

**2017/18
PUBLIC HEALTH SERVICES CONTRACT**

LEEDS CITY COUNCIL (1)

AS AUTHORITY

AND

..... **(2)**

AS PROVIDER

**CONTRACT FOR THE PROVISION OF
PUBLIC HEALTH SERVICES**

**PHARMACY SUPERVISED CONSUMPTION
SERVICE**

REFERENCE NUMBER [DN339056]

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THE PARTICULARS

**2017/18
PUBLIC HEALTH SERVICES CONTRACT**

This Contract is made on

2018

PARTIES

- (1) **LEEDS CITY COUNCIL** of **CIVIC HALL LEEDS LS1 1UR** (the **Authority**); and
(2) (the **Provider**).

BACKGROUND

- (A) The Authority must exercise a number of health service functions set out in section 2B of the NHS Act 2006 and the Local Authorities (Public Health Functions and Entry to Premises by Local Healthwatch Representatives) Regulations. In order to satisfy these obligations the Authority wishes to secure the provision of the Services and the Provider wishes to provide the Services.
- (B) The Parties have agreed for the Provider to provide the Services in accordance with the terms and conditions of this Contract.

IT IS AGREED

A1. CONTRACT

A1.1. This Contract is comprised of:

- (a) these Particulars (Section A);
- (b) the General Terms and Conditions (Section B, including the Appendices) (the **General Conditions**); and
- (c) the Special Terms and Conditions (Section C) (the **Special Conditions**),

as completed and agreed by the Parties and as varied from time to time in accordance with clause B22 (*Variations*) of the General Conditions (this **Contract**).

A2. INTERPRETATION

A2.1. This Contract shall be interpreted in accordance with Appendix O (*Definitions and Interpretation*), unless the context requires otherwise.

A2.2. If there is any conflict or inconsistency between the provisions of this Contract, such conflict or inconsistency must be resolved according to the following order of priority:

- (a) Section C
- (b) Section B (including the Appendices); and
- (c) Section A

A2.3. If there is any conflict or inconsistency between the provisions of Appendix A (Service Specifications) and Appendix P (Tender Documents), Appendix A shall take priority.

A3. COMMENCEMENT AND DURATION

- A3.1. This Contract shall take effect on 01 July 2018 (the **Commencement Date**).
- A3.2. The Provider shall, subject to having satisfied the Conditions Precedent where applicable, provide the Services from 01 July 2018 (the **Service Commencement Date**).
- A3.3. Subject to Clause C1, this Contract shall expire automatically on 30 June 2021 (the **Expiry Date**), unless it is extended or terminated earlier in accordance with the provisions of this Contract.

A4. REPRESENTATIVES

- A4.1. The person set out below is authorised from the Commencement Date to act on behalf of the Authority on all matters relating to this Contract (the **Authority Representative**).

Name: Helen Moran
Title: Commissioning and Contracts Officer
Contact Details: SubstanceMisuse@leeds.gov.uk

- A4.2. The person set out below is authorised from the Commencement Date to act on behalf of the Provider on all matters relating to this Contract (the **Provider Representative**).

Name:
Title:
Contact Details:

- A4.3. The Provider may replace the Provider Representative and the Authority may replace the Authority Representative at any time by giving written notice to the other Party.

A5. NOTICES

- A5.1. Any notices given under this Contract shall be in writing and shall be served by hand or post by sending the same to the address for the relevant Party set out in clause A5.3.

- A5.2. Notices:

- a) by post and correctly addressed shall be effective upon the earlier of actual receipt, or 5 Business Days after mailing; or
- b) by hand shall be effective upon delivery.

- A5.3. For the purposes of clause A5.2, the address for service of notices on each Party shall be as follows:

- (a) For the Authority:
Address: Leeds City Council, Leeds Civic Hall, Calverley Street, Leeds, LS1 1UR
For the attention of: Helen Moran, Commissioning and Contracts Officer, Adults and Health
Tel: 0113 37 87851

- (b) For the Provider:
Address:
For the attention of:
Tel:

- A5.4. Either Party may change its address for service by serving a notice in accordance with this clause A5.

A6. ENTIRE CONTRACT

This Contract constitutes the entire agreement and understanding of the Parties and supersedes any previous agreement between the Parties relating to the subject matter of this Contract, except for any contract entered into between the Authority and the Provider which relates to the same or similar services to the Services and is designed to remain effective until the Services are provided under this Contract.

A7. COUNTERPARTS

This Contract may be executed in counterparts each of which when executed and delivered shall constitute an original but all counterparts together shall constitute one and the same instrument. No counterpart shall be effective until each Party has executed at least one counterpart.

IN WITNESS WHEREOF the Parties have signed this Contract on the date shown below

**SIGNED
on behalf of
the AUTHORITY**

.....
Signature

.....
Job Title

.....
Date

Name of Pharmacy:

Address of Pharmacy:

SIGNED by

.....
Signature

.....
Job Title

.....
Date

SECTION B
GENERAL TERMS AND CONDITIONS

B1. SERVICES

- B1.1. The Provider shall provide the Services in accordance with the Service Specification(s) in Appendix A (*Service Specifications*), including any service limitations set out in them, and in accordance with the provisions of this Contract.
- B1.2. The Provider shall satisfy any Conditions Precedent set out in Appendix B (*Conditions Precedent*) prior to commencing provision of the Services.

B2. WITHHOLDING AND/OR DISCONTINUATION OF SERVICE

- B2.1. Except where required by the Law, the Provider shall not be required to provide or to continue to provide Services to any Service User:
- a) who in the reasonable professional opinion of the Provider is unsuitable to receive the relevant Service, for as long as such unsuitability remains;
 - b) who displays abusive, violent or threatening behaviour unacceptable to the Provider acting reasonably and taking into account the mental health of that Service User;
 - c) in that Service User's domiciliary care setting or circumstances (as applicable) where that environment poses a level of risk to the Staff engaged in the delivery of the relevant Service that the Provider reasonably considers to be unacceptable; or
 - d) where expressly instructed not to do so by an emergency service provider who has authority to give such instruction, for so long as that instruction applies.
- B2.2. If the Provider proposes not to provide or to stop providing a Service to any Service User under clause B2.1:
- a) where reasonably possible, the Provider must explain to the Service User, taking into account any communication or language needs, the action that it is taking, when that action takes effect, and the reasons for it (confirming that explanation in writing within 2 Business Days);
 - b) the Provider must tell the Service User of the right to challenge the Provider's decision through the Provider's complaints procedure and how to do so;
 - c) the Provider must inform the Authority in writing without delay and wherever possible in advance of taking such action;

provided that nothing in this clause B2.2 entitles the Provider not to provide or to stop providing the Services where to do so would be contrary to the Law.

B3. SERVICE AND QUALITY OUTCOMES INDICATORS

- B3.1. The Provider must carry out the Services in accordance with the Law and Good Clinical Practice and must, unless otherwise agreed (subject to the Law) with the Authority in writing:
- a) comply, where applicable, with the registration and regulatory compliance guidance of CQC and any other Regulatory Body;
 - b) respond, where applicable, to all requirements and enforcement actions issued from time to time by CQC or any other Regulatory Body;
 - c) consider and respond to the recommendations arising from any audit, death, Serious Incident report or Patient Safety Incident report;
 - d) comply with the recommendations issued from time to time by a Competent Body;

- e) comply with the recommendations from time to time contained in guidance and appraisals issued by NICE;
- f) respond to any reports and recommendations made by Local HealthWatch; and
- g) comply with the Quality Outcomes Indicators set out in Appendix C (*Quality Outcomes Indicators*).

B4. SERVICE USER INVOLVEMENT

- B4.1. The Provider shall engage, liaise and communicate with Service Users, their Carers and Legal Guardians in an open and clear manner in accordance with the Law, Good Clinical Practice and their human rights.
- B4.2. As soon as reasonably practicable following any reasonable request from the Authority, the Provider must provide evidence to the Authority of the involvement of Service Users, Carers, Legal Guardians and Staff in the development of Services.
- B4.3. The Provider must carry out Service User surveys (and Legal Guardian and Carer surveys if relevant) and shall carry out any other surveys reasonably required by the Authority in relation to the Services. The form (if any), frequency and method of reporting such surveys must comply with the requirements set out in Appendix D (*Service User, Legal Guardian, Carer and Staff Surveys*) or as otherwise agreed between the Parties in writing from time to time.
- B4.4. The Provider must review and provide a written report to the Authority on the results of each survey carried out under clause B4.3 and identify any actions reasonably required to be taken by the Provider in response to the surveys. The Provider must implement such actions as soon as practicable. If required by the Authority, the Provider must publish the outcomes and actions taken in relation to such surveys.

B5. EQUITY OF ACCESS, EQUALITY AND NO DISCRIMINATION

- B5.1. The Parties must not discriminate between or against Service Users, on the grounds of age, disability, gender reassignment, marriage or civil partnership, pregnancy or maternity, race, religion or belief, sex, sexual orientation or any other non-medical characteristics except as permitted by the Law.
- B5.2. The Provider must provide appropriate assistance and make reasonable adjustments for Service Users, who do not speak, read or write English or who have communication difficulties (including without limitation hearing, oral or learning impairments).
- B5.3. In performing this Contract the Provider must comply with the Equality Act 2010 and have due regard to the obligations contemplated by section 149 of the Equality Act 2010 to:
 - a) eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by the Equality Act 2010;
 - b) advance equality of opportunity between persons who share a relevant protected characteristic (as defined in the Equality Act 2010) and persons who do not share it; and
 - c) foster good relations between persons who share a relevant protected characteristic (as defined in the Equality Act 2010) and persons who do not share it,

and for the avoidance of doubt this obligation shall apply whether or not the Provider is a public authority for the purposes of section 149 of the Equality Act 2010.

- B5.4. As soon as reasonably practicable following any reasonable request from the Authority, the Provider must provide the Authority with a plan detailing how it will comply with its obligations under clause B5.3.

B5.5. The Provider must provide to the Authority as soon as reasonably practicable, any information that the Authority reasonably requires to:

- a) monitor the equity of access to the Services; and
- b) fulfil their obligations under the Law.

B6. MANAGING ACTIVITY

B6.1. The Provider must manage Activity in accordance with any activity planning assumptions and any caseloads set out in a Service Specification and must comply with all reasonable requests of the Authority to assist it with understanding and managing the levels of Activity for the Services.

B7. STAFF

B7.1. At all times, the Provider must ensure that:

- a) each of the Staff is suitably qualified and experienced, adequately trained and capable of providing the applicable Services in respect of which they are engaged;
- b) there is an adequate number of Staff to provide the Services properly in accordance with the provisions of the applicable Service Specification;
- c) where applicable, Staff are registered with the appropriate professional regulatory body;
- d) Staff are aware of and respect equality and human rights of colleagues and Service Users; and
- e) it can provide a clear DBS Certificate (Standard, Enhanced or Enhanced and DBS Barred List at the Provider's discretion) for each of the Staff engaged in the Services.

B7.2. If requested by the Authority, the Provider shall as soon as practicable and by no later than 20 Business Days following receipt of that request, provide the Authority with evidence of the Provider's compliance with clause B7.1.

B7.3. The Provider must have in place systems for seeking and recording specialist professional advice and must ensure that every member of Staff involved in the provision of the Services receives:

- a) proper and sufficient continuous professional and personal development, training and instruction; and
- b) full and detailed appraisal (in terms of performance and on-going education and training),

each in accordance with Good Clinical Practice and the standards of any applicable relevant professional body.

B7.4. Where applicable under section 1(F)(1) of the NHS Act 2006, the Provider must co-operate with and provide support to the Local Education and Training Boards and/or Health Education England to help them secure an effective system for the planning and delivery of education and training.

B7.5. The Provider must carry out Staff surveys in relation to the Services at intervals and in the form set out in Appendix D (*Service User, Legal Guardian, Carer and Staff Surveys*) or as otherwise agreed in writing from time to time.

- B7.6. Subject to clause B7.7, before the Provider engages or employs any person in the provision of the Services, or in any activity related to, or connected with, the provision of the Services, the Provider must without limitation, complete:
- a) the Employment Checks; and
 - b) such other checks as required by the DBS.
- B7.7. Subject to clause B7.8, the Provider may engage a person in a Standard DBS Position or an Enhanced DBS Position (as applicable) pending the receipt of the Standard DBS Check or Enhanced DBS Check or Enhanced DBS & Barred List Check (as appropriate) with the agreement of the Authority.
- B7.8. Where clause B7.7 applies, the Provider will ensure that until the Standard DBS Check or Enhanced DBS Check or Enhanced DBS & Barred List Check (as appropriate) is obtained, the following safeguards will be put in place:
- a) an appropriately qualified and experienced member of Staff is appointed to supervise the new member of Staff; and
 - b) wherever it is possible, this supervisor is on duty at the same time as the new member of Staff, or is available to be consulted; and
 - c) the new member of Staff is accompanied at all times by another member of staff, preferably the appointed supervisor, whilst providing services under this Contract; and
 - d) any other reasonable requirement of the Authority.
- B7.9. Where the Authority has notified the Provider that it intends to tender or retender any of the Services, the Provider must on written request of the Authority and in any event within 20 Business Days of that request (unless otherwise agreed in writing), provide the Authority with all reasonably requested information on the Staff engaged in the provision of the relevant Services to be tendered or retendered that may be subject to TUPE.
- B7.10. The Provider shall indemnify and keep indemnified the Authority and any Successor Provider against any Losses incurred by the Authority and/or the Successor Provider in connection with any claim or demand by any transferring employee under TUPE.

B8. CHARGES AND PAYMENT

- B8.1. Subject to any provision of this Contract to the contrary (including without limitation those relating to withholding and/or retention, and clause C16), in consideration for the provision of the Services in accordance with the terms of this Contract, the Authority shall pay the Provider the Charges.
- B8.2. The Parties shall to the extent reasonably practicable agree the Charges in a transparent and equitable manner and the Charges shall be set out at Appendix A 3.3, subject to the application of Clause C16 if relevant.
- B8.3. From the Service Commencement Date, the Authority shall pay the provider based on the activity that has been recorded on PharmOutcomes at the end of each calendar month (or such other frequency agreed between the Parties in writing). Payments are administered by Community Pharmacies West Yorkshire (CPWY) on behalf of the Council through a separate contract. Payments are made on or after the 28th of the following calendar month after service provision. Where the 28th falls on a weekend, or Bank Holiday, then the payment will be made on the first working day following the 28th. The provider must ensure that all information recorded on PharmOutcomes is a fair and accurate recording of the activity it has undertaken.

- B8.4. The Charges are stated exclusive of VAT, which shall be added at the prevailing rate as applicable and paid by the Authority following delivery of a valid VAT invoice.
- B8.5. In its performance of this Contract the Provider shall not provide or offer to a Service User any clinical or medical services for which any charges would be payable by the Service User (other than in accordance with this Contract, the Law and/or Guidance).
- B8.6. If a Party, acting in good faith, contests all or any part of any payment calculated in accordance with this clause B8:
- a) the contesting Party shall within 5 Business Days notify the other Party, setting out in reasonable detail the reasons for contesting the requested payment, and in particular identifying which elements are contested and which are not contested;
 - b) any uncontested amount shall be paid in accordance with this Contract; and
 - c) the contested amount shall be withheld.
- B8.7. If a Party contests a payment under clause B8.6 and the Parties have not resolved the matter within 20 Business Days of the date of notification under clause B8.6, the contesting Party may refer the matter to dispute resolution under clause B30 (*Dispute Resolution*) and following the resolution of any dispute referred to dispute resolution, where applicable the relevant Party shall pay any amount agreed or determined to be payable in accordance with clause B8.3.
- B8.8. Subject to any express provision of this Contract to the contrary each Party shall be entitled, without prejudice to any other right or remedy it has under this Contract, to receive interest at the Default Interest Rate on any payment not made from the day after the date on which payment was due up to and including the date of payment.
- B8.9. The Authority may retain or set off any sums owed to it by the Provider which have fallen due and payable against any sum due to the Provider under this Contract or any other agreement between the Parties.

B9. SERVICE IMPROVEMENTS AND BEST VALUE DUTY

- B9.1. The Provider must to the extent reasonably practicable co-operate with and assist the Authority in fulfilling its Best Value Duty.
- B9.2. In addition to the Provider's obligations under clause B9.1, where reasonably requested by the Authority, the Provider at its own cost shall participate in any relevant Best Value Duty reviews and/or benchmarking exercises (including without limitation providing information for such purposes) conducted by the Authority and shall assist the Authority with the preparation of any Best Value performance plans.
- B9.3. During the term of this Contract at the reasonable request of the Authority, the Provider must:
- a) demonstrate how it is going to secure continuous improvement in the way in which the Services are delivered having regard to a combination of economy, efficiency and effectiveness and the Parties may agree a continuous improvement plan for this purpose;
 - b) implement such improvements; and
 - c) where practicable following implementation of such improvements decrease the price to be paid by the Authority for the Services.

- B9.4. If requested by the Authority, the Provider must identify the improvements that have taken place in accordance with clause B9.3, by reference to any reasonable measurable criteria notified to the Provider by the Authority.

B10. SAFEGUARDING CHILDREN AND VULNERABLE ADULTS

- B10.1. The Provider shall adopt Safeguarding Policies and such policies shall comply with the Authority's Safeguarding Policy as amended from time to time and may be appended at Appendix F (*Safeguarding Policies*), and the requirements of Appendix F (*Safeguarding Policies*).
- B10.2. At the reasonable written request of the Authority and by no later than 10 Business Days following receipt of such request, the Provider must provide evidence to the Authority that it is addressing any safeguarding concerns.
- B10.3. If requested by the Authority, the Provider shall participate in the development of any local multi-agency safeguarding quality indicators and/or plan.

B11. INCIDENTS REQUIRING REPORTING

- B11.1. If the Provider is CQC registered it shall comply with the requirements and arrangements for notification of deaths and other incidents to CQC in accordance with CQC Regulations and if the Provider is not CQC registered it shall notify Serious Incidents to any Regulatory Body as applicable, in accordance with the Law.
- B11.2. If the Provider gives a notification to the CQC or any other Regulatory Body under clause B11.1 which directly or indirectly concerns any Service User, the Provider must send a copy of it to the Authority within 5 Business Days or within the timescale set out in Appendix G (*Incidents Requiring Reporting Procedure*).
- B11.3. The Parties must comply with the arrangements for reporting, investigating, implementing and sharing the Lessons Learned from Serious Incidents, Patient Safety Incidents and non-Service User safety incidents that are agreed between the Provider and the Authority and set out in Appendix G (*Incidents Requiring Reporting Procedure*).
- B11.4. Subject to the Law, the Authority shall have complete discretion to use the information provided by the Provider under this clause B.11 and Appendix G (*Incidents Requiring Reporting Procedure*).

B12. CONSENT

- B12.1. The Provider must publish, maintain and operate a Service User consent policy which complies with Good Clinical Practice and the Law.

B13. SERVICE USER HEALTH RECORDS

- B13.1. The Provider must create, maintain, store and retain Service User health records for all Service Users. The Provider must retain Service User health records for the periods of time required by Law and thereafter shall notify the Authority that such period of time for retention has expired and seek the Authority's instruction as to what should be done with such Service User health records (which may include, without limitation, providing such Service User health records to the Authority or securely destroying them in accordance with any applicable Guidance).
- B13.2. The Provider must:
- a) use Service User health records solely for the execution of the Provider's obligations under this Contract;
 - b) give each Service User full and accurate information regarding his/her treatment and Services received; and
 - c) provide copies of the such Service User health records to the Authority as Authority data on expiry or early termination of this Contract as part of the Succession Plan, or otherwise following written request from the Authority.
- B13.3. The Provider must at all times during the term of this Contract have a Caldicott Guardian and shall notify the Authority of their identity and contact details prior to the Service Commencement Date. If the Provider replaces its Caldicott Guardian at any time during the term of this Contract, it shall promptly notify the Authority of the identity and contact details of such replacements.
- B13.4. Subject to Guidance and where appropriate, the Service User health records should include the Service User's verified NHS number.

B14. INFORMATION

- B14.1. The Provider must provide the Authority with the information specified in Appendix H (*Information Provision*) to measure the quality, quantity or otherwise of the Services.
- B14.2. The Provider must deliver the information required under clause B14.1 in the format, manner, frequency and timescales specified in Appendix H (*Information Provision*) and must ensure that the information is accurate and complete.
- B14.3. If the Provider fails to comply with any of the obligations in this clause B14 and/or Appendix H (*Information Provision*), the Authority may (without prejudice to any other rights it may have under this Contract) exercise any consequence for failing to satisfy the relevant obligation specified in Appendix H (*Information Provision*).
- B14.4. In addition to the information required under clause B14.1, the Authority may request from the Provider any other information it reasonably requires in relation to this Contract and the Provider must deliver such requested information in a timely manner.

B15. EQUIPMENT

B15.1. The Provider must provide and maintain at its own cost (unless otherwise agreed in writing) all Equipment necessary for the supply of the Services in accordance with any required Consents and must ensure that all Equipment is fit for the purpose of providing the applicable Services.

B16. TRANSFER OF AND DISCHARGE FROM CARE OBLIGATIONS

B16.1. The Provider must comply with any Transfer of and Discharge from Care Protocols agreed by the Parties set out in Appendix I (*Transfer of and Discharge from Care Protocols*).

B17. COMPLAINTS

B17.1. The Provider must at all times comply with the relevant regulations for complaints relating to the provision of the Services.

B17.2. If a complaint is received about the standard of the provision of the Services or about the manner in which any of the Services have been supplied or work has been performed or about the materials or procedures used or about any other matter connected with the performance of the Provider's obligations under this Contract, then the Authority may take any steps it considers reasonable in relation to that complaint, including investigating the complaint and discussing the complaint with the Provider, CQC and/or any Regulatory Body. Without prejudice to any other rights the Authority may have under this Contract, the Authority may, in its sole discretion, uphold the complaint and take any action specified in clause B28 (*Default and Failure to Supply*).

B18. SERVICE REVIEW

B18.1. The Provider must record their service provision in accordance with the Service Specification against the factors set out in Appendix A 3.1.

B19. REVIEW MEETINGS

B19.1. The Parties must review and discuss Service Quality Performance Reports and monitor performance of the Contract and consider any other matters reasonably required by either Party at Review Meetings which should be held in the form and intervals set out in Appendix K (*Details of Review Meetings*).

B19.2. Notwithstanding clause B19.1, if either the Authority or the Provider:

- a) reasonably considers a circumstance constitutes an emergency or otherwise requires immediate resolution; or
- b) considers that a JI Report requires consideration sooner than the next scheduled Review Meeting,

that Party may by notice require that a Review Meeting be held as soon as practicable and in any event within 5 Business Days following that notice.

B20. CO-OPERATION

B20.1. The Parties must at all times act in good faith towards each other.

B20.2. The Provider must co-operate fully and liaise appropriately with:

- a) the Authority;
- b) any third party provider who the Service User may be transferred to or be transferring from;

- c) any third party provider which may be providing care to the Service User at the same time as the Provider's provision of the relevant Services to the Service User; and
- d) primary, secondary and social care services,

in order to:

- e) ensure that a consistently high standard of care for the Service User is at all times maintained;
- f) ensure a co-ordinated approach is taken to promoting the quality of Service User care across all pathways spanning more than one provider;
- g) achieve a continuation of the Services that avoids inconvenience to, or risk to the health and safety of, Service Users, employees of the Authority or members of the public.

B21. WARRANTIES AND REPRESENTATIONS

B21.1. The Provider warrants and represents that:

- a) it has full capacity and authority to enter into this Contract and all necessary Consents have been obtained and are in full force and effect;
- b) its execution of this Contract does not and will not contravene or conflict with its constitution, any Law, or any agreement to which it is a party or which is binding on it or any of its assets ;
- c) in entering this Contract it has not committed any Fraud;
- d) all reasonably material information supplied by it to the Authority during the award procedure leading to the execution of this Contract is, to its reasonable knowledge and belief, true and accurate and it is not aware of any material facts or circumstances which have not been disclosed to the Authority which would, if disclosed, be likely to have an adverse effect on a reasonable public sector entity's decision whether or not to contract with the Provider substantially on the terms of this Contract;
- e) to the best of its knowledge, nothing will have, or is likely to have, a material adverse effect on its ability to perform its obligations under this Contract;
- f) it has the right to permit disclosure and use of Confidential Information for the purpose of this Contract;
- g) in the 3 years prior to the Commencement Date:
 - (i) It has conducted all financial accounting and reporting activities in compliance in all material respects with the generally accepted accounting principles that apply to it in any country where it files accounts;
 - (ii) It has been in full compliance with all applicable securities and tax laws and regulations in the jurisdiction in which it is established; and
 - (iii) It has not done or omitted to do anything which could have a material adverse effect on its assets, financial condition or position as an on going business concern or its ability to fulfil its obligations under this Contract;

- h) no proceedings or other steps have been taken and not discharged (nor, to the best of its knowledge are threatened) for the winding up of the Provider or for its dissolution or for the appointment of a receiver, administrative receiver, liquidator, manager, administrator or similar officer in relation to any of the Provider's assets or revenue; and
- i) it owns has obtained or is able to obtain valid licenses for all intellectual property rights that are necessary for the performance of its obligations under this Contract,

and these warranties are given on the Commencement Date and repeated on every day during the term of this Contract, and the Authority relies on such warranties and representations.

B21.2. The Authority warrants and represents that:

- a) it has full power and authority to enter into this Contract and all necessary approvals and consents have been obtained and are in full force and effect;
- b) its execution of this Contract does not and will not contravene or conflict with its constitution, any Law, or any agreement to which it is a party or which is binding on it;
- c) it has the right to permit disclosure and use of Confidential Information for the purpose of this Contract; and
- d) to the best of its knowledge, nothing will have, or is likely to have, a material adverse effect on its ability to perform its obligations under this Contract.

B21.2A The Authority gives no warranty as to the relevance, completeness, accuracy or fitness for purpose of any information provided by the Authority to the Provide and the Provider will be deemed to have satisfied itself as to the adequacy of the same. Nothing in this clause B21.2A shall exclude any liability of the Authority in respect of statements made fraudulently prior to the date of this Contract.

B21.3. The Provider undertakes that for so long as this Contract remains in full force:

- a) it will upon becoming aware that any litigation, arbitration, administrative or adjudication or mediation proceedings before or of any court, arbitrator or relevant authority may be threatened or pending and immediately after the commencement thereof (or within twenty (20) Business Days of becoming aware the same may be threatened or pending or with twenty (20) Business Days after the commencement thereof where the litigation or arbitration or administrative or adjudication or mediation proceedings is against a Sub-Contractor) give the Authority notice of such litigation, arbitration, administrative or adjudication or mediation proceedings which would adversely affect, to an extent which is material in the context of the Provider's ability to perform its obligations under this Contract;
- b) it will not without the prior written consent of the Authority
 - (i) (whether by a single transaction or by a series of transactions whether related or not) sell, transfer, lend or otherwise dispose of (other than by way of security) the whole or any part of its business or assets; or
 - (ii) Change its business in any waywhich would materially affect the ability of the Provider to perform its obligations under this Contract;
- c) it will not cease to be resident in the United Kingdom or transfer in whole or in part its undertaking, business or trade outside the United Kingdom;

- d) it will not undertake the performance of its obligations under this Contract for the provision of the Services otherwise than through itself or a Sub-Contractor.

B22. VARIATIONS

- B22.1. This Contract may not be amended or varied other than in accordance with this clause B22.
- B22.2. Either Party may from time to time during the term of this Contract, by written notice to the other Party, request a Variation. A Variation Notice must set out in as much detail as is reasonably practicable the proposed Variation(s).
- B22.3. If a Variation Notice is issued, the Authority and the Provider must enter into good faith negotiations for a period of not more than 30 Business Days from the date of that notice (unless such period is extended by the Parties in writing) with a view to reaching agreement on the proposed Variation, including on any adjustment to the Charges that, in all the circumstances, properly and fairly reflects the nature and extent of the proposed Variation. If the Parties are unable to agree a proposed Variation within such time period (or extended time period), the proposed Variation shall be deemed withdrawn and the Parties shall continue to perform their obligations under this Contract.
- B22.4. No Variation to this Contract will be valid or of any effect unless agreed in writing by the Authority Representative (or his nominee) and the Provider Representative (or his nominee) in accordance with clause A5 (*Notices*). All agreed Variations shall form an addendum to this Contract and shall be recorded in Appendix L (*Agreed Variations*).

B23. ASSIGNMENT AND SUB-CONTRACTING

- B23.1. The Provider must not assign, delegate, transfer, sub-contract, charge or otherwise dispose of all or any of its rights or obligations under this Contract without the Authority in writing:
 - a) consenting to the appointment of the Sub-contractor (such consent not to be unreasonably withheld or delayed); and
 - b) approving the Sub-contract arrangements (such approval not to be unreasonably withheld or delayed), which shall include the addition of any of the clauses in this Contract to the Sub-Contract as the Authority may reasonably require.
- B23.2. The Authority's consent to sub-contracting under clause B23.1 will not relieve the Provider of its liability to the Authority for the proper performance of any of its obligations under this Contract and the Provider shall be responsible for the acts, defaults or neglect of any Sub-contractor, or its employees or agents in all respects as if they were the acts, defaults or neglect of the Provider.
- B23.3. Any sub-contract submitted by the Provider to the Authority for approval of its terms, must impose obligations on the proposed sub-contractor in the same terms as those imposed on it pursuant to this Contract to the extent practicable.
- B23.4. The Authority may assign, transfer, novate or otherwise dispose of any or all of its rights and obligations under this Contract without the consent of the Provider.

B24. AUDIT AND INSPECTION

- B24.1. The Provider must comply with all reasonable written requests made by the Authority, the CQC, the National Audit Office, the General Pharmaceutical Council, any Authorised Person and the authorised representative of the Local HealthWatch (i) for entry to the Provider's Premises and/or the premises of any Sub-contractor for the purposes of auditing, viewing, observing or inspecting such premises and/or the provision of the Services, and (ii) for information relating to the provision of the Services (and, to avoid doubt and without limitation, the Parties agree that it shall be reasonable for the Authority and any of the other parties referred to above to request and be granted access on an open book basis to records of account of income and expenditure relating to the provision of the Services). The Provider may refuse such request to enter the Provider's Premises and/or the premises of any Sub-contractor where it would adversely affect the provision of the Services or, the privacy or dignity of a Service User.
- B24.2. Subject to Law and notwithstanding clause B24.1, an Authorised Person may enter the Provider's Premises and/or the premises of any Sub-contractor without notice for the purposes of auditing, viewing, observing or inspecting such premises and/or the provision of the Services. During such visits, subject to Law and Good Clinical Practice (also taking into consideration the nature of the Services and the effect of the visit on Service Users), the Provider must not restrict access and must give all reasonable assistance and provide all reasonable facilities to the Authorised Person.
- B24.3. Within 10 Business Days of the Authority's reasonable request, the Provider must send the Authority a verified copy of the results of any audit, evaluation, inspection, investigation or research in relation to the Services, or services of a similar nature to the Services delivered by the Provider, to which the Provider has access and which it can disclose in accordance with the Law.
- B24.4. The Authority shall use its reasonable endeavours to ensure that the conduct of any audit does not unreasonably disrupt the Provider or delay the provision of the Services.
- B24.5. During any audit undertaken under clause B24.1 or B24.2, the Provider must provide the Authority with all reasonable co-operation and assistance in relation to that audit, including:
- a) all reasonable information requested within the scope of the audit;
 - b) reasonable access to the Provider's Premises and/or the premises of any Sub-contractor; and
 - c) access to the Staff.

B25. INDEMNITIES

- B25.1. The Provider shall indemnify and keep indemnified the Authority against all actions, proceedings, costs, claims, demands, liabilities, losses and expenses whatsoever, whether arising in tort (including negligence) default or breach of this Contract, breach of statutory duty or breach of an obligation under the DPA, save to the extent that the same is directly caused by or directly arises from the negligence, breach of this Contract or breach of statutory duty or breach of an obligation under the DPA by the Authority.

B26. LIMITATION OF LIABILITY

- B26.1. Neither Party shall be liable to the other Party (as far as permitted by Law) for Indirect Losses in connection with this Contract.
- B26.2. Each Party must at all times take all reasonable steps to minimise and mitigate any Losses for which it is entitled to be indemnified by or bring a claim against the other Party pursuant to this Contract.
- B26.3. Nothing in this Contract will exclude or limit the liability of either Party for:

- a) death or personal injury caused by its negligence; or
- b) fraud or fraudulent misrepresentation.

B27. INSURANCE

- B27.1. The Provider must comply with the provisions of clause C3 (Insurance).
- B27.2. The Provider must give the Authority, on request, a copy of or a broker's placement verification of the Required Insurances insurance, together with receipts or other evidence of payment of the latest premiums due under those policies.
- B27.3. The provision of any insurance or the amount or limit of cover will not relieve or limit the Provider's liabilities under this Contract.

B28. DEFAULTS AND FAILURE TO SUPPLY

- B28.1. In the event that the Authority is of the reasonable opinion that there has been a Default which is a material breach of this Contract by the Provider, then the Authority may, without prejudice to any other rights or remedies it may have under this Contract including under clause B29 (*Contract Management*), consult with the Provider and then do any of the following:
 - a) require the Provider to submit a performance improvement plan detailing why the material breach has occurred and how it will be remedied within 10 Business Days or such other period of time as the Authority may direct;
 - b) without terminating this Contract, suspend the affected Service in accordance with the process set out in clause B31 (*Suspension and Consequences of Suspension*);
 - c) without terminating the whole of this Contract, terminate this Contract in respect of the affected part of the Services only in accordance with clause B32 (*Termination*) (whereupon a corresponding reduction in the Charges shall be made) and thereafter the Authority may supply or procure a third party to supply such part of the Services.
- B28.2. If the Authority exercises any of its rights under clause B28.1, the Provider must indemnify the Authority for any costs reasonably incurred (including reasonable professional costs and any reasonable administration costs) in respect of the supply of any part of the Services by the Authority or a third party to the extent that such costs exceed the payment which would otherwise have been payable to the Provider for such part of the Services and provided that the Authority uses its reasonable endeavours to mitigate any additional expenditure in obtaining replacement Services.

B29. CONTRACT MANAGEMENT

- B29.1. If the Parties have agreed a consequence in relation to the Provider failing to meet a Quality Outcomes Indicator as set out in Appendix C (*Quality Outcomes Indicators*) and the Provider fails to meet the Quality Outcomes Indicator, the Authority may exercise the agreed consequence immediately and without issuing a Contract Query, irrespective of any other rights the Authority may have under this clause B29.
- B29.2. The provisions of this clause B29 do not affect any other rights and obligations the Parties may have under this Contract.
- B29.3. Clauses B29.19, B29.23, B29.24 and B29.26 will not apply if the Provider's failure to agree or comply with a Remedial Action Plan (as the case may be) is as a result of an act or omission or the unreasonableness of the Authority.

Contract Query

- B29.4. If the Authority has a Contract Query it may issue a Contract Query Notice to the Provider.

B29.5 If the Provider has a Contract Query it may issue a Contract Query Notice to the Authority.

Excusing Notice

B29.6 The Receiving Party may issue an Excusing Notice to the Issuing Party within 5 Business Days of the date of the Contract Query Notice.

B29.7 If the Issuing Party accepts the explanation set out in the Excusing Notice, it must withdraw the Contract Query Notice in writing within 10 Business Days following the date of the Contract Query Notice.

Contract Management Meeting

B29.8 Unless the Contract Query Notice has been withdrawn, the Authority and the Provider must meet to discuss the Contract Query and any related Excusing Notice within 10 Business Days following the date of the Contract Query Notice.

B29.9 At the Contract Management Meeting the Authority and the Provider must agree either:

- a) that the Contract Query Notice is withdrawn; or
- b) to implement an appropriate Remedial Action Plan; or
- c) to conduct a Joint Investigation.

B29.10 If a Joint Investigation is to be undertaken:

- a) the Authority and the Provider must agree the terms of reference and timescale for the Joint Investigation (being no longer than 4 weeks) and the appropriate clinical and/or non-clinical representatives from each Party to participate in the Joint Investigation.
- b) the Authority and the Provider may agree an Immediate Action Plan to be implemented concurrently with the Joint Investigation.

Joint Investigation

B29.11 On completion of a Joint Investigation, the Authority and the Provider must produce and agree a JI Report. The JI Report must include (without limitation) a recommendation to be considered at the next Review Meeting that either:

- a) the Contract Query be closed; or
- b) Remedial Action Plan be agreed and implemented.

B29.12 Either the Authority or the Provider may require a Review Meeting to be held at short notice in accordance with the provisions of this Contract to consider a JI Report.

Remedial Action Plan

B29.13 If a Remedial Action Plan is to be implemented, the Authority and the Provider must agree the contents of the Remedial Action Plan within:

- a) 5 Business Days following the Contract Management Meeting; or
- b) 5 Business Days following the Review Meeting in the case of a Remedial Action Plan recommended under clause B29.11.

B29.14 The Remedial Action Plan must set out:

- a) milestones for performance to be remedied;
- b) the date by which each milestone must be completed; and
- c) subject to the maximum sums identified in clause B29.23, the consequences for failing to meet each milestone by the specified date.

B29.15 The Provider and the Authority must implement or meet the milestones applicable to it within the timescales set out in the Remedial Action Plan.

B29.16 The Authority and the Provider must record progress made or developments under the Remedial Action Plan in accordance with its terms. The Authority and the Provider must review and consider that progress on an ongoing basis and in any event at the next Review Meeting.

B29.17 If following implementation of a Remedial Action Plan:

- a) the matters that gave rise to the relevant Contract Query Notice have been resolved, it must be noted in the next Review Meeting that the Remedial Action Plan has been completed;
- b) any matter that gave rise to the relevant Contract Query Notice remains in the reasonable opinion of the Authority or the Provider unresolved, either may issue a further Contract Query Notice in respect of that matter.

Withholding Payment for Failure to Agree Remedial Action Plan

B29.18 If the Authority and the Provider cannot agree a Remedial Action Plan within the relevant period specified in clause B29.13, they must jointly promptly notify the Boards of Directors of both the Provider and the Authority.

B29.19 If, 10 Business Days after notifying the Boards of Directors, the Authority and the Provider still cannot agree a Remedial Action Plan, the Authority may withhold up to 2% of the monthly sums payable by it under clause B8 (*Charges and Payment*) for each further month the Remedial Action Plan is not agreed.

B29.20 The Authority must pay the Provider any sums withheld under clause B29.19 within 10 Business Days of receiving the Provider's agreement to the Remedial Action Plan. Unless clause B29.25 applies, those sums are to be paid without interest.

Exception Reports

B29.21 If a Party breaches a Remedial Action Plan and does not remedy the breach within 5 Business Days of its occurrence, the Provider or the Authority (as the case may be) may issue a First Exception Report to that Party's chief executive and/or Board of Directors. If the Party in breach is the Provider, the Authority may withhold payment from the Provider in accordance with clause B29.23.

B29.22 If following issue of the First Exception Report, the breach of the Remedial Action Plan is not rectified within the timescales indicated in the First Exception Report, the Authority or the Provider (as the case may be) may issue a Second Exception Report to:

- a) the relevant Party's chief executive and/or Board of Directors; and/or;
- b) CQC or any other Regulatory Body,

in order that each of them may take whatever steps they think appropriate.

Withholding of Payment at First Exception Report for Breach of Remedial Action Plan

- B29.23 If the Provider breaches a Remedial Action Plan:
- a) the Authority may withhold, in respect of each milestone not met, up to 2% of the aggregate monthly sums payable by the Authority under clause B8 (*Charges and Payment*), from the date of issuing the First Exception Report and for each month the Provider's breach continues, subject to a maximum monthly withholding of 10% of the aggregate monthly sums payable by the Authority under clause B8 (*Charges and Payment*) in relation to each Remedial Action Plan;
 - b) subject to clauses B29.6 and B29.7, the Authority must pay the Provider any sums withheld under clause B29.23a) within 10 Business Days following the Authority's confirmation that the breach of the Remedial Action Plan has been rectified. Subject to clause B29.25, no interest will be payable on those sums.

Retention of Sums Withheld at Second Exception Report for Breach of Remedial Action Plan

- B29.24 If the Provider is in breach of a Remedial Action Plan the Authority may, when issuing any Second Exception Report retain permanently any sums withheld under clause B29.23.

Unjustified Withholding or Retention of Payment

- B29.25 If the Authority withholds sums under clause B29.19 or clause B29.23 or retain sums under clause B29.24, and within 20 Business Days of the date of that withholding or retention (as the case may be) the Provider produces evidence satisfactory to the Authority that the relevant sums were withheld or retained unjustifiably, the Authority must pay those sums to the Provider within 10 Business Days following the date of the Authority's acceptance of that evidence, together with interest at the Default Interest Rate for the period for which the sums were withheld or retained. If the Authority does not accept the Provider's evidence the Provider may refer the matter to Dispute Resolution.

Retention of Sums Withheld on Expiry or Termination of this Contract

- B29.26 If the Provider does not agree a Remedial Action Plan:
- B29.26.1 within 6 months following the expiry of the relevant time period set out in clause B29.13; or
- B29.26.2 before the Expiry Date or earlier termination of this Contract,
- whichever is the earlier, the Authority may retain permanently any sums withheld under clause B29.19.
- B29.27 If the Provider does not rectify a breach of a Remedial Action Plan before the Expiry Date or earlier termination of this Contract, the Authority may retain permanently any sums withheld under clause B29.23.

B30. DISPUTE RESOLUTION

- B30.1. If the Parties are in Dispute, they must seek in good faith to resolve the Dispute following the process set out in Appendix M (*Dispute Resolution*), unless the Parties agree and set out an alternative dispute resolution process in the Special Conditions in which case the process in the Special Conditions will prevail.

B31. SUSPENSION AND CONSEQUENCES OF SUSPENSION

- B31.1. A suspension event shall have occurred if:

- a) the Authority reasonably considers that a breach by the Provider of any obligation under this Contract:
 - (i) may create an immediate and serious threat to the health or safety of any Service User; or
 - (ii) may result in a material interruption in the provision of any one or more of the Services; or
- b) clause B31.1 does not apply, but the Authority, acting reasonably, considers that the circumstances constitute an emergency, (which may include, without limitation, an event of Force Majeure) affecting provision of a Service or Services; or
- c) the Provider is prevented, or will be prevented, from providing a Service due to the termination, suspension, restriction or variation of any Consent,

(each a **Suspension Event**).

B31.2. Where a Suspension Event occurs the Authority:

- a) may by written notice to the Provider and with immediate effect suspend any affected Service, or the provision of any affected Service, until the Provider demonstrates to the reasonable satisfaction of the Authority that it is able to and will perform the suspended Service, to the required standard; and
- b) must where applicable promptly notify CQC and/or any relevant Regulatory Body of the suspension.

B31.3. During the suspension of any Service under clause B31.2, the Provider must comply with any steps the Authority reasonably specifies in order to remedy the Suspension Event, including where the Authority's decision to suspend pursuant to clause B31.2 has been referred to dispute resolution under clause B30 (*Dispute Resolution*).

B31.4. During the suspension of any Service under clause B31.2, the Provider will not be entitled to claim or receive any payment for the suspended Service except in respect of:

- a) all or part of the suspended Service the delivery of which took place before the date on which the relevant suspension took effect in accordance with clause B31.2; and/or.
- b) all or part of the suspended Service which the Provider continues to deliver during the period of suspension in accordance with clause B31.5.

B31.5. The Parties must use all reasonable endeavours to minimise any inconvenience caused or likely to be caused to Service Users as a result of the suspension of the Service.

B31.6. Except where suspension occurs by reason of an event of Force Majeure, the Provider must indemnify the Authority in respect of any Losses directly and reasonably incurred by the Authority in respect of that suspension (including for the avoidance of doubt Losses incurred in commissioning the suspended Service).

B31.7. Following suspension of a Service the Provider must at the reasonable request of the Authority and for a reasonable period:

- a) co-operate fully with the Authority and any Successor Provider of the suspended Service in order to ensure continuity and a smooth transfer of the suspended Service and to avoid any inconvenience to or risk to the health and safety of Service Users, employees of the Authority or members of the public; and
- b) at the cost of the Provider:

- (i) promptly provide all reasonable assistance and all information necessary to effect an orderly assumption of the suspended Service by an alternative Successor Provider; and
- (ii) deliver to the Authority all materials, papers, documents and operating manuals owned by the Authority and used by the Provider in the provision of the suspended Service.

B31.8. As part of its compliance with clause B31.7 the Provider may be required by the Authority to agree a transition plan with the Authority and/or any alternative Successor Provider.

B31.9. If it is determined, pursuant to clause B30 (*Dispute Resolution*), that the Authority acted unreasonably in suspending a Service, the Authority must indemnify the Provider in respect of any Loss directly and reasonably incurred by the Provider in respect of that suspension.

B31.10. During any suspension of a Service the Provider where applicable will implement the relevant parts of the Business Continuity Plan to ensure there is no interruption in the availability to the relevant Service.

B32. TERMINATION

B32.1. NOT USED

B32.2. The Authority may terminate this Contract in whole or part with immediate effect by written notice to the Provider:

- a) if the Provider is in persistent or repetitive breach of the Quality Outcomes Indicators;
- b) if the Provider is in persistent breach of its obligations under this Contract;
- c) if the Provider:
 - (i) fails to obtain any Consent;
 - (ii) loses any Consent; or
 - (iii) has any Consent varied or restricted;

the effect of which might reasonably be considered by the Authority to have a material adverse effect on the provision of the Services;

- d) if the Provider has breached the terms of clause B39 (*Prohibited Acts*);
- e) if any of the Provider's necessary registrations are cancelled by the CQC or other Regulatory Body as applicable;
- f) if the Provider materially breaches its obligations in clause B37 (*Data Protection*);
- g) if two or more Second Exception Reports are issued to the Provider under clause B29.22 (*Contract Management*) within any rolling 6 month period which are not disputed by the Provider, or if disputed, are upheld under Dispute Resolution;
- h) if the Provider breaches the terms of clause B23 (*Assignment and Sub-contracting*);
- i) if a resolution is passed or an order is made for the winding up of the Provider (otherwise than for the purpose of solvent amalgamation or reconstruction) or the Provider becomes subject to an administration order or a receiver or administrative receiver is appointed over or an encumbrancer takes possession of any of the Provider's property or equipment;

- j) if the Provider ceases or threatens to cease to carry on business in the United Kingdom; or
- k) if the Provider has breached any of its obligations under this Contract and that breach materially and adversely affects the provision of the Services in accordance with this Contract, and the Provider has not remedied that breach within 20 Business Days following receipt of notice from the Authority identifying the breach;
- l) in accordance with clause B35;
- m) following a breach by the Provider of its obligations to take out and maintain any of the Required Insurances; or
- n) in accordance with clause C7.

B32.3. Either Party may terminate this Contract or any Service by written notice, with immediate effect, if and to the extent that the Authority or the Provider suffers an event of Force Majeure and such event of Force Majeure persists for more than 30 Business Days without the Parties agreeing alternative arrangements.

B32.4. The Provider may terminate this Contract or any Service with immediate effect by written notice to the Authority if the Authority is in material breach of any obligation under this Contract provided that if the breach is capable of remedy, the Provider may only terminate this Contract under this clause B32.4 if the Authority has failed to remedy such breach within 40 Business Days of receipt of notice from the Provider to do so.

B33. CONSEQUENCE OF EXPIRY OR TERMINATION

B33.1. Expiry or termination of this Contract, or termination of any Service, will not affect any rights or liabilities of the Parties that have accrued before the date of that expiry or termination or which later accrue.

B33.2. On the expiry or termination of this Contract or termination of any Service for any reason the Authority, the Provider, and if appropriate any successor provider, will agree a Succession Plan and the Parties will comply with the provisions of the Succession Plan.

B33.3. On the expiry or termination of this Contract or termination of any Service the Provider must co-operate fully with the Authority to migrate the Services in an orderly manner to the successor provider.

B33.4. In the event of termination or expiry of this Contract, the Provider must cease to use the Authority's Confidential Information and on the earlier of the receipt of the Authority's written instructions or 12 months after the date of expiry or termination, return all copies of the Confidential Information to the Authority.

B33.5. If, as a result of termination of this Contract or of any Service in accordance with this Contract, the Authority procures any terminated Service from an alternative provider, and the cost of doing so (to the extent reasonable) exceeds the amount that would have been payable to the Provider for providing the same Service, then the Authority, acting reasonably, will be entitled to recover from the Provider (in addition to any other sums payable by the Provider to the Authority in respect of that termination) the excess cost and all reasonable related professional and administration costs it incurs (in each case) for a period of 6 months following termination.

B33.6. The provisions of clauses B7 (*Staff*), B8 (*Charges and Payment*), B11 (*Incidents Requiring Reporting*), B13 (*Service User Health Records*), B14 (*Information*), B23 (*Assignment and Sub-contracting*), B24 (*Audit and Inspection*), B33 (*Consequence of Expiry or Termination*), B36 (*Confidentiality*), B37 (*Data Protection*), B38 (*Freedom of Information and Transparency*) and B39 (*Prohibited Acts*) will survive termination or expiry of this Contract.

B34. BUSINESS CONTINUITY

- B34.1. The Provider must comply with the Civil Contingencies Act 2004 and with any applicable national and local civil contingency plans.
- B34.2. The Provider must, unless otherwise agreed by the Parties in writing, maintain a Business Continuity Plan and must notify the Authority as soon as reasonably practicable of its activation and in any event no later than 5 Business Days from the date of such activation.

B35. COUNTER-FRAUD AND SECURITY MANAGEMENT

- B35.1. The Provider must put in place and maintain appropriate counter fraud and security management arrangements.
- B35.2. The Provider must take all reasonable steps, in accordance with good industry practice, to prevent Fraud by Staff and the Provider in connection with the receipt of monies from the Authority.
- B35.3. The Provider must notify the Authority immediately if it has reason to suspect that any Fraud has occurred or is occurring or is likely to occur.
- B35.4. If the Provider or its Staff commits Fraud in relation to this or any other contract with the Authority, the Authority may terminate this Contract by written notice to the Provider with immediate effect (and terminate any other contract the Provider has with the Authority) and recover from the Provider the amount of any Loss suffered by the Authority resulting from the termination, including the cost reasonably incurred by the Authority of making other arrangements for the supply of the Services for the remainder of the term of this Contract had it not been terminated.

B36. CONFIDENTIALITY

- B36.1. Other than as allowed in this Contract, Confidential Information is owned by the Party that discloses it (the “**Disclosing Party**”) and the Party that receives it (the “**Receiving Party**”) has no right to use it.
- B36.2. Subject to Clauses B36.3 and B36.4, the Receiving Party agrees:
- a) to use the Disclosing Party’s Confidential Information only in connection with the Receiving Party’s performance under this Contract;
 - b) not to disclose the Disclosing Party’s Confidential Information to any third party or to use it to the detriment of the Disclosing Party; and
 - c) to maintain the confidentiality of the Disclosing Party’s Confidential Information and to return it immediately on receipt of written demand from the Disclosing Party.
- B36.3. The Receiving Party may disclose the Disclosing Party’s Confidential Information:
- a) in connection with any dispute resolution under clause B30 (*Dispute Resolution*);
 - b) in connection with any litigation between the Parties;
 - c) to comply with the Law;
 - d) to its staff, consultants and sub-contractors, who shall in respect of such Confidential Information be under a duty no less onerous than the Receiving Party’s duty set out in clause B36.2;
 - e) to comply with a Regulatory Body’s request.

- B36.4. The obligations in clause B36.1 and clause B36.2 will not apply to any Confidential Information which:
- a) is in or comes into the public domain other than by breach of this Contract;
 - b) the Receiving Party can show by its records was in its possession before it received it from the Disclosing Party; or
 - c) the Receiving Party can prove that it obtained or was able to obtain from a source other than the Disclosing Party without breaching any obligation of confidence.
- B36.5. The Receiving Party shall indemnify the Disclosing Party and shall keep the Disclosing Party indemnified against Losses and Indirect Losses suffered or incurred by the Disclosing Party as a result of any breach of this clause B36.
- B36.6. The Parties acknowledge that damages would not be an adequate remedy for any breach of this clause B36 by the Receiving Party, and in addition to any right to damages the Disclosing Party shall be entitled to the remedies of injunction, specific performance and other equitable relief for any threatened or actual breach of this clause B36.
- B36.7. This clause B36 shall not limit the Public Interest Disclosure Act 1998 in any way whatsoever.
- B36.8. The obligations in clause B36.1 and clause B36.2 shall not apply where the Confidential Information is related to an item of business at a board meeting of the Authority or of any committee, sub-committee or joint committee of the Authority or is related to an executive decision of the Authority and it is not reasonably practicable for that item of business to be transacted or that executive decision to be made without reference to the Confidential Information, provided that the Confidential Information is exempt information within the meaning of Section 101 of the Local Government Act 1972 (as amended), the Authority shall consider properly whether or not to exercise its powers under Part v of that Act or (in the case of executive decisions) under the Local Authorities (Executive Arrangements) (Meetings and Access to Information) (England) Regulations 2012 as amended to prevent the disclosure of that Confidential Information and in doing so shall give due weight to the interests of the Provider and where reasonably practicable shall consider any representations made by the Provider.

B37. DATA PROTECTION

- B37.1 For the purposes of this clause B37 the terms Data Controller, Processor, Data Subject, Personal Data, Processing and Personal Data Breach shall have the meanings prescribed under the Data Protection Legislation.
- B37.2 Where the Contractor is Processing Personal Data as a Processor as defined in Regulation (EU) 2016/679 of the European Parliament and of the European Council of 27 April 2016 (Regulation) on behalf of the Council, the Contractor will implement appropriate technical and organisational measures in such a manner that Processing will meet the requirements of the Regulation and ensure the protection of the rights of Data Subjects.
- B37.3 The Contractor will not engage another Processor without prior specific written authorisation of the Council, such authorisation not be unreasonably withheld or delayed, and it shall be deemed to be reasonable for the Council to withhold such authorisation unless and until such other Processor shall have entered into a binding Data Protection Agreement, in a form to be agreed by the Council at its absolute discretion, with the Council whereby such other Processor agrees to observe and perform the same obligations as regards compliance with the Regulation as are imposed upon the Contractor by this Clause E1. Notwithstanding the completion of such binding agreement, the Contractor will

remain fully liable to the Council for any breach, non-performance or non-observance of this Clause B37 by such other Processor in the same way and to the same extent as if such breach, non-performance or non-observance had been committed by the Contractor.

B37.4 The Contractor will Process Personal Data as set out in paragraphs 3.1 of the Specification at Appendix A.

B37.5 The Contractor will Process Personal Data only in accordance with the written instructions of the Council. Such instructions will include the Council's requirements with regard to transfers of Personal Data to a third country or an international organisation by the Contractor, unless the Contractor is required to do so by law, and in such a case, the Contractor shall inform the Council of that legal requirement before processing, unless so informing the Council is prohibited by law on important grounds of public interest. The Contractor shall immediately inform the Council if, in its opinion, any such instruction of the Council infringes the Regulations or other Data Protection Legislation.

B37.6 The Contractor will ensure that all persons authorised or permitted by the Contractor to Process Personal Data have entered into binding agreements with the Contractor as regards confidentiality and such agreements will require in particular that such employees will not disclose, divulge or publish any of the personal data to any third party except in accordance with this Agreement or with the written instructions of the Council.

B37.7 The Contractor will take all measures required pursuant to Article 32 of the Regulation. In particular, the Contractor will demonstrate and provide reasonable evidence to the Council on demand, that the Contractor has implemented appropriate technical and organisational measures to ensure a level of security appropriate to the risk, and in the event that the Council is made/becomes aware that the Contractor has failed to implement such appropriate technical and organisational measures, the Council may, acting reasonably, direct the Contractor to implement without delay all or any of the following measures

- the pseudonymisation and encryption of Personal Data
- measures to ensure the ongoing confidentiality, integrity, availability and resilience of the Contractor's processing systems and services
- measures to ensure the ability to restore the availability and access to personal data in a timely manner in the event of a physical or technical incident
- a process for regularly testing, assessing and evaluating the effectiveness of technical and organisational measures for ensuring the security of the Processing.
- follow the Dispute Resolution Procedure set out at Clause I in the event that the Contractor disagrees with directions by the Council.

B37.8 The Contractor will provide all reasonable assistance to the Council by taking appropriate technical and organisational measures, insofar as is possible, for the fulfilment of the Council's obligations to respond to requests for exercising

Data Subjects' rights laid down in Chapter III of the Regulation, and in particular the Contractor will

- provide all relevant Personal Data to the Council without undue delay and in any event within 14 days of receipt by the Council of a request under Articles 15 to 22 of the Regulation.
- provide to the Council details of all recipients or categories of recipients to whom such Personal Data have been or will be disclosed, in particular recipients in third countries or international organisations, and details of appropriate safeguards in respect of transfers of Personal Data to such recipients in third countries or international organisations.
- at the Council's request complete any incomplete Personal Data, including by means of storing a supplementary statement by the relevant Data Subject.
- at the Council's request erase and delete any Personal Data.
- at the Council's request to implement a "restriction of Processing" as defined by the Regulation.
- at the Council's request to communicate any rectification or erasure or restriction of processing of Personal Data to each recipient to whom the Personal Data have been disclosed by the Contractor, unless the Council agrees that this is impossible or involves disproportionate effort, and the Contractor shall inform Data Subjects about those recipients if Data Subjects request this from the Council.

B37.9

The Contractor will provide all reasonable assistance to the Council in ensuring compliance with the obligations pursuant to Articles 32 to 36 of the Regulation taking into account the nature of Processing and the information available to the Contractor, and in particular the Contractor will

- notify the Council of any Personal Data Breach (as defined in the Regulation) without undue delay and in any event not later than 24 hours after becoming aware of such breach, and if the Contractor fails to notify the Council of any such breach within such time and as a result the Council fail to notify such breach to the Information Commissioners Office (ICO) within 72 hours, the Contractor will provide the Council with reasons for the Contractor's delay.
- whenever the Contractor notifies the Council of a Personal Data Breach as aforesaid, provide the Council without undue delay with details of the nature of the Personal Data Breach including where possible, the categories and approximate number of Data Subjects concerned and the categories and approximate number of Personal Data records concerned, and provide the Council with details of the likely consequences of the Personal Data Breach, and the measures taken or proposed to be taken by the Contractor to address the Personal Data Breach including, where appropriate, measures to mitigate its possible adverse effects.
- implement such technical and organisational measures as may be required or recommended by the ICO in relation to the Personal Data Breach, or to reduce risks arising from future similar Processing.

- At the request of the Council, assist the Council with the carrying out of a data protection impact assessment in the event that the Council, acting reasonably, decides that such an assessment is necessary pursuant to Article 35 of the Regulation, and with any review to assess if Processing is performed in accordance with such assessment.
- At the request of the Council, assist the Council with any consultation with the ICO in relation to such assessment, and implement all measures recommended by the ICO in any written advice which the ICO provides to the Council.

B37.10 The Contractor will at the direction and discretion of the Council delete, return to the Council or provide to the incoming contractor all Personal Data upon the expiry or other termination of this Contract, and the Contractor will delete any copy of such Personal Data unless required by law to continue to store such Personal Data.

B37.11 The Contractor will make available to the Council upon demand all information which is reasonably necessary to demonstrate compliance with the obligations laid down in Article 28 of the Regulation, and will permit and contribute to audits, including inspections, conducted by the Council or another auditor mandated by the Council for such purposes.

B37.12 If the Contractor infringes the Regulation by determining the purposes and means of Processing, the Contractor shall be deemed to be a Data Controller in respect of that Processing.

B37.13 The Contractor will maintain a record of all categories of Processing activities carried out on behalf of the Council and such record will contain

- the name and contact details of the Contractor and the Council, and where applicable their representatives, and the Council's data protection officer.
- the categories of Processing carried out by the Contractor.
- where applicable, transfers of data to a third country or an international organisation, including identifying such third country or international organisation, and where appropriate the documentation of appropriate safeguards.
- where possible, a general description of the technical and organisational security measures implemented by the Contractor.

B37.14 The Contractor will make such record available to the ICO on request.

B37.15 The Contractor shall indemnify and keep indemnified the Council in full from and against all claims, proceedings, actions, damages, costs, fines, expenses and any other liabilities which may arise out of, or in consequence of, the breach or purported breach of the Regulations or the performance or non-performance by the Contractor of its obligations under the Contract in relation to the Regulations, including loss of or damage to property, financial loss arising from any breach of the Regulations, or any other loss which is caused directly or indirectly by any act or omission of the Contractor arising from any breach of the Regulations. The Contractor shall not be responsible for any loss, damage, cost or expense if and to the extent that it is caused by the negligence or wilful

misconduct of the Council or by breach by the Council of its obligations under the Contract.

B37. FREEDOM OF INFORMATION AND TRANSPARENCY

B37.1. The Parties acknowledge their respective duties under the FOIA and must give all reasonable assistance to each other where appropriate or necessary to comply with such duties.

B37.2. If the Provider is not a Public Authority, the Provider acknowledges that the Authority is subject to the requirements of the FOIA and will assist and co-operate with the Authority to enable the Authority to comply with its disclosure obligations under the FOIA. Accordingly the Provider agrees:

- a) that this Contract and any other recorded information held by the Provider on the Authority's behalf for the purposes of this Contract are subject to the obligations and commitments of the Authority under the FOIA;
- b) 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 is a decision solely for the Authority;
- c) that if the Provider receives a request for information under the FOIA, it will not respond to such request (unless directed to do so by the Authority) and will promptly (and in any event within 2 Business Days) transfer the request to the Authority;
- d) that the Authority, acting in accordance with the codes of practice issued and revised from time to time under both section 45 of the FOIA, and regulation 16 of the Environmental Information Regulations 2004, may disclose information concerning the Provider and this Contract either without consulting with the Provider, or following consultation with the Provider and having taken its views into account; and
- e) to assist the Authority in responding to a request for information, by processing information or environmental information (as the same are defined in the FOIA) in accordance with a records management system that complies with all applicable records management recommendations and codes of conduct issued under section 46 of the FOIA, and providing copies of all information requested by a Authority within 5 Business Days of such request and without charge.

B37.3. The Parties acknowledge that, except for any information which is exempt from disclosure in accordance with the provisions of the FOIA, the content of this Contract is not Confidential Information.

B37.4. Notwithstanding any other provision of this Contract, the Provider hereby consents to the publication of this Contract in its entirety including from time to time agreed changes to this Contract subject to the redaction of information that is exempt from disclosure in accordance with the provisions of the FOIA.

B37.5. In preparing a copy of this Contract for publication pursuant to clause B38.4 the Authority may consult with the Provider to inform its decision making regarding any redactions but the final decision in relation to the redaction of information shall be at the Authority's absolute discretion.

B37.6. The Provider must assist and co-operate with the Authority to enable the Authority to publish this Contract.

B37.7. In order to comply with the Government's policy on transparency in the areas of contracts and procurement the Authority will be disclosing information on its website in relation to monthly expenditure over £500 (five hundred pounds) in relation to this Contract. The information will include the Provider's name and the monthly Charges paid. The Parties acknowledge that this information is not Confidential Information or commercially sensitive information.

B38. PROHIBITED ACTS

B38.1. Neither Party shall do any of the following:

- a) offer, give, or agree to give the other Party (or any of its officers, employees or agents) 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 of performance of this Contract or any other contract with the other Party, or for showing or not showing favour or disfavour to any person in relation to this Contract or any other contract with the other Party; and
- b) in connection with this Contract, pay or agree 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 other Party,

(together "**Prohibited Acts**").

B38.2. If either Party or its employees or agents (or anyone acting on its or their behalf) commits any Prohibited Act or commits any offence under the Bribery Act 2010 with or without the knowledge of the other Party in relation to this Contract, the non-defaulting Party shall be entitled:

- a) to exercise its right to terminate under clause B32.2 (*Termination*) and to recover from the defaulting Party the amount of any loss resulting from the termination; and
- b) to recover from the defaulting Party the amount or value of any gift, consideration or commission concerned; and
- c) to recover from the defaulting Party any loss or expense sustained in consequence of the carrying out of the Prohibited Act or the commission of the offence.

B38.3. Each Party must provide the other Party upon written request with all reasonable assistance to enable that Party to perform any activity required for the purposes of complying with the Bribery Act 2010. Should either Party request such assistance the Party requesting assistance must pay the reasonable expenses of the other Party arising as a result of such request.

B38.4. The Provider must have in place an anti bribery policy for the purposes of preventing any of its Staff from committing a prohibited act under the Bribery Act 2010. Such policy must be disclosed to the Authority within 5 Business Days of the Authority requesting it and enforced by the Provider where applicable.

B38.5. Should the Provider become aware of or suspect any breach of this clause B39, it will notify the Authority immediately. Following such notification, the Provider must respond promptly and fully to any enquiries of the Authority, co-operate with any investigation undertaken by the Authority and allow the Authority to audit any books, records and other relevant documentation.

B39. FORCE MAJEURE

B39.1. Where a Party is (or claims to be) affected by an event of Force Majeure, it must take all reasonable steps to mitigate the consequences of it, resume performance of its obligations under this Contract as soon as practicable and use its reasonable efforts to remedy its failure to perform its obligations under this Contract.

- B39.2. Subject to clause B40.1, the Party claiming relief as a result of an event of Force Majeure will be relieved from liability under this Contract to the extent that because of the event of Force Majeure it is not able to perform its obligations under this Contract.
- B39.3. The Party claiming relief as a result of an event of Force Majeure must serve an initial written notice on the other Party immediately it becomes aware of the event of Force Majeure. This initial notice shall give sufficient details to identify the particular event. The Party claiming relief must then serve a detailed written notice within a further 15 Business Days. This detailed notice shall contain all relevant available information relating to the failure to perform the relevant obligations under this Contract as is available, including the effect of the event of Force Majeure, the mitigating action being taken and an estimate of the period of time required to overcome it and resume full delivery of Services.
- B39.4. A Party cannot claim relief as a result of an event of Force Majeure, if the event of Force Majeure is attributable to that Party's wilful act, neglect or failure to take reasonable precautions against the relevant event of Force Majeure.
- B39.5. The Authority shall not be entitled to exercise its rights to withholdings and/or deduction of payments under this Contract, to the extent that the circumstances giving rise to such rights arise as a result of an event of Force Majeure.

B40. THIRD PARTY RIGHTS

- B40.1. No term of this Contract is intended to confer a benefit on, or to be enforceable by, any person who is not a party to this Contract.

B41. CAPACITY

- B41.1. Without prejudice to the contractual rights and/or remedies of the Provider expressly set out in this Contract, the obligations of the Authority under this Contract are obligations of the Authority in its capacity as a contracting counterparty and nothing in this Contract shall operate as an obligation upon the Authority or in any way fetter or constrain the Authority in any other capacity, nor shall the exercise by the Authority of its duties and powers in any other capacity lead to any liability on the part of the Authority under this Contract (howsoever arising) in any capacity other than as contracting counterparty.

B42. SEVERABILITY

- B42.1. If any provision or part of any provision of this Contract is declared invalid or otherwise unenforceable, the provision or part of the provision as applicable will be severed from this Contract and this will not affect the validity and/or enforceability of the remaining part of that provision or other provisions of this Contract.

B43. WAIVER

- B43.1. Any relaxation or delay by either Party in exercising any right under this Contract will not be taken as a waiver of that right and will not affect the ability of that Party subsequently to exercise that right.

B44. PUBLICITY

- B44.1. Without prejudice to clause B38 (*Freedom of Information and Transparency*), except with the written consent of the Authority, (such consent not to be unreasonably withheld or delayed), the Provider must not make any press announcements in relation to this Contract in any way.
- B44.2. The Provider must take all reasonable steps to ensure the observance of the provisions of clause B45.1 by all its staff, servants, agents, consultants and sub-contractors.

B45. EXCLUSION OF PARTNERSHIP, JOINT VENTURE OR AGENCY

B45.1. Nothing in this Contract creates a partnership or joint venture or relationship of employer and employee or principal and agent between the Authority and the Provider.

B46. GOVERNING LAW AND JURISDICTION

B46.1. This Contract will be governed by and interpreted in accordance with English Law and will be subject to the exclusive jurisdiction of the Courts of England and Wales.

B46.2. Subject to the provisions of clause B30 (*Dispute Resolution*), the Parties agree that the courts of England have exclusive jurisdiction to hear and settle any action, suit, proceeding or dispute in connection with this Contract.

APPENDIX A



SERVICE SPECIFICATION

Contract title	PHARMACY SUPERVISED CONSUMPTION SERVICE
Contract ID	DN339056

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SECTION 1

1 PREAMBLE

1.1 INTRODUCTION

This Specification sets out the Council's requirements in respect of a Pharmacy Supervised Consumption Service. It must be read in conjunction with Chapter 4 (Pharmacological interventions) of the Department of Health's *Drug misuse and dependence (UK guidelines on clinical management)* 2017 document. <https://www.gov.uk/government/publications/drug-misuse-and-dependence-uk-guidelines-on-clinical-management>

It details the standards and outputs which the Contractor (the pharmacy) is required to achieve and how these will be measured.

It will form part of the contract with the Council.

1.2 GENERAL DESCRIPTION

The Council commissions a comprehensive and integrated drug and alcohol treatment service (Forward Leeds) which provides a full range of structured treatment and support interventions. This includes delivery of evidence based psycho-social interventions (individual, family and group work) and the delivery of a full range of pharmacological interventions including prescribing and clinical support for withdrawal, stabilisation, reduction and detoxification. A key element in the recovery journey of a significant number of service users is the prescription of opioid substitution medication i.e. replacing an addictive substance with a prescribed medication. The pharmacist will supervise the consumption of opiate substitution medication to service users who have had this prescribed as part of their package of treatment.

Supervised consumption (of methadone or buprenorphine) is an important service provided by pharmacies to target misuse of illicit substances, prevent withdrawal symptoms and reduce risk to service users. Prior to prescription, a full assessment of the service user will have been undertaken by a prescribing clinician. As with any other prescription received in the pharmacy, the pharmacist has a responsibility to undertake a clinical check for interactions and appropriateness.

Treatment for addiction that includes the use of medication along with counselling and other support is often the best choice for opioid addiction. For service users who are addicted, medication allows them to regain a normal state of mind, free of drug-induced highs and lows. It can reduce problems of withdrawal and craving. These changes can give service users the chance they need to focus on the lifestyle changes that lead back to healthy living. Used properly, the medication does not create a new addiction but helps manage addiction so that the benefits of recovery can be maintained.

Local pharmacies are well-placed to deliver this service. Not only are they widely based in all communities across the city, making it easier for service users to access the service, the pharmacists and support staff also have the relevant

knowledge and training to deliver the service and provide additional support and advice.

Safety of service users is an integral part of the service. The person supervising the consumption will be the pharmacist or another appropriately trained pharmacy staff member. As well as administering the buprenorphine or methadone to a professional standard, the pharmacist will also provide harm reduction advice and sign-post service users to relevant treatment or health services (e.g. One You).

1.3 VISION AND OUTCOMES

Leeds has a vision to be the best city in the UK: one that is compassionate with a strong economy that tackles poverty and reduces the inequalities that still exist. We want Leeds to be a city that is fair, sustainable, ambitious, fun and creative for all.

The Leeds Drug and Alcohol Strategy and Action Plan 2016-18 sets out the ambition:

“Leeds is a city that promotes a responsible attitude to alcohol and where individuals, families and communities affected by the use of drugs and alcohol can reach their potential and lead safer, healthier and happier lives”.

The provision of an efficient and effective supervised consumption service, working hand in hand with the package of support provided by the commissioned integrated drug and alcohol service, will contribute to this ambition by:

- helping service users to stabilise and / or reduce their drug usage and ultimately become drug free
- providing a free, accessible, effective and efficient service
- providing a professional, user-friendly, non-judgmental, person-centred and confidential service
- ensuring the safe and consistent consumption of prescribed substitute medication
- supporting service users to adhere to their treatment plan, thereby reducing the harm caused by illicit drug use
- helping service users to maintain and improve their level of health through the provision of support and advice on general health and wellbeing
- keeping to a minimum the misdirection of controlled drugs, thus contributing to a reduction in drug related deaths in the community
- promoting access and making referrals to other primary care agencies where appropriate
- accurately recording information relating to supervisions to inform service delivery and development

1.4 DRIVERS AND BENEFITS

The commissioning of this Pharmacy Supervised Consumption Service directly supports the delivery of key outcomes and priorities within a number of national and local strategies, policies and initiatives.

National

2017 Drug Strategy	Aims are to reduce all illicit and other harmful drug use, and increase the rate of individuals recovering from their dependence
The Department of Health publication: Drug misuse and dependence - UK guidelines on clinical management (often referred to as the Orange Book)	Guidelines intended primarily for clinicians (including pharmacists) providing drug treatment for people who misuse or are dependent on drugs. For the purposes of this specification, Chapter 4 – Pharmacological interventions – is of particular relevance
NICE Guidance (TA114)	Recommendations relating to the use of methadone and buprenorphine for the management of opioid dependence
Royal College of General Practitioners: Guidance for the use of substitute prescribing in the treatment of opioid dependence in primary care	Provides detailed guidance covering the use of substitute medication
General Pharmaceutical Council: Standards for pharmacy professionals	Clearly sets out the standards that pharmacy professionals must meet in order to deliver safe and effective care

Local

Strategy	Priorities	Indicators
Vision for Leeds 2011-30	<ul style="list-style-type: none"> • best city for communities • best city for health and wellbeing 	<ul style="list-style-type: none"> • people are safe and feel safe • people are active and involved in their communities • people live longer and healthier lives • people are supported by high quality services to live full, active and independent lives
Best Council	<ul style="list-style-type: none"> • better lives – giving people 	<ul style="list-style-type: none"> • reduced avoidable years of

Plan 2017-18	<p>with care and support needs the right care and support at the right time</p> <ul style="list-style-type: none"> • health and wellbeing- improving physical and mental health 	life lost
Health and Wellbeing Strategy 2016-21	<ul style="list-style-type: none"> • people will live longer and have healthier lives • people will live full, active independent lives • people's quality of life will be improved by access to quality services 	<ul style="list-style-type: none"> • avoidable years of life lost • people supported to manage their health condition
Leeds Drug and Alcohol Strategy 2016-2018	<ul style="list-style-type: none"> • early identification and support of people who want to change their alcohol and/or drug using behaviour • ensure good quality drug and alcohol treatment services that respond rapidly and effectively to changing patterns of drug and alcohol misuse • ensure that the harms caused to health by the use of drugs and alcohol are prevented and reduced to improve health outcomes 	<ul style="list-style-type: none"> • number of successful completions from drug and alcohol treatment

SECTION 2

2 STATEMENT OF REQUIREMENTS

2.1 Scope

2.1.1 Principles

There are certain elements of the service that are integral to its delivery and are emphasised here as they should be considered throughout the specification.

Person-centred

The service will play an important role in supporting individuals in their treatment journey. It is crucial the service user is at the heart of what is delivered and how. This means focusing on what is important to them, ensuring ease of access, understanding their context, any barriers, and providing opportunities for the service user voice to be heard throughout delivery. Within this however, it is important to note that reducing drug related deaths is the most important outcome of this service. Being on supervised consumption reduces risk and sometimes goes against service user wishes, but nevertheless is mandatory until risk to individual and the public is seen to be at an acceptable level. This restriction of choice needs to be handled with due sensitivity and a willingness to uphold unpopular boundaries.

Accessible and inclusive

Support around drug and alcohol use can be required by people from a range of different ethnicities, religions, class, age, sexual orientation, disability and lifestyle. It is essential therefore that the service recognises, understands and addresses the barriers that can prevent individuals from all communities in Leeds from fully engaging with support. Pharmacy staff need to make service users feel welcome and safe in the pharmacy building and be able to provide information and advice in an easy-to-understand and engaging manner.

Responsive

The service must be responsive to changes in a service users condition and follow up concerns regarding the health and wellbeing of service users in a timely manner. This will involve providing information and advice, contacting the prescriber / key worker and signposting to other services as appropriate.

Holistic approach

The service will ensure all staff are skilled at having 'better conversations', with service users to enable them to build positive relationships. This may enable them to identify additional needs, with a view to either addressing those needs or encouraging the service user to make links with other organisations. The client group is likely to have other health and wellbeing needs, e.g. housing-related support, care support, social isolation or mental ill health, and the service should be able to signpost appropriately, including to other Forward Leeds services, thereby making a more sustainable outcome for the service user more likely.

2.1.2 Scope of the Service and Eligibility

This specification relates to the provision of a supervised consumption service carried out on pharmacy premises only. All pharmacies must be located in Leeds.

The service is primarily for Forward Leeds service users.

Short-term arrangements for service users where the prescriber is not Forward Leeds are acceptable. The Council will monitor and review the number and level of these supervisions, in particular those from out of the Leeds area and reserves the right, in particular where such arrangements appear long term or excessive and are not for the benefit of Leeds residents, to make it the pharmacy's responsibility to seek payment from the prescribing agency instead of from the Council.

Regarding Leeds residents where the prescriber is not Forward Leeds, work will be undertaken, in conjunction with Forward Leeds to support GPs/agencies in referring service users into Forward Leeds where they can benefit from the full range of recovery-focused, specialist services available. Where service users do not wish to transfer, these prescribers will be encouraged to ensure supervision is part of a longer-term plan with other wrap-around support provided and regular review of prescriptions.

Opiate addiction is relatively uncommon in under 18 year olds, but nevertheless does occur and then opiate substitute prescribing may be required. In these instances additional support for the service user will be required and the pharmacist will be expected to work very closely with the young person's key worker to ensure appropriate support is provided.

The Department of Health publication: Drug misuse and dependence - UK guidelines on clinical management (often referred to as the Orange Book) states that *the aims of a community pharmacy based supervised consumption service include:*

- *ensuring the patient receives the prescribed dose*
- *reducing diversion of prescribed doses*
- *providing an opportunity for the pharmacist to make a regular assessment of patient compliance with treatment and of their general health and wellbeing*
- *providing an opportunity for the pharmacist to build a therapeutic relationship with the patient that is beneficial to promote health and harm reduction*
- *reducing the risks of drug related overdose and deaths*
- *minimising the risk of accidental consumption by children*

2.1.3 Funding

The pharmacy will be paid per supervision and the unit price is:

- £1.45 per methadone supervision

- £2.85 per buprenorphine supervision

This payment is for the act of supervision only. There are separate arrangements in place for funding the cost of the methadone and buprenorphine.

If two different strengths of buprenorphine or methadone are supplied to a service user and are supervised together this only qualifies as one supervision fee. To ensure that claims are accurate and there are no duplications, only 1 prescription per service user per day should be recorded. If more than one supervision is claimed for a service user on any day, this will be viewed as a duplicate and appropriate action will be taken to rectify any over payment.

2.1.4 Core activities

Supervise the consumption of prescribed methadone or buprenorphine

In order to safely and effectively deliver the supervised consumption service, the pharmacist must:

- confirm the identity of the service user – the person receiving the dose of medication must be the person named on the prescription. If there are any concerns regarding a service user's identity the pharmacist must get in touch with the prescriber or key worker. The pharmacist should not supply the prescription until they have confirmed the service user's identity
- at the first visit a treatment agreement should be discussed; this will outline areas such as the role of the pharmacist and the service user, opening hours, missed dose procedures, unacceptable behaviour and under what circumstances the pharmacy would share data/information with other agencies etc; the treatment agreement should be signed by both the pharmacist and the service user and a copy kept by both; it is the responsibility of the pharmacy to develop a robust and appropriate treatment agreement
- undertake a full clinical check of the prescription and ensure that it is legally compliant
- dispense exactly what the prescription specifies, contacting the prescriber for clarification if the prescription is unclear or ambiguous
 - if possible, prepare daily doses in advance in order to avoid delays when the service user comes into the pharmacy
 - pack daily methadone doses in a standard dispensing bottle, label and store
 - pharmacies using automated dispensing systems may measure a daily dose for supervised consumption into a labelled cup
 - daily buprenorphine tablets should be placed in a labelled container; where there are suspicions that buprenorphine is being diverted in order to abuse, sell or swap, crushing tablets can be an option to support adherence to treatment (noting that tablets do not need to be ground to a powder but merely broken into a few small fragments); this course of action must only be undertaken with agreement from the prescriber

Crushing of buprenorphine tablets is permitted in the Orange Book:

“Some pharmacists have been crushing buprenorphine tablets before consumption to make the supervision process more straightforward. This practice, while technically off-licence, may sometimes be undertaken with appropriate clinical governance approval and protocols”

- all methadone and buprenorphine supplies must be kept in the pharmacy’s Controlled Drugs cabinet
- offer a quiet, discreet and confidential area where consumption of substitute medications can take place
- ensure that each dose is fully supervised
- monitor the service user’s response to the prescribed treatment
- provide general health advice, including service user safety and information on minimising harm
- offer access to appropriate health promotion materials and signpost to further advice and support
- promote safe practice to the service user, including advice on storage and handling of medication where appropriate, especially if living with children and/or other vulnerable adults

The right to request pharmacies to issue a receipt for prescriptions received is reserved and will be implemented where there is a history of lost/misplaced prescriptions. This procedure will be discussed with individual pharmacies on a case by case basis.

When to withhold dose and/or contract prescriber/key worker

The pharmacist must withhold the dose if the service user:

- has missed 3 doses; tolerance may be lost quickly and it is important that the prescriber has the opportunity to reassess the service user before treatment is continued
- appears intoxicated; it may be appropriate to ask the service user to return later in the day

The pharmacist must withhold the dose until the prescriber has been contacted when:

- the service user asks someone to collect a dose on their behalf e.g. in case of illness
- the prescription is ambiguous or incorrectly written
- the identity of the service user is in doubt
- a prescription is presented for a new service user and prior contact has not been made by the prescriber

- a prescription is presented that states the name and address of a different pharmacy

The pharmacist must contact the prescriber or key worker when the service user:

- has missed 2 consecutive doses
- misses single doses on a regular basis
- appears intoxicated
- tries to avoid supervision or does not consume the whole dose under supervision
- is abusive or threatening

A Standard Operating Procedure must be in place, clearly setting out the roles and responsibilities of both the pharmacy staff and the service user. It is the responsibility of the pharmacy to develop a robust and appropriate Standard Operating Procedure.

All of the above activities must be carried out within the context of a user-friendly, non-judgmental, person-centred and confidential service.

2.1.5 Access

It is important to have numerous pharmacies delivering the service across the city, as having a pharmacy that is easy to access (e.g. one that is close to home or work) reduces barriers for service users accessing the service. Any potential barrier to being able to access substitute medication might encourage service users to swap their substitute medication for illegal street drugs. As well as proximity being a factor in reducing barriers, having pharmacies with late night and weekend opening will also encourage better engagement with the service.

The pharmacy must make it clear to service users what days and hours the supervised consumption service is available. It is expected that the service will be available during the pharmacy's normal opening hours, unless there is strong justification for this not being the case.

If a pharmacy intends to change the days or hours during which it is open, or the hours during which the supervised consumption service is available where this is different to standard opening hours, three months notice must be given in writing to the Council of any intended change.

2.1.6 Partnership working with key agencies

The Orange Book states that:

As part of the service, there should be systems to ensure information about patients can be fed to and from the prescriber and keyworker, as well as agreement from the patient that confidential information can be shared between the pharmacist and named members of the multidisciplinary team.

The service is part of community treatment provision for drug users and as such is commissioned to work closely with other treatment service providers, especially Forward Leeds. For the service to operate effectively, it is essential that good working relationships are developed and maintained with Forward Leeds and other prescribing and complementary services within Leeds. The pharmacy will be expected to develop its own working links with local health and social care agencies as appropriate.

The relationship with the prescriber and key worker is particularly important when there are concerns about the health of a service user and/or when they are missing pick-ups. In these instances it is important to have effective 2-way communication routes and a prompt response to telephone messages and emails is essential. Pharmacies should consider and may be requested to provide Forward Leeds with an alternative means of contacting the pharmacy in the event of difficulties using the main pharmacy telephone number.

In terms of service users missing pick-ups of medicines, the Orange Book states:

If a patient has not taken their regular prescribed dose of opioid, there is the possibility that their tolerance to the drug could have reduced, increasing risk of overdose if the usual dose of medication is then taken...It is good practice for the pharmacist and prescriber to communicate about a patient failing to collect methadone or buprenorphine doses as it may be an indicator of instability or increasing risk.

Judgement is required over how to respond to single or repeated missed pick-ups. However, failure to collect medication should prompt the dispensing pharmacist to consider contacting the prescribing clinician, especially during induction. If the medication is not collected for three consecutive days, then the pharmacist should obtain advice from the prescriber on what action to take. A pharmacist should not normally dispense the fourth day's dose unless they have confirmed with the prescriber that it is appropriate to do so. Depending on what the prescribing service knows about the circumstances of the patient, and on their assessment of risk, this will result in advice to the pharmacist either to continue to dispense or to ask the patient to attend the prescribing service for urgent clinical review.

2.1.7 Staffing

The pharmacy must have a named Accountable Officer who is responsible for ensuring the service is delivered effectively. This is likely to be the Lead Pharmacist or the Store Manager. The pharmacy must inform the Council of any changes to the

named Accountable Officer and have in place a hand-over procedure for any new or replacement staff members who will be involved in delivering the service.

The pharmacy must employ sufficient numbers of suitably qualified staff to enable it to effectively carry out the service. The pharmacists and support staff involved must have relevant knowledge and be appropriately trained.

All staff involved in the delivery of the service must adhere to the standards for pharmacy professionals as set out by the General Pharmaceutical Council set out below:

Pharmacy professionals must:

Standard 1: provide person-centred care

Standard 2: work in partnership with others

Standard 3: communicate effectively

Standard 4: maintain, develop and use their professional knowledge and skills

Standard 5: use their professional judgement

Standard 6: behave in a professional manner

Standard 7: respect and maintain a person's confidentiality

Standard 8: speak up when they have concerns or when things go wrong

Standard 9: demonstrate leadership

In addition to the above standards, it is important that staff have knowledge of drug and alcohol issues in order to:

- listen to, respect and reflect on the concerns of the service user with his/her drug use and use this to determine the most appropriate action for further information, advice or referral
- have a better understanding of the challenges faced by service users
- explain clearly the harm reduction messages associated with drug use and identify factors that might discourage service users from practicing harm reduction methods and seek to help with those factors by simple measures or suggestions

The CPPE (Centre for Pharmacy Postgraduate Education) offers a range of training relating to substance use and misuse and it is expected that pharmacy staff will complete this training. All staff involved in the delivery of this service must complete the CPPE Declaration of Competence (DoC) relating to supervised consumption. This must be recorded on PharmOutcomes.

2.2 KEY CONTRACT DATES

The contract will take effect from 1st July 2018 and expire automatically on 30th June 2021. The Council may extend the term of this contract (the extension period) up to a period of 36 months. If the Council wishes to extend this contract, it shall give the pharmacy at least 3 months' written notice of such intention before the expiry date.

The pharmacist should be aware that when reviewing whether to take up any contract extension provision which is at the sole discretion of the Council, the Council will, under its duty to obtain best value, consider a range of factors when deciding whether to extend or retender this contract. The most important factors will be contract performance, efficiency improvements and/or cost reductions in line with the potential

savings the Council has reason to believe would be achievable by retendering the contract.

2.3 CLIENT DETAILS

See Section A “The Particulars”, paragraph A.4

2.4 ORDERING OF SERVICES

NOT USED

2.5 COMMUNICATIONS STRATEGY

Communicating with service users

The pharmacy will ensure that information provided verbally and in written and other formats follows good practice guidance and recommendations, such as Plain English Crystal Mark.

The pharmacy will be required to respond appropriately to any differing communication needs, requirements and preferences of the community and to provide a service which addresses issues of language, literacy, hearing, visual, and / or cognitive impairment, and other forms of support in communication.

Service user involvement

The pharmacy will develop mechanisms to routinely collect feedback on service user satisfaction and respond to any issues raised. Feedback will be shared with the prescriber and the Council as appropriate.

Complaints

There will be a clear complaints procedure which will be made available to service users. All complaints will be logged and recorded and documents must be made available to the Council when requested. Where complaints cannot be resolved within the service, the Council reserves the right to investigate and take action where required and appropriate, including escalating concerns to NHS England, the Police and other agencies as appropriate.

2.6 INFORMATION GOVERNANCE

The pharmacy must retain records of service activity and ensure that service user records are retained in line with NHS code of practice for records management and associated guidance.

The pharmacy will be responsible for collecting a wide range of sensitive data as part of the delivery. The collection, storage, and transfer of this data must be carried out in accordance with the General Data Protection Regulation (GDPR) 2018.

The legal basis established for the processing of this data is to comply with the legal obligation for provision of health or social care services.

For the purposes of this contract the pharmacy has been identified as the Data Processor in relation to the collection, storage and transfer of data.

The Council will act as Data Controller.

The GDPR places specific legal obligations on data processors; for example, data processors are required to maintain records of personal data and processing activities. They have legal liability if responsible for a breach.

Further information about the principles of the GDPR and obligations as Data Processor can be found on the Information Commissioner's website (<https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/>).

Information and reporting

The Council reserves the right to audit throughout the contract the pharmacy's processes as required under this specification.

The pharmacy must provide the Council on request evidence to demonstrate compliance with GDPR requirements.

The pharmacy shall immediately advise the Council if any GDPR requirements have been breached, and shall inform the Council what steps have been taken to remedy the breach and ensure any such breach will not be repeated.

2.7 TRANSITION AND MOBILISATION

No mobilisation period is required but the pharmacy is expected to familiarise themselves with the new specification and make sure that the transition into the new contract period is managed smoothly.

2.8 EXIT PLAN

If the pharmacy should decide to stop delivering the service at the end of this contract, they will be required to provide sufficient notice to the prescriber to allow alternative arrangements and support to be put in place for existing service users.

2.9 EQUALITY

The pharmacy shall comply with all relevant Equality legislation as set out in Part 3 Terms and Conditions Clause.

The pharmacy must not discriminate between or against service users, on the grounds of age, disability, gender reassignment, marriage or civil partnership, pregnancy or maternity, race, religion or belief, sex, sexual orientation or any other non-medical characteristics except as permitted by the Law.

The pharmacy must provide appropriate assistance and make reasonable adjustments for service users who do not speak, read or write English or who have

communication difficulties (including without limitation hearing, oral or learning impairments).

In performing this contract, the pharmacy must comply with the Equality Act 2010 and have due regard to the obligations contemplated by section 149 of the Equality Act 2010 to:

- eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by the Equality Act 2010
- advance equality of opportunity between persons who share a relevant protected characteristic (as defined in the Equality Act 2010) and persons who do not share it
- foster good relations between persons who share a relevant protected characteristic (as defined in the Equality Act 2010) and persons who do not share it and for the avoidance of doubt this obligation shall apply whether or not the Contractor is a public authority for the purposes of section 149 of the Equality Act 2010

The pharmacy must provide to the Council as soon as reasonably practicable, any information that the Council reasonably requires to:

- monitor the equity of access to the services
- fulfil their obligations under the Law

All communication and branding must be accessible to a wide range of audiences and make it clear that the service is fully inclusive and available to all (subject to eligibility criteria).

The service will be accessible to all Leeds residents (subject to eligibility criteria).

2.10 ENVIRONMENT AND SUSTAINABILITY

The pharmacy shall in performing the service for this contract meet all Legislation, Guidance and Good Industry Practice in environmental management and meeting the objectives of the Councils sustainability policies.

The Council is committed to reducing both its direct and indirect carbon dioxide CO₂ emissions. Internally, many steps have been taken to address the impacts, including the implementation of relevant policies to embrace the sustainable procurement concept. A key focus of the drive is to reduce the impact of the transportation associated with the delivery of our services. As such, there is an expectation from providers to implement initiatives to reduce and / or offset the travel emissions linked to commissioned contracts.

2.11 HEALTH AND SAFETY

The pharmacy must comply with all relevant health and safety legislation and requirements during this contract.

Controlled drug error reporting

Methadone dispensed in excess of that prescribed can lead to toxicity. The risk of overdose is particularly high during induction, therefore extreme caution is required in the early stages of treatment. If an amount greater than the prescribed dose is dispensed and given to the service user, either as supervised or 'take home', the pharmacist must:

- advise the service user of the mistake and explain the possible seriousness of consequences
- inform the service user of signs/symptoms of toxicity and advise they go to hospital if these symptoms develop
- advise the service user to remain in the company of others for the following few hours
- if the service user has left before the mistake is realised, every attempt must be made to contact them; if they cannot be contacted it may be appropriate to request the assistance of the local police in locating the person should this be deemed necessary to ensure the person's safety
- contact the prescriber and key worker immediately and update them on the situation
- if the prescriber decides that the service user needs to go to hospital it is important that they are accompanied to ensure accurate information is provided and to support service user safety. Examples of when hospitalisation would be advised are when:
 - service user has taken two doses of the prescribed daily dose on the same day
 - service user has taken more than the prescribed dose in addition to alcohol and/or other substances

- record the details of the incident and all action taken following the serious incident reporting procedure as outlined in Appendix 1

2.12 EMPLOYMENT SKILLS AND ENGAGEMENT PLAN

NOT USED

2.13 CORPORATE SOCIAL RESPONSIBILITY

NOT USED

2.14 INSURANCE AND LIMITATION OF LIABILITY

See Section C “Special Terms and Conditions”, paragraph C3

2.15 QUALITY MANAGEMENT

The pharmacy will ensure that all provision is delivered safely and to a high standard of quality, working within the standards as described in 2.1.8. and 2.16. This will include:

- reviewing its Standard Operating Procedure on an annual basis
- demonstrating that all pharmacists and staff involved in the provision of the service have undertaken relevant training
- demonstrating that clear and accurate records are kept
- participating in any evaluation of the service as requested by the Council, including the assessment of service user experience.

2.16 STATUTORY GUIDANCE AND GOOD INDUSTRY PRACTICE REQUIREMENTS AND GUIDELINES

Pharmacy staff must be familiar with and compliant with:

- NHS Pharmaceutical Services Regulations (NHS Contractual Framework for Community Pharmacy)
- Department of Health: Drug misuse and dependence (UK guidelines on clinical management)
- General Pharmaceutical Council: Standards for pharmacy professionals
- NICE guidance: Methadone and buprenorphine for the management of opioid dependence

The pharmacy will provide and maintain a safe and suitable environment for service users and comply with all relevant statutory requirements, legislation, Department of Health Guidance and professional codes of practice and all health and safety regulations.

The pharmacy will ensure that all relevant consents and certification required by legislation, guidance or good industry / working practice are obtained and maintained.

Legislation - The pharmacy is expected to comply with all relevant legislation in so far as they are applicable to the service. Relevant legislation includes:

- The Equality Act 2010

- The Protection of Freedoms Act 2012
- General Data Protection Regulations 2018
- Disabled Person Act 1986
- Race Relations Amendment Act 2000
- Safeguarding Vulnerable Groups Act 2006

2.17 SAFEGUARDING

See Appendix F

2.18 LEEDS CITY COUNCIL POLICIES

The Council policies detailed below are relevant to the service described within this specification but not exhaustive:

- Vision for Leeds 2011 – 2030
- Leeds Drug and Alcohol Strategy 2016-18
- The City Priority Plans
- The Council Business Plan
- Clear Desk & Screen Policy
- Leeds Interagency Policy for Sharing Information (2009)
- Raising Concerns Policy
- LCC Whistle Blowing Policy
- Code of Conduct for Contractors, Service Contractors and Suppliers
- Equality and Diversity
- LCC Information Sharing Policy

SECTION 3

3.1 CONTRACT MONITORING, MEASUREMENT AND PERFORMANCE

Contracts will be managed by officers from the Council to ensure safe and effective delivery of the service. This will include ongoing performance monitoring, risk management and cost analysis which will be undertaken in conjunction with public health colleagues, Forward Leeds and Community Pharmacies West Yorkshire (CPWY) as appropriate to ensure the service continues to meet requirements including quality standards and value for money.

It is important that the pharmacy accurately records all activity taking place through this service. CPWY act as the service administrator for the Council for this contract. All pharmacies delivering the supervised consumption service must use PharmOutcomes - a web-based system designed to help pharmacies provide services more effectively and to make it easier for commissioners to audit and manage these services.

The process is:

- pharmacy receives prescription
- if the service user is new they are registered on the system with date of birth and initials – this will create a unique and anonymous identification number
- each prescription is then input onto the system, with the number of days / days that are supervised
- the system will notify the pharmacist when the prescription has ended to make sure that the record is up-to-date and complete
- each day of the prescription should be marked as one of the following, with only 'Supervised' generating a cost:

PharmOutcomes Entry	Description
Supervised	Medication supervised as per prescription
Take home dose	Not supervised as dose supplied on a previous day
Missed dose - did not attend	Script indicated supervision but service user did not attend pharmacy
Missed dose - refused supply	Script indicated supervision, service user attended pharmacy but was refused supply
New prescription issued	New script was issued to replace existing script
Prescription complete	Script was for less than 14 days. Mark all days not covered by the script with this option
Poured but not collected	Where methadone was measured and prepared for the service user but the service user did not attend to collect

The system will prevent multiple prescriptions being entered for a service user, e.g. where a drug is prescribed at different doses on separate prescriptions that run concurrently, only one supervision is recorded for payment.

The aggregated data provided by the individual pharmacies will be used to monitor the overall service, measure the demand for the service and help forecast future budget requirements.

The information stored on PharmOutcomes will be used to generate reports which include the following information:

- system created patient identification number
- age, initials and partial postcode of service user
- number of service users each month
- number of provision / prescriptions
- prescription start date
- details of prescriber
- drug details (methadone or buprenorphine)
- status of supervision on each given day of prescription (supervised, take home, missed etc.)

The Council will have quarterly meetings with CPWY. Due to the number of pharmacies delivering the service, CPWY is an effective channel for the Council to communicate with pharmacies via PharmOutcomes and newsletters. Any key messages or opportunities that the Council wishes to share with pharmacies can be delivered via CPWY.

3.2 GOVERNANCE

The provider must have a robust quality assurance procedure, which includes regular internal monitoring of the service (to ensure compliance with the contract and other regulations and good industry practice standards), gathering of information about service user satisfaction and analysis and action on findings.

3.3 PAYMENT TERMS AND INVOICING

Pharmacies are paid per supervision of either methadone (£1.45) or buprenorphine (£2.85) with CPWY administering payments on behalf of the Council through a separate contract.

Payments are made on a monthly basis, generated by the data input onto PharmOutcomes. All service activity should be entered promptly and the provider must ensure that all information recorded on PharmOutcomes is a fair and accurate recording of the activity it has undertaken. If supervisions are recorded after 4 weeks following the last supervision date they may not be paid.

3.4 INDEXATION

Indexation shall not be applicable to the agreed contract price.

3.5 VARIATIONS

See Section B “General Terms and Conditions”, paragraph B22

3.6 OPTIONAL ADDITIONAL FINANCIAL REQUIREMENTS

NOT USED

SECTION 4
DEFINITIONS AND BACKGROUND INFORMATION

4.1 DEFINITIONS AND INTERPRETATIONS

See Appendix O

4.2 PRESENT PROVISION

The service is currently available at 164 pharmacy outlets across Leeds through 64 separate contracts with a wide range of pharmacies from small independents to large national chains. This represents the majority of pharmacies in Leeds and provides city-wide coverage facilitating access to provision and service user choice. The service is currently used by an average of 1,700 service users per month. Service users select which pharmacy to use, basing their choice on factors such as proximity to home, transport routes and opening hours. The pharmacy is remunerated for each individual supervision at a rate of £1.45 per methadone supervision and £2.85 per buprenorphine supervision.

4.3 LEEDS CITY COUNCIL INFORMATION

The Service is to be delivered within the Leeds Metropolitan District. More information can be found at www.leeds.gov.uk.

APPENDIX B

CONDITIONS PRECEDENT

1. Provide the Authority with a copy of the Provider's registration with the CQC where the Provider must be so registered under the Law
2. Provide a copy of the Provider's Insurance Certificates including appropriate public liability and professional indemnity insurance as required for the provision of these Services

APPENDIX C

QUALITY OUTCOMES INDICATORS

See Specification – Appendix A, paragraph 2.15

APPENDIX D

SERVICE USER, LEGAL GUARDIAN, CARER AND STAFF SURVEYS

See Specification – Appendix A, paragraph 2.5

APPENDIX E

CHARGES

See Specification – Appendix A , paragraph 3.3

APPENDIX F

SAFEGUARDING POLICIES

Safeguarding is the term used for a range of measures employed to keep children and adults at risk safe and protected from harm. Safeguarding is an important role that must be embedded into organisations that come into contact with children, young people and adults at risk. This is not just restricted to social care services; safeguarding is everyone's business and includes anyone that comes into contact with other humans as part of their work.

Pharmacy staff are likely to have regular contact with adults who may be vulnerable for a variety of reasons and it is important that they are alert to and act on indications that a person may be at risk of harm and need safeguarding and/or support. Similarly, staff need to be aware of their responsibility to safeguard and promote a child's welfare. All pharmacy staff involved in delivering this service must therefore be familiar with the Leeds Safeguarding Children Partnership and the Leeds Safeguarding Adults Board's safeguarding policies and procedures. These can be found at www.LeedsSCP.org.uk and www.leedssafeguardingadults.org.uk .

All pharmacy staff involved in delivering this service must understand the signs and symptoms of child abuse and abuse of adults at risk. If anybody suspects that there is any incident of child abuse or abuse of adults at risk, it must be reported to the Leeds Safeguarding Children Partnership or Leeds Safeguarding Adults Board in accordance with their published procedures.

If it is suspected that a child is at risk of harm or being harmed, call:

- **During office hours** (9.00am – 5.00pm) call the Duty & Advice Team on 0113 376 0336 (option 3)
- **Out of office hours** (evenings, weekends and bank holidays) call the Children's Emergency Duty Team (EDT) on 0113 376 0469
- **In an emergency** call 999

If it is suspected that an adult is at risk of harm or being harmed, call:

- **During office hours** (9.00am – 5.00pm) call the Adults and Health contact centre on 0113 222 4401
- **Out of hours** call the Emergency Duty Team (EDT): 07712 106378

- **In an emergency** call 999
- The pharmacy will have robust policies and procedures in place for safeguarding and protecting children, young people, pregnant individuals and adults at risk of abuse and neglect such as people with physical or mental health conditions, with learning disabilities, those who are dependent on substances and frail older people.

The service must follow regulatory requirements and ensure that appropriate checks are carried out for all staff and volunteers. The service is ultimately responsible for the safety of the people receiving its service.

Domestic Violence and Abuse

Tackling domestic violence and abuse in the city is a key priority for the Council and its partners.

Pharmacy staff will make sure they are able to identify risk and respond appropriately and effectively to any disclosures of domestic violence and abuse by service users.

Pharmacies will display and provide details about domestic violence and abuse services in Leeds to service users. The Safer Leeds Domestic Violence Team at dvteam@leeds.gov.uk can provide up to date cards/leaflets/posters which can be used for this purpose.

Further information and advice can be found at <https://www.leeds.gov.uk/domesticviolence>

Serious Incident Reporting

The pharmacy will be required to have robust policies and procedures in place to identify, document and respond to all serious incidents. All serious incidents should be reported to the Council following the “Serious Incident Reporting Procedure for National Health Service Providers” as outlined in Appendix 1.

Statutory Reviews

The pharmacy will participate in statutory reviews led by Leeds Safeguarding Adults Board (Safeguarding Adults Reviews), the Leeds Safeguarding Children Partnership (Serious Case Reviews) and the Safer Leeds Community Safety Partnership (Domestic Homicide Reviews) as required.

APPENDIX G

INCIDENTS REQUIRING REPORTING PROCEDURE

Pursuant to clause B11 (Incidents Requiring Reporting) the provider must comply with the following procedure for reporting, investigating and implementing and sharing lessons learned from (1) Serious Incidents (2) reportable Patient Safety Incidents; and (3) Non-Service User safety incidents:

All incidents categorised as a Serious Incident must be reported to commissioners within 2 working days via ph.serious.incidents@leeds.gov.uk

Public Health Commissioned Care Quality Commission Registered Providers**Serious Incident Reporting Procedure for National Health Service Providers****August 2017****Purpose**

This procedure sets out the responsibilities and actions of both Leeds City Council (LCC) Public Health commissioners (the Authority) and the provider for dealing with serious incidents (SIs). It follows the principles set out in the NHS England publication: Serious Incident Framework, March 2015.

This procedure applies to all Public Health NHS contracts and contracts held with General Practitioners and Pharmacies. As Third Sector contracts (non Care Quality Commission (CQC) registered providers) are based on Leeds City Council Terms and Conditions, these providers will be required to comply with the clause included within the Local Authority contracts on the reporting of and responding to a serious incident.

Introduction

Public Health commissions health and wellbeing services from a wide range of providers and is responsible for performance managing its providers of services, both NHS and non-NHS, in relation to SI management.

Public Health must be satisfied that all service providers with whom it commissions operate within a sound Incident Management Policy and that, as a minimum, comply with the NHS England Serious Incident Framework. This is a formal condition of all service level agreements and contracts in relation to Public Health services, including those contracts with General Practitioners and Pharmacies.

Providers who are registered on the Strategic Executive Information System (STEIS) must report the incident on STEIS. The STEIS is used to report and view serious incidents that involve NHS funded patients. STEIS is not directly accessible by Local Authorities and so Public Health will be notified of incidents through the Leeds NHS contract and quality governance process as per the national framework, via NHS Leeds Clinical Commissioning Group.

All Providers (those registered and not registered on STEIS) must report incidents to the LCC Public Health Governance Manager within two days of the incident being identified. All providers will be monitored against the standards of the National Serious Incident Framework.

Public Health reserves the right to intervene in any serious incident where it is felt to be of significant risk to patient safety.

This procedure is aligned with the NHS Leeds Clinical Commissioning Groups (CCG) Provider Serious Incident Assurance Process 2016.

Definition of Serious Incidents

Serious Incidents requiring investigation are defined in the Serious Incident Framework and include:

1) Acts and/or omissions occurring as part of NHS-funded healthcare (including in the community) that result in:

(a) Unexpected or avoidable death of one or more people. This includes:

- (i) suicide/self-inflicted death; and
- (ii) homicide by a person in receipt of mental health care within the recent past.

(b) Unexpected or avoidable injury to one or more people that has resulted in serious harm;

(c) Unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent:

- (i) the death of the service user; or
- (ii) serious harm;

(d) Actual or alleged abuse; sexual abuse, physical or psychological ill-treatment, or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminative and organisational abuse, self-neglect, domestic abuse, human trafficking and modern day slavery where:

- (i) healthcare did not take appropriate action/intervention to safeguard against such abuse occurring; or
- (ii) where abuse occurred during the provision of NHS-funded care.

This includes abuse that resulted in (or was identified through) a Serious Case Review (SCR), Safeguarding Adult Review (SAR), Safeguarding Adult Enquiry or other externally-led investigation, where delivery of NHS funded care caused/contributed towards the incident.

(2) A Never Event - all Never Events are defined as serious incidents, although not all Never Events necessarily result in serious harm or death;

(3) An incident (or series of incidents) that prevents, or threatens to prevent, an organisation's ability to continue to deliver an acceptable quality of healthcare services, including (but not limited to) the following:

- (i) Failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issues;
- (ii) Property damage;
- (iii) Security breach/concern;
- (iv) Incidents in population-wide healthcare activities like screening and immunisation programmes where the potential for harm may extend to a large population;
- (v) Inappropriate enforcement/care under the Mental Health Act (1983) and the Mental Capacity Act (2005) including Mental Capacity Act, Deprivation of Liberty Safeguards (MCA DOLS);

(vi) Systematic failure to provide an acceptable standard of safe care (this may include incidents, or series of incidents, which necessitate ward/unit closure or suspension of services); or

(vii) Activation of Major Incident Plan (by provider, commissioner or relevant agency).

(4) Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation. Examples of Serious Incidents are outlined in Appendix 1.

Principles for Monitoring Serious Incidents

- The principal accountability of all providers and commissioners is to patients/clients and their families/carers.
- The first consideration following a serious incident is that the patient/client must be cared for, their (and other patients/clients) health and welfare secured and further risk mitigated.
- The primary responsibility for investigating and responding to serious incidents sits with the Boards of service providers.
- Clear requirements for responding to serious incidents are specified in contracts with all providers.
- The Authority needs to assure itself that providers have in place robust processes for reporting, investigating and learning from serious incidents.
- The Authority works in an open and transparent manner with providers when a serious incident has happened.
- The Authority and provider ensure a transparent process is in place to complete file closures.
- The Authority will work closely with the Leeds NHS Clinical Commissioning Groups (CCG) and NHS England in their role as the link between other NHS organisations; and other organisations to manage serious incidents.

Governance

The serious incident process is governed via the LCC formal committee structure through the following routes:

LCC Executive Board	The Executive Board is the principal decision making body of the Council and has overall accountability for safety.
LCC Corporate Governance and Audit Committee	The Corporate Governance and Audit Committee reviews the adequacy of policies and practices to ensure compliance with statutory and other guidance. The Committee also reviews the adequacy of the Council's Corporate Governance arrangements (including matters such as internal control and risk management).
LCC Adults and Health Directorate Leadership Team	The Adults and Health Directorate Leadership Team receives a summary of Serious Incidents

	<p>considered by the Public Health Serious Incident Review Panel/NHS Leeds CCGs Serious Incident Review Panel and reviews/monitors all Serious Incident Action Plans, including monitoring emerging themes/concerns.</p>
LCC Public Health Serious Incident Review Panel	<p>The panel receives and considers Serious Incident investigation reports prepared by providers who are not registered on the Strategic Executive Management System.</p> <p>The panel confirms either formal sign off or deferral of Serious Incident Investigation Reports directly to the provider.</p>
NHS Leeds CCGs Serious Incident Review Panel	<p>The panel receives Serious Incident investigation reports from its own and Leeds City Council's provider organisations, reviewing them against a template of good practice for serious incident reports. The group is responsible for identifying emerging trends, either within providers or across the city, and disseminating learning locally, regionally and nationally as appropriate.</p> <p>The group is ultimately responsible for formally closing any Serious Incidents recorded on STEIS as Leeds City Council does not have access to this system.</p> <p>An appropriate representative of Public Health will be invited to attend the Panel to consider any Serious Incident Investigation Reports from Providers that are registered on STEIS and provide services that the Leeds City Council Public Health team commissions.</p>
Leeds Quality Surveillance Group	<p>The group receives a confidential report of all ongoing serious incidents logged with the Local Authority and its providers.</p> <p>The group monitors the action plans of all serious incidents reported by the Local Authority until completed (excluding safeguarding incidents).</p>
LCC Public Health/Provider contract performance management groups	<p>The groups discuss issues relating to serious incidents.</p> <p>The groups receive assurance of a robust process in providers for SI management and monitor SI themes and trends in each provider.</p>

Reporting of a Serious Incident

The following describes the process that must be followed when a SI occurs. A flow diagram to support this description is in Appendix 3.

Reporting

Public Health receives notification of serious incident direct from the provider via the Public Health Governance Manager's dedicated serious incident mailbox.

The Public Health Governance Manager will receive notification of serious incidents reported via STEIS from the Leeds CCG.

Public Health receives notification of serious incidents from the provider, (as stipulated in the PH Services Contract) via the Public Health Governance Manager's dedicated serious incident email account ph.serious.incidents@leeds.gov.uk. NHS Leeds CCG will be notified of Serious Incidents via the STEIS mechanism from the provider and will alert the Director of Public Health and Public Health Governance Manager. A Serious Incident Notification form will be completed by the Public Health Governance Manager (see Appendix 2) to summarise and record the incident and to also clarify who will be informed.

The provider will investigate the Serious Incident and submit a SI investigation report to the CCG through the established SI route, within the timeframe outlined in the Serious Incident Framework. The CCG will then send this report to the Director of Public Health and Public Health Governance Manager, which will be reviewed at an NHS Leeds CCGs Serious Incident Review Panel. An appropriate representative from Public Health will be invited to attend this panel. . If the provider is not registered on STEIS, its investigation report will be sent directly to the Public Health Governance Manager via the email account provided above and this will be considered at a specially convened Public Health Serious Incident Review Panel.

Full details of all Serious Incidents relating to Public Health commissioned services will be shared with the Executive Member for Health, Wellbeing and Adults and the Adults and Health Directorate Leadership Team. The Communications Team will also be informed as there may be the possibility of media coverage. An appropriate media handling strategy will therefore be established and agreed. The Communications Team will also ensure that the Chief Executive and Leader of the Council are informed as appropriate.

The lead commissioner has final say and sign-off of the incident and the CCG is ultimately responsible for formally closing a Serious Incident which has been registered on STEIS.

The CCG will share the annual SI figures for the provider with the lead Commissioner to give context to the proportion of SIs between the specific service and the provider as a whole.

Internal Reporting

The Public Health Governance Manager will inform the relevant Consultant in Public Health via email of the serious incident.

The Director of Public Health will inform the Director of Adults and Health and the Executive Member for Health, Wellbeing and Adults.

The Public Health Governance Manager will inform the Public Health communications team as there may be the possibility of media coverage. An appropriate media handling strategy will therefore be established and agreed. The Communications Team will ensure that the Chief Executive and Leader are informed as appropriate.

Acknowledgement

If the Provider is not registered on STEIS, the Public Health Governance Manager will acknowledge receipt of the incident and inform the Provider of when the final report should be submitted.

Recording

All reported serious incidents will be logged on a Serious Incident Notification form and recorded on a register held by the Public Health Governance Manager.

Investigation

The provider should commence an investigation immediately, once safe and legal to do so, in accordance with their serious incident investigation procedures and root cause analysis principles.

Investigation report

The provider should submit to the Public Health Governance Manager, (via NHS Leeds CCG if the SI has been reported on STEIS), a full root cause analysis report and action plan within the timescales defined by the national framework.

In exceptional circumstances where this may not be possible then an interim report is required, detailing the progress of the investigation so far, any immediate actions taken to ensure patient safety and a projected timeframe for completion of the final report.

Quality Assurance

The Public Health Serious Incident Review Panel will review all submitted SI investigation reports and quality assess them against the Serious Incident Framework for a robust Root Cause Analysis Investigation. The NHS Leeds CCG Serious Incident Review Panel carries out a review (for all SIs reported on STEIS) in order to advise the specialist commissioner of whether there are any common issues with other SIs from the provider.

Closure of SI records

For those investigation reports approved by the Public Health Serious Incident Review Panel, confirmation will be sent directly from the Public Health Governance Manager to the provider that the Serious Incident has been formally closed.

For those investigation reports approved by the NHS Leeds CCGs Serious Incident Review Panel, confirmation will be sent by the Head of Governance, Leeds CCGs that the Serious Incident will be closed formally on STEIS.

Approval will be given if the final report is deemed to demonstrate a thorough investigation in accordance with RCA principles and contains a robust action plan to reduce the risk of a similar incident from happening again. If the Public Health Serious Incident Review Panel deems it necessary for the investigation report to be deferred pending further information/assurance, this will be communicated to the Service Provider requesting a response within four weeks.

The quality of every incident investigation report will be audited against regional NHS standards when they are submitted for closure. Leeds City Council, as lead commissioner has final say and sign-off of the incident.

The Adults and Health Directorate Leadership Team will review and monitor all action plans produced as part of the Serious Incident Reporting process. The Public Health lead for the commissioned service will also ensure that the incident is reviewed directly with the service provider.

Audit and Monitoring

NHS Leeds CCG will share with Leeds City Council the annual SI figures for the provider to give context to the proportion of SIs between the specific service and the provider as a whole.

Monitoring is performed on a continuous basis via the serious incident monitoring database. All serious incidents are measured against the requirements of national serious incident guidance and reported to the Adults and Health Directorate Leadership Team.

References

NHS England – Serious Incident Framework (March 2015) [NHS England Serious Incident Framework 2015](#)
Care Quality Commission, Essential Standards of Quality & Safety
<http://www.cqc.org.uk/>

APPENDIX 1

Examples of Serious Incidents

Only the most serious of incidents require reporting to STEIS. It is difficult to be prescriptive, but the following are examples of events that would warrant reporting.

- Death or serious injury to a patient or member of the public which is alleged to be at the hands of another patient or member of the public while on provider premises
- Suspected homicide by a person currently in receipt of mental health services (or within the last six months)
- Suicide/suspected suicide of a person currently in receipt of services or who have received services in the last six months
- Serious injury of a person currently in receipt of care (or within the last six months) as a result of deliberate self-harm (e.g. attempted Suicide) or accidental injury
- Any death on GP premises (in line with Shipman recommendations)
- Safeguarding incidents meeting the criteria specified in the Leeds City Council Safeguarding policy.
- Death or serious injury to a member of staff (including independent contractors e.g. GPs, pharmacists) in the course of their duties
- Patients/clients in receipt of substance misuse services who die as a direct result of their substance misuse should be reported as a SI
- Medication incidents resulting in death/serious injury e.g. incorrect medication dispensed to patient; drugs given to patients with known allergy
- Failure of medical equipment resulting in death/major injury
- Clinical incidents resulting in death/serious injury
- Serious fires or other serious damage, which occurs on provider premises. Of particular concern would be any fire which resulted in casualties or major disruption to services
- Serious or unexplained outbreaks of infection or disease in the provider premises or the wider community (e.g. food poisoning, Legionnaire's Disease) or the confirmed transmission of serious infectious disease between a provider staff member and a patient (e.g. HIV/Hepatitis B)
- Major system failure e.g. patient referral system failure for further consultation/treatment

- Major environmental incident (e.g. inappropriate disposal of clinical waste) which has or could have harmed the public
- Major service disruption e.g. due to power failure, flooding, etc.
- Breach of patient confidentiality e.g. theft of patient notes or unencrypted computers/laptops/media containing patient information; discovery of patient records in public area
- Incidents/concerns regarding the actions of provider staff (including independent contractors). Examples include fraudulent behaviour, gross misconduct and actions resulting in harm to patients. This could lead to suspension/summary dismissal, media interest and the involvement of the criminal justice system
- A pattern emerging that is causing concern such as a high number of complaints regarding a member of staff (including independent contractors), a particular service and/or hospital that may warrant further investigation and action.

This list is NOT exhaustive nor in any order of importance. Personal judgement will need to be exercised when deciding whether or not to report and manage an incident as a SI.

**Leeds City Council – Serious Incident Notification Form
Confidential**

Reporting

Date and time of log	
Name of person reporting	
Contact number	
Department and service area	

Incident/ issue

Date and time	
Location	
Department and service area	
Name of employee (if relevant)	
Lead officer dealing with issue	

Brief description of incident/issue:

Is this already in the public domain?	
If so, how?	

Who needs to be informed? (Please note the communications team will inform the Leader, chief executive, corporate leadership team, and cabinet member as appropriate.)

- | | | | |
|---------------------|--------------------------|-------------------------|--------------------------|
| Communications team | <input type="checkbox"/> | HR | <input type="checkbox"/> |
| Employee’s manager | <input type="checkbox"/> | Chief officer/ director | <input type="checkbox"/> |
| Safeguarding | <input type="checkbox"/> | LADO | <input type="checkbox"/> |

Serious Incident Occurs



APPENDIX H

INFORMATION PROVISION

See Specification – Appendix A, paragraph 3.1

APPENDIX I

TRANSFER OF AND DISCHARGE FROM CARE PROTOCOLS

Not used

APPENDIX J

SERVICE QUALITY PERFORMANCE REPORT

See Specification – Appendix A, paragraph 2.15

APPENDIX K

DETAILS OF REVIEW MEETINGS

The Authority and the Provider will arrange review meetings as required.

APPENDIX L

AGREED VARIATIONS

Agreed variations to be inserted in due course as relevant.

APPENDIX M

DISPUTE RESOLUTION

Part 1 of Appendix M – Dispute Resolution Process

1. ESCALATED NEGOTIATION

1.1 Except to the extent that any injunction is sought relating to a matter arising out of clause B36 (*Confidentiality*), if any Dispute arises out of or in connection with this Contract, the Parties must first attempt to settle it by either of them making a written negotiation offer to the other, and during the 15 Business Days following receipt of the first such offer (the “**Negotiation Period**”) each of the Parties shall negotiate in good faith and be represented:

1.1.1 for the first 10 Business Days, by a senior person who where practicable has not had any direct day-to-day involvement in the matter that led to the Dispute and has authority to settle the Dispute; and

1.1.2 for the last 5 Business Days, by its chief executive, director, or board member who has authority to settle the Dispute,

provided that no Party in Dispute where practicable shall be represented by the same individual under paragraphs 1.1.1 and 1.1.2.

2. MEDIATION

2.1 If the Parties are unable to settle the Dispute by negotiation, they must within 5 Business Days after the end of the Negotiation Period submit the Dispute to mediation by CEDR or other independent body or organisation agreed between the Parties and set out in Part 2 of this Appendix M.

2.2 The Parties will keep confidential and not use for any collateral or ulterior purpose all information, whether given orally, in writing or otherwise, arising out of or in connection with any mediation, including the fact of any settlement and its terms, save for the fact that the mediation is to take place or has taken place.

2.3 All information, whether oral, in writing or otherwise, arising out of or in connection with any mediation will be without prejudice, privileged and not admissible as evidence or disclosable in any current or subsequent litigation or other proceedings whatsoever.

3. EXPERT DETERMINATION

3.1 If the Parties are unable to settle the Dispute through mediation, then either Party may give written notice to the other Party within 10 Business Days of closure of the failed mediation of its intention to refer the Dispute to expert determination. The Expert Determination Notice must include a brief statement of the issue or issues which it is desired to refer, the expertise required in the expert, and the solution sought.

3.2 If the Parties have agreed upon the identity of an expert and the expert has confirmed in writing his readiness and willingness to embark upon the expert determination, then that person shall be appointed as the Expert.

3.3 Where the Parties have not agreed upon an expert, or where that person has not confirmed his willingness to act, then either Party may apply to CEDR for the appointment of an expert. The request must be in writing, accompanied by a copy of the Expert Determination Notice and the appropriate fee and must be copied simultaneously to the other Party. The other Party may make representations to CEDR regarding the expertise required in the expert. The person nominated by CEDR will be appointed as the Expert.

3.4 The Party serving the Expert Determination Notice must send to the Expert and to the other Party within 5 Business Days of the appointment of the Expert a statement of its case

including a copy of the Expert Determination Notice, the Contract, details of the circumstances giving rise to the Dispute, the reasons why it is entitled to the solution sought, and the evidence upon which it relies. The statement of case must be confined to the issues raised in the Expert Determination Notice.

- 3.5 The Party not serving the Expert Determination Notice must reply to the Expert and the other Party within 5 Business Days of receiving the statement of case, giving details of what is agreed and what is disputed in the statement of case and the reasons why.
- 3.6 The Expert must produce a written decision with reasons within 30 Business Days of receipt of the statement of case referred to in paragraph 1.9, or any longer period as is agreed by the Parties after the Dispute has been referred.
- 3.7 The Expert will have complete discretion as to how to conduct the expert determination, and will establish the procedure and timetable.
- 3.8 The Parties must comply with any request or direction of the Expert in relation to the expert determination.
- 3.9 The Expert must decide the matters set out in the Expert Determination Notice, together with any other matters which the Parties and the Expert agree are within the scope of the expert determination. The Expert must send his decision in writing simultaneously to the Parties. Within 5 Business Days following the date of the decision the Parties must provide the Expert and each other with any requests to correct minor clerical errors or ambiguities in the decision. The Expert must correct any minor clerical errors or ambiguities at his discretion within a further 5 Business Days and send any revised decision simultaneously to the Parties.
- 3.10 The Parties must bear their own costs and expenses incurred in the expert determination and are jointly liable for the costs of the Expert.
- 3.11 The decision of the Expert is final and binding, except in the case of fraud, collusion, bias, or material breach of instructions on the part of the Expert at which point a Party will be permitted to apply to Court for an Order that:
 - 3.11.1 the Expert reconsider his decision (either all of it or part of it); or
 - 3.11.2 the Expert's decision be set aside (either all of it or part of it).
- 3.12 If a Party does not abide by the Expert's decision the other Party may apply to Court to enforce it.
- 3.13 All information, whether oral, in writing or otherwise, arising out of or in connection with the expert determination will be inadmissible as evidence in any current or subsequent litigation or other proceedings whatsoever, with the exception of any information which would in any event have been admissible or disclosable in any such proceedings.
- 3.14 The Expert is not liable for anything done or omitted in the discharge or purported discharge of his functions, except in the case of fraud or bad faith, collusion, bias, or material breach of instructions on the part of the Expert.
- 3.15 The Expert is appointed to determine the Dispute or Disputes between the Parties and his decision may not be relied upon by third parties, to whom he shall have no duty of care.

Part 2 of Appendix M - Nominated Mediation Body

Part 3 of Appendix M - Recorded Dispute Resolutions

APPENDIX N

NOT USED

APPENDIX O

Definitions and Interpretation

1. The headings in this Contract shall not affect its interpretation.
2. References to any statute or statutory provision include a reference to that statute or statutory provision as from time to time amended, extended or re-enacted.
3. References to a statutory provision shall include any subordinate legislation made from time to time under that provision.
4. References to Sections, clauses and Appendices are to the Sections, clauses and Appendices of this Contract, unless expressly stated otherwise.
5. References to any body, organisation or office shall include reference to its applicable successor from time to time.
6. Any references to this Contract or any other documents includes reference to this Contract or such other documents as varied, amended, supplemented, extended, restated and/or replaced from time to time.
7. Use of the singular includes the plural and vice versa.
8. The following terms shall have the following meanings:

Activity means any levels of clinical services and/or Service User flows set out in a Service Specification

Authorised Person means the Authority and any body or person concerned with the provision of the Service or care of a Service User

Authority Representative means the person identified in clause A4.1 (*Representatives*) or their replacement

Best Value Duty means the duty imposed by section 3 of the Local Government Act 1999 (the **LGA 1999**) as amended and under which the Authority is under a statutory duty to continuously improve the way its functions are exercised, having regard to a combination of economy, efficiency and effectiveness and to any applicable guidance issued from time to time (and “**Best Value**” shall be construed accordingly)

Board of Directors means the executive board or committee of the relevant organisation

Business Continuity Plan means the Provider’s plan referred to in Clause B34.2 (*Business Continuity*) relating to continuity of the Services, as agreed with the Authority and as may be amended from time to time

Business Day means a day (other than a Saturday or a Sunday) on which commercial banks are open for general business in London

Caldicott Guardian means the senior health professional responsible for safeguarding the confidentiality of patient information

Care Quality Commission or CQC means the care quality commission established under the Health and Social Care Act 2008

Carer means a family member or friend of the Service User who provides day-to-day support to the Service User without which the Service User could not manage

CEDR means the Centre for Effective Dispute Resolution

Charges means the charges which shall become due and payable by the Authority to the Provider in respect of the provision of the Services in accordance with the provisions of this Contract, as such charges are set out in Appendix E (*Charges*)

Commencement Date means the date identified in clause A3.1 (*Commencement and Duration*)

Competent Body means any body that has authority to issue standards or recommendations with which either Party must comply

Conditions Precedent means the conditions precedent, if any, to commencement of service delivery referred to in clause A3.2 (*Commencement and Duration*) and set out in Appendix B (*Conditions Precedent*)

Confidential Information means any information or data in whatever form disclosed, which by its nature is confidential or which the Disclosing Party acting reasonably states in writing to the Receiving Party is to be regarded as confidential, or which the Disclosing Party acting reasonably has marked 'confidential' (including, without limitation, financial information, or marketing or development or work force plans and information, and information relating to services or products) but which is not Service User Health Records or information relating to a particular Service User, or Personal Data, pursuant to an FOIA request, or information which is published as a result of government policy in relation to transparency

Consents means:

- (i) any permission, consent, approval, certificate, permit, licence, statutory agreement, authorisation, exception or declaration required by Law for or in connection with the performance of Services; and/or
- (ii) any necessary consent or agreement from any third party needed either for the performance of the Provider's obligations under this Contract or for the provision by the Provider of the Services in accordance with this Contract

Contract Query means:

- (i) a query on the part of the Authority in relation to the performance or non-performance by the Provider of any obligation on its part under this Contract; or
- (ii) a query on the part of the Provider in relation to the performance or non-performance by the Authority of any obligation on its part under this Contract,

as appropriate

Contract Query Notice means a notice setting out in reasonable detail the nature of a Contract Query

Contract Management Meeting means a meeting of the Authority and the Provider held in accordance with clause B29.8 (*Contract Management*)

CQC means the Care Quality Commission

CQC Regulations means the Care Quality Commission (Registration) Regulation 2009

Data Protection Legislation means the Data Protection Act 1998, the new Data Protection Act 2018, the Data Protection Directive (95/46/EC), Regulation (EU) 2016/679 of the European Parliament and of the European Council of 27 April 2016 (commonly known as the General Data Protection Regulation) once in force, the Privacy and Electronic Communications (EC Directive) Regulations 2003 (SI 2426/2003), and all other applicable laws and regulations relating to the processing of personal data and privacy and any subordinate legislation relating to the processing of personal data and privacy from time to time together with any applicable guidance and/or codes of practice issued by the Information Commissioner or relevant government department in relation to such legislation;

DBS means the Disclosure and Barring Service established under the Protection of Freedoms Act 2012

Default means any breach of the obligations of the Provider (including but not limited to fundamental breach or breach of a fundamental term) or any other default, act, omission, negligence or statement of the Provider or the Staff in connection with or in relation to the subject-matter of this Contract and in respect of which the Provider is liable to the Authority

Default Interest Rate means LIBOR plus 2% per annum

Disclosing Party means the Party disclosing Confidential Information

Dispute means a dispute, conflict or other disagreement between the Parties arising out of or in connection with this Contract

Employment Checks means the pre-appointment checks that are required by law and applicable guidance, including without limitation, verification of identity checks, right to work checks, registration and qualification checks, employment history and reference checks, criminal record checks and occupational health checks

Enhanced DBS & Barred List Check means an Enhanced DBS & Barred List Check (child) or Enhanced DBS & Barred List Check (adult) or Enhanced DBS & Barred List Check (child & adult) (as appropriate)

Enhanced DBS & Barred List Check (child) means a disclosure of information comprised in an Enhanced DBS Check together with information from the DBS children's barred list

Enhanced DBS & Barred List Check (adult) means a disclosure of information comprised in an Enhanced DBS Check together with information from the DBS adult's barred list

Enhanced DBS & Barred List Check (child & adult) means a disclosure of information comprised in an Enhanced DBS Check together with information from the DBS children's and adult's barred list

Enhanced DBS Check means a disclosure of information comprised in a Standard DBS Check together with any information held locally by police forces that it is reasonably considered might be relevant to the post applied for

Enhanced DBS Position means any position listed in the Rehabilitation of Offenders Act 1974 (Exceptions) Order 1975 (as amended), which also meets the criteria set out in the Police Act 1997 (Criminal Records) Regulations 2002 (as amended), and in relation to which an Enhanced DBS Disclosure or an Enhanced DBS & Barred List Check (as appropriate) is permitted

Equipment means the Provider's equipment, plant, materials and such other items supplied and used by the Provider in the performance of its obligations under this Contract

Excusing Notice means a notice setting out in reasonable detail the Receiving Party's reasons for believing that a Contract Query is unfounded, or that the matters giving rise to the Contract Query are:

- (i) due wholly or partly to an act or omission by the Issuing Party; or
- (ii) a direct result of the Receiving Party following the instructions of the Issuing Party; or
- (iii) due to circumstances beyond the Receiving Party's reasonable control but which do not constitute an event of Force Majeure

Expert means the person designated to determine a Dispute by virtue of paragraphs 1.6 or 1.7 of Appendix M (*Dispute Resolution*)

Expert Determination Notice means a notice in writing showing an intention to refer Dispute for expert determination

Expiry Date means the date set out in clause A3.3 (*Commencement and Duration*)

First Exception Report means a report issued in accordance with clause B29.21 (*Contract Management*) notifying the relevant Party's chief executive and/or Board of Directors of that Party's breach of a Remedial Action Plan and failure to remedy that breach

FOIA means the Freedom of Information Act 2000 and any subordinate legislation made under this Act from time to time together with any guidance and/or codes of practice issued by the Information Authority or relevant government department in relation to such legislation and the Environmental Information Regulations 2004

Force Majeure means any event or occurrence which is outside the reasonable control of the Party concerned and which is not attributable to any act or failure to take preventative action by that Party, including fire; flood; violent storm; pestilence; explosion; malicious damage; armed conflict; acts of terrorism; nuclear, biological or chemical warfare; or any other disaster, natural or man-made, but excluding:

- (i) any industrial action occurring within the Provider's or any Sub-contractor's organisation; or
- (ii) the failure by any Sub-contractor to perform its obligations under any Sub-contract

Fraud means any offence under the laws of the United Kingdom creating offences in respect of fraudulent acts or at common law in respect of fraudulent acts or defrauding or attempting to defraud or conspiring to defraud the Authority

General Conditions has the meaning given to it in clause A1.1(b) (*Contract*)

Good Clinical Practice means using standards, practices, methods and procedures conforming to the Law 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, or a person providing services the same as or similar to the Services, at the time the Services are provided, as applicable

Guidance means any applicable local authority, health or social care guidance, direction or determination which the Authority and/or the Provider have a duty to have regard to including any document published under section 73B of the NHS Act 2006

Immediate Action Plan means a plan setting out immediate actions to be undertaken by the Provider to protect the safety of Services to Service Users, the public and/or Staff

Indirect Losses means loss of profits (other than profits directly and solely attributable to the provision of the Services), loss of use, loss of production, increased operating costs, loss of business, loss of business opportunity, loss of reputation or goodwill or any other consequential or indirect loss of any nature, whether arising in tort or on any other basis

Issuing Party means the Party which has issued a Contract Query Notice

JI Report means a report detailing the findings and outcomes of a Joint Investigation

Joint Investigation means an investigation by the Issuing party and the Receiving Party into the matters referred to in a Contract Query Notice

Law means:

- (i) any applicable statute or proclamation or any delegated or subordinate legislation or regulation;
- (ii) any enforceable EU right within the meaning of Section 2(1) of the European Communities Act 1972;

- (iii) any applicable judgment of a relevant court of law which is a binding precedent in England and Wales;
- (iv) National Standards;
- (v) Guidance; and
- (vi) any applicable industry code

in each case in force in England and Wales

Legal Guardian means an individual who, by legal appointment or by the effect of a written law, is given custody of both the property and the person of one who is unable to manage their own affairs

Lessons Learned means experience derived from provision of the Services, the sharing and implementation of which would be reasonably likely to lead to an improvement in the quality of the Provider's provision of the Services

LIBOR means the London Interbank Offered Rate for 6 months sterling deposits in the London market

Local HealthWatch means the local independent consumer champion for health and social care in England

Losses means all damage, loss, liabilities, claims, actions, costs, expenses (including the cost of legal and/or professional services) proceedings, demands and charges whether arising under statute, contract or at common law but, excluding Indirect Losses

National Institute for Health and Clinical Excellence or **NICE** means the special health authority responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health (or any successor body)

National Standards means those standards applicable to the Provider under the Law and/or Guidance as amended from time to time

Negotiation Period means the period of 15 Business Days following receipt of the first offer

NHS Act 2006 means the National Health Service Act 2006

Parties means the Authority and the Provider and "Party" means either one of them

Patient Safety Incident means any unintended or unexpected incident that occurs in respect of a Service User that could have led, or did lead, to harm to that Service User

Personal Data has the meaning set out in the DPA

Prohibited Acts has the meaning given to it in clause B39.1 (*Prohibited Acts*)

Provider Representative means the person identified in clause A4.2 (*Representatives*) or their replacement

Provider's Premises means premises controlled or used by the Provider for any purposes connected with the provision of the Services which may be set out or identified in a Service Specification

Public Authority means as defined in section 3 of the FOIA

Quality Outcomes Indicators means the agreed key performance indicators and outcomes to be achieved as set out in Appendix C (*Quality Outcomes Indicators*)

Receiving Party means the Party which has received a Contract Query Notice or Confidential Information as applicable

Regulations means the General Data Protection Regulation (EU) 2016/679

Regulatory Body means any body other than CQC carrying out regulatory functions in relation to the Provider and/or the Services

Remedial Action Plan means a plan to rectify a breach of or performance failure under this Contract specifying targets and timescales within which those targets must be achieved

Required Insurances means the types of policy or policies providing levels of cover as specified in clause C3 (Insurance)

Review Meeting means a meeting to be held in accordance with clause B19 (*Review Meetings*) or as otherwise requested in accordance with clause B19.2 (*Review Meetings*)

Safeguarding Policies means the written policies for safeguarding children and adults, as amended from time to time, and as may be appended at Appendix F (*Safeguarding Children and Vulnerable Adults*)

Second Exception Report means a report issued in accordance with clause B29.22 (*Contract Management*) notifying the recipients of a breach of a Remedial Action Plan and the continuing failure to remedy that breach

Serious Incident means an incident or accident or near-miss where a patient (whether or not a Service User), member of staff, or member of the public suffers serious injury, major permanent harm or unexpected death on the Provider's Premises or where the actions of the Provider, the Staff or the Authority are likely to be of significant public concern

Service Commencement Date means the date set out in clause A3.2 (*Commencement and Duration*)

Service Specification means each of the service specifications defined by the Authority and set out at Appendix A (*Service Specifications*)

Service User means the person directly receiving the Services provided by the Provider as specified in the Service Specifications and includes their Carer and Legal Guardian where appropriate

Service Quality Performance Report means a report as described in Appendix J (*Service Quality Performance Report*)

Services means the services (and any part or parts of those services) described in each of, or, as the context admits, all of the Service Specifications, and/or as otherwise provided or to be provided by the Provider under and in accordance with this Contract

Special Conditions has the meaning given to it in clause A1.1(c) (*Contract*)

Staff means all persons employed by the Provider to perform its obligations under this Contract together with the Provider's servants, agents, suppliers and Sub-contractors used in the performance of its obligations under this Contract

Standard DBS Check means a disclosure of information which contains certain details of an individual's convictions, cautions, reprimands or warnings recorded on police central records and includes both 'spent' and 'unspent' convictions

Standard DBS Position means any position listed in the Rehabilitation of Offenders Act 1974 (Exceptions) Order 1975 (as amended) and in relation to which a Standard DBS Check is permitted

Sub-contract means a contract approved by the Authority between the Provider and a third party for the provision of part of the Services

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Sub-contractor means any third party appointed by the Provider and approved by the Authority under clause B23.1 (*Assignment and Sub-contracting*) to deliver or assist with the delivery of part of the Services as defined in a Service Specification

Succession Plan means a plan agreed by the Parties (acting reasonably) to deal with transfer of the Services to an alternative provider following expiry or termination of this Contract

Successor Provider means any provider to whom a member of Staff is transferred pursuant to TUPE in relation to the Services immediately on termination or expiry of this Contract

Transfer of and Discharge from Care Protocols means the protocols set out in Appendix I (*Transfer and Discharge from Care Protocols*)

TUPE means the Transfer of Undertakings (Protection of Employment) Regulations 2006

VAT means value added tax in accordance with the provisions of the Value Added Tax Act 1994

Variation means a variation to a provision or part of a provision of this Contract

Variation Notice means a notice to vary a provision or part of a provision of this Contract issued under clause B22.2 (*Variations*).

APPENDIX P

TENDER DOCUMENTS

Not used

SECTION C
SPECIAL TERMS AND CONDITIONS

C1. EXTENDING THE DURATION OF CONTRACT

- C1.1 The Authority may extend the term of this Contract on one or more occasions by a further period (or periods) up to and including 31st March 2024 (the **Extension Period**). If the Authority wishes to extend this Contract, it shall give the Provider at least 3 months' written notice of such extension.
- C1.2 If the Authority gives such notice, the Expiry Date will be extended by the period set out in the notice.

C2. LIMITATION OF LIABILITY

- C2.1 Subject to clauses B25.1 and B26.3, the Provider's total liability to the Authority, whether in contract, tort (including negligence), breach of statutory duty, or otherwise, arising under or in connection with this Contract shall:
- C2.1.1 in respect of liabilities which the Provider is required to insure against pursuant to clause C3 (Insurance), be limited to the level of cover required to be procured in respect of the relevant Required Insurance (whether such insurance policy is in fact effected and maintained or not); or
- C2.1.2 in respect of any other liabilities not referred to in clause C2.1.1, be limited to (in aggregate) an amount equal to the aggregate of the Charges payable by the Authority to the Provider under this Contract.

C3. INSURANCE

- C3.1 The Provider shall at its own cost effect and maintain with a reputable insurance company a policy or policies of insurance providing (as a minimum) the following levels of cover to commence at the Service Commencement Date and expire a minimum of six (6) years after the Expiry Date:
- C3.1.1 public liability insurance with a limit of indemnity of not less than five million pounds (£5,000,000) in relation to any one claim or series of claims;
- C3.1.2 employer's liability insurance with a limit of indemnity of not less than ten million pounds (£10,000,000);
- C3.1.3 professional indemnity insurance with a limit of indemnity of not less than two million pounds (£2,000,000) in relation to any one claim or series of claims shall ensure that all professional consultants and sub-contractors involved in the provision of the Services hold and maintain appropriate cover;
- C3.1.4 product liability insurance with a limit of indemnity of not less than five million pounds (£5,000,000) in relation to any one claim or series of claims.
- (together the **Required Insurances**).
- C3.2 If, for whatever reason, the Provider fails to give effect to and maintain the Required Insurances, the Authority may make alternative arrangements to protect its interests and may recover the costs of such arrangements from the Provider.
- C3.3 Subject to clause C2.1, the terms of any insurance policy including any limit of liability shall not act to relieve the Provider of any liabilities under this Contract.

C4. CONTRACT BINDING ON SUCCESSORS

- C4.1 This Contract will be binding on and will be to the benefit of the Authority and Provider and their respective successors and permitted transferees and assigns.

C5. DATA PROTECTION

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- C5.1 If Authority data is corrupted, lost or sufficiently degraded as a result of the Provider's omission or negligence so as to be unusable, the Authority may:
- C5.1.1 require the Provider (at the Provider's expense) to restore or procure the restoration of such data and the Provider must do so as soon as practicable but not later than 3 months after the identification of the loss, corruption or degradation; and/or
 - C5.1.2 Itself restore or procure the restoration of such data. The Provider must reimburse the Authority for any reasonable expenses incurred in doing so.
- C5.2 If at any time the Provider suspects or has reason to believe that Authority data has or may become corrupted, lost or degraded in any way for any reason, the Provider must notify the Authority immediately and inform the Authority of the remedial action the Provider proposes to take.
- C5.3 The Provider shall not store, copy, disclose or use Authority data except as necessary for the performance by the Provider of its obligations under this Contract or as otherwise expressly authorised in writing by the Authority.
- C5.4 To the extent that Authority data is held and / or processed by the Provider the Provider shall supply that Authority data to the Authority as requested by the Authority in a format specified by the Authority.
- C5.5 Upon receipt or creation by the Provider of any Authority data and during any collection, processing, storage and transmission by the Provider of any Authority data the Provider shall take all precautions necessary to preserve the integrity of the Authority data and to prevent any corruption or loss of the Authority data.
- C5.6 The Provider shall perform secure back-ups of all Authority data and shall ensure that any system on which the Provider holds any Authority data including any back-up system is a secure system.

C6. AGENCY

- C6.1 The Provider must not in any circumstances hold itself out as being the servant or agent of the Authority. The Provider must not hold itself out as being authorised to enter into any agreement on behalf of the Authority or in any way bind the Authority to the performance, variation, release or discharge of any obligation to a third party. The Provider's staff shall not hold themselves out to be and shall not be held out by the Provider as being servants or agents of the Authority.

C7. HUMAN RIGHTS AND ANTI-SLAVERY/HUMAN TRAFFICKING

- C7.1 The Provider must not do or permit to allow anything to be done which is incompatible with the rights contained in the European Convention on Human Rights and/or the Human Rights Act 1998. Without prejudice to the rights of the Authority under clause B25 (*Indemnities*), the Provider must indemnify the Authority against any loss, claims and expenditure resulting from the Provider's breach of this clause.
- C7.2 In performing its obligations under this Contract, the Provider shall:
- a) comply with all applicable anti-slavery and human trafficking laws, statutes, regulations and codes from time to time in force including but not limited to the Modern Slavery Act 2015; and
 - b) comply with the Authority's Combating Modern Day Slavery in Leeds Strategy, as may be amended from time to time AND have and maintain throughout the term of the Contract its own policies and procedures to ensure its compliance; and
 - c) not engage in any activity, practice or conduct that would constitute an offence under sections 1, 2 or 4, of the Modern Slavery Act 2015 if such activity, practice or conduct were carried out in the UK; and

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- d) include in its contracts with its direct subcontractors and suppliers anti-slavery and human trafficking provisions that are at least as onerous as those set out in this clause.
- C7.3 The Provider represents and warrants that:
- a) its responses to the Authority's slavery and human trafficking questions within its pre-qualification questionnaire or Tender are complete, accurate and up to date; and
 - b) neither the Provider nor any of its officers, employees or other persons associated with it:
 - (i) has been convicted of any offence involving slavery and human trafficking; and
 - (ii) having made reasonable enquiries, so far as it is aware and to the best of its knowledge, has been or is the subject of any investigation, inquiry or enforcement proceedings by any governmental, administrative or regulatory body regarding any offence or alleged offence of or in connection with slavery and human trafficking.
- C7.4 The Provider shall implement due diligence procedures for its direct subcontractors, and suppliers and other participants in its supply chains, to ensure that there is no slavery or human trafficking in its supply chains.
- C7.5 The Provider shall notify the Authority as soon as it becomes aware of:
- a) any breach, or potential breach, of clause C7.2; or
 - b) any actual or suspected slavery or human trafficking in a supply chain which has a connection with this agreement.
- C7.6 The Provider shall prepare and deliver to the Authority, on an annual basis, an annual slavery and human trafficking report setting out the steps it has taken to ensure that slavery and human trafficking is not taking place in any of its supply chains or in any part of its business.
- C7.7 The Provider shall:
- a) maintain a complete set of records to trace the supply chain of all Services provided to the Authority in connection with this Contract; and
 - b) permit the Authority on reasonable notice during normal business hours, to have access to and take copies of the Provider's records and any other information and to meet with the Provider's personnel to audit the Provider's compliance with its obligations of this clause; and
 - c) implement annual audits of its compliance and its direct subcontractors' and suppliers' compliance with all applicable anti-slavery and human trafficking laws, statutes, regulations and codes from time to time in force including but not limited to the Modern Slavery Act 2015; and
 - d) implement a system of training for its employees, suppliers and subcontractors to ensure compliance with all applicable anti-slavery and human trafficking laws, statutes, regulations and codes from time to time in force including but not limited to the Modern Slavery Act 2015; and
 - e) keep a record of all training offered and completed by its employees, suppliers and subcontractors to ensure compliance with all applicable anti-slavery and human trafficking laws, statutes, regulations and codes from time to time in force including but not limited to the Modern Slavery Act 2015 and shall make a copy of the record available to the Authority on request.
- C7.8 The Provider shall indemnify the Authority against any losses, liabilities, damages, costs (including but not limited to legal fees) and expenses incurred by, or awarded against, the Authority as a result of any breach of any applicable anti-slavery and human trafficking laws, statutes, regulations and codes from time to time in force including but not limited to the Modern Slavery Act 2015.

C7.9 The Provider represents warrants and undertakes that it conducts its business in a manner that is consistent with all applicable anti-slavery and human trafficking laws, statutes, regulations and codes from time to time in force including but not limited to the Modern Slavery Act 2015.

C7.10 The Authority may terminate the Contract with immediate effect by giving written notice to the Provider if the Provider commits a breach of this clause C7.

C8. SCRUTINY BOARD/EXECUTIVE BOARD ASSISTANCE

C8.1 If required or reasonably requested by the Authority to do so, the Provider must throughout the period of this Contract and for a period of six (6) years after the expiry of this Contract give all reasonable assistance to the Authority's Scrutiny Board and/or Executive Board and to any other board with a similar status, including attending the Authority's Scrutiny Board and/or Executive Board in order to answer questions pertaining to this Contract.

C9. HEALTH AND SAFETY

C9.1 The Provider must promptly notify the Authority of any health and safety hazards which may arise in connection with the performance of this Contract.

C9.2 The Provider must comply with the requirements of the Health and Safety at Work Act 1974 and any other Acts, orders, regulations and codes of practice relating to health and safety which may apply to the Provider's staff and other persons working on the Provider's Premises in the performance of this Contract.

C9.3 The Provider must on written request of the Authority and in any event within 5 Business Days of that request, provide the Authority with a copy of its health and safety policy statement (as required by the Health and Safety at Work Act 1974).

C10. DISCLOSURE AND BARRING SERVICE

C10.1 The Provider must have policies and procedures which acknowledge and provide for ongoing monitoring of the Staff, including undertaking further DBS disclosures every three years.

C10.2 The Provider must keep and must procure that the Authority is kept advised at all times of any Staff who, subsequent to their commencement of employment, receives a relevant conviction, caution, reprimand or warning or whose previous relevant convictions, cautions, reprimands or warnings become known to the Provider (or any employee of a Sub-Contractor involved in the provision of the Services).

C11. BRANDING POLICY

C11.1 The Provider must comply with the Authority's local brand policy and guidelines, as revised, updated or re-issued from time to time.

C12. CONFLICTS OF INTEREST

C12.1 If a Party becomes aware of any conflict of interest which is likely to have an adverse effect on the other Party's decision whether or not to contract or continue to contract substantially on the terms of this Contract, the Party aware of the conflict must immediately declare it to the other. The other Party may then take whatever action under this Contract as it deems necessary.

C13. INTELLECTUAL PROPERTY

C13.1 Except as set out expressly in this Contract, no Party will acquire the IPR of the other Party.

- C13.2 The Provider now grants the Authority a fully paid-up non-exclusive licence to use Provider IPR for the duration of this Contract for the purposes of the exercise of its functions and obtaining the full benefit of the Services, which will include the dissemination of best practice to other providers who have a contract with the Authority.
- C13.3 The Authority now grants the Provider a fully paid up non-exclusive licence to use Authority IPR for the duration of this Contract (including without limitation, in the event of early termination, up to the date that would have been the Expiry Date but for such early termination arising) for the sole purpose of providing the Services (or services equivalent to the Services, in the event that this Contract is terminated early).
- C13.4 In the event that the Provider or the Authority at any time devise, discover or acquire rights in any Improvement, they must promptly notify the other Party of the IPR to which that Improvement relates giving full details of the Improvement and whatever information and explanations as that Party may reasonably require to be able to use the Improvement effectively and must assign to that Party all rights and title in any such Improvement without charge.
- C13.5 For the purposes of this clause:

Authority IPR means any IPR owned by or licensed to the Authority which is relevant and necessary to the performance of the Services by the Provider, including Improvements

Improvements means any improvement, enhancement or modification to the Provider IPR which cannot be used independently of the Provider IPR or any improvement, enhancement or modification to the Authority IPR which cannot be used independently of the Authority IPR

IPR means inventions, copyright, patents, database right, trademarks, designs and confidential know-how and any similar rights anywhere in the world whether registered or not, including applications and the right to apply for any such rights

Provider IPR means any IPR owned by or licensed to the Provider (other than by the Authority) that will be used by the Provider in the delivery of the Services, including Improvements.

C14. CHANGE IN CONTROL

- C14.1 This clause applies to any Provider Change in Control and/or any Sub-Contractor Change in Control, but not to a Change in Control of a company which is a Public Company.
- C14.2 The Provider must:
- C14.2.1 as soon as possible on, and in any event within 5 Business Days following, a Provider Change in Control; and/or
 - C14.2.2 immediately on becoming aware of a Sub-contractor Change in Control, notify the Authority of that Change in Control and submit to the Authority a completed Change in Control Notification.
- C14.3 If the Provider indicates in the Change in Control Notification an intention or proposal to make any consequential changes to its operations then, to the extent that those changes require a change to the terms of this Contract in order to be effective, they will only be effective when a Variation is made in accordance with clause B22 (*Variations*). The Authority will not and will not be deemed by a failure to respond or comment on the Change in Control Notification to have agreed to or otherwise to have waived its rights under clause B22 (*Variations*) in respect of that intended or proposed change.
- C14.4 The Provider must specify in the Change in Control Notification any intention or proposal to make a consequential change to its operations which would or would be likely to have an adverse effect on the Provider's ability to provide the Services in accordance with this Contract. If the Provider does not do so it will not be entitled to propose a Variation in respect

of that for a period of 6 months following the date of that Change in Control Notification, unless the Authority agrees otherwise.

C14.5 If the Provider does not specify in the Change in Control Notification an intention or proposal to sell or otherwise dispose of any legal or beneficial interest in the Provider's Premises as a result of or in connection with the Change in Control then, unless the Authority provides its written consent to the relevant action, the Provider must:

C14.5.1 ensure that there is no such sale or other disposal which would or would be likely to have an adverse effect on the Provider's ability to provide the Services in accordance with this Contract; and

C14.5.2 continue providing the Services from the Provider's Premises,

in each case for at least 12 months following the date of that Change in Control Notification. The provisions of this clause will not apply to an assignment by way of security or the grant of any other similar rights by the Provider consequent upon a financing or re-financing of the transaction resulting in Change of Control.

C14.6 The Provider must supply (and must use its reasonable endeavours to procure that the relevant Sub-contractor supplies) to the Authority, whatever further information relating to the Change in Control the Authority may, within 20 Business Days after receiving the Change in Control Notification, reasonably request.

C14.7 The Provider must use its reasonable endeavours to ensure that the terms of its contract with any Sub-contractor include a provision obliging the Sub-contractor to inform the Provider in writing on, and in any event within 5 Business Days following, a Sub-contractor Change in Control in respect of that Sub-contractor.

C14.8 If:

C14.8.1 there is a Sub-contractor Change in Control; and

C14.8.2 following consideration of the information provided to the Authority in the Change in Control Notification or under clause C14.6, the Authority reasonably concludes that, as a result of that Sub-contractor Change in Control, there is (or is likely to be) an adverse effect on the ability of the Provider and/or the Sub-contractor to provide Services in accordance with this Contract (and, in reaching that conclusion, the Authority may consider any factor, in its absolute discretion, that it considers relevant to the provision of Services),

then:

C14.8.3 the Authority may, by serving a written notice upon the Provider, require the Provider to replace the relevant Sub-contractor within 10 Business Days (or other period reasonably specified by the Authority taking into account the interests of Service Users and the need for the continuity of Services); and

C14.8.4 the Provider must duly replace the relevant Sub-contractor within the period specified under clause C14.8.3.

C14.9 Notwithstanding any other provision of this Contract:

C14.9.1 a Restricted Person must not hold, and the Provider must not permit a Restricted Person to hold, at any time 5% or more of the total value of any Security in the Provider or in the Provider's Holding Company or any of the Provider's subsidiaries (as defined in the Companies Act 2006); and

C14.9.2 a Restricted Person must not hold, and the Provider must not permit (and must procure that a Sub-contractor must not at any time permit) a Restricted Person to hold, at any time 5% or more of the total value of any Security in a Sub-contractor

or in any Holding Company or any of the subsidiaries (as defined in the Companies Act 2006) of a Sub-contractor.

C14.10 If the Provider breaches clause C14.9.2, the Authority may by serving written notice upon the Provider, require the Provider to replace the relevant Sub-contractor within:

C14.10.1 5 Business Days; or

C14.10.2 whatever period may be reasonably specified by the Authority (taking into account any factors which the Authority considers relevant in its absolute discretion, including the interests of Service Users and the need for the continuity of Services),

and the Provider must replace the relevant Sub-contractor within the period specified in that notice.

C14.11 Nothing in this clause will prevent or restrict the Provider from discussing with the Authority a proposed Change in Control before it occurs. In those circumstances, all and any information provided to or received by the Authority in relation to that proposed Change in Control will be Confidential Information.

C14.12 Subject to the Law and to the extent reasonable the Parties must co-operate in any public announcements arising out of a Change in Control.

C14.13 For the purposes of this clause:

Change in Control means any sale or other disposal of any legal, beneficial or equitable interest in any or all of the equity share capital of a corporation (the effect of which is to confer on any person (when aggregated with any interest(s) already held or controlled) the ability to control the exercise of 50% or more of the total voting rights exercisable at general meetings of that corporation on all, or substantially all, matters), provided that a Change in Control will be deemed not to have occurred if after any such sale or disposal the same entities directly or indirectly exercise the same degree of control over the relevant corporation

Change in Control Notification means a notification in the form to be provided to the Provider by the Authority and to be completed as appropriate by the Provider

Holding Companies means has the definition given to it in section 1159 of the Companies Act 2006

Institutional Investor means an organisation whose primary purpose is to invest its own assets or those held in trust by it for others, including a bank, mutual fund, pension fund, private equity firm, venture capitalist, insurance company or investment trust

Provider Change in Control means any Change in Control of the Provider or any of its Holding Companies

Public Company means:

a company which:

- (i) has shares that can be purchased by the public; and
- (ii) has an authorised share capital of at least £50,000 with each of the company's shares being paid up at least as to one quarter of the nominal value of the share and the whole of any premium on it; and
- (iii) has securities listed on a stock exchange in any jurisdiction

Restricted Person means:

- (i) any person, other than an Institutional Investor, who has a material interest in the production of tobacco products or alcoholic beverages; or
- (ii) any person who the Authority otherwise reasonably believes is inappropriate for public policy reasons to have a controlling interest in the Provider or in a Sub-contractor

Security means shares, debt securities, unit trust schemes (as defined in the Financial Services and Markets Act 2000), miscellaneous warrants, certificates representing debt securities, warrants or options to subscribe or purchase securities, other securities of any description and any other type of proprietary or beneficial interest in a limited company

Sub-contractor Change in Control means any Change in Control of a Sub-contractor or any of its Holding Companies

C15. TUPE

- C15.1 If the Authority has notified the Provider that it intends to tender or retender any Services, the Provider must within 20 Business Days following written request (unless otherwise agreed in writing) provide the Authority with anonymised details of Staff engaged in the provision of the relevant Services who may be subject to TUPE. The Provider must indemnify and keep indemnified the Authority and at the Authority's request, any new provider who provides any services equivalent to the Services or any of them after expiry or termination of this Contract or termination of a Service, against any Losses in respect of any inaccuracy in or omission from the information provided under this clause.
- C15.2 During the 3 months immediately preceding the expiry of this Contract or at any time following a notice of termination of this Contract or of any Service being provided, the Provider must not and must procure that its sub-contractors do not, without the prior written consent of the Authority, in relation to any persons engaged in the provision of the Services or the relevant Service:
- C15.2.1 terminate or give notice to terminate the employment of any person engaged in the provision of the Services or the relevant Service (other than for gross misconduct);
 - C15.2.2 increase or reduce the total number of people employed or engaged in the provision of the Services or the relevant Service by the Provider and any sub-contractor by more than 5% (except in the ordinary course of business);
 - C15.2.3 propose, make or promise to make any material change to the remuneration or other terms and conditions of employment of the individuals engaged in the provision of the Services or the relevant Service;
 - C15.2.4 replace or relocate any persons engaged in the provision of the Services or the relevant Service or reassign any of them to duties unconnected with the Services or the relevant Service; and/or
 - C15.2.5 assign or redeploy to the Services or the relevant Service any person who was not previously a member of Staff engaged in the provision of the Services or the relevant Service.
- C15.3 The Provider must indemnify and keep indemnified the Authority and, at the Authority's request, any new provider who provides any services equivalent to the Services or any of them after expiry or termination of this Contract or any Service, against any Losses in respect of:
- C15.3.1 the employment or termination of employment of any person employed or engaged in the delivery of the relevant Services by the Provider and/or any sub-contractor before the expiry or termination of this Contract or of any Service which arise from the acts or omissions of the Provider and/or any sub-contractor;

- C15.3.2 claims brought by any other person employed or engaged by the Provider and/or any sub-contractor who is found to or is alleged to transfer to the Authority or new provider under TUPE; and/or
- C15.3.3 any failure by the Provider and/or any sub-contractor to comply with its obligations under TUPE in connection with any transfer to the Authority or new provider.
- C15.4 The Authority must use all reasonable endeavours to procure that any new provider who provides any services equivalent to the Services or the relevant Service after expiry or termination of this Contract or of any Service will indemnify and keep indemnified the Provider and/or any sub-contractor against any Losses in respect of:
 - C15.4.1 any failure by the new provider to comply with its obligations under TUPE in connection with any relevant transfer under TUPE to the new provider;
 - C15.4.2 any claim by any person that any proposed or actual substantial change by the new provider to the persons' working conditions or any proposed measures of the new provider are to that person's detriment, whether that claim arises before or after the date of any relevant transfer under TUPE to the new provider on expiry or termination of this Contract or of any Service; and/or
 - C15.4.3 any claim by any person in relation to any breach of contract arising from any proposed measures of the new provider, whether that claim arises before or after the date of any relevant transfer under TUPE to the new provider on expiry or termination of this Contract or of any Service.

C16 Worker treated as receiving earnings from employment

- C16.1 For the purposes of this Clause C16, the following terms shall have the meanings given to them below:

“Agency” means a person or business that engages workers on behalf of the Authority and is responsible for paying such workers;

“Employment Status Service Digital Tool” means the digital tool developed by HMRC to help parties decide whether the provisions of ITEPA 2003 Part 2 Chapter 10 apply to the Personal Service Company, Partnership or Self Employed Individual;

“ITEPA 2003” means the Income Tax (Earnings and Pensions Act) (ITEPA) 2003;

“Partnership” means (for the purposes of Chapter 10 Part 2 of ITEPA) a partnership where the worker alone or with one or more relatives is entitled to 60% or more of the profits of the partnership or that most of the profits of the partnership derive from a single client or a single client together with associates of the client;

“Personal Service Company” means (for the purposes of Chapter 10 Part 2 of ITEPA 2003) a limited company in which the worker alone, or with one or more associates of the worker has a material interest; a material interest is the beneficial ownership of, or the ability to control, directly or through the medium of other companies or by any other indirect means, more than 5% of the ordinary share capital of the company (s51 (4) Chapter 8 ITEPA 2003); and

“Self Employed Individual” means (for the purposes of Chapter 10 Part 2 of ITEPA) an individual worker engaged under a contract for the provision of services.

- C16.2 Where the Provider is a Self Employed Individual, a Partnership or a Personal Service Company and the Authority has determined that the provisions of Chapter 10 Part 2 of the ITEPA 2003 apply (Worker treated as receiving earnings from employment) the Provider acknowledges and agrees that the Authority will, prior to making any payment of the Charges to the Provider, make appropriate PAYE tax and national insurance deductions from the Charges inclusive of expenses.

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- C16.3 Where the Provider is an Agency which, acting on behalf of the Authority, engages and pays workers who operate through Personal Service Companies, Partnerships or as Self Employed Individuals:
- a) subject to Clause C16.4, the Provider will pay the Personal Service Company, Partnerships or Self Employed Individual via the Provider's payroll system, and make the appropriate PAYE tax and national insurance deductions unless;
 - b) the Provider provides the Authority with accurate and timely information such that the Authority is able to complete the HMRC's Employment Status Service Digital Tool check in respect of the workers supplied by the Provider.
- C16.4 If, pursuant to Clause C16.3(b) the HMRC's Employment Status Service Digital Tool check is completed by the Authority then:
- a) where the Authority determines that Chapter 10 Part 2 ITEPA 2003 applies to a Personal Service Company, Partnership or Self Employed Individual, the Contractor acknowledges and agrees that the Contractor will make payments to the Personal Service Company, Partnership or Self Employed Individual in accordance with Clause C16.3(a) above; and
 - b) where the Authority determines that Chapter 10 Part 2 ITEPA 2003 does not apply, the Provider will pay the Personal Service Company, Partnership or Self Employed Individual in accordance with the value of the invoice submitted by the Personal Service Company, Partnership or Self Employed Individual.