](#_bookmark12) of these Call- off Terms and Conditions;
     2. any act or omission by the Supplier or Sub-contractor in respect of the Subsequent Transferring Employees occurring on or before the Subsequent Transfer Date;
     3. any allegation or claim by any person who is not a Subsequent Transferring Employee but who alleges that their employment should transfer or has transferred to the Successor or the Authority, as appropriate;
     4. any emoluments payable to a person employed or engaged by the Supplier or Sub-contractor (including without limitation all wages, accrued holiday pay, bonuses, commissions, PAYE, national insurance contributions, pension contributions and other contributions) payable in respect of any period on or before the Subsequent Transfer Date;
     5. any allegation or claim by any of the Subsequent Transferring Employees on the grounds that the Successor or Authority, as appropriate, has failed to continue a benefit provided by the Supplier or Sub-contractor as a term of such Subsequent Transferring Employee’s contract as at the Subsequent Transfer Date where it was not reasonably practicable for the Successor or Authority, as appropriate, to provide an identical benefit but where the Successor or Authority, as appropriate, has provided (or offered to provide where such benefit is not accepted by the Subsequent Transferring Employee) an alternative benefit which, taken as a whole, is no less favourable to such Subsequent Transferring Employee; and
     6. any act or omission of the Supplier or any Sub-contractor in relation to its obligations under regulation 13 of TUPE, or in respect of an award of compensation under regulation 15 of TUPE except to the extent that the liability arises from the Successor’s or Authority’s failure to comply with regulation 13(4) of TUPE.
  3. The Supplier will, or shall procure that any Sub-contractor will, on request by the Authority provide a written and legally binding indemnity in the same terms as set out in Clause [17.13](#_bookmark75) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions to any Successor in relation to any Employment Liabilities arising up to and including the Subsequent Transfer Date.
  4. The Supplier will indemnify and keep indemnified the Authority and/or any Successor in respect of any Employment Liabilities arising from any act or omission of the Supplier or Sub-contractor in relation to any other Supplier Personnel who is not a Subsequent Transferring Employee arising during any period whether before, on or after the Subsequent Transfer Date.
  5. If any person who is not a Subsequent Transferring Employee claims or it is determined that their contract of employment has been transferred from the

Supplier or any Sub-contractor to the Authority or Successor pursuant to TUPE or claims that their employment would have so transferred had they not resigned, then:

* + 1. the Authority will, or shall procure that the Successor will, within seven (7) days of becoming aware of that fact, give notice in writing to the Supplier;
    2. the Supplier may offer (or may procure that a Sub-contractor may offer) employment to such person within twenty eight (28) days of the notification by the Authority or Successor;
    3. if such offer of employment is accepted, the Authority will, or shall procure that the Successor will, immediately release the person from their employment; and
    4. if after the period in Clause [17.16.2](#_bookmark77) of this [Schedule 2](#_bookmark12) of these Call- off Terms and Conditions has elapsed, no such offer of employment has been made or such offer has been made but not accepted, the Authority will, or shall procure that the Successor will (whichever is the provider of the Services or services of the same or similar nature to the Services), employ that person in accordance with its obligations and duties under TUPE and shall be responsible for all liabilities arising in respect of any such person after the Subsequent Transfer Date.

## Packaging, identification, end of use and coding requirements

* 1. The Supplier shall comply with all obligations imposed on it by Law relevant to the Goods in relation to packaging, identification, and obligations following end of use by the Authority.
  2. Unless otherwise specified in the Specification and Tender Response Document or otherwise agreed with the Authority in writing, the Goods shall be securely packed in trade packages of a type normally used by the Supplier for deliveries of the same or similar goods in the same quantities within the United Kingdom.
  3. The Supplier shall comply with any labelling requirements in respect of the Goods: (a) specified in the Specification and Tender Response Document; (b) agreed with the Authority in writing; and/or (c) required to comply with Law or Guidance.
  4. The Supplier shall ensure that all Goods that are required by Law or Guidance to bear any safety information, environmental information, any mark, tab, brand, label, serial numbers or other device indicating place of origin, inspection by any government or other body or standard of quality at the point such Goods are delivered shall comply with such requirements at the point of delivery. Without prejudice to the generality of the foregoing, the Supplier be

entitled to split packs of the Goods delivered to the Supplier and to repackage such Goods prior to delivery to Patients and/or the Authority provided that the repackaged Goods comply with any packaging, labelling, information and marking requirements as required by any Law or Guidance applicable to such repackaged Goods.

* 1. Unless otherwise set out in the Specification and Tender Response Document or agreed with the Authority in writing, the Supplier shall collect without charge any returnable containers and/or packaging.
  2. Unless otherwise confirmed and/or agreed by the Authority in writing and subject to Clause [18.7](#_bookmark78) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions, the Supplier shall ensure full compliance with any Guidance issued by the Department of Health in relation to the adoption of GS1 and PEPPOL standards (to include, without limitation, any supplier compliance timeline and other policy requirements published by the Department of Health in relation to the adoption of GS1 and PEPPOL standards for master data provision and exchange, barcode labelling, and purchase-to-pay transacting).
  3. Once compliance with any published timelines has been achieved by the Supplier pursuant to Clause [18.6](#_bookmark79) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions, the Supplier shall, during the Term, maintain the required level of compliance relating to the Goods in accordance with any such requirements and Guidance referred to as part of this Contract.
  4. Once product information relating to Goods is placed by the Supplier into a GS1 certified data pool, the Supplier shall, during the Term, keep such information updated with any changes to the product data relating to the Goods.

## Sustainable development

* 1. The Supplier shall comply in all material respects with applicable environmental, social and labour Law requirements in force from time to time in relation to the Goods and Services. Where the provisions of any such Law are implemented by the use of voluntary agreements, the Supplier shall comply with such agreements as if they were incorporated into English law subject to those voluntary agreements being cited in the Specification and Tender Response Document. Without prejudice to the generality of the foregoing, the Supplier shall:
     1. comply with all Policies and/or procedures and requirements set out in the Specification and Tender Response Document in relation to any stated environmental, social and labour requirements, characteristics and impacts of the Goods and Services and the Supplier’s supply chain;
     2. maintain relevant policy statements documenting the Supplier’s significant labour, social and environmental aspects as relevant to

the Goods and Services being supplied and provided and as proportionate to the nature and scale of the Supplier’s business operations; and

* + 1. maintain plans and procedures that support the commitments made as part of the Supplier’s significant labour, social and environmental policies, as referred to at Clause [19.1.2](#_bookmark81) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions.
  1. The Supplier shall meet reasonable requests by the Authority for information evidencing the Supplier’s compliance with the provisions of Clause [19](#_bookmark80) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions.

## Electronic product and services information

* 1. Where requested by the Authority, the Supplier shall provide the Authority the Product Information and the Services Information in such manner and upon such media as agreed between the Supplier and the Authority from time to time for the sole use by the Authority.
  2. The Supplier warrants that the Product Information and the Services Information is complete and accurate as at the date upon which it is delivered to the Authority and that the Product Information and the Services Information shall not contain any data or statement which gives rise to any liability on the part of the Authority following publication of the same in accordance with Clause [20](#_bookmark82) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions.
  3. If the Product Information and/or the Services Information ceases to be complete and accurate, the Supplier shall promptly notify the Authority in writing of any modification or addition to or any inaccuracy or omission in the Product Information and/or the Services Information.
  4. The Supplier grants the Authority a perpetual, non-exclusive, royalty free licence to use and exploit the Product Information and the Services Information and any Intellectual Property Rights in the Product Information and the Services Information for the purpose of illustrating the range of goods and services (including, without limitation, the Goods and Services) available pursuant to the Authority’s contracts from time to time. Subject to Clause [20.5](#_bookmark84) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions, no obligation to illustrate or advertise the Product Information or the Services Information is imposed on the Authority, as a consequence of the licence conferred by this Clause [20.4](#_bookmark83) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions.
  5. The Authority may reproduce for its sole use the Product Information and the Services Information provided by the Supplier in the Authority's product and/or services catalogues from time to time which may be made available on any NHS communications networks in electronic format and/or made available on the Authority's external website and/or made available on other digital media from time to time.
  6. Before any publication of the Product Information and the Services Information (electronic or otherwise) is made by the Authority, the Authority will submit a copy of the relevant sections of the Authority's product and/or services catalogues to the Supplier for approval, such approval not to be unreasonably withheld or delayed. For the avoidance of doubt the Supplier shall have no right to compel the Authority to exhibit the Product Information and/or the Services Information in any product and/or services catalogues as a result of the approval given by it pursuant to this Clause [20.6](#_bookmark85) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions or otherwise under the terms of this Contract.
  7. If requested in writing by the Authority, and to the extent not already agreed as part of the Specification and Tender Response Document, the Supplier and the Authority shall discuss and seek to agree in good faith arrangements to use any Electronic Trading System.

## Change management

* 1. The Supplier acknowledges to the Authority that the Authority’s requirements for the Goods and/or Services may change during the Term and the Supplier shall not unreasonably withhold or delay its consent to any reasonable variation or addition to the Specification and Tender Response Document, as may be requested by the Authority from time to time.
  2. Subject to Clause [21.3](#_bookmark86) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions, any change to the Goods and/or Services or other variation to this Contract shall only be binding once it has been agreed either: (a) in accordance with any change management provisions set out the Specification and Tender Response Document (i.e. that specify certain changes are subject to certain processes); or (b) if such change is agreed in writing and signed by an authorised representative of both Parties.
  3. Any change to the Data Protection Protocol shall be made in accordance with the relevant provisions of that protocol.

## Dispute resolution

* 1. During any Dispute, including a Dispute as to the validity of the Contract, it is agreed that the Supplier shall continue its performance of the provisions of the Contract (unless the Authority requests in writing that the Supplier does not do so).
  2. In the case of a Dispute the Supplier and the Authority shall make every reasonable effort to communicate and cooperate with each other with a view to resolving the Dispute and shall follow the procedure set out in this Clause [22](#_bookmark87) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions.
  3. In the event of a Dispute either Party may serve a Dispute Notice on the other Party to commence formal resolution of the Dispute. The Dispute Notice shall set out:
     1. the material particulars of the Dispute; and
     2. the reasons why the Party serving the Dispute Notice believes the Dispute has arisen.
  4. Following the service of a Dispute Notice the Parties shall first seek to resolve the Dispute by convening a meeting between the Authority’s Contract Manager and the Supplier’s Contract Manager (together the “**Contract** **Managers**”).
     1. The meeting of the Contract Managers must take place within five (5) Business Days of the date of the Dispute Notice (the “**Dispute Meeting**”).
     2. The Contract Managers shall be given ten (10) Business Days following the date of the Dispute Meeting to resolve the Dispute.
     3. The Contract Managers can agree to further meetings at levels 2 and/or 3 as referred to at Clause 5.1 of the Key Provisions in Schedule 1 of these Call-off Terms and Conditions, in addition to the Dispute Meeting, but such meetings must be held within the ten (10) Business Day timetable set out in paragraph [22.4.2](#_bookmark89) of [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions.
     4. If at any point it becomes clear that the timetable set out cannot be met or has passed, the Parties may (but shall be under no obligation to) agree in writing to extend the timetable. Any agreed extension to the timetable shall have the effect of delaying the start of the subsequent stages by the period agreed in the extension.
  5. If the procedure set out in Clause [22.4](#_bookmark88) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions has been exhausted and fails to resolve the Dispute either Party may request the Dispute be resolved by way of a binding expert determination (pursuant to Clause [22.6](#_bookmark90) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions). For the avoidance of doubt, the Expert shall determine all matters (including, without limitation, matters of contractual construction and interpretation) in connection with any Dispute referred to binding expert determination pursuant to Clause [22.6](#_bookmark90) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions.
  6. Where the Dispute is referred to binding expert determination the following process will apply:
     1. The Party wishing to refer the Dispute to expert determination shall give notice in writing to the other Party informing it of its wish to refer

the Dispute to expert determination and giving brief details of its position in the Dispute.

* + 1. The Parties shall attempt to agree upon a single expert (who must have no connection with the Dispute unless both Parties have consented in writing) (an “**Expert**”). For the avoidance of doubt, where the Dispute relates to contractual interpretation and construction, the Expert may be Queen’s Counsel. In the event that the Parties fail to agree upon an Expert within five (5) Business Days following the date of the notice referred to in paragraph [22.6.1](#_bookmark91) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions (or if the person agreed upon is unable or unwilling to act), the Parties agree that the Expert will be nominated and confirmed to be appointed by the Centre for Effective Dispute Resolution.
    2. The Expert must be willing and able to complete the expert determination process within thirty (30) Business Days of the Date of Final Representations (as defined below in Clause [22.6.5](#_bookmark92) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions).
    3. The Expert shall act as an expert not as an arbitrator or legal advisor. There will be no formal hearing and the Expert shall regulate the procedure as she or he sees fit.
    4. The Parties shall each have the right to make written representations to the Expert and will, with reasonable promptness, provide the Expert with such assistance and documents as the Expert reasonably requires for the purpose of reaching a decision. Such representations must be made within twenty eight (28) Business Days of the Expert being appointed, or fourteen (14) Business Days after the last documents requested by the Expert have been provided to the Expert, whichever is the later (“**Date of Final Representations**”). Any documents provided to the Expert and any correspondence to or from the Expert, including email exchanges, shall be copied to the other Party simultaneously.
    5. The Expert shall have the power to open up, review and revise any certificate, opinion, requisition or notice and to determine all matters in Dispute (including his jurisdiction to determine matters that have been referred to him).
    6. The Expert may take such advice and assistance from professional advisers or other third parties as he reasonably considers appropriate to enable him to reach a determination of the Dispute and may issue orders that one or both of the Parties are to pay such third party costs, stating the proportion. For the avoidance of doubt, where the Expert is not Queen’s Counsel, and the Expert requires advice or assistance on matters of contractual interpretation and construction, the Expert may take such advice and assistance from a third party

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|  |  | Queen’s Counsel of their choosing under this Clause [22.6.7](#_bookmark93) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions. The Parties will pay any such third party costs incurred pursuant to this Clause [22.6.7](#_bookmark93) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions in such proportions as the Expert shall order. In the absence of such order such third party costs will be paid equally. |
| 22.6.8 | The Expert shall provide the Parties with a written determination of the Dispute (the “**Expert’s Decision**”) within thirty (30) Business Days of the Date of Final Representations, which shall, in the absence of fraud or manifest error, be final and binding on the Parties. |
| 22.6.9 | The Expert’s Decision shall include reasons. |
| 22.6.10 | The Parties agree to implement the Expert’s Decision within five (5) Business Days of the Expert’s Decision being provided to them or as otherwise specified as part of the Expert’s Decision. |
| 22.6.11 | The Parties agree that the Expert shall be entitled to proceed to give his binding determination should one or both Parties fail to act in accordance with the procedural timetable set out above. |
| 22.6.12 | The Parties will pay the Expert’s costs in such proportions as the Expert shall determine. In the absence of such determination such costs will be shared equally. |
| 22.6.13 | The Parties agree to keep confidential all information arising out of or in connection with the expert determination, including details of the underlying Dispute, except where disclosure is required by Law. |
| 22.7 | Nothing | in this Contract shall prevent: |
|  | 22.7.1 | the Authority taking action in any court in relation to any death or personal injury arising or allegedly arising in connection with the supply of Goods and/or the provision of Services; |
|  | 22.7.2 | either Party seeking from any court any interim or provisional relief that may be necessary to protect the rights or property of that Party (including Intellectual Property Rights) or which relates to the safety of patients and other service users or the security of Confidential Information, pending the resolution of the relevant Dispute in accordance with the Dispute Resolution Procedure. |
| 22.8 | Subject | to Clause [22.7](#_bookmark94) of this [Schedule 2](#_bookmark12) of these Call-off Terms and |

Conditions, neither Party may commence legal proceedings in relation to a Dispute until the dispute resolution procedures set out in this Clause [22](#_bookmark87) have been exhausted. For the avoidance of doubt, either Party may commence legal action to enforce the Expert’s Decision.

22.9 This Clause [22](#_bookmark87) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions shall survive the [expi](#_bookmark87)ry of or [earlier ter](#_bookmark12)mination of this Contract for any reason.

## Force majeure

* 1. Subject to Clause [23.2](#_bookmark96) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions neither Party shall be liable to the other for any failure to perform all or any of its obligations under this Contract nor liable to the other Party for any loss or damage arising out of the failure to perform its obligations to the extent only that such performance is rendered impossible by a Force Majeure Event.
  2. The Supplier shall only be entitled to rely on a Force Majeure Event and the relief set out in Clause [23](#_bookmark95) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions and will not be considered to be in default or liable for breach of any obligations under this Contract if:
     1. the Supplier has fulfilled its obligations pursuant to Clause [6](#_bookmark25) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions;
     2. the Force Majeure Event does not arise directly or indirectly as a result of any wilful or negligent act or default of the Supplier; and
     3. the Supplier has complied with the procedural requirements set out in Clause [23](#_bookmark95) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions.
  3. Where a Party is (or claims to be) affected by a Force Majeure Event it shall use reasonable endeavours to mitigate the consequences of such a Force Majeure Event upon the performance of its obligations under this Contract, and to resume the performance of its obligations affected by the Force Majeure Event as soon as practicable.
  4. Where the Force Majeure Event affects the Supplier’s ability to perform part of its obligations under the Contract the Supplier shall fulfil all such contractual obligations that are not so affected and shall not be relieved from its liability to do so.
  5. If either Party is prevented or delayed in the performance of its obligations under this Contract by a Force Majeure Event, that Party shall as soon as reasonably practicable serve notice in writing on the other Party specifying the nature and extent of the circumstances giving rise to its failure to perform or any anticipated delay in performance of its obligations.
  6. Subject to service of such notice, the Party affected by such circumstances shall have no liability for its failure to perform or for any delay in performance of its obligations affected by the Force Majeure Event only for so long as such circumstances continue and for such time after they cease as is necessary for

that Party, using its best endeavours, to recommence its affected operations in order for it to perform its obligations.

* 1. The Party claiming relief shall notify the other in writing as soon as the consequences of the Force Majeure Event have ceased and of when performance of its affected obligations can be resumed.
  2. If the Supplier is prevented from performance of its obligations as a result of a Force Majeure Event, the Authority may at any time if the Force Majeure Event subsists for thirty (30) days or more, terminate this Contract by issuing a Termination Notice to the Supplier.
  3. Following such termination in accordance with Clause [23.8](#_bookmark97) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions and subject to Clause [23.10](#_bookmark98) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions, neither Party shall have any liability to the other.
  4. Any rights and liabilities of either Party which have accrued prior to such termination in accordance with Clause [23.8](#_bookmark97) of this [Schedule 2](#_bookmark12) of these Call- off Terms and Conditions shall continue in full force and effect unless otherwise specified in this Contract.

## Records retention and right of audit

* 1. Subject to any statutory requirement and Clause [24.2](#_bookmark100) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions, the Supplier shall keep secure and maintain for the Term and six (6) years afterwards, or such longer period as may be agreed between the Parties, full and accurate records of all matters relating to this Contract.
  2. Where any records could be relevant to a claim for personal injury such records shall be kept secure and maintained for a period of twenty one (21) years from the date of expiry or earlier termination of this Contract.
  3. The Authority shall have the right to audit the Supplier’s compliance with this Contract. The Supplier shall permit or procure permission for the Authority or its authorised representative during normal business hours having given advance written notice of no less than five (5) Business Days, access to any premises and facilities, books and records reasonably required to audit the Supplier’s compliance with its obligations under this Contract.
  4. Should the Supplier Sub-contract any of its obligations under this Contract, the Authority shall have the right to audit and inspect such third party. The Supplier shall procure permission for the Authority or its authorised representative during normal business hours no more than once in any twelve

(12) months, having given advance written notice of no less than five (5) Business Days, access to any premises and facilities, books and records used in the performance of the Supplier’s obligations under this Contract that are Sub-contracted to such third party. The Supplier shall cooperate with

such audit and inspection and accompany the Authority or its authorised representative if requested.

* 1. The Supplier shall grant to the Authority or its authorised representative, such access to those records as they may reasonably require in order to check the Supplier’s compliance with this Contract for the purposes of:
     1. the examination and certification of the Authority’s accounts; or
     2. any examination pursuant to section 6(1) of the National Audit Act 1983 of the economic efficiency and effectiveness with which the Authority has used its resources.
  2. The Comptroller and Auditor General may examine such documents as they may reasonably require which are owned, held or otherwise within the control of the Supplier and may require the Supplier to provide such oral and/or written explanations as they consider necessary. Clause [24](#_bookmark99) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions does not constitute a requirement or agreement for the examination, certification or inspection of the accounts of the Supplier under sections 6(3)(d) and 6(5) of the National Audit Act 1983.
  3. The Supplier shall provide reasonable cooperation to the Authority, its representatives and any regulatory body in relation to any audit, review, investigation or enquiry carried out in relation to the subject matter of this Contract.
  4. The Supplier shall provide all reasonable information as may be reasonably requested by the Authority to evidence the Supplier’s compliance with the requirements of this Contract.

## Conflicts of interest and the prevention of fraud

* 1. The Supplier shall take appropriate steps to ensure that neither the Supplier nor any Staff are placed in a position where, in the reasonable opinion of the Authority, there is or may be an actual conflict, or a potential conflict, between the pecuniary or personal interests of the Supplier and the duties owed to the Authority under the provisions of this Contract. The Supplier will disclose to the Authority full particulars of any such conflict of interest which may arise.
  2. The Authority reserves the right to terminate this Contract immediately by notice in writing and/or to take such other steps it deems necessary where, in the reasonable opinion of the Authority, there is or may be an actual conflict, or a potential conflict, between the pecuniary or personal interests of the Supplier and the duties owed to the Authority under the provisions of this Contract. The actions of the Authority pursuant to this Clause [25.2](#_bookmark101) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions shall not prejudice or affect any right of action or remedy which shall have accrued or shall subsequently accrue to the Authority.
  3. The Supplier shall take all reasonable steps to prevent Fraud by Staff and the Supplier (including its owners, members and directors). The Supplier shall notify the Authority immediately if it has reason to suspect that any Fraud has occurred or is occurring or is likely to occur.
  4. If the Supplier or its Staff commits Fraud the Authority may terminate this Contract and recover from the Supplier the amount of any direct loss suffered by the Authority resulting from the termination.

## Equality and human rights

* 1. The Supplier shall:
     1. ensure that (a) it does not, whether as employer, a supplier of Goods or as provider of the Services, engage in any act or omission that would contravene the Equality Legislation, and (b) it complies with all its obligations as an employer, a supplier of Goods or provider of the Services as set out in the Equality Legislation and take reasonable endeavours to ensure its Staff do not unlawfully discriminate within the meaning of the Equality Legislation;
     2. in the management of its affairs and the development of its equality and diversity policies, cooperate with the Authority in light of the Authority’s obligations to comply with its statutory equality duties whether under the Equality Act 2010 or otherwise. The Supplier shall take such reasonable and proportionate steps as the Authority considers appropriate to promote equality and diversity, including race equality, equality of opportunity for disabled people, gender equality, and equality relating to religion and belief, sexual orientation and age; and
     3. the Supplier shall impose on all its Sub-contractors and suppliers, obligations substantially similar to those imposed on the Supplier by Clause [26](#_bookmark103) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions.
  2. The Supplier shall meet reasonable requests by the Authority for information evidencing the Supplier’s compliance with the provisions of Clause [26](#_bookmark103) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions.

## Notice

* 1. Any notice required to be given by either Party under this Contract shall be in writing quoting the date of the Contract and shall be delivered by hand or sent by prepaid first class recorded delivery or by email to the person referred to in the Order Form or such other person as one Party may inform the other Party in writing from time to time or to a director of the relevant Party at the head office, main UK office or registered office of such Party.
  2. A notice shall be treated as having been received:
     1. if delivered by hand within normal business hours when so delivered or, if delivered by hand outside normal business hours, at the next start of normal business hours; or
     2. if sent by first class recorded delivery mail on a normal Business Day, at 9.00 am on the second Business Day subsequent to the day of posting, or, if the notice was not posted on a Business Day, at

9.00 am on the third Business Day subsequent to the day of posting; or

* + 1. if sent by email, if sent within normal business hours when so sent or, if sent outside normal business hours, at the next start of normal business hours provided the sender has either received an electronic confirmation of delivery or has telephoned the recipient to inform the recipient that the email has been sent.

## Assignment, novation and Sub-contracting

* 1. The Supplier shall not, except where Clause 28.2 of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions applies, assign, Sub-contract, novate, create a trust in, or in any other way dispose of the whole or any part of this Contract without the prior consent in writing of the Authority such consent not to be unreasonably withheld or delayed. If the Supplier Sub-contracts any of its obligations under this Contract, every act or omission of the Sub-contractor shall for the purposes of this Contract be deemed to be the act or omission of the Supplier and the Supplier shall be liable to the Authority as if such act or omission had been committed or omitted by the Supplier itself.
  2. Notwithstanding Clause [28.1](#_bookmark104) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions, the Supplier may assign to a third party (“**Assignee**”) the right to receive payment of any sums due and owing to the Supplier under this Contract for which an invoice has been issued. Any assignment under this Clause 28.2 of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions shall be subject to:
     1. the deduction of any sums in respect of which the Authority exercises its right of recovery under Clause [9.9](#_bookmark31) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions;
     2. all related rights of the Authority in relation to the recovery of sums due but unpaid;
     3. the Authority receiving notification of the assignment and the date upon which the assignment becomes effective together with the Assignee’s contact information and bank account details to which the Authority shall make payment;
     4. the provisions of Clause [9](#_bookmark30) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions continui[ng](#_bookmark30) to appl[y in all ot](#_bookmark12)her respects after the assignment which shall not be amended without the prior written approval of the Authority; and
     5. payment to the Assignee being full and complete satisfaction of the Authority’s obligation to pay the relevant sums in accordance with this Contract.
  3. Any authority given by the Authority for the Supplier to Sub-contract any of its obligations under this Contract shall not impose any duty on the Authority to enquire as to the competency of any authorised Sub-contractor. The Supplier shall ensure that any authorised Sub-contractor has the appropriate capability and capacity to perform the relevant obligations and that the obligations carried out by such Sub-contractor are fully in accordance with this Contract.
  4. Where the Supplier enters into a Sub-contract in respect of any of its obligations under this Contract (to include, without limitation, in connection with any Relevant Activities), the Supplier shall include provisions in each such Sub-contract, unless otherwise agreed with the Authority in writing, which:
     1. contain at least equivalent obligations as set out in this Contract in relation to the supply of the Goods and/or the performance of the Services to the extent relevant to such Sub-contracting (to include, without limitation, in relation to any Relevant Activities Sub- contracted under such Sub-contract);
     2. contain at least equivalent obligations as set out in this Contract in respect of confidentiality, information security, data protection, Intellectual Property Rights, compliance with Law and Guidance, provision of information and record keeping;
     3. contain a prohibition on the Sub-contractor Sub-contracting, assigning or novating any of its rights or obligations under such Sub-contract without the prior written approval of the Authority (such approval not to be unreasonably withheld or delayed);
     4. contain a right for the Authority to take an assignment or novation of the Sub-contract (or part of it) upon expiry or earlier termination of this Contract;
     5. requires the Supplier or other party receiving goods or services under the contract to consider and verify invoices under that contract in a timely fashion;
     6. provides that if the Supplier or other party fails to consider and verify an invoice in accordance with Clause [28.4.5](#_bookmark106) of this [Schedule](#_bookmark12)

[2](#_bookmark12) of these Call-off Terms and Conditions, the invoice shall be

regarded as valid and undisputed for the purpose of Clause [28.4.7](#_bookmark107) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions after a reasonable time has passed;

* + 1. requires the Supplier or other party to pay any undisputed sums which are due from it to the Sub-contractor within a specified period not exceeding thirty (30) days of verifying that the invoice is valid and undisputed;
    2. permitting the Supplier to terminate, or procure the termination of, the relevant Sub-contract in the event the Sub-contractor fails to comply in the performance of its Sub-contract with legal obligations in the fields of environmental, social or labour Law where the Supplier is required to replace such Sub-contractor in accordance with Clause [15.7.4](#_bookmark66) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions;
    3. permitting the Supplier to terminate, or to procure the termination of, the relevant Sub-contract where the Supplier is required to replace such Sub-contractor in accordance with Clause [28.5](#_bookmark108) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions; and
    4. requires the Sub-contractor to include a clause to the same effect as this Clause [28.4](#_bookmark105) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions in any Sub-contract which it awards.
  1. Where the Authority considers that the grounds for exclusion under Regulation 57 of the Public Contracts Regulations 2015 apply to any Sub- contractor, then:
     1. if the Authority finds there are compulsory grounds for exclusion, the Supplier shall ensure, or shall procure, that such Sub-contractor is replaced or not appointed; or
     2. if the Authority finds there are non-compulsory grounds for exclusion, the Authority may require the Supplier to ensure, or to procure, that such Sub-contractor is replaced or not appointed and the Supplier shall comply with such a requirement.
  2. The Supplier shall pay any undisputed sums which are due from it to a Sub- contractor within thirty (30) days of verifying that the invoice is valid and undisputed. Where the Authority pays the Supplier’s valid and undisputed invoices earlier than thirty (30) days from verification in accordance with any applicable government prompt payment targets, the Supplier shall use its reasonable endeavours to pay its relevant Sub-contractors within a comparable timeframe from verifying that an invoice is valid and undisputed.
  3. The Authority shall upon written request have the right to review any Sub- contract entered into by the Supplier in respect of the supply of the Goods

and/or the provision of the Services and the Supplier shall provide a certified copy of any Sub-contract within five (5) Business Days of the date of a written request from the Authority. For the avoidance of doubt, the Supplier shall have the right to redact any confidential pricing information in relation to such copies of Sub-contracts.

* 1. The Authority may at any time transfer, assign, novate, sub-contract or otherwise dispose of its rights and obligations under this Contract or any part of this Contract and the Supplier warrants that it will carry out all such reasonable further acts required to effect such transfer, assignment, novation, sub-contracting or disposal. If the Authority novates this Contract to any body that is not a Contracting Authority, from the effective date of such novation, the party assuming the position of the Authority shall not further transfer, assign, novate, sub-contract or otherwise dispose of its rights and obligations under this Contract or any part of this Contract without the prior written consent of the Supplier, such consent not to be unreasonably withheld or delayed by the Supplier.

## Prohibited Acts

* 1. The Supplier warrants and represents that:
     1. it has not committed any offence under the Bribery Act 2010 or done any of the following (“**Prohibited Acts**”):
        1. offered, given or agreed to give any officer or employee of the Authority any gift or consideration of any kind as an inducement or reward for doing or not doing or for having done or not having done any act in relation to the obtaining or performance of this or any other agreement with the Authority or for showing or not showing favour or disfavour to any person in relation to this or any other agreement with the Authority; or
        2. in connection with this Contract paid or agreed to pay any commission other than a payment, particulars of which (including the terms and conditions of the agreement for its payment) have been disclosed in writing to the Authority; and
     2. it has in place adequate procedures to prevent bribery and corruption, as contemplated by section 7 of the Bribery Act 2010.
  2. If the Supplier or its Staff (or anyone acting on its or their behalf) has done or does any of the Prohibited Acts or has committed or commits any offence under the Bribery Act 2010 with or without the knowledge of the Supplier in relation to this or any other agreement with the Authority:
     1. the Authority shall be entitled:
        1. to terminate this Contract and recover from the Supplier the amount of any loss resulting from the termination;
        2. to recover from the Supplier the amount or value of any gift, consideration or commission concerned; and
        3. to recover from the Supplier any other loss or expense sustained in consequence of the carrying out of the Prohibited Act or the commission of the offence under the Bribery Act 2010;
     2. any termination under Clause [29.2.1](#_bookmark111) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions shall be without prejudice to any right or remedy that has already accrued, or subsequently accrues, to the Authority; and
     3. notwithstanding Clause [22](#_bookmark87) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions, any Dispute relating to:
        1. the interpretation of Clause [29](#_bookmark109) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions; or
        2. the amount or value of any gift, consideration or commission,

shall be determined by the Authority, acting reasonably, and the decision shall be final and conclusive.

## General

* 1. Each of the Parties is independent of the other and nothing contained in this Contract shall be construed to imply that there is any relationship between the Parties of partnership or of principal/agent or of employer/employee nor are the Parties hereby engaging in a joint venture and accordingly neither of the Parties shall have any right or authority to act on behalf of the other nor to bind the other by agreement or otherwise, unless expressly permitted by the terms of this Contract.
  2. Failure or delay by either Party to exercise an option or right conferred by this Contract shall not of itself constitute a waiver of such option or right.
  3. The delay or failure by either Party to insist upon the strict performance of any provision, term or condition of this Contract or to exercise any right or remedy consequent upon such breach shall not constitute a waiver of any such breach or any subsequent breach of such provision, term or condition.
  4. Any provision of this Contract which is held to be invalid or unenforceable in any jurisdiction shall be ineffective to the extent of such invalidity or unenforceability without invalidating or rendering unenforceable the remaining provisions of this Contract and any such invalidity or unenforceability in any

jurisdiction shall not invalidate or render unenforceable such provisions in any other jurisdiction.

* 1. Each Party acknowledges and agrees that it has not relied on any representation, warranty or undertaking (whether written or oral) in relation to the subject matter of this Contract and therefore irrevocably and unconditionally waives any rights it may have to claim damages against the other Party for any misrepresentation or undertaking (whether made carelessly or not) or for breach of any warranty unless the representation, undertaking or warranty relied upon is set out in this Contract or unless such representation, undertaking or warranty was made fraudulently.
  2. Each Party shall bear its own expenses in relation to the preparation and execution of this Contract including all costs, legal fees and other expenses so incurred.
  3. The rights and remedies provided in this Contract are independent, cumulative and not exclusive of any rights or remedies provided by general law, any rights or remedies provided elsewhere under this Contract or by any other contract or document. In this Clause [30.7](#_bookmark113) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions, right includes any power, privilege, remedy, or proprietary or security interest.
  4. Unless otherwise expressly stated in this Contract, a person who is not a party to this Contract shall have no right to enforce any terms of it which confer a benefit on such person except that a Successor and/or a Third Party may directly enforce any indemnities or other rights provided to it under this Contract. No such person shall be entitled to object to or be required to consent to any amendment to the provisions of this Contract.
  5. This Contract, any variation in writing signed by an authorised representative of each Party and any document referred to (explicitly or by implication) in this Contract or any variation to this Contract, contain the entire understanding between the Supplier and the Authority relating to the supply of the Goods and the provision of the Services to the exclusion of all previous agreements, confirmations and understandings and there are no promises, terms, conditions or obligations whether oral or written, express or implied other than those contained or referred to in this Contract. Nothing in this Contract seeks to exclude either Party's liability for Fraud. Any tender conditions and/or disclaimers set out in the Authority’s procurement documentation leading to the award of this Contract shall form part of this Contract.
  6. This Contract, and any Dispute or claim arising out of or in connection with it or its subject matter (including any non-contractual claims), shall be governed by, and construed in accordance with, the laws of England and Wales.
  7. Subject to Clause [22](#_bookmark87) of this [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions, the Parties irrevocably agree that the courts of England and

Wales shall have non-exclusive jurisdiction to settle any Dispute or claim that arises out of or in connection with this Contract or its subject matter.

* 1. All written and oral communications and all written material referred to under this Contract shall be in English.

**Schedule 3**

**Information Governance Provisions**

1. **Confidentiality**
   1. In respect of any Confidential Information it may receive directly or indirectly from the other Party (“**Discloser**”) and subject always to the remainder of Clause [1](#_bookmark115) of this [Schedule 3](#_bookmark114) of these Call-off Terms and Conditions, each Party (“**Recipient**”) undertakes to keep secret and strictly confidential and shall not disclose any such Confidential Information to any third party without the Discloser’s prior written consent provided that:
      1. the Recipient shall not be prevented from using any general knowledge, experience or skills which were in its possession prior to the Commencement Date;
      2. the provisions of Clause [1](#_bookmark115) of this [Schedule 3](#_bookmark114) of these Call-off Terms and Conditions shall not apply to any Confidential Information:
         1. which is in or enters the public domain other than by breach of this Contract or other act or omissions of the Recipient;
         2. which is obtained from a third party who is lawfully authorised to disclose such information without any obligation of confidentiality;
         3. which is authorised for disclosure by the prior written consent of the Discloser;
         4. which the Recipient can demonstrate was in its possession without any obligation of confidentiality prior to receipt of the Confidential Information from the Discloser; or
         5. which the Recipient is required to disclose purely to the extent to comply with the requirements of any relevant stock exchange.
   2. Nothing in Clause [1](#_bookmark115) of this [Schedule 3](#_bookmark114) of these Call-off Terms and Conditions shall prevent the Recipient from disclosing Confidential Information where it is required to do so by judicial, administrative, governmental or regulatory process in connection with any action, suit, proceedings or claim or otherwise by applicable Law, including the Freedom of Information Act 2000 (“**FOIA**”), Codes of Practice on Access to Government Information, on the Discharge of Public Authorities’ Functions or on the Management of Records (“**Codes of Practice**”) or the Environmental Information Regulations 2004 (“**Environmental Regulations**”).
   3. The Authority may disclose the Supplier’s Confidential Information:
      1. on a confidential basis, to any Contracting Authority (the Parties agree that all Contracting Authorities receiving such Confidential Information shall be entitled to further disclose the Confidential Information to other Contracting Authorities on the basis that the information is confidential and is not to be disclosed to a third party which is not part of any Contracting Authority);
      2. on a confidential basis, to any consultant, contractor or other person engaged by the Authority and/or the Contracting Authority receiving such information;
      3. to any relevant party for the purpose of the examination and certification of the Authority’s accounts;
      4. to any relevant party for any examination pursuant to section 6(1) of the National Audit Act 1983 of the economy, efficiency and effectiveness with which the Authority has used its resources;
      5. to Parliament and Parliamentary Committees or if required by any Parliamentary reporting requirements; or
      6. on a confidential basis to a proposed successor body in connection with any proposed or actual, assignment, novation or other disposal of rights, obligations, liabilities or property in connection with this Contract;

and for the purposes of this Contract, references to disclosure "on a confidential basis" shall mean the Authority making clear the confidential nature of such information and that it must not be further disclosed except in accordance with Law or this Clause [1.3](#_bookmark116) of this [Schedule 3](#_bookmark114) of these Call-off Terms and Conditions.

* 1. The Supplier may only disclose the Authority’s Confidential Information, and any other information provided to the Supplier by the Authority in relation to this Contract, to the Supplier’s Staff or professional advisors who are directly involved in the performance of or advising on the Supplier’s obligations under this Contract. The Supplier shall ensure that such Staff or professional advisors are aware of and shall comply with the obligations in Clause [1](#_bookmark115) of this [Schedule 3](#_bookmark114) of these Call-off Terms and Conditions as to confidentiality and that all information, including Confidential Information, is held securely, protected against unauthorised use or loss and, at the Authority’s written discretion, destroyed securely or returned to the Authority when it is no longer required. The Supplier shall not, and shall ensure that the Staff do not, use any of the Authority’s Confidential Information received otherwise than for the purposes of performing the Supplier’s obligations in this Contract.
  2. For the avoidance of doubt, save as required by Law or as otherwise set out in this [Schedule 3](#_bookmark114) of these Call-off Terms and Conditions, the Supplier shall not, without the prior written consent of the Authority (such consent not to be

unreasonably withheld or delayed), announce that it has entered into this Contract and/or that it has been appointed as a Supplier to the Authority and/or make any other announcements about this Contract.

* 1. Clause [1](#_bookmark115) of this [Schedule 3](#_bookmark114) of these Call-off Terms and Conditions shall remain in force:
     1. without limit in time in respect of Confidential Information which comprises Personal Data or which relates to national security; and
     2. for all other Confidential Information for a period of three (3) years after the expiry or earlier termination of this Contract unless otherwise agreed in writing by the Parties.

## Data protection

* 1. The Parties acknowledge their respective duties under Data Protection Legislation and shall give each other all reasonable assistance as appropriate or necessary to enable each other to comply with those duties. For the avoidance of doubt, the Supplier shall take reasonable steps to ensure it is familiar with the Data Protection Legislation and any obligations it may have under such Data Protection Legislation and shall comply with such obligations.
  2. Where the Supplier is Processing Personal Data under or in connection with this Contract, the Parties shall comply with the Data Protection Protocol.
  3. The Supplier and the Authority shall ensure that Personal Data is safeguarded at all times in accordance with the Law, and this obligation will include (if transferred electronically) only transferring Personal Data (a) if essential, having regard to the purpose for which the transfer is conducted; and (b) that is encrypted in accordance with any international data encryption standards for healthcare, and as otherwise required by those standards applicable to the Authority under any Law and Guidance (this includes, data transferred over wireless or wired networks, held on laptops, CDs, memory sticks and tapes).
  4. Where, as a requirement of this Contract, the Supplier is Processing Personal Data on behalf of the Authority relating to Patients as part of the Services, the Supplier shall:
     1. complete and publish an annual information governance assessment using the NHS information governance toolkit;
     2. achieve a minimum level 2 performance against all requirements in the relevant NHS information governance toolkit;
     3. nominate an information governance lead able to communicate with the Authority’s board of directors or equivalent governance body, who will be responsible for information governance and from whom

its board of directors or equivalent governance body will receive regular reports on information governance matters including, but not limited to, details of all incidents of data loss and breach of confidence;

* + 1. report all incidents of data loss and breach of confidence in accordance with Department of Health and/or the NHS England and/or Health and Social Care Information Centre guidelines;
    2. put in place and maintain policies that describe individual personal responsibilities for handling Personal Data and apply those policies vigorously;
    3. put in place and maintain a policy that supports its obligations under the NHS Care Records Guarantee (being the rules which govern information held in the NHS Care Records Service, which is the electronic patient/Patient record management service providing authorised healthcare professionals access to a patient’s integrated electronic care record);
    4. put in place and maintain agreed protocols for the lawful sharing of Personal Data with relevant NHS organisations and (as appropriate) with non-NHS organisations in circumstances in which sharing of that data is required under this Contract;
    5. where appropriate, have a system in place and a policy for the recording of any telephone calls in relation to the Services, including the retention and disposal of those recordings;
    6. at all times comply with any information governance requirements and/or processes as may be set out in the Specification and Tender Response Document; and
    7. comply with any new and/or updated requirements, Guidance and/or Policies notified to the Supplier by the Authority from time to time (acting reasonably) relating to the Processing and/or protection of Personal Data.
  1. Where any Personal Data is Processed by any Sub-contractor of the Supplier in connection with this Contract, the Supplier shall procure that such Sub- contractor shall comply with the relevant obligations set out in Clause 2 of this [Schedule 3](#_bookmark114) of these Call-off Terms and Conditions, as if such Sub-contractor were the Supplier.
  2. The Supplier shall indemnify and keep the Authority indemnified against, any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings whatsoever or howsoever arising from the Supplier’s unlawful or unauthorised Processing, destruction and/or damage to Personal Data in connection with this Contract.

## Freedom of Information and Transparency

* 1. The Parties acknowledge the duties of Contracting Authorities under the FOIA, Codes of Practice and Environmental Regulations and shall give each other all reasonable assistance as appropriate or necessary to enable compliance with those duties.
  2. The Supplier shall assist and cooperate with the Authority to enable it to comply with its disclosure obligations under the FOIA, Codes of Practice and Environmental Regulations. The Supplier agrees:
     1. that this Contract and any recorded information held by the Supplier on the Authority’s behalf for the purposes of this Contract are subject to the obligations and commitments of the Authority under the FOIA, Codes of Practice and Environmental Regulations;
     2. that the decision on whether any exemption to the general obligations of public access to information applies to any request for information received under the FOIA, Codes of Practice and Environmental Regulations is a decision solely for the Authority;
     3. that where the Supplier receives a request for information under the FOIA, Codes of Practice and Environmental Regulations and the Supplier itself is subject to the FOIA, Codes of Practice and Environmental Regulations it will liaise with the Authority as to the contents of any response before a response to a request is issued and will promptly (and in any event within two (2) Business Days) provide a copy of the request and any response to the Authority;
     4. that where the Supplier receives a request for information under the FOIA, Codes of Practice and Environmental Regulations and the Supplier is not itself subject to the FOIA, Codes of Practice and Environmental Regulations, it will not respond to that request (unless directed to do so by the Authority) and will promptly (and in any event within two (2) Business Days) transfer the request to the Authority;
     5. that the Authority, acting in accordance with the Codes of Practice issued and revised from time to time under both section 45 of FOIA, and regulation 16 of the Environmental Regulations, may disclose information concerning the Supplier and this Contract; and
     6. to assist the Authority in responding to a request for information, by processing information or environmental information (as the same are defined in FOIA and the Environmental Regulations) in accordance with a records management system that complies with all applicable records management recommendations and codes of conduct issued under section 46 of FOIA, and providing copies of

all information requested by the Authority within five (5) Business Days of that request and without charge.

* 1. The Parties acknowledge that, except for any information which is exempt from disclosure in accordance with the provisions of the FOIA, Codes of Practice and Environmental Regulations, the content of this Contract is not Confidential Information.
  2. Notwithstanding any other term of this Contract, the Supplier consents to the publication of this Contract in its entirety (including variations), subject only to the redaction of information that is exempt from disclosure in accordance with the provisions of the FOIA, Codes of Practice and Environmental Regulations.
  3. In preparing a copy of this Contract for publication under Clause [3.4](#_bookmark119) of this [Schedule 3](#_bookmark114) of these Call-off Terms and Conditions, the Authority may consult with the Supplier to inform decision making regarding any redactions but the final decision in relation to the redaction of information will be at the Authority’s absolute discretion.
  4. The Supplier shall assist and cooperate with the Authority to enable the Authority to publish this Contract.
  5. Where any information is held by any Sub-contractor of the Supplier in connection with this Contract, the Supplier shall procure that such Sub- contractor shall comply with the relevant obligations set out in Clause 3 of this [Schedule 3](#_bookmark114) of these Call-off Terms and Conditions, as if such Sub-contractor were the Supplier.

## Information Security

* 1. Without limitation to any other information governance requirements set out in this [Schedule 3](#_bookmark114) of these Call-off Terms and Conditions, the Supplier shall:
     1. notify the Authority forthwith of any information security breaches or near misses (including without limitation any potential or actual breaches of confidentiality or actual information security breaches) in line with the Authority’s information governance Policies; and
     2. fully cooperate with any audits or investigations relating to information security and any privacy impact assessments undertaken by the Authority and shall provide full information as may be reasonably requested by the Authority in relation to such audits, investigations and assessments.
  2. Where required in accordance with the Specification and Tender Response Document, the Supplier will ensure that it puts in place and maintains an information security management plan appropriate to this Contract, the type of Services being provided and the obligations placed on the Supplier under this Contract. The Supplier shall ensure that such plan is consistent with any

relevant Policies, Guidance, Good Industry Practice and with any relevant quality standards as may be set out in the Specification and Tender Response Document.

* 1. Where required in accordance with the Specification and Tender Response Document, the Supplier shall obtain and maintain certification under the HM Government Cyber Essentials Scheme at the level set out in the Specification and Tender Response Document.

## Definitions

**Schedule 4 Definitions and Interpretations**

* 1. In this Contract the following words shall have the following meanings unless the context requires otherwise:

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| “**Actual Services Commencement Date**” | means the date the Supplier actually commences delivery of all of the Services; |
| **“Authority”** | means the authority named on the Order Form; |
| “**Authority’s Obligations**” | means the Authority’s further obligations, if any, referred to in the Specification and Tender Response Document; |
| **“Breach Notice”** | means a written notice of breach given by one Party to the other, notifying the Party receiving the notice of its breach of this Contract.; |
| **“Business Continuity Event”** | means any event or issue that could impact on the operations of the Supplier and its ability to supply the Goods and/or provide the Services including an influenza pandemic and any Force Majeure Event; |
| **“Business Continuity Plan”** | means the Supplier’s business continuity plan which includes its plans for continuity of the supply of the Goods and the provision of the Services during a Business Continuity Event; |
| **“Business Day”** | means any day other than Saturday, Sunday, Christmas Day, Good Friday or a statutory bank holiday in England and Wales; |
| **“Cabinet Office Statement”** | the Cabinet Office Statement of Practice – Staff Transfers in the Public Sector 2000 (as revised 2013) as may be amended or replaced; |
| **“Call-off Terms and Conditions”** | means these Call-off Terms and Conditions for the Supply of Goods and Provision of Services (Homecare Medicines); |
| **“Codes of Practice”** | shall have the meaning given to the term in Clause [1.2](#_bookmark117) of [Schedule 3](#_bookmark114) of these Call-off Terms and Conditions; |

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| **“Commencement Date”** | means the date of the Purchase Order forming part of the Order Form; |
| **“Confidential Information”** | means information, data and material of any nature, which either Party may receive or obtain in connection with the conclusion and/or operation of the Contract including any procurement process which is:   1. Personal Data including without limitation which relates to any patient or other Patient or his or her treatment or clinical or care history; 2. designated as confidential by either party or that ought reasonably to be considered as confidential (however it is conveyed or on whatever media it is stored); and/or 3. Policies and such other documents which the Supplier may obtain or have access to through the Authority’s intranet; |
| “**Contract**” | means the Order Form, the provisions on the front page and all Schedules of these Call-off Terms and Conditions, the Specification and Tender Response Document and the applicable provisions of the Framework Agreement; |
| **“Contracting Authority”** | means any contracting authority as defined in Regulation 3 of the Public Contracts Regulations 2015 (SI 2015/102) (as amended), other than the Authority; |
| **“Contract Manager”** | means for the Authority and for the Supplier the individuals specified in the Order Form or as otherwise agreed between the Parties in writing or such other person notified by a Party to the other Party from time to time in accordance with Clause [8.1](#_bookmark27) of [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions; |
| **“Contract Price”** | means the price exclusive of VAT that is payable to the Supplier by the Authority under the Contract for the full and proper performance by the Supplier of its obligations under the Contract calculated in accordance with the provisions of the Framework Agreement and as confirmed in the Order Form; |
| **“Controller”** | shall have the same meaning as set out in the GDPR; |
| **“Convictions”** | means, other than in relation to minor road traffic offences, any previous or pending prosecutions, convictions, cautions and binding-over orders (including any spent |

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|  | convictions as contemplated by Section 1(1) of the Rehabilitation of Offenders Act 1974 or any replacement or amendment to that Act); |
| **“Critical Service Failure”** | shall have the meaning given to the term in Clause [2.2](#_bookmark14) of [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions; |
| **“Data Protection Legislation”** | means (i) the Data Protection Act 1998 or, from the date it comes into force, the Data Protection Act 2018 to the extent that it relates to processing of personal data and privacy; (ii) the GDPR, the Law Enforcement Directive (Directive (EU) 2016/680) and any applicable national implementing Law as amended from time to time; and (iii) all applicable Law about the processing of personal data and privacy; |
| **“Data Protection Protocol”** | means any document of that name as provided to the Supplier by the Authority (as amended from time to time in accordance with its terms) which shall include, without limitation, any such document appended to the Order Form; |
| **“Dispute(s)”** | means any dispute, difference or question of interpretation or construction arising out of or in connection with this Contract, including any dispute, difference or question of interpretation relating to the Goods and/or Services, any matters of contractual construction and interpretation relating to the Contract, or any matter where this Contract directs the Parties to resolve an issue by reference to the Dispute Resolution Procedure; |
| **“Dispute Notice”** | means a written notice served by one Party to the other stating that the Party serving the notice believes there is a Dispute; |
| **“Dispute Resolution Procedure”** | means the process for resolving Disputes as set out in Clause [22](#_bookmark87) of [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions; |
| **“DOTAS”** | means the Disclosure of Tax Avoidance Schemes rules which require a promoter of tax schemes to tell HM Revenue and Customs of any specified notifiable arrangements or proposals and to provide prescribed information on those arrangements or proposals within set time limits as contained in Part 7 of the Finance Act 2004 and in secondary legislation made under vires contained in Part 7 of the Finance Act 2004 and as extended to National Insurance Contributions by the National Insurance Contributions (Application of Part 7 of the Finance Act |

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|  | 2004) Regulations 2012, SI 2012/1868 made under s.132A Social Security Administration Act 1992; |
| **“Electronic Trading System(s)”** | means such electronic data interchange system and/or world wide web application and/or other application with such message standards and protocols as the Authority may specify from time to time; |
| **“Employment Liabilities”** | means all claims, demands, actions, proceedings, damages, compensation, tribunal awards, fines, costs (including but not limited to reasonable legal costs), expenses and all other liabilities whatsoever; |
| **“Environmental Regulations”** | shall have the meaning given to the term in Clause [1.2](#_bookmark117) of [Schedule 3](#_bookmark114) of these Call-off Terms and Conditions; |
| **“eProcurement** **Guidance”** | means the NHS eProcurement Strategy available via:  [http://www.gov.uk/government/collections/nhs-](http://www.gov.uk/government/collections/nhs-procurement) [procurement](http://www.gov.uk/government/collections/nhs-procurement)  together with any further Guidance issued by the Department of Health in connection with it; |
| **“Equality Legislation”** | means any and all legislation, applicable guidance and statutory codes of practice relating to equality, diversity, non-discrimination and human rights as may be in force in England and Wales from time to time including, but not limited to, the Equality Act 2010, the Part-time Workers (Prevention of Less Favourable Treatment) Regulations 2000 and the Fixed-term Employees (Prevention of Less Favourable Treatment) Regulations 2002 (SI 2002/2034) and the Human Rights Act 1998; |
| **“Fair Deal for Staff Pensions”** | means guidance issued by HM Treasury entitled “Fair Deal for staff pensions: staff transfer from central government” issued in October 2013 (as amended, supplemented or replaced); |
| **“FOIA”** | shall have the meaning given to the term in Clause [1.2](#_bookmark117) of [Schedule 3](#_bookmark114) of these Call-off Terms and Conditions; |
| **“Force Majeure Event”** | means any event beyond the reasonable control of the Party in question to include, without limitation:  (a) war including civil war (whether declared or undeclared), riot, civil commotion or armed conflict materially affecting either Party’s ability to perform its obligations under this Contract; |

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|  | 1. acts of terrorism; 2. flood, storm or other natural disasters; 3. fire; 4. unavailability of public utilities and/or access to transport networks to the extent no diligent supplier could reasonably have planned for such unavailability as part of its business continuity planning; 5. government requisition or impoundment to the extent such requisition or impoundment does not result from any failure by the Supplier to comply with any relevant regulations, laws or procedures (including such laws or regulations relating to the payment of any duties or taxes) and subject to the Supplier having used all reasonable legal means to resist such requisition or impoundment; 6. compliance with any local law or governmental order, rule, regulation or direction applicable outside of England and Wales that could not have been reasonably foreseen; 7. industrial action which affects the ability of the Supplier to supply the Goods and/or to provide the Services, but which is not confined to the workforce of the Supplier or the workforce of any Sub- contractor of the Supplier; and 8. a failure in the Supplier’s and/or Authority’s supply chain to the extent that such failure is due to any event suffered by a member of such supply chain, which would also qualify as a Force Majeure Event in accordance with this definition had it been suffered by one of the Parties;   but excluding, for the avoidance of doubt, the withdrawal of the United Kingdom from the European Union and any related circumstances, events, changes or requirements; |
| **“Framework Agreement”** | means the Framework Agreement referred as part of the Order Form; |
| **“Fraud”** | means any offence under any law in respect of fraud in relation to this Contract or defrauding or attempting to defraud or conspiring to defraud the government, |

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|  | parliament or any Contracting Authority; |
| **“GDPR”** | means the General Data Protection Regulation (Regulation (EU) 2016/679); |
| **“General Anti-Abuse Rule”** | means:   1. the legislation in Part 5 of the Finance Act 2013; and 2. any future legislation introduced into parliament to counteract tax advantages arising from abusive arrangements to avoid national insurance contributions; |
| **“Good Clinical Practice”** | means using standards, practices, methods and procedures conforming to the Law and reflecting up-to- date published evidence and using that degree of skill and care, diligence, prudence and foresight which would reasonably and ordinarily be expected from a skilled, efficient and experienced clinical services provider and a person providing services the same as or similar to the Services at the time the Services are provided; |
| **“Good Industry Practice”** | means the exercise of that degree of skill, diligence, prudence, risk management, quality management and foresight which would reasonably and ordinarily be expected from a skilled and experienced supplier and/or service provider engaged in the manufacture and/or supply of goods and/or the provision of services similar to the Goods and Services under the same or similar circumstances as those applicable to this Contract; including, without limitation, in accordance with Good Clinical Practice; |
| **“Goods”** | means all goods, materials or items that the Supplier is required to supply to the Authority and/or Patients under this Contract (including, without limitation, to meet the requirements of the Specification and Tender Response Document). For the avoidance of doubt, this shall include, without limitation, any medicinal products supplied and/or administered direct to Patients by the Supplier in accordance with this Contract and any medical devices, products ancillary to medicinal products and/or medical devices and/or any other equipment, products and/or items supplied and/or administered to Patients by the Supplier; |
| **“Guidance”** | means any applicable guidance, direction or determination and any policies, advice or industry alerts which apply to |

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|  | the Goods and/or Services, to the extent that the same are published and publicly available or the existence or contents of them have been notified to the Supplier by the Authority and/or have been published and/or notified to the Supplier by the Department of Health, Monitor, NHS England, the Medicines and Healthcare Products Regulatory Agency, the European Medicine Agency, the European Commission, the Care Quality Commission and/or any other regulator or competent body; |
| **“Halifax Abuse Principle”** | means the principle explained in the CJEU Case C-255/02 Halifax and others; |
| **“HM Government Cyber Essentials Scheme** | means the HM Government Cyber Essentials Scheme as further defined in the documents relating to this scheme published at:  [https://www.gov.uk/government/publications/cyber-](https://www.gov.uk/government/publications/cyber-essentials-scheme-overview) [essentials-scheme-overview](https://www.gov.uk/government/publications/cyber-essentials-scheme-overview); |
| **“Implementation Requirements”** | means the Authority’s implementation and mobilisation requirements (if any), as may set out in the Specification and Tender Response Document and/or otherwise as part of this Contract, which the Supplier must comply with as part of implementing the Services; |
| **“Intellectual Property Rights”** | means all patents, copyright, design rights, registered designs, trade marks, know-how, database rights, confidential formulae and any other intellectual property rights and the rights to apply for patents and trade marks and registered designs; |
| **“Interested Party”** | means any organisation which has a legitimate interest in providing services of the same or similar nature to the Services in immediate or proximate succession to the Supplier or any Sub-contractor and who had confirmed such interest in writing to the Authority; |
| **“Key Provisions”** | means the key provisions set out in [Schedule 1](#_bookmark8) of these Call-off Terms and Conditions and/or as part of the Order Form, if any; |
| **“KPI”** | means the key performance indicators, Service performance requirements, Service levels and Service standards as set out in the Specification and Tender Response Document and/or elsewhere as part of this Contract and/or as part of any management information (to include, without limitation, as part of any relevant templates) that the Supplier is required to provide in |

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|  | accordance with the Specification and Tender Response Document; |
| **“Law”** | means any applicable legal requirements including, without limitation,:   1. any applicable statute or proclamation, delegated or subordinate legislation, bye-law, order, regulation or instrument as applicable in England and Wales; 2. any retained EU law (as defined by section 6(7) of the European Union (Withdrawal) Act 2018; 3. (subject to EU Exit) any applicable European Union directive, regulation, decision or law; 4. (subject to EU Exit) any enforceable community right within the meaning of section 2(1) European Communities Act 1972; 5. any applicable judgment of a relevant court of law which is a binding precedent in England and Wales; 6. requirements set by any regulatory body as applicable in England and Wales; and 7. any applicable code of practice as applicable in England and Wales; and 8. any relevant collective agreement and/or international law provisions (to include, without limitation, as referred to in (a) to (f) above); |
| **“NHS”** | means the National Health Service; |
| **“Occasion of Tax Non-Compliance”** | means:   1. any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1 October 2012 is found on or after 1 April 2013 to be incorrect as a result of:    1. a Relevant Tax Authority successfully challenging the Supplier under the General Anti-Abuse Rule or the Halifax Abuse Principle or under any tax rules or legislation that have an effect equivalent or similar to the General Anti-Abuse Rule or the Halifax Abuse Principle;    2. the failure of an avoidance scheme which the Supplier was involved in, and which was, or should |

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|  | have been, notified to a Relevant Tax Authority under the DOTAS or any equivalent or similar regime; and/or  (b) any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1 October 2012 gives rise, on or after 1 April 2013, to a criminal conviction in any jurisdiction for tax related offences which is not spent at the Effective Date or to a civil penalty for fraud or evasion; |
| **“Order Form”** | means the order form for the Goods and/or Services issued by the Authority in accordance with the Framework Agreement; |
| **“Party”** | means the Authority or the Supplier as appropriate and Parties means both the Authority and the Supplier; |
| **“Patient**” | means any patient receiving Goods and/or Services from the Supplier in accordance with this Contract; |
| **“Personal Data”** | shall have the same meaning as set out in the GDPR; |
| **“Policies”** | means the policies, rules and procedures of the Authority as notified to the Supplier from time to time; |
| **“Premises and Locations”** | has the meaning given under Clause [4.1](#_bookmark17) of [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions; |
| **“Process”** | shall have the same meaning as set out in the GDPR. Processing and Processed shall be construed accordingly; |
| **“Processor”** | shall have the same meaning as set out in the GDPR; |
| **“Product Information”** | means information concerning the Goods as may be set out in the Specification and Tender Response Document or as reasonably requested by the Authority and supplied by the Supplier to the Authority in accordance with Clause [20](#_bookmark82) of [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions for inclusion in the Authority's product catalogue from time to time; |
| **“Purchase Order”** | means the purchase order issued by the Authority (in accordance with its financial systems) in relation to any required Goods and/or Services; |
| **“Relevant Activities”** | means the procurement, purchasing, sale, manufacture, assembly, compounding, importation, storage, distribution, dispensing, supply, delivery, installation, administration of the Goods or any other activities and services required to |

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|  | be carried out under and/or in connection with this Contract by the Supplier and/or a member of the Supplier’s supply chain; |
| **“Relevant Tax Authority”** | means HM Revenue and Customs, if applicable, a tax authority in the jurisdiction in which the Supplier is established; |
| **“Remedial Proposal”** | has the meaning given under Clause [15.3](#_bookmark60) of [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions; |
| **“Requirement to Recall”** | has the meaning given under [3.9](#_bookmark15) of [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions; |
| **“Services”** | means the homecare medicines services and all related services set out in this Contract that the Supplier is required to provide (including, without limitation, the services required to meet the requirements of the Specification and Tender Response Document), which shall include, without limitation, any services provided in connection with any Relevant Activities and/or direct to Patients by the Supplier and/or a member of its supply chain under and/or in connection with this Contract; |
| **“Services Commencement Date”** | means the date delivery of the Services shall commence as specified in the Order Form. If no date is specified in the Order Form, this services commencement date shall be the same date as the Commencement Date; |
| **“Services Information”** | means information concerning the Services as may be set out in the Specification and Tender Response Document and/or as reasonably requested by the Authority and supplied by the Supplier to the Authority in accordance with Clause [20](#_bookmark82) of [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions for inclusion in the Authority's services catalogue from time to time; |
| **“Specification and Tender Response Document”** | means the Specification and Tender Response Document set out in the Framework Agreement as supplemented by any further information set out and/or referred to in the Order Form and as amended and/or updated in accordance with this Contract; |
| **“Staff”** | means all persons employed or engaged by the Supplier to perform its obligations under this Contract including any Sub-contractors and person employed or engaged by such Sub-contractors; |
| **“Sub-contract”** | means a contract between two or more suppliers, at any stage of remoteness from the Supplier in a sub-contracting |

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|  | chain, made wholly or substantially for the purpose of performing (or contributing to the performance of) the whole or any part of this Contract; |
| **“Sub-contractor”** | means a party to a Sub-contract other than the Supplier; |
| **“Subsequent Transfer Date”** | means the point in time, if any, at which services which are fundamentally the same as the Services (either in whole or in part) are first provided by a Successor or the Authority, as appropriate, giving rise to a relevant transfer under TUPE; |
| **“Subsequent Transferring Employees”** | means any employee, agent, consultant and/or contractor who, immediately prior to the Subsequent Transfer Date, is wholly or mainly engaged in the performance of services fundamentally the same as the Services (either in whole or in part) which are to be undertaken by the Successor or Authority, as appropriate; |
| **“Successor”** | means any third party who provides services fundamentally the same as the Services (either in whole or in part) in immediate or subsequent succession to the Supplier upon the expiry or earlier termination of this Contract; |
| **“Supplier”** | means the supplier named in the Order Form; |
| **“Supplier Code of Conduct”** | means the code of that name published by the Government Commercial Function originally dated September 2017, as may be amended, restated, updated, re-issued or re-named from time to time; |
| **“Supplier Personnel”** | means any employee, agent, consultant and/or contractor of the Supplier or Sub-contractor who is either partially or fully engaged in the performance of the Services; |
| **“Term”** | means the term as referred to in the Key Provisions; |
| **“Termination Notice”** | means a written notice of termination given by one Party to the other notifying the Party receiving the notice of the intention of the Party giving the notice to terminate this Contract on a specified date and setting out the grounds for termination; |
| **“Third Party”** | means any supplier of services fundamentally the same as the Services (either in whole or in part) immediately before the Transfer Date; |
| **“Third Party Body”** | has the meaning given under Clause [8.5](#_bookmark28) of [Schedule 2](#_bookmark12) of |

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|  | these Call-off Terms and Conditions; |
| **“Transfer Date”** | means the Actual Services Commencement Date; |
| **"TUPE"** | means the Transfer of Undertakings (Protection of Employment) Regulations 2006 (2006/246) and/or any other regulations or other legislation enacted for the purpose of implementing or transposing the Acquired Rights Directive (77/187/EEC, as amended by Directive 98/50 EC and consolidated in 2001/23/EC) into English law; and |
| **“VAT”** | means value added tax chargeable under the Value Added Tax Act 1994 or any similar, replacement or extra tax. |

* 1. References to any Law shall be deemed to include a reference to that Law as amended, extended, consolidated, re-enacted, restated, implemented or transposed from time to time.
  2. References to any legal entity shall include any body that takes over responsibility for the functions of such entity.
  3. References in this Contract to a “Schedule”, “Appendix”, “Paragraph” or to a “Clause” are to schedules, appendices, paragraphs and clauses of this Contract.
  4. References in this Contract to a day or to the calculation of time frames are references to a calendar day unless expressly specified as a Business Day.
  5. Unless set out in the Contract as a chargeable item and subject to Clause

[30.6](#_bookmark112) of [Schedule 2](#_bookmark12) of these Call-off Terms and Conditions, the Supplier shall bear the cost of complying with its obligations under this Contract.

* 1. The headings are for convenience only and shall not affect the interpretation of this Contract.
  2. Words denoting the singular shall include the plural and vice versa.
  3. Where a term of this Contract provides for a list of one or more items following the word “including” or “includes” then such list is not to be interpreted as an exhaustive list. Any such list shall not be treated as excluding any item that might have been included in such list having regard to the context of the contractual term in question. General words are not to be given a restrictive meaning where they are followed by examples intended to be included within the general words.
  4. Where there is a conflict between the Supplier’s responses to the Authority’s requirements set out in the Specification and Tender Response Document

and any other part of this Contract, such other part of this Contract shall prevail.

* 1. Where a document is required under this Contract, the Parties may agree in writing that this shall be in electronic format only.
  2. Where there is an obligation on the Authority to procure any course of action from any third party, this shall mean that the Authority shall use its reasonable endeavours to procure such course of action from that third party.
  3. Any guidance notes in grey text do not form part of this Contract.
  4. Any Breach Notice issued by a Party in connection with this Contract shall not be invalid due to it containing insufficient information. A Party receiving a Breach Notice (“**Receiving Party**”) may ask the Party that issued the Breach Notice (“**Issuing Party**”) to provide any further information in relation to the subject matter of the Breach Notice that it may reasonably require to enable it to understand the Breach Notice and/or to remedy the breach. The Issuing Party shall not unreasonably withhold or delay the provision of such further information as referred to above as may be requested by the Receiving Party but no such withholding or delay shall invalidate the Breach Notice.
  5. Any terms defined as part of a Schedule or other document forming part of this Contract shall have the meaning as defined in such Schedule or document.

 

**COVER NOTES**

This Protocol updates and replaces the data protection protocol which was published in January 2018 as part of the January 2018 update to the standard NHS Terms and Conditions for the supply of goods and the provision of services. This update reflects changes to the model clauses relating to data protection brought in by the PPN 02/18 which was published in May 2018. Please see the relevant Crown Commercial Service Procurement Policy Notice (**PPN**) and related model clauses (Changes to Data Protection Legislation & General Data Protection Regulation) here:

[https://www.gov.uk/government/publications/procurement-policy-note-0218-changes-to-data-](https://www.gov.uk/government/publications/procurement-policy-note-0218-changes-to-data-protection-legislation-general-data-protection-regulation) [protection-legislation-general-data-protection-regulation](https://www.gov.uk/government/publications/procurement-policy-note-0218-changes-to-data-protection-legislation-general-data-protection-regulation)).

As part of this update, the Department of Health and Social Care’s policy approach has been to adopt the Crown Commercial Service PPN model clauses with some changes:

* + 1. to ensure consistent use of terminology with the NHS Terms and Conditions;
    2. to add clarity to the scope of the obligations under the PPN in an NHS context; and
    3. to allow for appropriate variations. .

This Protocol contains model clauses for completion in connection with relevant contracts where the Supplier will be Processing personal data under or in connection with the Contract, where the parties will be acting as Joint Controllers, or where the parties may be sharing personal data as independent Controllers. This is required by Schedule 3

(Information and Data Provisions) of the NHS Terms and Conditions.

It is important that the Protocol is completed and/or tailored in such a way to reflect the actual data Processing activities taking place under a particular contract. In the context of more complex data sharing arrangement the Protocol will need more substantial changes and tailoring to reflect any data controlled by the Supplier and Processed by the Authority and/or any data shared with third parties as part of such arrangements.

Thought also needs to be given as to whether any changes need to be made to reflect any practical considerations that may apply to a particular contract. For example, the Protocol provides that the Supplier must ensure that it does not transfer Personal Data outside of the EU without the prior written consent of the Authority. If it is impractical for the Authority to provide such consent each and every time an item of Personal Data is transferred, you will need to agree specific overarching provisions with the Supplier as to how to deal with, and manage, such transfers in compliance with Data Protection Legislation

*Developed in partnership with*

**September 2019**

**DATA PROTECTION PROTOCOL**

*Guidance: This Data Protection Protocol is for use alongside the NHS terms and conditions. The table at the beginning of the Protocol should be completed by the Authority setting out the nature of the relationship and processing that will be taking place under the Contract.*

**Table A – Processing, Personal Data and Data Subjects**

This Table shall be completed by the Authority, who may take account of the view of the Supplier, however the final decision as to the content of this Table shall be with the Authority at its absolute discretion.

1. The contact details of the Authority’s Data Protection Officer are: **[Insert Contact details**]
2. The contact details of the Supplier’s Data Protection Officer are: **[Insert Contact details**]

|  |  |
| --- | --- |
| **Description** | **Details** |
| Identity of the Controller and Processor | *[The Parties acknowledge that the Authority is the Controller and the Supplier is the Processor for the purposes of the Data Protection Legislation in respect of:*  *[Insert the scope of Personal Data which the purposes and means of the Processing is determined by the both Parties]*  *In respect of Personal Data where the Authority is the Controller and the Supplier is the Processor, Clause 1 of this Protocol will apply.]*  *[The Parties acknowledge that they are Joint Controllers for the purposes of the Data Protection Legislation in respect of:*  *[Insert the scope of Personal Data which the purposes and means of the Processing is determined jointly by the both Parties]*  *In respect of Personal Data under joint control, Clause 2 of this Protocol will apply].*  *[The Parties acknowledge that they are independent Controllers for the purposes of the Data Protection Legislation in respect of:*  *[Insert the scope of Personal Data shared which the purposes and means of the Processing means that they are independent Controllers.]*  *In respect of Personal Data shared under the Contract in circumstances where the Authority and the Supplier are* |

|  |  |
| --- | --- |
| Subject matter of the Processing | *[This should be a high level, short description of what the Processing is about i.e. its subject matter of the contract.*  *Example: The Processing is needed in order to ensure that the Processor can effectively deliver the contract to provide a service to members of the public. ]* |
| Duration of the Processing | *[Clearly set out the duration of the Processing including dates]* |
| Nature and purposes of the Processing | *[Please be as specific as possible, but make sure that you cover all intended purposes.*  *The nature of the Processing means any operation such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction of data (whether or not by automated means) etc.*  *The purpose might include: employment Processing, statutory obligation, recruitment assessment etc]* |
| Type of Personal Data being Processed | *[Examples here include: name, address, date of birth, NI number, telephone number, pay, images, biometric data etc]* |
| Categories of Data Subject | *[Examples include: Staff (including volunteers, agents, and temporary workers), customers/ clients, suppliers, patients, students / pupils, members of the public, users of a particular*  *website etc]* |
| Plan for return and destruction of the data once the Processing is complete  UNLESS requirement under union or member state law to preserve that type of data | *[Describe how long the data will be retained for, how it be returned or destroyed]* |

**Definitions**

The definitions and interpretative provisions at Schedule 4 (Definitions and Interpretations) of the Contract shall also apply to this Protocol. For example, the following terms are defined in Schedule 4 of the Contract: “Authority”, “Controller”,

“Process” and “Processer” and “Supplier” are defined in Schedule 4 of the Contract. Additionally, in this Protocol the following words shall have the following meanings unless the context requires otherwise:

|  |  |
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| “**Data Loss Event**” | means any event that results, or may result, in unauthorised access to Personal Data held by the Processor under this Contract, and/or actual or potential loss and/or destruction of Personal Data in breach of this Contract, including any Personal Data Breach; |
| “**Data Protection Legislation**” | means (i) the GDPR, the LED and any applicable national implementing Laws as amended from time to time (ii) the DPA 2018 to the extent that it relates to Processing of personal data and privacy; (iii) all applicable Law about the Processing of Personal Data and privacy; |
| “**Data Protection Impact Assessment**” | means an assessment by the Controller of the impact of the envisaged Processing on the protection of Personal Data; |
| “**Data Protection Officer**” | shall have the same meaning as set out in the GDPR; |
| “**Data Recipient**” | means that Controller who receives the relevant Personal Data; |
| “**Data Subject**” | shall have the same meaning as set out in the GDPR; |
| “**Data Subject Request**” | means a request made by, or on behalf of, a Data Subject in accordance with rights granted pursuant to the Data Protection Legislation to access their Personal Data; |
| “**Data Transferor**” | means that Controller who transfers the relevant Personal Data; |
| “**DPA 2018**” | means the Data Protection Act 2018; |

|  |  |
| --- | --- |
| “**Joint Controllers**” | means where two or more Controllers jointly determine the purposes and means of Processing; |
| “**LED**” | means the Law Enforcement Directive  *(Directive (EU) 2016/680)*; |
| “**Personal Data Breach**” | shall have the same meaning as set out in the GDPR; |
| “**Protective Measures**” | means appropriate technical and organisational measures which may include: pseudonymising and encrypting Personal Data, ensuring confidentiality, integrity, availability and resilience of systems and services, ensuring that availability of and access to Personal Data can be restored in a timely manner after an incident, putting in place appropriate training of staff involved in the processing of Personal Data and regularly assessing and evaluating the  effectiveness of the such measures adopted by it [including those outlined in Schedule [*insert schedule number and name (e.g. if there is a relevant security schedule*)]]; |
| “**Protocol**” or “**Data Protection Protocol**” | means this Data Protection Protocol; |
| “**Sub-processor**” | means any third Party appointed to Process Personal Data on behalf of that Processor related to this Contract. |

1. **SUPPLIER AS DATA PROCESSOR**
   1. Where, in Table A, the Parties acknowledge that for the purposes of the Data Protection Legislation, the Authority is the Controller and the Supplier is the Processor for the relevant purposes specified in Table A this Clause [1](#_bookmark119) shall apply. The only Processing that the Supplier is authorised to do is listed in Table A of this Protocol by the Authority and may not be determined by the Supplier.
   2. The Supplier shall notify the Authority immediately if it considers that any of the Authority’s instructions infringe the Data Protection Legislation.
   3. The Supplier shall provide all reasonable assistance to the Authority in the preparation of any Data Protection Impact Assessment prior to commencing any Processing. Such assistance may, at the discretion of the Authority, include:
      1. a systematic description of the envisaged Processing operations and the purpose of the Processing;
      2. an assessment of the necessity and proportionality of the Processing operations in relation to the Services;
      3. an assessment of the risks to the rights and freedoms of Data Subjects; and
      4. the measures envisaged to address the risks, including safeguards, security measures and mechanisms to ensure the protection of Personal Data.
   4. The Supplier shall, in relation to any Personal Data Processed in connection with its obligations under this Contract:
      1. Process that Personal Data only in accordance with Table A, unless the Supplier is required to do otherwise by Law. If it is so required the Supplier shall promptly notify the Authority before Processing the Personal Data unless prohibited by Law;
      2. ensure that it has in place Protective Measures, which are appropriate to protect against a Data Loss Event, which the Authority may reasonably reject (but failure to reject shall not amount to approval by the Authority of the adequacy of the Protective Measures), having taken account of the:
         1. nature of the data to be protected;
         2. harm that might result from a Data Loss Event;
         3. state of technological development; and
         4. cost of implementing any measures;
      3. ensure that:
         1. the Supplier Personnel do not Process Personal Data except in accordance with this Contract (and in particular Table A);
         2. it takes all reasonable steps to ensure the reliability and integrity of any Supplier Personnel who have access to the Personal Data and ensure that they:
            1. are aware of and comply with the Supplier’s duties under this Protocol;
            2. are subject to appropriate confidentiality undertakings with the Supplier or any Sub-processor;
            3. are informed of the confidential nature of the Personal Data and do not publish, disclose or divulge any of the Personal Data to any third Party unless directed in writing to do so by the Authority or as otherwise permitted by this Contract; and
            4. have undergone adequate training in the use, care, protection and handling of Personal Data;
      4. not transfer Personal Data outside of the EU unless the prior written consent of the Authority has been obtained and the following conditions are fulfilled:
         1. the Authority or the Supplier has provided appropriate safeguards in relation to the transfer (whether in accordance with GDPR Article 46 or LED Article 37) as determined by the Authority;
         2. the Data Subject has enforceable rights and effective legal remedies;
         3. the Supplier complies with its obligations under the Data Protection Legislation by providing an adequate level of protection to any Personal Data that is transferred (or, if it is not so bound, uses its best endeavours to assist the Authority in meeting its obligations); and
         4. the Supplier complies with any reasonable instructions notified to it in advance by the Authority with respect to the Processing of the Personal Data; and
      5. at the written direction of the Authority, delete or return Personal Data (and any copies of it) to the Authority on termination of the Contract unless the Supplier is required by Law to retain the Personal Data.
   5. Subject to Clause 1.6 of this Protocol, the Supplier shall notify the Authority immediately if in relation to any Personal Data Processed in connection with its obligations under this Contract it:
      1. receives a Data Subject Request (or purported Data Subject Request);
      2. receives a request to rectify, block or erase any Personal Data;
      3. receives any other request, complaint or communication relating to either Party’s obligations under the Data Protection Legislation;
      4. receives any communication from the Information Commissioner or any other regulatory authority in connection with Personal Data Processed under this Contract;
      5. receives a request from any third party for disclosure of Personal Data where compliance with such request is required or purported to be required by Law; or
      6. becomes aware of a Data Loss Event.
   6. The Supplier’s obligation to notify under Clause 1.5 of this Protocol shall include the provision of further information to the Authority in phases, as details become available.
   7. Taking into account the nature of the Processing, the Supplier shall provide the Authority with full assistance in relation to either Party’s obligations under Data Protection Legislation in relation to any Personal Data Processed in connection with its obligations under this Contract and any complaint, communication or request made under Clause 1.5 of this Protocol (and insofar as possible within the timescales reasonably required by the Authority) including by promptly providing:
      1. the Authority with full details and copies of the complaint, communication or request;
      2. such assistance as is reasonably requested by the Authority to enable the Authority to comply with a Data Subject Request within the relevant timescales set out in the Data Protection Legislation;
      3. the Authority, at its request, with any Personal Data it holds in connection with its obligations under this Contract in relation to a Data Subject;
      4. assistance as requested by the Authority following any Data Loss Event;
      5. assistance as requested by the Authority with respect to any request from the Information Commissioner’s Office, or any consultation by the Authority with the Information Commissioner’s Office.
   8. The Supplier shall maintain complete and accurate records and information to demonstrate its compliance with this Protocol. This requirement does not apply where the Supplier employs fewer than 250 staff, unless:
      1. the Authority determines that the Processing is not occasional;
      2. the Authority determines the Processing includes special categories of data as referred to in Article 9(1) of the GDPR or Personal Data relating to criminal convictions and offences referred to in Article 10 of the GDPR; or
      3. the Authority determines that the processing is likely to result in a risk to the rights and freedoms of Data Subjects.
   9. The Supplier shall allow for audits of its data Processing activity by the Authority or the Authority’s designated auditor in relation to any Personal Data Processed in connection with its obligations under this Contract.
   10. Each Party shall designate its own Data Protection Officer if required by the Data Protection Legislation.
   11. Before allowing any Sub-processor to Process any Personal Data related to this Contract, the Supplier must:
       1. notify the Authority in writing of the intended Sub-processor and Processing;
       2. obtain the written consent of the Authority;
       3. enter into a written agreement with the Sub-processor which give effect to the terms set out in this Protocol such that they apply to the Sub-processor; and
       4. provide the Authority with such information regarding the Sub-processor as the Authority may reasonably require.
   12. The Supplier shall remain fully liable for all acts or omissions of any of its Sub- processors.
   13. The Authority may, at any time on not less than 30 Working Days’ notice, revise this Protocol by replacing it with any applicable controller to Processor standard clauses or similar terms forming part of an applicable certification scheme (which shall apply when incorporated by attachment to this Contract).
   14. The Parties agree to take account of any guidance issued by the Information Commissioner’s Office. The Authority may on not less than 30 Working Days’ notice to the Supplier amend this Protocol to ensure that it complies with any guidance issued by the Information Commissioner’s Office.
   15. The Supplier shall comply with any further instructions with respect to Processing issued by the Authority by written notice. Any such further written instructions shall be deemed to be incorporated into Table A from the date at which such notice is treated as having been received by the Supplier in accordance with Clause 27.2 of Schedule 2 of the Contract.
2. **PARTIES AS JOINT CONTROLLERS**
   1. Where in, Table A, the Parties acknowledge that for the purposes of the Data Protection Legislation, the Authority and the Supplier are Joint Controllers this Clause [2](#_bookmark123) shall apply. The only Processing that a Joint Controller is authorised to do is listed in Table A of this Protocol by the Authority and may not be determined by the Supplier.
   2. The Parties shall in accordance with GDPR Article 26 enter into a Joint Controller Agreement based on the terms outlined in Schedule 1.
3. **BOTH DATA CONTROLLERS**
   1. To the extent that the nature of the Services means that the Parties are acting both as Controllers (as may be referred to in Table A), each Party undertakes to comply at all times with its obligations under the Data Protection Legislation and shall:
      1. implement such measures and perform its obligations (as applicable) in compliance with the Data Protection Legislation;
      2. be responsible for determining its data security obligations taking into account the state of the art, the costs of implementation and the nature,

scope, context and purposes of the Processing as well as the risk of varying likelihood and severity for the rights and freedoms of the Data Subjects, and implement appropriate technical and organisational measures to protect the Personal Data against unauthorised or unlawful Processing and accidental destruction or loss and ensure the protection of the rights of the Data Subject, in such a manner that Processing will meet the requirements of the Data Protection Legislation where Personal Data has been transmitted by it, or while the Personal Data is in its possession or control;

* + 1. where appropriate, promptly refer to the other Party any requests, from (i) Data Subjects in regards to the right of access to Personal Data by that Data Subject in accordance with the Data Protection Legislation; (ii) the Information Commissioner; or (iii) any other law enforcement authority and to the extent it is reasonable and practical to do so consult with the other Party (for the avoidance of doubt at no additional cost) before responding to such request.
  1. Where Personal Data is shared between the Parties, each acting as Controller:
     1. the Data Transferor warrants and undertakes to the Data Recipient that such Personal Data have been collected, Processed and transferred in accordance with the Data Protection Legislation and this Clause [3](#_bookmark124);
     2. the Data Recipient will Process the Personal Data in accordance with the Data Protection Legislation and this Clause [3](#_bookmark124); and
     3. where the Data Recipient is in breach of its obligations under this Protocol and the Data Protection Legislation, the Data Transferor may temporarily suspend the transfer of the Personal Data to the Data Recipient until the breach is repaired.

*Guidance: there are limited requirements in the GDPR when parties act as separate Controllers. Clause 3 above provides a sensible starting point. However, Authorities are advised to review the Information Commissioner’s Guidance (ICO GDPR Guidance) and consultant their Information Governance team when considering whether further provisions or a separate data sharing agreement should be used.*

1. **CHANGES TO THIS PROTOCOL**
   1. Subject to Clauses [1.13](#_bookmark120), [1.14](#_bookmark121) and [1.15](#_bookmark122) of this Protocol, any change or other variation to this Protocol shall only be binding once it has been agreed in writing and signed by an authorised representative of both Parties.

**Schedule 1 – Joint Controller Agreement**

In this Schedule the Parties must outline each party’s responsibilities for:

* providing information to data subjects under Article 13 and 14 of the GDPR.
* responding to data subject requests under Articles 15-22 of the GDPR
* notifying the Information Commissioner (and data subjects) where necessary about data breaches
* maintaining records of Processing under Article 30 of the GDPR
* carrying out any required Data Protection Impact Assessment

The joint controller agreement must include a statement as to who is the point of contact for data subjects. The essence of this relationship shall be published. You may wish to incorporate some clauses equivalent to those specified in Clause 1.2-1.14 of Clause 1.

Situations where both parties act as Joint Controllers are likely to be relatively novel. Therefore, in such circumstances, it will be important to seek specific legal advice on the approach to the joint controller agreement. As part of this, you may wish to include an additional clause apportioning liability between the parties arising out of data protection in respect of data that is jointly controlled.