SHROPSHIRE COUNCIL (1)

AS AUTHORITY

AND

[*XXXXXXXXX*] (2)[1]

AS PROVIDER

Contract Reference: ……[2]

CONTRACT FOR THE

PROVISION OF PUBLIC HEALTH SERVICES

Lot 1: Not Used
Lot 2: Not Used
Lot 3: Not Used
Lot 4: Pharmacy Sexual Health Services: Issue of treatment for Chlamydia
Lot 5: Pharmacy Sexual Health Services: Issue of Emergency Hormonal Contraception.
Lot 6: Pharmacy Sexual Health Services: Issue of Chlamydia/Gonorrhoea Self-sampling Smartkits
Lot 7: Pharmacy Sexual Health Services: Registration and issue of Condoms as part of the Local Condom Distribution Scheme (CDS)
Lot 8: Not Used
Lot 9. Not Used
Lot 10: Pharmacy Community Needle and Syringe Programme
Lot 11: Pharmacy Observed Consumption
Lot 12: Not Used

---

[1] Insert name of Provider
[2] Authority to insert Contract Reference Number

CONTENTS

TERMS AND CONDITIONS

SECTION A: THE PARTICULARS

This Contract is made on …….. 2022

PARTIES

(1) SHROPSHIRE COUNCIL of Shirehall, Abbey Foregate, Shrewsbury, Shropshire SY2 6ND (the ***Authority***); and

(2) *[insert name of Provider*] of [*insert address*] [3](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.

(B) the Authority wishes to secure the provision of the following Services:

Lot 1: Not Used
Lot 2: Not Used
Lot 3: Not Used
Lot 4: Pharmacy Sexual Health Services: Issue of treatment for Chlamydia
Lot 5: Pharmacy Sexual Health Services: Issue of Emergency Hormonal Contraception.
Lot 6: Pharmacy Sexual Health Services: Issue of Chlamydia/Gonorrhoea Self-sampling Smartkits
Lot 7: Pharmacy Sexual Health Services: Registration and issue of Condoms as part of the Local Condom Distribution Scheme (CDS)
Lot 8: Not Used
Lot 9. Not Used
Lot 10: Pharmacy Community Needle and Syringe Programme
Lot 11: Pharmacy Observed Consumption
Lot 12: Not Used

(C) the Provider wishes to provide the services described in Lots XXX[4] ("Services")

[3] Insert details
[4] Insert relevant Lot Numbers

(D) The Parties have agreed for the Provider to provide the Services in accordance with the respective Service Specifications for Lots XXX[5] as set out in Appendix A to this Contract and in accordance with the terms and conditions of this Contract.

(E) The Provider confirms its agreement to and acceptance of the terms 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 (the 'General Conditions') in (Section B); and
c) Appendices A – O
as completed and agreed by the Parties and as varied from time to time in accordance with clause A.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) Service Specification(s);
b) Section B; and
c) Section A.

A3. COMMENCEMENT AND DURATION

A3.1. This Contract has been executed by or on behalf of the Parties with effect from the date set out above (the 'Commencement Date').

A3.2. The Provider shall, subject to having satisfied the Conditions Precedent where applicable, provide the Services from 1st May 2022 (the 'Service Commencement Date').

A3.3. It is agreed between the Parties that the duration of this Contract shall be for the Initial Term commencing on the Service Commencement Date to the Initial Expiry Date and shall thereafter continue until terminated by either Party in accordance with the provisions of this Contract.

A3.4. It is further agreed between the Parties that, where during the term of this Contract:

a) the Authority is of the view that it no longer requires the Provider to deliver one or more of the Lots comprising the Services; or
b) the Provider is no longer in a position to deliver one or more of the Lots comprising the Services,

[5] Insert relevant Lot Numbers

that notice shall be given in writing to the other Party to cease delivery of the applicable Lot(s) without such notice giving rise to the termination of this Contract. Where notice is given to either of the Parties further to this clause A3.4, it is agreed that the remaining Lot(s) comprising the Services shall continue to be delivered by the Provider in accordance with the terms of this Contract and that this Contract shall remain in full force and effect with regard to the remaining Services.

A3.5. Upon termination of this Contract, howsoever occurring, the provisions of B33 (Consequences of Expiry or Termination) shall apply.

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:	Paula Mawson
Title:	Assistant Director -Integration & Healthy Population
Contact Details:	Public Health Department, Shirehall, Abbey Foregate, Shrewsbury, SY2 6ND. Telephone: 01743 256039. Email: Paula.Mawson@shropshire.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:	[*insert name*][6]
Title:	[*insert title*]
Contact Details:	[*insert*]

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: Shropshire Council

[6] Insert details of the Provider Representative

Address: Shirehall, Abbey Foregate
Shrewsbury
Shropshire
SY2 6ND.

For the attention of: Paula Mawson
Tel: 01743 256039.
Email: Paula.Mawson@shropshire.gov.uk

b) For the Provider:
Address: [*to be completed*][7]
For the attention of: [*to be completed*]
Tel: [*to be completed*]

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 by and on behalf of the AUTHORITY

Name and Position: Rachel Robinson

Executive Director Health, Wellbeing & Prevention

……..
Signature -

Name and Position: Paula Mawson

Assistant Director -Integration & Healthy Population

……..
Signature

[7] Insert contact details of the Provider

SIGNED for and on behalf of
the PROVIDER

Name and Position: ……

……..

……..
Signature

SECTION B: GENERAL TERMS AND CONDITIONS

B1. SERVICES

B1.1. The Provider shall provide the Services in accordance with the relevant Service Specification(s) (*Service Specifications*) set out in Appendix A to this Contract 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, Covid-19 Safe Working Practices 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 referred to in Appendix C (*Quality Outcomes Indicators*) and or the Service Specification(s).

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 and Staff in the development of Services.

B4.3. The Provider must carry out Service User surveys (and Carer surveys) 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 referred to in Appendix D (*Service User, Carer and Staff Surveys*) and/or the Service Specifications 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 NON 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 and any Sub-Contractor will take all reasonable steps to observe as far as possible the Codes of Practice produced by Equality and Human Rights Commission, which give practical guidance to Local Authorities on the elimination of discrimination.

B5.6 In the event of any finding of unlawful discrimination being made against the Provider and any Sub-Contractor during the contract period, by any court or employment tribunal, or any adverse finding or formal investigation by the Equality and Human Rights Commission over the same period, the Provider and any Sub-Contractor shall inform the Authority of this finding and shall take appropriate steps to prevent repetition of the unlawful discrimination.

B5.7 The Provider and any Sub-Contractor employed by the Provider will provide a copy of its policies to the Authority at any time upon request. In addition, the Authority may reasonably request other information from time to time for the purpose of assessing the Provider's compliance with the above conditions.

B5.8. 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) whether by provision of a translation service or referral to an appropriate service provider.

B5.9. 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.

B5.10. In performing its obligations under this Contract, the Provider shall and shall ensure that each of its sub-contractors shall 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

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; and

d) Staff are aware of and respect equality and human rights of colleagues and Service Users.

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 set out in Appendix D (*Service User, Carer and Staff Surveys*) and/or Service Specification(s) 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 must comply and must ensure that any Sub-Contractor will comply with their respective obligations under TUPE in relation to any persons who transfer to the employment of the Provider or that Sub-Contractor by operation of TUPE as a result of this Contract or any Sub-Contract, and that the Provider or the relevant Sub-Contractor (as appropriate) will ensure a smooth transfer of those persons to its employment.

B7.11. 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 including but not limited to:

B7.11.1 any failure by the Provider and/or any Sub-Contractor to comply with its obligations under TUPE in connection with any relevant transfer under TUPE;

B7.11.2 any claim by any person that any proposed or actual substantial change by the Provider and/or any Sub-Contractor to that person's working conditions or any proposed measures on the part of the Provider and/or any Sub-Contractor are to that person's detriment, whether that claim arises before or after the date of any relevant transfer under TUPE to the Provider and/or Sub-Contractor; and/or

B7.11.3 any claim by any person in relation to any breach of contract arising from any proposed measures on the part of the Provider and/or any Sub-Contractor, whether that claim arises before or after the date of any relevant transfer under TUPE to the Provider and/or Sub-Contractor.

B7.12 The Provider must indemnify and keep indemnified the Authority and any Successor Provider against any Losses in respect of any inaccuracy in or omission from the information provided under clause B7.9 above

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), in consideration for the provision of the Services in accordance with the terms of this Contract, the Authority shall pay the Provider the Charges as they shall apply to each respective Lot being delivered by the Provider and which constitute the Services.

B8.2. The Parties shall to the extent reasonably practicable agree the Charges in a transparent and equitable manner and the Charges shall be payable as set out in section 9 of each respective Service Specification and/or at Appendix E (*Charges*).

B8.3. The Provider shall provide a Valid Invoice to the Authority monthly in arrears (or such other frequency agreed between the Parties in writing) for payment of the Charges payable for Activity carried out with respect to each Lot forming the Services which the Authority shall pay within 30 days of receipt. Where the Provider does not submit a request for payment in a form which constitutes a Valid Invoice, the parties agree that the Authority is entitled to withhold payment of the Charges until the Provider remedies the situation and submits a Valid Invoice for payment. No interest, further to clause B8.4, below shall be payable relating to late payment of invoices which do not comply with the requirements of a Valid Invoice.

B8.4 Subject to B8.3 above, in the event of late payment of a Valid Invoice, interest thereon shall be charged at the Default Interest Rate. Such interest shall accrue on a daily basis from the due date until actual payment of the overdue amount, whether before or after Judgment.

B8.5. 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.

B8.6. 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).

B8.7. 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.

B8.8. If a Party contests a payment under clause B8.7 B8.6 and the Parties have not resolved the matter within 20 Business Days of the date of notification under clause B8.7, the contesting Party may refer the matter to dispute resolution under clause A.B30 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 B8.7.
.

B8.9. 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.

B8.10. Each Party may retain or set off any sums owed to the other Party which have fallen due and payable against any sum due to the other Party under this Contract or any other agreement between the Parties.

B8.11. This Contract is contingent upon the Authority receiving adequate funding from central government to enable it to commission the Services and the Authority can in no way warrant represent or guarantee the continuation of such funding throughout the duration of the term of this Contract. In the event that central government withdraws or reduces funding the Authority may at any time either terminate or modify (as is appropriate and reasonable subject to any funding constraints placed upon it) the Services commissioned by this Contract by serving reasonable written notice on the Provider. Where notice to terminate this Contract is given pursuant to this clause B8.10, this Contract will terminate on the date specified in the notice.

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*).

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.

B10.4. The Parties acknowledge that the Provider is a Regulated Activity Provider with ultimate responsibility for the management and control of the Regulated Activity provided under this Contract and for the purposes of the Safeguarding Vulnerable Groups Act 2006.

B10.5. The Provider must fulfil its commitment to safeguard and promote the welfare of vulnerable adults and children and shall have the following in place:

a) clear priorities for safeguarding and protecting vulnerable adults and children explicitly stated in strategic policy documents and Safeguarding Policies;

b) a clear commitment by the Provider's senior management to the importance of safeguarding and protecting vulnerable adults and children

c) a clear line of accountability within the Provider's organisation for overseeing safeguarding and protecting vulnerable adults and children and that roles and accountability for taking action and reporting internally and in accordance with the Authority's Multi Agency Adult Protection Policy and Procedure and Shropshire Safeguarding Children's Board Procedures are properly defined and understood by those involved

d) recruitment and human resources management procedures to take account of the need to safeguard and protect vulnerable adults including safe recruitment policies and practices and enhanced DBS checks for all Staff including agency staff students and volunteers working with vulnerable adults and children.

e) procedures for instigating the Authority's Multi Agency Adult Protection Policy and Shropshire Safeguarding Children's Board Procedures and for dealing with allegations of abuse against members of Staff and volunteers.

f) arrangements to ensure that all Staff receive supervision and undertake training in respect of safeguarding in order to equip them to carry out their safeguarding responsibilities effectively. Refresher training must be provided at regular intervals and all Staff including temporary Staff and volunteers who work with vulnerable adults and children must be made aware of the organisations arrangements for protecting vulnerable adults and children.

g) policies to safeguard and protect vulnerable adults and children and procedures that are in accordance with the Authority's Multi Agency Protection Policy and Shropshire Safeguarding Children's Board Procedures.

h) arrangements to work effectively with other organisations involved in the delivery of services to vulnerable adults and children in order to protect vulnerable adults and children including arrangements for sharing information.

i) a culture of listening to and engaging in dialogue with vulnerable adults and children in ways appropriate to their understanding and seeking their views and taking account of those views both in individual decisions and the establishment or development of services.

j) ensuring appropriate whistle blowing procedures are in place and there is a culture that enables issues about safeguarding and protecting vulnerable adults and children to be raised. A copy of the Authority's Speaking Up About Wrongdoing "Whistleblowing" Policy can be found on the Authority's website at www.shropshire.gov.uk.

B10.6. The Provider shall ensure that all policies required by the Authority are implemented in respect of the Services.

B10.7. Where the Service or activity being undertaken in this Contract is a Regulated Activity the Provider shall:

a) comply with the requirements of clause B7.6; and

b) monitor the level and validity of the checks under this clause B10.7 for each member of the Provider's Staff.

B10.8. The Provider warrants that at all times for the purposes of this Contract it has no reason to believe that any person who is or will be employed or engaged by the Provider in the provision of a Service or Activity that is a Regulated Activity is barred from the Activity in accordance with the provisions of the Safeguarding Vulnerable Groups Act 2006 and any regulations made thereunder, as amended from time to time.

B10.9. The Provider shall immediately notify the Authority of any information that it reasonably requests to enable it to be satisfied that the obligations of this clause have been met.

B10.10. The Provider shall refer information about any person carrying out the Services or the Activity to the DBS where it removes permission for such person to carry out the Services or Activity (or would have, if such person had not otherwise ceased to carry out the Services or the Activity) because, in its opinion, such person has harmed or poses a risk of harm to the Service Users, children or vulnerable adults.

B10.11. The Provider shall not employ or use the services of any person who is barred from, or whose previous conduct or records indicate that he or she would not be suitable to carry out Regulated Activity or who may otherwise present a risk to Service Users.

B11. INCIDENTS REQUIRING REPORTING

B11.1. If the Provider is and any approved Sub-Contractor is, CQC registered, the Provider shall and shall ensure that its Sub-Contractor 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 and its Sub-Contractor are not CQC registered the Provider shall and shall ensure that the Sub-Contractor shall, notify Serious Incidents to any Regulatory Body as applicable, in accordance with the Law.

B11.2. If the Provider and/or Sub-Contractor 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 and/or Sub-Contractor 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.

B11.4. Subject to the Law, the Authority shall have complete discretion to use the information provided by the Provider under this clause B11.1 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 securely destroy them thereafter 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; and

b) give each Service User full and accurate information regarding his/her treatment and Services received.

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.

B13.5. Where relevant and subject to compliance with the Law, the Provider shall:

a) at the reasonable request of the Authority promptly transfer or deliver a copy of the Service User health Record held by the Provider for any Service User for which the Authority is responsible to a third party provider of healthcare or social care services designated by the Authority;

b) may, subject to clause B13.6 and with the prior written consent of the Authority, where necessary for the delivery of health care, release Service User Health Records to health professionals employed by the Provider who are not directly responsible for the delivery of the Services under this Contract;

c) and, where reasonably required and subject to clause B13.6 and with the prior written consent of the Authority the Provider may pass on Service User Health Records onto third party healthcare partners

B13.6. The Provider may, with the express written consent of each Service User affected, use Service User Health Records for the purposes of identifying and evaluating long term recovery outcomes and to assist toward the continuing improvement of its services and practices PROVIDED that such Service User Health Records will only be used by the Provider for the specific purpose for which express written consent has been given by the Service User and PROVIDED FURTHER, that where a Service User subsequently withdraws consent to the use of its Service User Health Records the Provider shall immediately discontinue the use of such health records for any purpose other than as permitted by clause B13.2

B13.7. The Provider undertakes to:

a) implement and maintain security standards, processes, procedures, practice and controls to the same standard which they apply to personal confidential identifiable data and in accordance with the Data Security and Protection Toolkit (referred to as "Toolkit") standards to a minimum of Level 2 compliance for its 'organisation type' (as defined in the 2017/18 Data Security and Protection Requirements issued by the Department of Health);

b) The Provider shall provide assurance that good information governance practices are being maintained and must demonstrate, and will allow the Authority to audit, that the Provider (and all Sub-contractors processing Service User information) meets or exceeds the Toolkit standards required for its organisation type.

c) The Provider must, in accordance with Toolkit reporting requirements with respect to suspected and/or actual Information Governance Serious Incidents Requiring Investigation (IG SIRI) and/or Cyber Serious Incidents Requiring Investigation (Cyber SIRI) ensure that serious incidents related to suspected or actual breach of the principles of the Data Protection Legislation or any cyber related incident which has or is suspected of having compromised information assets within cyberspace are:

i) reported in writing to the Authority's SIRO and Information Governance Officer immediately of such incident having occurred or suspected of having occurred;

and

ii) that such IG SIRI and Cyber SIRIs are managed in accordance with the current version at the time of the incident of the "Checklist Guidance for Reporting, Managing and Investigation Information Governance and Cyber Security Serious Incidents Requiring Investigation" (or its replacement document) and reported via the Toolkit incident Reporting Tool where appropriate

B14. INFORMATION

B14.1. The Provider must provide the Authority the information specified in Appendix H (*Information Provision*) and/or the Service Specification(s) 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/or the Service Specification(s) 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 or as set out in the relevant Service Specification) 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 the relevant Service Specification and/or 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. In addition to the requirements of clause B17.1 the Provider shall operate a complaints procedure in respect of the Services to deal with any complaint received about the standard of services or the manner in which any Services have been supplied or work has been performed or any other matter connected with the performance of the Provider's obligations under this Contract ("the Complaints Procedure"). For the avoidance of doubt any complaint or issue that the Authority has in respect of the Provider's performance of this Contract shall be dealt with in accordance with the remainder of this Contract.

B17.3. The Provider's Complaints Procedure shall comply with applicable Law and the requirements of any regulatory body to which the Provider is subject or which are applicable to the Service being provided (including any change in such requirements) and shall meet the following minimum standards:

a) is easy for complainants to access and understand
b) clearly sets out time limits for responding to complaints and keeping the complainant and the Authority informed of progress;
c) provides confidential record keeping to protect employees under this Contract and the complainant
d) provides information to the Provider's management so that services can be improved
e) provides effective and suitable remedies
f) is regularly monitored and audited and which takes account of complainant and Authority feedback

B17.4. The Provider shall inform any users of the Services provided under this Contract of the existence of the complaints procedure and how to access it and will make its Complaints Procedure available on request.

B17.5. The Provider shall investigate and deal with any complaints it receives about the Services, whether direct from the public or Services Users, or referred to it by the Authority, in accordance with its published Complaints Procedure. The Provider shall ensure that:

a) it promptly, and within a maximum of 10 days of receiving the complaint, notifies the complainant that it is dealing with the complaint
b) under no circumstances is a complaint investigated by a member of its staff employed under this Contract who may be part of the complaint.
c) someone who is independent of the matter complained of carries out the investigation
d) the complainant is made aware that they are entitled to have the complaint investigated by the Authority if they are not satisfied with either the process of investigation or finding of the Provider's investigations
e) it deals with the complaint fully, expeditiously and fairly and shall use its reasonable endeavours to resolve the complaint within 30 Working Days of receiving the complaint
f) where a complaint is received by the Provider relating to the policy or decisions of the Authority rather than the Provider's delivery of its obligations under this Contract, the Provider shall promptly, and within two Working Days, refer the complaint to the Authority for investigation.

B17.6. The Provider shall ensure that all its employees and persons employed under this Contract are made aware of its Complaints Procedure and shall designate one employee (who shall be identified to the Authority) to whom a complaint may be referred should the complainant not be satisfied with the initial response to their complaint

B17.7. The Provider shall keep accurate and complete written records of all complaints received and the responses to them and shall make these records available to the Authority within 5 Working Days of being requested or at quarterly intervals in any event.

B17.8. Where the Authority is investigating a complaint the Provider is required to participate fully in all investigations within the timescales requested by the Authority.

B17.9. The Provider should note that if a complaint is made to the Authority by a third party relating to the services or works provided, the Local Government Ombudsman has the power to

investigate such a complaint and the Authority requires the Provider to fully to co-operate in such investigation. If the Authority is found guilty of maladministration or injustice by the Local Government Ombudsman because of the act or default of the Provider the Provider shall indemnify the Authority in respect of the costs arising from such maladministration or injustice.

B17.10. In addition to the above, 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 or/and 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, at intervals set out in the relevant Service Specification(s) of this Contract, from the Service Commencement Date deliver to the Authority a Service Quality Performance Report against the factors set out in Appendix J (*Service Quality Performance Report*) and/or the Service Specification(s).

B18.2. The Provider must submit each Service Quality Performance Report in the form and manner requested by the Authority

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 the relevant Specification(s) and/or 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.

B19.3. In the event that a Review Meeting reveals that the Provider is not, in the reasonable opinion of the Authority, satisfactorily performing or meeting its obligations under this Contract the Authority may take such action as it considers appropriate further to the provisions of clause 28 (*Defaults and Failure to Supply)*

B19.4. If after one calendar month following the issue by the Authority of a Review Notice to the Provider, the Provider has failed to remedy the failures specified in the Review Notice and has not contacted the Authority with a satisfactory explanation as to the reasons for such failure, then this will be considered a breach of the terms of this Contract and the Authority reserves the right to terminate this Contract in accordance with its terms

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 from the Provider;

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's 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; and

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.

i) the Provider warrants that the signing of this Contract on its behalf has been validly authorised and the obligations expressed as being assumed by the Provider under this Contract constitute valid legal and binding obligations of the Provider enforceable against the Provider in accordance with their terms.

j) The Provider acknowledges and confirms that:

(i) it has had an opportunity to carry out a thorough due diligence exercise in relation to the Services and has asked the Authority all the questions it considers to be relevant for the purpose of establishing whether it is able to provide the Services in accordance with the terms of this Contract;

(ii) it has received all information requested by it from the Authority pursuant to sub-clause B.21.1j(i) to enable it to determine whether it is able to provide the Services in accordance with the terms of this Contract;

(iii) it has made and shall make its own enquiries to satisfy itself as to the accuracy and adequacy of any information supplied to it by or on behalf of the Authority pursuant to sub-clause B.21.1.j(ii);

(iv) it has raised all relevant due diligence questions with the Authority before the Commencement Date; and

(v) it has entered into this Contract in reliance on its own diligence

(vi) as at the Commencement Date, the Provider warrants and represents that all information contained in the Tender remains true, accurate and not misleading, save as may have been specifically disclosed in writing to the Authority prior to execution of the Contract AND shall promptly notify the Authority in writing if it becomes aware during the performance of this Contract of any inaccuracies in any information provided to it by the Authority during such due diligence which materially and adversely affects its ability to perform the Services

(vii) The Provider shall not be entitled to recover any additional costs from the Authority which arise from, or be relieved from any of its obligations as a result of, any matters or inaccuracies notified to the Authority by the Provider in accordance with sub-clause B.21.1.j.(vi) save where such additional costs or adverse effect on performance have been caused by the Provider having been provided with fundamentally misleading information by or on behalf of the Authority and the Provider could not reasonably have known that the information incorrect or misleading at the time such information was provided.

k) The Provider agrees that where requested in writing during the term of this Contract it will ensure that an appropriately authorised representative of the Provider shall attend a Committee meeting of the Authority at its own cost upon being invited to do so by the Authority

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.

B21.3. The warranties set out in this clause B21 are given on the Commencement Date and repeated on every day during the term of this Contract.

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, CQC, the National Audit Office, the General Pharmaceutical Council, any Authorised Person and the authorised representative of the Local HealthWatch 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 for information 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 liabilities, costs, expenses, damages and losses (including any direct, indirect or consequential losses, loss of profit, loss of reputation, breach of its statutory duties or breach of an obligation under the Data Protection Legislation and all interest, penalties and legal and other reasonable professional costs and expenses) suffered or incurred by the Authority arising out of or in connection with:
(a) The performance, defective performance or otherwise of this Contract by the Provider its Staff or its Sub-Contractors
(b) Any claim made against the Authority for actual or alleged infringement of a third party's Intellectual Property Rights arising out of, or in connection with the provision of the Services
(c) Any claim made against the Authority by a third party arising out of, or in connection with, the supply of the Services, to the extent that such claim arises out of the breach, negligent performance or failure or delay in performance of this Contract by the Provider or the Staff; and
(d) Any claim made against the Authority by a third party for death, personal injury or damage to property arising out of, or in connection with the delivery of the Services and performance of this Contract to the extent that the defective performance is attributable to the acts or omissions of the Provider its Staff or its Sub-Contractors

B25.2. The Authority shall indemnify the Provider against all reasonable claims, costs and expenses which the Provider may incur and which arise, directly from the Authority's breach of any of its obligations under this Contract or breach of statutory duty or breach of an obligation under the Data Protection Legislation.

B26. LIMITATION OF LIABILITY

B26.1. 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

B26.2. 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 at its own cost effect and maintain with a reputable insurance company the Required Insurances as set out in each respective Service Specification. The cover shall be in respect of all risks which may be incurred by the Provider, arising out of the Provider's performance of this Contract, including death or personal injury, loss of or damage to property or any other such loss. Such policies must include cover in respect of any financial loss arising from any advice given or omitted to be given by the Provider.

B27.2. the Provider shall ensure that all professional consultants or Sub-Contractors involved in the provision of the Services hold and maintain equivalent policy cover which indemnifies the Provider and the Authority for negligent acts arising out of the performance of this Contract.

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.

B27.4 The Provider shall hold and maintain the insurances required under this Contract for a minimum of 6 years following the expiration or earlier termination of this Contract

B27.5 The Provider warrants that it has complied with this clause B27 and shall provide the Authority with **or** certified copies of the relevant policy documents (including any warranties or exclusions) together with receipts or other evidence of payment of the latest premiums due under those policies prior to the commencement of this Contract and annually thereafter throughout the duration of this Contract.

B27.6 The Provider shall:

(a) do nothing to invalidate any insurance policy

(b) notify the Authority if any policy is (or will be) cancelled or its terms are (or will be) subject to any material change

B27.7 Where the minimum limit of indemnity required in relation to any of the insurances is specified as being "in the aggregate":

B27.8 if a claim or claims which do not relate to this Contract are notified to the insurers which, given the nature of the allegations and/or the quantum claimed by the third party(ies), is likely to result in a claim or claims being paid by the insurers which could reduce the level of cover available below that minimum, the Provider shall immediately submit to the Authority:

(i) details of the policy concerned; and

(ii) its proposed solution for maintaining the minimum limit of indemnity specified; and

B27.9 if and to the extent that the level of insurance cover available falls below that minimum because a claim or claims which do not relate to this Contract are paid by insurers, the Provider shall:

(i) ensure that the insurance cover is reinstated to maintain at all times the minimum limit of indemnity specified for claims relating to this Contract; or

(ii) if the Provider is or has reason to believe that it will be unable to ensure that insurance cover is reinstated to maintain at all times the minimum limit of indemnity specified, immediately submit to the Authority full details of the policy concerned and its proposed solution for maintaining the minimum limit of indemnity specified.

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, 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;

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 (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 notify the Chief Officers of both the Provider and the Authority.

B29.19. If, 10 Business Days after notifying the Chief Officers, the Authority and the Provider still cannot agree a Remedial Action Plan, the Authority may withhold up to 2% of the 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) the Authority must pay the Provider any sums withheld under clause B29.23(a) 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:

a) within 6 months following the expiry of the relevant time period set out in clause B29.13; or

b) 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 a Force Majeure Event) 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 a Force Majeure Event, 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. Except where the Provider is responsible for delivering the Services included in Lot 12 either Party may:

a) voluntarily terminate this Contract by giving the other Party not less than three months' written notice at any time after the Service Commencement Date;

b) voluntarily terminate part of the Services being delivered under this Contract further to clause B32.6 below; and

where the Provider is delivering Services included in Lot 12:

c) may terminate this Contract by giving the other Party not less than six months' written notice to terminate at any time after the Service Commencement Date

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

a) the Provider and/or its Sub-Contractor's is in persistent or repetitive breach of the Quality Outcomes Indicators;

b) the Provider and/or its Sub-Contractor's is in persistent breach of its obligations under this Contract;

c) the Provider and/or its Sub-Contractor's:

(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) the Provider and/or its Sub-Contractor's has breached the terms of clause B39 (*Prohibited Acts*);

e) any of the Provider's and/or its Sub-Contractor's necessary registrations are cancelled by the CQC or other Regulatory Body as applicable;

f) the Provider and/or its Sub-Contractor's materially breaches its obligations in clause B37 (*Data Protection*);

g) 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) the Provider breaches the terms of clause B23 (*Assignment and Sub-contracting*);

i) 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) the Provider ceases or threatens to cease to carry on business in the United Kingdom; or

k) 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 30 Business Days following receipt of notice from the Authority identifying the breach.

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 a Force Majeure Event and such Force Majeure Event 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 30 Business Days of receipt of notice from the Provider to do so.

B32.5. The Authority may terminate this Contract by written notice further to clause B8.11

B32.6. Either Party may at any time terminate this Contract in part further to clause A3.4. The Party giving notice to partially terminate shall give a minimum of three months' prior written notice ("partial termination notice") or such other notice period as is required by section 13 of the relevant Service Specification, on the other Party and such partial termination notice shall, as a minimum, identify which Lot(s) are no longer required or are to be withdrawn and the date from which they shall cease to be delivered ("partial termination date(s)"). It is agreed between the Parties that this Contract will remain in full force and effect with regard to the delivery of the remaining Services contracted to be provided by the Provider under this

Contract. Where partial termination notice is served by either Party, the Provider shall be entitled to payments for the delivery of Activity (relating to the applicable Lot(s) specified in the partial termination notice) which have accrued up to and including the partial termination date(s).

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 (except any termination under clauses B32.4, B32.3 or if the Authority terminates under clause B32.1 (*Termination*), 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*) B.37 (*Data Protection*) and B38 (*Freedom of Information and Transparency*) 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 bodies 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 B36.2B 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 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. The Parties acknowledge their respective duties under the Data Protection Legislation and shall give all reasonable assistance to each other where appropriate or necessary to comply with such duties and agree to take account of any guidance issued by the Information Commissioner's Office. This clause B37 is in addition to, and does not relieve, remove or replace, a Party's obligations under the Data Protection Legislation.

B37.2. Subject to the explicit provisions of each Service Specification, the Parties to this Contract intend that all data shared between the Parties as part of the delivery of the Services shall be either be anonymised or pseudonymised data and shall not constitute the sharing of Personal Data but:

a) To the extent that any data constitutes Personal Data (or constitutes anonymised or pseudonymised data, but then the data becomes Personal Data in the hands of the Data Recipient), the Data Recipient shall hold and process such Personal Data at all times:
   (i) as Data Controller of the Personal Data;
   (ii) in accordance with Data Protection Legislation and in accordance with clauses B37.4-B37-7 below; and
   (iii) using appropriate technical and organisational security measures against unauthorised or unlawful processing of Personal Data and against accidental loss or destruction of, or damage to, the Personal Data.

B37.3 The Parties acknowledge that the Provider shall have access to and will process Personal Data for the purpose of the provision of the Services and whilst the Parties acknowledge that the Data Protection Legislation will ultimately determine the status of the parties under the legislation,

following an assessment of their respective roles under this Contract, the Parties agree that the Provider is not processing Personal Data on behalf of the Authority but is a Data Controller in its own right in respect of the Personal Data which it processes pursuant to the terms of this Contract. In the event that Personal Data is shared between the Parties, the Parties consider their relationship to be that of 'controller to controller' and will comply with the obligations of a Data Controller under the Data Protection Legislation and where the Parties share Personal Data as controllers it shall be undertaken in accordance with clause B37.4 to B37.7 below.

B37.4 Each Party acknowledges that one party (referred to in this clause as the Data Discloser) may disclose to the other party Personal Data, as more particularly identified in Schedule 1 in the applicable Service Specification, to be shared between the Parties under this Contract ("the Shared Personal Data") which has been collected by the Data Discloser for the purposes set out in Schedule 1 of the relevant Service Specification ("the Agreed Purposes").

B37.5 Each Party shall:

(a) ensure that it has all necessary notices and consents in place to enable lawful transfer of the Shared Personal Data to the permitted recipients identified in Schedule 1 of the relevant Service Specification ("the Permitted Recipients") for the Agreed Purposes;

(b) give full information to any Data Subject whose Personal Data may be processed under this Contract of the nature such processing;

(c) process the Shared Personal Data only for the Agreed Purposes;

(d) not disclose or allow access to the Shared Personal Data to anyone other than the Permitted Recipients;

(e) ensure that all Permitted Recipients are subject to written contractual obligations concerning the Shared Personal Data (including obligations of confidentiality) which are no less onerous than those imposed by this Contract;

(f) ensure that it has in place appropriate technical and organisational measures to protect against unauthorised or unlawful processing of Personal Data and against accidental loss or destruction of, or damage to, personal data.

(g) not transfer any Personal Data received from the Data Discloser outside the UK unless the following conditions are fulfilled:

(i) the Permitted Recipient has provided appropriate safeguards in relation to the transfer as determined by the Data Discloser;

(ii) the Data Subject has enforceable rights and effective legal remedies;

(iii) the Permitted Recipient complies with its obligations under the Data Protection Legislation by providing an adequate level of protection to any Personal Data that is transferred; and

(iv) the Permitted Recipient complies with reasonable instructions notified to it in advance by the Data Discloser with respect to the processing of the Personal Data;

B37.6 Each Party shall assist the other in complying with all applicable requirements of the Data Protection Legislation. In particular, each Party shall:

(a) consult with the other Party about any notices given to Data Subjects in relation to the Shared Personal Data;

(b) promptly inform the other Party about the receipt of any Data Subject Request;

(c) provide the other Party with reasonable assistance in complying with any Data Subject Request;

(d) not disclose or release any Shared Personal Data in response to a Data Subject Request without first consulting the other Party wherever possible;

(e) assist the other Party, at the cost of the other Party, in responding to any request from a Data Subject and in ensuring compliance with its obligations under the Data Protection Legislation with respect to security, Personal Data Breach notifications, Data

Protection Impact Assessments and consultations with supervisory authorities or regulators;

(f) notify the other Party without undue delay on becoming aware of any breach of the Data Protection Legislation;

(g) at the written direction of the Data Discloser, delete or return Shared Personal Data and copies thereof to the Data Discloser on termination of this Contract unless required by law to store the Personal Data; and

(h) maintain complete and accurate records and information to demonstrate its compliance with this clause and allow for audits by the other Party or the other Party's designated auditor.

B37.7 Each Party shall indemnify the other against all direct liabilities, costs, expenses, damages and losses (including all interest, penalties and legal costs (calculated on a full indemnity basis) and all other reasonable professional costs and expenses) suffered or incurred by the indemnified party arising directly out of or in connection with the breach of the Data Protection Legislation by the indemnifying party, its employees or agents, provided that the indemnified party gives to the indemnifier prompt notice of such claim, full information about the circumstances giving rise to it, reasonable assistance in dealing with the claim and sole authority to manage, defend and/or settle it (if requested).

Audit

B37.8 For the duration of this Contract and for a period of 6 years after the Expiry Date or date of termination if earlier, the Authority may conduct or be subject to an audit for the following purposes:

(a) to verify the accuracy of Charges (and proposed or actual variations to them in accordance with this Contract) and/or the costs of all suppliers (including Sub-Contractors) of the Services at the level of detail agreed in Appendix E (Charges);

(b) to review the integrity, confidentiality and security of any data relating to the Authority or any Service Users;

(c) to review the Provider's compliance with the DPA, the FOIA, in accordance with this clause B37 (Data Protection) and clause B38 (Freedom of Information) and any other legislation applicable to the Services;

(d) to review any records created during the provision of the Services;

(e) to review any books of account kept by the Provider in connection with the provision of the Services;

(f) to carry out the audit and certification of the Authority's accounts;

(g) for the purposes of the Local Government Finance Act 1982 (and any other Law relating to the inspection, examination and auditing of the Authority's accounts)

(h) to carry out an examination pursuant to the Authority's Best Value Duty;

(i) to verify the accuracy and completeness of the reports delivered or required by this Contract.

B37.9 Except where an audit is imposed on the Authority by a regulatory body or further audits are required as a result of any non-compliance by the Provider with their obligations under this Contract, the Authority may not conduct an audit under this clause B37 more than twice in any calendar year.

B37.10 The Authority shall use its reasonable endeavours to ensure that the conduct of each audit does not unreasonably disrupt the Provider or delay the provision of the Services

B37.11 Subject to the Authority's obligations of confidentiality, the Provider shall on demand provide the Authority and any relevant regulatory body (and/or their agents or representatives) with all reasonable co-operation and assistance in relation to each audit, including:

(a) all information requested by the above persons within the permitted scope of the audit, to include examining such documents as reasonably required which are owned, held or otherwise within the control of the Provider and any Sub-Contractor and may require the Provider and any Sub-Contractor to produce such oral or written explanations as the Authority or relevant regulatory body considers necessary;

(b) reasonable access to any sites controlled by the Provider and to any equipment (including, but not limited to, any software, IT systems, materials, data or information stored on, accessed by or used to operate the equipment) used (whether exclusively or non-exclusively) in the performance of the Services; and

(c) access to the Provider's Staff.

B37.12 The Authority shall endeavour to (but is not obliged to) provide at least 5 Business Days' notice of its or, where possible, a regulatory body's, intention to conduct an audit.

B37.13 For the purposes of this clause B37 any reference to the Authority carrying out an audit shall include the ability for that audit to be carried out by the District Auditor, the Authority's internal auditor or any external auditor appointed by the Authority

.

B37.14 The Parties agree that they shall bear their own respective costs and expenses incurred in respect of compliance with their obligations under this clause, unless the audit identifies a material failure to perform its obligations under this Contract in any material manner by the Provider in which case the Provider shall reimburse the Authority for all the Authority's reasonable costs incurred in the course of the audit.

B37.15 If an audit identifies that:

(a) the Provider has failed to perform its obligations under this Contract in any material manner, the parties shall agree and implement a Remedial Action Plan. If the Provider's failure relates to a failure to provide any information to the Authority about the Charges, proposed Charges or the Provider's costs, then the Remedial Action Plan shall include a requirement for the provision of all such information;

(b) the Authority has overpaid any Charges, the Provider shall pay to the Authority the amount overpaid within 20 days. The Authority may deduct the relevant amount from the Charges if the Provider fails to make this payment; and

the Authority has underpaid any Charges, the Authority shall pay to the Provider the amount of the under-payment less the cost of audit incurred by the Authority if this was due to a default by the Provider in relation to invoicing within 20 days

B38. FREEDOM OF INFORMATION AND TRANSPARENCY

B38.1. 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 and shall procure that all its sub-contractors agree:

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.

B38.2. 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.

B38.3. 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.

B38.4. In preparing a copy of this Contract for publication pursuant to clause B38.3 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.

B38.5. The Provider must assist and co-operate with the Authority to enable the Authority to publish this Contract.

B38.6. 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.

B38.7. The Authority shall in no event be liable for any loss, damage, harm or detriment, howsoever caused, arising from or in connection with the reasonable disclosure under FOIA or any other law, of any information (including exempt information) whether relating to this Contract or otherwise relating to any other party.

B38.8. The Provider shall ensure that all Information required to be produced or maintained under the terms of this Contract, or by law or professional practice or in relation to the Contract is retained for disclosure for at least the duration of the Contract plus one year together with such other time period as required by the Contract, law or practice and shall permit the Authority to inspect such records as requested from time to time.

B38.10 The Provider shall notify the Authority of any Commercially Sensitive Information provided to the Authority together with details of the reasons for its sensitivity and the Provider acknowledges that any lists or schedules of Commercially Sensitive Information so provided are of indicative value only and that the Authority may be obliged to disclose such information.

B38.11 Provide, at the Provider's expense, all necessary assistance as reasonably requested by the Authority to enable the Authority to respond to the Request for Information within the time for compliance set out in section 10 of the FOIA or regulation 5 of the Environmental Information Regulations.

B38.12 The Provider acknowledges that (notwithstanding the provisions of this Freedom of Information clause) the Authority may, acting in accordance with the Department of Constitutional Affairs' Code of Practice on the Discharge of the Functions of Public Authorities under Part 1 of the Freedom of Information Act 2000 ("the Code"), be obliged under the FOIA, or the Environmental Information Regulations to disclose information concerning the Provider or the Services:

B38.12.1 in certain circumstances without consulting the Provider; or

B38.12.2 following consultation with the Provider and having taken their views into account;

provided always that where sub-clause B38.12.1 above applies the Authority shall, in accordance with any recommendations of the Code, take reasonable steps, where appropriate, to give the Provider advanced notice, or failing that, to draw the disclosure to the Provider's attention after any such disclosure.

B38.13 The Provider shall ensure that all Information required to be produced or maintained under the terms of this Contract, or by law or professional practice or in relation to the Contract is retained for disclosure for at least the duration of the Contract plus one year together with such other time period as required by the Contract, law or practice and shall permit the Authority to inspect such records as requested from time to time.

B38.14 The Authority shall in no event be liable for any loss, damage, harm, or detriment, howsoever caused, arising from or in connection with the reasonable disclosure under FOIA, or any other law, of any information (including Exempt Information) whether relating to this Contract or otherwise relating to any other party.

B39. PROHIBITED ACTS

B39.1. 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**").

B39.2 The Provider:

a) shall not, and shall procure that all Staff shall not, in connection with this Contract commit a Prohibited Act

b) warrants, represents and undertakes that it is not aware of any financial or other advantage being given to any person working for or engaged by the Authority, or that an agreement has been reached to that effect, in connection with the execution of this Contract, excluding any arrangement of which full details have been disclosed in writing to the Authority before execution of this Contract

c) shall notify the Authority immediately if any breach of this clause B39 is suspected or known. Where such notification has been given to the Authority, the Provider must respond promptly to the Authority's enquiries, co-operate with any investigation and allow the Authority to audit books, records and any other relevant documentation. This obligation shall continue for two years following the expiry or termination of this Contract.

B39.3. 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.

B39.4. 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.

B39.5. 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.

B39.6. 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.

B39.7 The Provider shall, within 10 Working Days of a request from the Authority, certify to the Authority in writing (such certification to be signed by an authorised officer of the Provider) the Provider's compliance with this clause B39.

B39.8 Despite clause B30 (Dispute Resolution), any dispute relating to:

a) the interpretation of this clause B39; or

b) the amount or value of any gift, consideration or commission

Shall be determined by the Authority and its decision shall be final and conclusive

B39.9 Any termination under this clause B39 shall be without prejudice to any right or remedy which has already accrued or subsequently accrues to the Authority

B40. FORCE MAJEURE

B40.1. Where a Party is (or claims to be) affected by a Force Majeure Event, 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.

B40.2. Subject to clause B40.1, the Party claiming relief as a result of a Force Majeure Event will be relieved from liability under this Contract to the extent that because of the Force Majeure Event it is not able to perform its obligations under this Contract.

B40.3. In the event that either party is delayed or prevented from performing its obligations under this Contract by a Force Majeure Event, such party shall:

a) promptly give notice in writing of such delay or prevention to the other party as soon as reasonably possible, stating the commencement date and extent of such delay or prevention, the cause thereof and its estimated duration;

b) use all reasonable endeavours to mitigate the effects of such delay or prevention on the performance of its obligations under this Contract;

c) use reasonable endeavours to carry out its obligations under this Contract in any way that is reasonably practicable; and

d) resume performance of its obligations as soon as reasonably possible after the removal of the cause of the delay or prevention.

B40.4. 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.

B40.5. The Provider cannot claim relief if the Force Majeure Event is one where a reasonable service provider should have foreseen and provided for the cause in question.

B40.6. As soon as practicable following the affected party's notification, the parties shall consult with each other in good faith and use all reasonable endeavours to agree appropriate terms to mitigate the effects of the Force Majeure Event and to facilitate the continued performance of this Contract. Where the Provider is the affected party, it shall take and/or procure the taking of all steps to overcome or minimise the consequences of the Force Majeure Event in accordance with Good Clinical Practice.

B40.7. The affected party shall notify the other party as soon as practicable after the Force Majeure Event ceases or no longer causes the affected party to be unable to comply with its obligations under this Contract. Following such notification, this Contract shall continue to be performed on the terms existing immediately before the occurrence of the Force Majeure Event unless agreed otherwise by the parties.

B40.8. 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 a Force Majeure Event.

B40.9. The Authority may, during the continuance of any Force Majeure Event, terminate this Contract by written notice to the Provider if a Force Majeure Event occurs that affects all or a substantial part of the Services and which continues for more than 25 Business Days.

B41. THIRD PARTY RIGHTS

B41.1. 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.

B42. CAPACITY

B42.1. 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.

B43. SEVERABILITY

B43.1. 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.

B44. WAIVER

B44.1. 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.

B45. PUBLICITY

B45.1. 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.

B45.2. 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.

B46. EXCLUSION OF PARTNERSHIP, JOINT VENTURE OR AGENCY

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.

B47. TRANSFER OF UNDERTAKINGS (PROTECTION OF EMPLOYMENT REGULATIONS 2006 (TUPE)

The Parties agree that the provisions of TUPE and clause B7 shall apply to any Relevant Transfer of Staff under this Contract

B48 INTELLECTUAL PROPERTY

B48.1 In the absence of prior written agreement by the Authority to the contrary, all Intellectual Property created by the Provider or any employee, agent or sub-contractor of the Provider:

(a) in the course of performing the Services; or
(b) exclusively for the purpose of performing the Services,
(c) shall vest in the Authority on creation.

B48.2 The provisions of clause B48.1 shall not override any pre-existing binding contractual terms with agents or Sub-Contractors in respect of Intellectual Property which reserve rights of ownership to the agent or Sub-Contractor which the Provider entered into prior to the Commencement Date and which were within the knowledge of the Authority at the Commencement Date.

B48.3 The Provider shall indemnify the Authority against all claims, demands, actions, costs, expenses (including legal costs and disbursements on a solicitor and client basis), losses and damages arising from or incurred by reason of any infringement or alleged infringement (including the defence of such alleged infringement) of any Intellectual Property Right by the availability of the Services, except to the extent that they have been caused by or contributed to by the Authority's acts or omissions.

B48.4 This provision shall survive the expiration or termination of the Contract

B49. GOVERNING LAW AND JURISDICTION

B49.1. 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.

B49.2. 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 SPECIFICATIONS

Part A – Lot 1 – Health Check Service Specification

Part B – Lots 4-9 - Sexual Health Services, Service Specifications

Part C – Lots 10-12 Drug and Alcohol Recovery services – Service Specifications

Part A – Health Check Services – Not Used
Part B – Sexual Health Services

Lot 4 - Issue of treatment for Chlamydia

Service Specification Number	**Lot 4**
Service	Pharmacy Sexual Health Services Issue of Treatment for Chlamydia Trachomatis
Authority Lead	Ken Stringer Public Health Programme Lead
Provider Lead	
Period	**Initial Term: 1st May 2022 – 31st March 2023**
Date of Review	March 2023

For the purposes of this Service Specification for Lot 4, the following additional definitions to the main Contract apply:

EC/EHC	Means Emergency Contraception
Fraser Criteria	Means the criteria to determine if a child under 16 who is considered to be of sufficient age and understanding to be competent to receive contraceptive advice without parental knowledge or consent
IUD	Means intrauterine device
IUS	Means intrauterine systems
LARC	Means Long Acting Reversible Contraception

Medicines Management Team	Means Pharmacists, technicians and a team of staff who support GP practices and advise on anything related to medicines management in Shropshire
Integrated Community Sexual Health Services and the term Open Clinic	Means the service provided by Midlands Partnership NHS Foundation Trust (SSSFT) and delivered as OpenClinic: http://openclinic.org.uk/clinics/?contract=1 Tele: 0300 123 0994
PGD	Means Patient Group Direction
"PharmOutcomes"	Web-based information system for Community Pharmacies
Premises	Means the premises described in section 5 where the Services are to be delivered by the Provider
"Services"	Means the Issue of Treatment for Chlamydia services to be delivered further to this Specification and Lot 4
"Service Users"	Means individuals eligible to receive the Service being those persons who: Are aged 15 years or over; Are resident within the administrative area of the Authority
Sexual Health Services	Means Contraceptive and Sexual Health Services
STI	Sexually Transmitted Infection

1. Population Needs

Reducing the burden of sexually transmitted infections requires a sustained public health response and requires:

- easy access to high quality information for informed decision-making;
- easy access to prevention and treatment services,

These Services should be delivered alongside promotion of safer sexual health and prevention campaigns and initiatives.

However, alongside the effective clinical response, promoting safer sexual behaviours among individuals – including the use of the most effective contraceptives, condom use and easy access to regular testing – remains crucial.

Unprotected sex may lead not only to an unplanned pregnancy but also the possible transmission of a STI, including chlamydia, the most common bacterial sexually transmitted infection, with sexually active young people at highest risk. As chlamydia often has no symptoms and can have serious and costly

health consequences (e.g. pelvic inflammatory disease, ectopic pregnancy and tubal factor infertility) it is vital that it is diagnosed early and treated. As such offering tests during other healthcare consultations, i.e. whilst accessing EC, enables early diagnosis of infections and, with effective provision of treatment and partner notification, also stops onward transmission to partners and re-infection.

Relevant policy and guidance include:

A Framework for Sexual Health Improvement in England https://www.gov.uk/government/publications/a-framework-for-sexual-health-improvement-in-england (DH 2013)

Working together to Safeguard Children and Young People (2015,updated 2020)) https://www.gov.uk/government/publications/working-together-to-safeguard-children--2

Service Standards for Sexual and Reproductive Health Care https://www.fsrh.org/standards-and-guidance/documents/fsrh-service-standards-for-sexual-and-reproductive-healthcare/ (2016)

Healthy Lives, Healthy People https://www.gov.uk/government/publications/healthy-lives-healthy-people-our-strategy-for-public-health-in-england (2010)

Teenage Pregnancy Strategy Beyond 2010 https://www.education.gov.uk/consultations/downloadableDocs/4287_Teenage%20pregnancy%20strategy_aw8.pdf (2010)

You're Welcome Quality Criteria https://www.gov.uk/government/publications/quality-criteria-for-young-people-friendly-health-Services (2011)

Safeguarding Vulnerable Groups Act http://www.legislation.gov.uk/ukpga/2006/47/contents (2006)

Recommended Standards for sexual health Services https://www.fsrh.org/standards-and-guidance/documents/fsrh-service-standards-for-sexual-and-reproductive-healthcare/fsrh-service-standards-for-sexual-and-reproductive-healthcare-september-2016.pdf#:~:text=Services%20should%20provide%20comprehensive%20sexual%20and%20reproductive%20healthcare,to%20the%20FSRH%20Service%20Standard%20Workload%20in%20Services.

National Service Framework for children, young people and maternity Services https://www.gov.uk/government/publications/national-service-framework-children-young-people-and-maternity-Services (2004)

Every Child Matters https://www.education.gov.uk/consultations/downloadableDocs/EveryChildMatters.pdf (2004)

Sexual Offences Act http://www.legislation.gov.uk/ukpga/2003/42/contents (2003)

UK National Guideline for Consultations requiring Sexual History https://www.bashhguidelines.org/media/1078/sexual-history-taking-guideline-2013-2.pdf (2013)

BASHH UK National Guideline for the Treatment of Chlamydia Trachomatis (2018)

http://www.bashhguidelines.org/media/1191/update-on-the-treatment-of-chlamydia-trachomatis-infection-final-16-9-18.pdf

2. Key Service Outcomes

The Service will deliver the following outcomes to improve the sexual health in the administrative area of the Authority by providing:

- Provide clear, accessible and up to date information about Services providing emergency contraception and sexual health
- Improved access to the Services among those of highest risk of sexual ill health
- Reduced health inequalities amongst young people and adults
- A reduction in unwanted pregnancies in all ages as evidenced by teenage conception, abortion and repeat abortion rates
- Increased screening of sexually transmitted infections (chlamydia and gonorrhoea) The provision of accurate, high-quality and appropriate information that helps to make informed decisions about relationships, sex and sexual health

- Appropriate preventive interventions, such as condoms, literature; to help boost personal resilience, build self-esteem and promote healthy choices
- Rapid access to confidential, open-access, integrated Sexual Health Service in various settings that are accessible at convenient times
- When necessary, offer advice on where to find other sexual health service such as those at Level 2 and Level 3 e.g. Long Acting Reversible Contraception, testing and treatment for symptomatic STI's, and other gynaecological problems.

The Service will make a positive *contribution* to the following related indicators from the Public Health Outcomes Framework 2016-2019:

Domain 2: Health Improvement
Under 18 conceptions

Domain 3: Health Protection
Chlamydia Detection Rate (15 – 24-year olds)

3. Scope

3.1 Overall aims and objectives of the Service as a whole:

- To improve access for the treatment of asymptomatic chlamydia
- To improve access to free condoms as part of the Condom Distribution Scheme (CDS)
- To increase the use of EHC by women who have had unprotected sex and help contribute to reduction in the number of unplanned pregnancies in the client group.
- To increase the knowledge of risk associated with STIs.
- To refer Service Users who may have been at risk of STIs to an appropriate service.
- To strengthen the local network of contraceptive and sexual health service in the community to help ensure easy and swift access to advice and treatment.

3.2 Service Description/Pathway

Service Description

To issue treatment for chlamydia trachomatis, free of charge to Service Users in line with the terms and conditions of the Authority's Patient Group Directions for the Supply of Azithromycin or Doxycycline as appropriate to Service Users resident the administrative area of the Authority within Shropshire and available on PharmOutcomes..

Pathway:

The Service User will present to the pharmacy with a text message notification of a positive chlamydia result when accessing treatment.
Service users who disclose sexual contact of a service user with a positive chlamydia test will not have to prove evidence of a positive result and should be offered a chlamydia test and empirical treatment.

Azithromycin should be dispensed for consumption on the Provider's Premises only.

3.2.1 The Provider must take account of the following:

Those young people aged over 13 years and under the age of 16 years must be seen by a worker trained to assess Fraser[8] and Gillick competence to receive sexual health advice and interventions in the absence of a parent or guardian and to ensure that safeguarding issues are identified, dealt with and appropriately referred on if additional support is needed.[9]

3.3 Local Standards

Providers will:

- Ensure a consultation regarding chlamydia treatment will include advice regarding the importance of ongoing prevention of sexually transmitted Infections (STI's).
- Advise Service Users of the need for a follow up test 3 months after treatment.

Advise Service Users of the need for a full screen for all Sexually Transmitted Infections is advised following a positive chlamydia diagnosis.

- Advice Service Users with a positive chlamydia diagnosis of the importance of notifying their sexual partners to ensure they seek treatment and to prevent the risk of further transmission of chlamydia or reinfection.
- Signpost Service Users to sexual health services for quick starting of suitable contraception
- Offer and follow-up pregnancy testing if required.

[8] Available at https://www.gov.uk/government/organisations/**department-of-health**
[9] Department of Health (2004). *Best Practice Guidance for Doctors and other Health Professionals on the Provision of Advice and Treatment to Young People Under 16 on Contraception, Sexual and Reproductive Health* (http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4086960)

- Link into existing networks for sexual health services so that anyone who needs to see a suitably qualified medical professional can be signposted rapidly.

3.4 Records

The Provider shall use the PharmOutcomes on-line platform to record and provide accurate information and ensure modules - Patient Registration and Consultation and Supply - are completed on PharmOutcomes

3.5 The Service Responsibilities:

- As part of good clinical governance, the Provider is required to develop, implement, monitor and review the clinical quality of the Service that they deliver

The Provider will:

- Undertake a risk assessment to ensure adequate facilities and equipment are in place to deliver the Service and identify the resources available to support the Service.
- Develop appropriate systems for record keeping including Service User assessment, follow-up/recall and an appropriate clinical record
- The Provider has a duty to ensure that Staff involved in offering and issuing the kits have relevant knowledge and are appropriately trained in the operation of the Service, including sensitive, Service User centred communication skills.

- The Provider has a duty to ensure that the Service and Staff involved in the provision of the Service are aware of and operate within local protocols and standards, including any training facilitated by the Public Health department of the Authority
- Monitoring Safety and Reporting of Significant Events –The Provider will be responsible for operating a system for monitoring safety and reporting significant events.
- The Provider will be required to report incidents and significant events relating to the prescribing, dispensing, administration and record keeping involving medicines in relation to this scheme. Any root cause analysis following any incidents undertaken by the Provider or other parties will need to ensure input by all parties to demonstrate individual and organisational outcomes and change and should be of acceptable standard. They should be forwarded to Medicines Management Team subsequently for local learning. The Authority should also be directly informed.
- The Provider shall ensure all records are submitted on PharmOutcomes, which is acceptable to the Authority, and which allows measurement of the units of Activity. An anonymised summary will be reported to the Authority by PharmOutcomes to the Authority, and from which claims for payment for individual Activity will be authorised.
- Promotion of the Service. The Provider is required to undertake, in participation with the Authority, promotion of Public Health sexual health campaigns. The Provider's Premises or the Provider will not promote the Service to the public without the prior approval of the Authority.
- Where appropriate Service Users will be signposted to access a free of charge HIV self-sampling kit via https://www.test.hiv/

- Where required, arrangements must be made for a suitable chaperone, acceptable to the Service User, to be present. The cost of the chaperone will be borne by the Provider.

Self-Managed Care

The provision of the Services will empower Service Users to 'self-manage' their health care without the need to access a healthcare provider, although support must be provided if needed by the Service User by the provision of:

- Health information
- Generic information on pregnancy, STIs including and HIV prevention/safer sex advice
- Information on the full range of contraceptive methods and where these are available
- Primary prevention initiatives to improve overall sexual health to the community
- How to access condoms and lubricant.
- How to access the local Condom Distribution Scheme
- Provide advice and guidance on how to access Pregnancy test kits
- How to access an HIV Home Sampling Kit.
- How to access a Chlamydia/Gonorrhoea Self-Sample Smartkit.

The Provider will be expected to work towards achieving the 'Your Welcome' or other similar mark of quality provision certification for young people.

Workforce

As this is an outcomes-based Specification, it will not specify workforce capacity or management. However, it is expected that all Staff of the Provider will be the correct mix of clinical and other professional staff, working within safe and robust clinical governance protocols, which can help to offer better and more cost-effective provision for the Authority.

Applicable national standards (e.g. NICE) and training requirements

The Provider must adhere to all national standards and training requirements. It is the Provider's responsibility to keep up to date and adhere to any changes to national training requirements, guidance and service standards.

3.6 Discharge Criteria and Planning

All Service Users issued with treatment for chlamydia should be advised to access OpenClinic, (Integrated Community Sexual Health Services) for a full STI screen.

http://openclinic.org.uk/clinics/?contract=1
Tele: 0300 404 2996

All Service Users with symptoms of an STI should be signposted to OpenClinic for treatment and further investigation.

3.7 Population covered

Service Users aged 15 years and over and resident in the administrative area of the Authority

3.8 Any acceptance and exclusion criteria and thresholds

Service Users with symptoms of an STI should be signposted to Openclinic:

http://openclinic.org.uk/

Tele: 0300 404 2996

Service Users who are not resident within the administrative area of the Authority in Shropshire are excluded and should be referred to Sexual Health Services or their GP for treatment: http://openclinic.org.uk/ Tel: 0300 404 2996

The Provider has the right to refuse Service provision to a Service User*:

- Who are unsuitable for treatment under the conditions of the PGD.
- Who have not validly consented to the treatment provided under the Service
- For any unreasonable behaviour unacceptable to the Provider, it's Staff, or the named professional clinically responsible for the care of the Service User.

*The Provider must immediately inform the Authority of any service complaints or serious or untoward incidents. in accordance with the terms of this Contract

3.9 Interdependencies with other Services

The Provider cannot deliver the Services in isolation and is required to:
work with partners to address the needs of Service Users and increase the opportunity for Service Users to achieve optimum sexual health outcomes; and
maintain efficient working partnerships with allied Services, agencies and stakeholders in order to support effective signposting and referrals, reduce transition trauma, enhance the quality of care delivered, attain best outcomes for the Service User and ensure the holistic nature of the wider sexual health provision across the administrative area of the Authority within Shropshire

Partners include:

- Shropshire Public Health Department
- Shropshire Clinical Commissioning Group (CCG) - Medicines Management Team
- National Chlamydia Screening Programme (NCSP)
- Shropshire General Practitioner and Primary Care Services
- Shropshire Community pharmacies
- OpenClinic Sexual Health Services
- Safeguarding Adults and Children Provision

3.10 Any Activity planning assumptions

Activity planning assumptions are made annually by the Authority based on the previous year's Activity. Service Activity will be based on information submitted by the Provider through the relevant monitoring and Reporting Arrangements of this Specification (Section 7.2) . All fields specified in Service User Registration and Consultation modules and must be completed by the Provider and submitted on PharmOutcomes.

4. Applicable Service Standards

The Provider is required to work to the latest national standards including (this list is not exhaustive):

Current edition of BNF www.bnf.org.bnf

Faculty of Reproductive and Sexual Healthcare. CEU Clinical Guidance: Emergency Contraception. March 2017 updated December 2017. https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/

NICE: One to one interventions to reduce the transmission of STI's and to reduce the rate of under 18's conceptions, especially among vulnerable and at risk groups (PH3) (2007 updated September 2017) https://www.nice.org.uk/Guidance/PH3

FRSH: Recommended standards for sexual health Service (2015) https://www.fsrh.org/standards-and-guidance/documents/fsrh-service-standards-for-sexual-and-reproductive-healthcare/

National Chlamydia Screening Programme Standards (7th Edition 2016) https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/574351/NCSP_Standards_7th_edition.pdf

Progress and Priorities - Working Together for High Quality Sexual Health (2008) https://www.nat.org.uk/sites/default/files/publications/progress_and_priorities_working_together_for_high_quality_sexual_health_0.pdf

UK National Guidelines on Safer Sex (BASHH 2012) https://www.bashhguidelines.org/media/1080/4452.pdf

Quality Criteria for Young People's Health Service (2011) https://www.gov.uk/government/publications/quality-criteria-for-young-people-friendly-health-Services

When providing Services for young people the Department of Health's *You're Welcome* quality criteria[10] should be used as guiding principles when planning and implementing changes and improvements, in order to become young people friendly.

Service planning and improvement should always include consultation with Service Users and local populations.

4.1 Training Requirement

It is mandatory that Staff providing consultations where treatment will be issued in accordance with a PGD have the necessary skills and competencies needed to provide the Service.

CPPE Safeguarding and Vulnerable Adults Training Packages must have been completed after 1st April 2016. CPPE. Training which was undertaken prior to 31st March 2016 is not valid. Staff should undertake regular safeguarding updates at minimum annually.

The training process is critical to ensure that treatment for Chlamydia is used in accordance with manufacturer's instructions, and British Association of Sexual Health and HIV (BASHH) guidance. Training will also ensure that clinical governance, Service User safety, and local & national policies are adhered to.

It is essential that the Provider undertaking the Service must ensure:

[10] Department of Health (2011). *You're Welcome: Quality Criteria for Young People Friendly Health Service* (http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126813)

- Its Registered Pharmacist has undertaken appropriate training in sexual health including periodic updates that are required to maintain competency.

- Its Staff are competent in all aspects of the treatment of chlamydia, including appropriate knowledge of the pharmacology of the medication, exclusion criteria, contraindications and warnings.

- That treatment for chlamydia is only supplied by a pharmacist accredited under the accompanying PGD. Medicine counter Staff must be trained to refer each request for chlamydia treatment.

- Hold a valid Disclosure and Barring Service (DBS) Check /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 or evidence of annual declaration made to the GPhC. (http://www.pharmacyregulation.org/raising-concerns/registrants/definition-fitness-practise/declarations)

The pharmacist has completed the Centre for Pharmacy Postgraduate Education (CPPE) training detailed below:

- Attends a workshop on PGD EHC/Chlamydia treatment every three years organised or designated by the Authority's Public Health Department.

- NHS: Spotting the Signs of Child Exploitation 2016 https://www.cppe.ac.uk/programmes/l/cse-e-01/
- Safeguarding Children and Vulnerable Adults: Level 2 2018 https://www.cppe.ac.uk/programmes/l/safegrdingl2-a-02/
- CPPE Sexual Health learning module 2018 https://www.cppe.ac.uk/programmes/l/tlp-e-07/
- CPPE Dealing with Difficult Discussions 2018 https://www.cppe.ac.uk/programmes/l/diffdisc-e-01/
- CPPE Sexual Health in Pharmacies 2017 https://www.cppe.ac.uk/programmes/l/sexual-e-01/
- EHC and Chlamydia 2017 https://www.cppe.ac.uk/programmes/l/sexualech-w-01/
- Chlamydia testing and treatment 2017 https://www.cppe.ac.uk/programmes/l/chlamydia-w-06
- Patient Group Directions 2018 https://www.cppe.ac.uk/programmes/l/ptgpdir-e-01/

For CPPE accreditations the Provider's pharmacist must allow 'see all' on the CPPE website to enable audit training accreditation. If the Provider is a Group pharmacy it will have contracts and accreditation managed by their group managers.

Amnesty period for those holding up to date documents provided by other training organisations:-

Some pharmacists may have certificates that are current but relate to previous training organisations or have been acquired in other areas. Providing these documents are still up to date pharmacists can provide the Service subject to a review of documentation by the Authority. Documents should be sent to the Public Health Department of the Authority (see Contacts). Within six months of the Service

Commencement Date the Provider must ensure that its pharmacist(s) have completed the CPPE accredited requirements www.cppe.ac.uk

The Provider must ensure that its pharmacy professionals revisit the DoC at least every three years to ensure compliance

The Authority's Public Health Department authorise the supply of following items under Shropshire's PGD

The PGDs are accessible via the relevant section on PharmOutcomes https://pharmoutcomes.org/pharmoutcomes/

- Supply of Azithromycin under PGD
- Supply Doxycycline under PGD

The Authority will:

- ensure an up to date PGD is available via the chlamydia section of PharmOutcomes.
- ensure that the EHC/Chlamydia template, reflects clinical changes and guidance;
- conduct an annual review of this Service to determine whether the needs of the local population are being met;
- arrange at least one Provider meeting per year to promote service development and update the knowledge of the Provider's Staff;
- provide details of relevant referral points which the Provider's Staff may use to signpost Service Users who require further assistance;
- disseminate information on the Service to other pharmacies and health care professionals in order that they may signpost Service Users to the Service; and

The Provider:

- must ensure all Activity is included in their professional indemnity cover

The Authority may from time to time request evidence of training and accreditation and this must be provided by the Provider upon written request.

The Provider will ensure that all members of Staff are aware of the Service and full details will be made available to locum Staff to ensure continuity of provision of the Service. The Provider will introduce a Standard Operating Procedure (SOP). This must be made available to the Authority when requested.

4.2 Information Provision:

- Data must be recorded in full on PharmOutcomes modules registration and consultation as part of the Service User clinical record.
- All data must be auditable and payment is conditional on receipt of accurate and full data reports for all Service Users accessing the Services

- Data will be recorded and reported to allow:
  - Pseudonymised data for reporting local and National outcome measures
  - Audit of data for payment and outcome monitoring
  - Compliance with Data Protection Legislation

- Follow up of Service Users where consent has been obtained by the Authority for
- Service User records must be securely stored and used strictly in accordance with the terms of this Contract.
- Data collected must be accessible to the Authority to audit payments and report outcomes

5. Location of Provider Premises

The Provider's Premises are to be located within the administrative area of the Authority. The Provider shall provide the Authority with a written schedule of the location of each of the Premises from which the Services under this Lot are to be delivered **within one month** of the Service Commencement Date

The Provider must:

- Notify the Authority of any planned changes to service locations.
- Ensure the Service is carried out in suitable premises with facilities for private consultations and in line with Covid-19 Safe Working Practices
- Ensure the design and layout of the premises are suitable for carrying out the Services or Activity with appropriate measures being in place to ensure the security of the premises.
- Ensure the Premises protect Service User's rights to privacy, dignity, choice, autonomy and safety.
- Ensure the Premises have space, heating, lighting and ventilation that conform to relevant and recognised standards.
- Ensure the Premises are accessible to Service Users who need to enter the Premises and meet the appropriate requirements of the Equality Act.
- Ensures the Premises and any grounds are adequately maintained and comply with any legal requirements relating to the Premises.
- Take account of any relevant design, technical and operational standards and manages all risks in relation to the Premises.

6. Required Insurances

Public Liability Level of cover of a minimum of 5 MILLION POUNDS (£5,000,000.00)

Professional Liability Level of cover of a minimum of 5 MILLION POUNDS (£5,000,000.00)

Employers Liability Level of cover of a minimum of 5 MILLION POUNDS (£5,000,000.00)

Product Liability Level of cover 5 MILLION POUNDS (£5,000,000.00)

Medical Mal-practice Level of cover 5 Million Pounds (£5,000,000.00)

Insurances are required to be maintained for a minimum period of 6 years following termination/expiry of this Contract

7. QUALITY OUTCOME INDICATORS

ACTIVITY OUTCOMES DATA			
Outcome indicator	**Threshold**	**Method of measurement**	**Consequence of breach**
Number of consultations where supply made of Azithromycin for treatment of chlamydia	90%	PharmOutcomes	n/a
Number of consultations where supply made of Doxycycline for treatment of chlamydia	10%	PharmOutcomes	n/a

7.1 Monitoring and Review

7.1.1 The Provider shall ensure that the necessary documentation, as detailed in this Specification, is maintained and made available to the Authority to enable the Service to be monitored and for the purpose of post payment verification.

7.1.2 The Authority may undertake a visit to the Provider's participating Premises to inspect the provision of the Service and to ensure that the Provider is meeting this Specification.

7.2.3 The Provider will be monitored on the following data which will be accessible to the Authority from PharmOutcomes on a quarterly basis:

Issuing Pharmacy.
Date of attendance.
Service User age:
Drug prescribed.
LSOA of Service User.

7.2.4 **Use of PharmOutcomes**

The Provider shall ensure that all consultations are logged on PharmOutcomes to enable the Authority to monitor Activity and verify payments for Services provided.

7.2.5 **Supply of Chlamydia/Gonorrhoea Self-Sampling Smartkits:**
The Authority will provide the Smartkits at no cost to the provider.
Contact: Alison.cartwright@shropshire.gov.uk
Tele: 01743 253939

All information should be available for audit if required

8. SERVICE USER EXPERIENCE

All Service Users must be provided with a copy of, or a link to, a Service User satisfaction questionnaire within 4 weeks of attending the Service.

9. CHARGES

The service fee will comprise the following component:

Payment for this Service will be made on a quarterly basis in arrears.

Payment Schedule

Activity	Price per consultatio
Consultation fee. Note this fee applies to a chlamydia treatment consultation only.	£12:00
Supply of Azithromycin including drug cost	£5:00
Supply of Doxycycline including drug cost	£5:00

9.2 Claims for Payment

9.2.1 Details of the consultation must be entered on to PharmOutcomes in a timely manner to meet claims deadlines.

9.2.2 Only under exceptional circumstances will paper claims be accepted.

9.2.3 No claim shall be submitted more than one month after the Expiry Date of this Contract.

9.2.4 Claims for Activity more than 2 months old will not be paid.

9.3 The Provider will be paid on an Activity basis.

9.4 Payment for this Service will be made on a quarterly basis, based on actual Activity. Payment to the Provider will be provided according to timely and complete data submitted to Pharmoutcomes in line with the requirements included in this Specification.

9.5 Payment will be in accordance with the payment schedule set out above

9.6 Only information submitted to and reported to the Authority by Pharmoutcomes will be eligible for payment.

9.7 Valid Invoices for payment must be submitted and sent to ali.cartwright@shropshire.gov.uk

Term of contract: Initial Term 1st May 2022 – 31st March 2023

All prices exclude VAT

Not included in the fees payable and listed above;

The Provider will bear the costs of consumables used in providing the Service, cleaning equipment and the treatment room.

10. DISCHARGE FROM CARE PROTOCOL

- All Service Users issued with treatment for chlamydia should be advised to access OpenClinic, (Integrated Community Sexual Health Services) for a full STI screen

11. SERVICE QUALITY PERFORMANCE REPORT

Quantitative and qualitative information may be used to evaluate the Services.

Data will be collected through the PharmOutcomes clinical patient record system and should be held by the Provider according to the guidance issued by the Information Commissioner's Office in regard to the storage and handling of patient details and the terms of this Contract including Schedule 1 to this Specification (GDPR).

The Provider must submit details of complaints received on a quarterly basis throughout the duration of the Term of the Contract EXCEPT in circumstances where a complaint arises from a safeguarding issue or an issue that has a significant impact upon a Service User. In these circumstances, details of complaints received must be notified to the Authority as soon as practicably possible and in any event within 48 hours of receipt. . In all other circumstances complaints shall be dealt with in accordance with clause B.17 of this Contract.

For local data monitoring, to trigger payments and for quality monitoring purposes, quarterly submission of quantitative and qualitative data will be supplied to the Authority on a quarterly basis see **Section 7.2** Monitoring and review.

All information should be available for audit and quality reporting if required.

Qualitative information may also be gathered via informal patient feedback

12 REVIEW MEETINGS:
Reviews shall take place in accordance with section 7 above and in addition the Authority may undertake a visit to the Provider's participating Premises to inspect the provision of the Service and to ensure that the Provider is meeting this Specification.

13 NOTICE REQUIRED TO WITHDRAW DELIVERY OF THIS LOT

Either Party may serve the other with three months' prior written notice to terminate the provision of this Lot

Schedule 1 – Processing Personal Data and Data Subjects – Lot 4

1) The Provider shall comply with any further instructions with respect to processing by this Authority
2) Any such further instructions shall be incorporated into this Schedule

Description	Details
Subject matter of the processing	Processing of data collected in PharmOutcome record for Service Users receiving Sexual Health Services in community pharmacies e.g. Chlamydia treatment.
Duration of the processing	For the duration of this Contract
Nature and purposes of the processing	The nature of the processing shall include any operation such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or

	combination, restriction, erasure or destruction of date (whether or not by automated means) The purpose for the processing shall be: Data is collected via secure, web-based record management programme; PharmOutcomes to enable safe and secure reporting of data to the Authority Following Service User consent, Service User data captured at each consultation. Pseudonymised data returned to the Local Authority quarterly to enable payment, audit and management of contract and monitoring of service outcomes. Processing allows local and national level analysis and reporting on the effectiveness of commissioned services. Commissioning and monitoring of emergency contraception, testing and treatment of sexually transmitted infections is a mandatory Public Health function. Identifiable data may also be used should audits require and where it is of benefit to the healthcare of the individual.
Type of Personal Data	Collected by provider: Name, address, date of birth, NI number, telephone number, demographic data, relevant sexual health data including last monthly period, number of previous pregnancies, last time of sexual intercourse, current contraception and any allergies.
Categories of Data Subject	Service Users Aged 15years and over.
Plan for return and destruction of the data once the processing is complete UNLESS requirement under union or member state law to preserve that type of data	Plan will follow the Council's "Information and Records Management Standards". The records entered onto PharmOutcomes by providers remain the providers as it forms part of a clinical record for a healthcare professional/provider. This information is held by PharmOutcomes for as long as necessary and the current NHS guidelines indicate that this is 8 years (or 8 years after an individual passes their 16th birthday), unless the contract is terminated prior to the end of that period

Lot 5 - Issue of Emergency Contraception (EHC)

Service Specification No.	**Lot 5**
Service	Pharmacy Sexual Health Services Issue of Emergency Contraception (EHC)
Authority Lead	Ken Stringer Public Health Programme Lead
Provider Lead	
Period	Initial Term: 1st May 2022 – 31st March 2023
Date of Review	March 2023

For the purposes of this Service Specification for Lot 5, the following additional definitions to the main Contract apply:

EC/EHC	Means Emergency Contraception
Fraser guidelines	Means The guideline to be followed to determine if a child under 16 who is considered to be of sufficient age and understanding to be competent to receive contraceptive advice without parental knowledge or consent.
Integrated Community Sexual Health Services and the term OpenClinic	Means the service provided by Midlands Partnership Foundation Trust (MPFT) and delivered as OpenClinic
IUD	Means intrauterine device
IUS	Means intrauterine systems
LARC	Means Long Acting Reversible Contraception
Medicines Management Team	Means Pharmacists, technicians and a team of staff who support GP practices and advise on anything related to medicines management in Shropshire
PGD	Means Patient Group Direction
"PharmOutcomes"	Web-based information system for Community Pharmacies

Premises	Means the premises described in section 5 where the Services are to be delivered by the Provider
"Services"	Means the Issue of Emergency Contraception services to be delivered further to this Specification and Lot 5
"Service Users"	Means individuals eligible to receive the Service being females who: Are aged 13 years or over;

	Are resident within the administrative area of the Authority
STI	Means Sexually Transmitted Infection

2. Population Needs

Reducing the burden of unplanned pregnancy (whether this leads to maternity, miscarriage or abortion) requires a sustained public health response and requires

easy access to high quality information for informed decision-making;
easy access to prevention and treatment services,
easy access to the full range of contraception (particularly the most effective long-acting reversible contraception [LARC],
the contraceptive implant, intrauterine systems [IUS] and intrauterine device [IUD]) for pregnancy prevention;
and accessible pregnancy testing with rapid referral to abortion Services for unwanted pregnancy.
These Services should be delivered alongside promotion of safer sexual health and prevention campaigns and initiatives.
.
It is also important to eliminate local barriers to pregnancy diagnosis, by easily available testing and, where requested, referral to abortion Services, testing for sexually transmitted infections (STI) and contraception provision (which should be made available free and confidentially at easily accessible Services). The consistent and correct use of contraception is the best way for sexually active women and their partners to avoid an unplanned pregnancy. There is a correlation between good contraception Services and lowering rates of unintended pregnancies amongst teenagers (Santelli, 2007).

However, alongside the effective clinical response, promoting safer sexual behaviours among individuals – including the use of the most effective contraceptives, condom use and easy access to regular testing – remains crucial.

Relevant policy and guidance includes::

A Framework for Sexual Health Improvement in England https://www.gov.uk/government/publications/a-framework-for-sexual-health-improvement-in-england (DH 2013)

Working together to Safeguard Children and Young People
https://www.gov.uk/government/publications/working-together-to-safeguard-children (2015)

Service Standards for Sexual and Reproductive Health Care https://www.fsrh.org/standards-and-guidance/documents/fsrh-service-standards-for-sexual-and-reproductive-healthcare/ (updated 2020)

Healthy Lives, Healthy People https://www.gov.uk/government/publications/healthy-lives-healthy-people-our-strategy-for-public-health-in-england (2010)

Teenage Pregnancy Strategy Beyond 2010
https://www.education.gov.uk/consultations/downloadableDocs/4287_Teenage%20pregnancy%20strategy_aw8.pdf (2010)

You're Welcome Quality Criteria https://www.gov.uk/government/publications/quality-criteria-for-young-people-friendly-health-Services (2011)

Safeguarding Vulnerable Groups Act http://www.legislation.gov.uk/ukpga/2006/47/contents (2006)

Recommended Standards for Sexual Health Services
https://www.bashh.org/about-bashh/publications/standards-for-the-management-of-stis/ (2019)

STI Outreach Standards
https://www.bashh.org/about-bashh/publications/sti-outreach-standards/ (2016)

National Service Framework for children, young people and maternity Services
https://www.gov.uk/government/publications/national-service-framework-children-young-people-and-maternity-Services (2004)

Every Child Matters https://www.gov.uk/government/publications/every-child-matters (2004)

Sexual Offences Act http://www.legislation.gov.uk/ukpga/2003/42/contents (2003)

UK Medical Eligibility Criteria for Contraceptive Use https://www.fsrh.org/standards-and-guidance/documents/ukmec-2016/fsrh-ukmec-full-book-2019.pdf

Faculty of Sexual & Reproductive Healthcare Clinical Guidance – Emergency Contraception
https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/ (2017)

UK National Guideline for Consultations requiring Sexual History
https://www.bashhguidelines.org/media/1078/sexual-history-taking-guideline-2013-2.pdf (2013)

UK National Guideline for the Treatment of Chlamydia
https://www.bashhguidelines.org/media/1191/update-on-the-treatment-of-chlamydia-trachomatis-infection-final-16-9-18.pdf (2018)

2. Key Service Outcomes

The Service will deliver the following outcomes to improve the sexual health to those people living in the administrative area of the Authority as a whole by providing:

- Provide clear, accessible and up to date information about Services providing emergency contraception and sexual health
- Reduced health inequalities amongst young people and adults
- A reduction in unwanted pregnancies in all ages as evidenced by teenage conception, abortion and repeat abortion rates
- Increased screening of sexually transmitted infections (chlamydia and gonorrhoea)
- Appropriate preventive interventions, such as condoms, literature; to help boost personal resilience, build self-esteem and promote healthy choices

- When necessary, offer advice on where to find other sexual health service such as those at Level 2 and Level 3 e.g. Long Acting Reversible Contraception, testing and treatment for symptomatic STI's, and other gynaecological problems.

  The service will make a positive *contribution* to the following related indicators from the Public Health Outcomes Framework 2016-2019:

  Domain 2: Health Improvement
  Under 18 conceptions
  Domain 3: Health Protection
  Chlamydia Detection Rate (15 – 24 year olds)

3. Scope

3.1 Overall aims and objectives of service

- To facilitate improved access to EHC for women at risk of unintended pregnancy.
- To improve access for the treatment of asymptomatic chlamydia
- To improve access to free condoms as part of the Condom Distribution Scheme (CDS)
- To increase the knowledge, especially among young people, of the availability of emergency contraception and contraception from pharmacies.
- To improve access to free emergency contraception and sexual health advice.
- To increase the use of EHC by women who have had unprotected sex and help contribute to reduction in the number of unplanned pregnancies in the client group.
- To increase the knowledge of risk associated with STIs.
- To refer Service Users who may have been at risk of STIs to an appropriate service.
- To strengthen the local network of contraceptive and sexual health service in the community to help ensure easy and swift access to advice and treatment.

3.2 Service Description/Pathway

To issue Emergency Hormonal Contraception (EHC), free of charge to Service Users in line with the terms and conditions of the Authority's Patient Group Directions for the Supply of Levonelle 1500® or ellaOne® as appropriate to Service Users resident in the administrative area of the Authority within Shropshire and available to view on PharmOutcomes

The PGDs are accessible via the relevant section on PharmOutcomes
https://pharmoutcomes.org/pharmoutcomes/

Levonorgestrel PGD -

Ulipristal Acetate PGD -

All EHC should be dispensed for consumption only on the Provider's Premises.

3.3 Local Standards

Providers will:

- Ensure a consultation regarding EHC will include advice regarding the importance of ongoing contraception and information about the available contraceptive methods.

- Ensure that after taking EHC a Service User has been signposted in order to access her contraceptive method of choice.

- Signpost Service Users to their GP for quick starting of suitable contraception.

- Offer and follow-up pregnancy testing

3.4 Records

The Provider shall use the PharmOutcomes on-line platform to record and provide accurate information and ensure modules 1. EHC - Patient Registration and 2. EHC Consultation and Supply are completed on PharmOutcomes

The Service Responsibilities:

- As part of good clinical governance the Provider is required to develop, implement, monitor and review the clinical quality of the Services that they deliver.

The Provider will:

- Undertake a risk assessment to ensure adequate facilities and equipment are in place to deliver the Service and identify the resources available to support the Service.

- Develop appropriate systems for record keeping including Service User assessment, follow-up/recall and an appropriate clinical record

- The Provider has a duty to ensure that Staff involved in the provision of EHC have relevant knowledge and are appropriately trained in the operation of the Service, including sensitive, Service User centred communication skills.

- The Provider has a duty to ensure that the Services and Staff involved in the provision of the Service are aware of and operate within local protocols and Patient Group Directions (PGD's), including any training facilitated by Public Health Department of the Authority.

- Monitoring Safety and Reporting of Significant Events – The Provider will be responsible for operating a system for monitoring safety and reporting significant events. The Provider will be required to report incidents and significant events relating to the prescribing, dispensing, administration and record keeping involving medicines in relation to this scheme. Any root cause analysis following any incidents undertaken by the Provider or other parties will need to ensure input by all parties to demonstrate individual and organisational outcomes and change and should be of acceptable standard. They should be forwarded to Medicines Management Team subsequently for local learning. The Public Health Department of the local Authority should also be directly informed.

- The Provider shall maintain records, in a form acceptable to the Authority, which allow measurement of the units of Activity. An anonymised summary shall be sent to the Authority alongside claims for payment for individual Activity which is a requirement before payment can be authorised.

- Where required, arrangements must be made for a suitable chaperone, acceptable to the Service User accessing the Service, to be present. The cost of the chaperone will be borne by the Provider.

Self-Managed Care

The provision of the Service will empower users to 'self-manage' their health care without the need to access a healthcare Provider, although support must be provided if needed by the provision of:

- Health information
- Generic information on pregnancy, STIs including and HIV prevention/safer sex advice
- Information on the full range of contraceptive methods and where these are available
- Primary prevention initiatives to improve overall sexual health to the community
- How to access the local Condom Distribution Scheme
- Provide advice and guidance on how to access Pregnancy test kits
- How to access a Chlamydia/Gonorrhoea Self Sample Smartkit.

The Provider will be expected to work towards achieving the 'Your Welcome' or other similar mark of quality provision certification for young people.

Workforce

As this is an outcomes based Service Specification, it will not specify workforce capacity or management. However, it is expected that all Staff will be the correct mix of clinical and other professional Staff, working within safe and robust clinical governance protocols, which can help to offer better and more cost effective provision for the Authority.

Applicable national standards (e.g. NICE) and training requirements

The Provider must adhere to all national standards and training requirements. It is the Provider's responsibility to keep up to date and adhere to any changes to national training requirements, guidance and service standards.

3.5 Discharge Criteria and Planning

All Service Users issued with Emergency Hormonal Contraception should be advised to visit their GP for long term contraception management.

3.6 Population covered

- Service Users aged 13 years and over and resident the administrative area of the Authority

3.7 Any acceptance and exclusion criteria and thresholds

Any female aged over 13 years who fulfils the PGD criteria and consents to treatment.

Service User acceptance of an IUCD as preferred method of emergency contraception should be signposted to OpenClinic Sexual Health Services. http://openclinic.org.uk/ Tel: 0300 123 0994

Service Users who are not resident within the administrative area of the Authority in Shropshire are excluded and should be referred to their GP or OpenClinic Sexual Health Services for treatment: http://openclinic.org.uk/ Tel: 0300 123 0994

The Provider has the right to refuse Service provision to Service Users*:

- Who are unsuitable for treatment under the conditions of the PGD.
- Who have not validly consented to the treatment provided under the Service
- For any unreasonable behaviour unacceptable to the Provider, it's Staff, or the named professional clinically responsible for the care of the Service User.

*The Provider must immediately inform the Authority of any service complaints or serious or untoward incidents.in accordance with the terms of this Contract

3.8 Interdependencies with other Services

The Provider cannot deliver the Services in isolation and is required to work with partners to address the needs of Service Users and increase the opportunity for Service Users to:
and
maintain efficient working partnerships with allied Services, agencies and stakeholders in order to support effective signposting and referrals, reduce transition trauma, enhance the quality of care delivered.

Partners include:

- Shropshire Public Health Department
- Shropshire Clinical Commissioning Group (CCG) - Medicines Management Team
- National Chlamydia Screening Programme (NCSP)
- Shropshire General Practitioner and Primary Care Services
- Shropshire Community pharmacies
- OpenClinic OpenClinic Sexual Health Services
- Safeguarding Adults and Children Provision
- Shropshire's school nurses

3.9 Any activity planning assumptions

Activity planning assumptions are made annually by the Authority based on the previous year's Activity. Service Activity will be based on information submitted by the Provider through the relevant monitoring and Reporting Arrangements of this Specification. All fields specified in service user proformas and claim forms must be completed by the Provider and submitted on PharmOutcomes.

4. Applicable Service Standards

The Provider is required to work to the latest national standards including (this list is not exhaustive

NICE: One to one interventions to reduce the transmission of STI's and to reduce the rate of under 18's conceptions, especially among vulnerable and at risk groups (PH3) (2007 updated September 2017) https://www.nice.org.uk/Guidance/PH3

Faculty of Reproductive and Sexual Healthcare. CEU Clinical Guidance: Emergency Contraception. March 2017 updated December 2017 amended December 2020. https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/

Faculty of Sexual and Reproductive Healthcare, Quick Starting Contraception, Clinical Effectiveness Unit, September 2010, updated 2017.
www.fsrh.org/pdfs/CEUGuidanceQuickStartingContraception.pdf

Faculty of Sexual and Reproductive Health UK Medical Eligibility Guidelines. 2016
file:///C:/Users/cc142085/AppData/Local/Microsoft/Windows/INetCache/IE/YMV7RFFK/1ukmec-2016-entire-book-single-page-a4.pdf

Clinical Guidance – Emergency Contraception (March 2017) https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/

FRSH: Recommended standards for sexual health Service (2015) https://www.fsrh.org/standards-and-guidance/documents/fsrh-service-standards-for-sexual-and-reproductive-healthcare/

National Chlamydia Screening Programme Standards (7th Edition 2016)
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/574351/NCSP_Standards_7th_edition.pdf

Progress and Priorities - Working Together for High Quality Sexual Health (MEDFASH 2008)
http://www.medfash.org.uk/uploads/files/p17abl1iai1e961d438j2pjl1rp7p.pdf

UK National Guidelines on Safer Sex (BASHH 2012)
https://www.bashhguidelines.org/media/1080/4452.pdf

Quality Criteria for Young People's Health Service (2011)
https://www.gov.uk/government/publications/quality-criteria-for-young-people-friendly-health-Services

When providing Services for young people the Department of Health's *You're Welcome* quality criteria[11] should be used as guiding principles when planning and implementing changes and improvements, in order to become young people friendly.

Service planning and improvement should always include consultation with Service Users and local populations.

4.1 Training Requirement

The training process is critical to ensure that emergency contraceptives are used in accordance with manufacturer's instructions, and Faculty of Reproductive and Sexual Healthcare guidance. Training will also ensure that clinical governance, Service User safety, and local & national policies are adhered to.

It is essential that the Provider undertakes the Service must ensure:

- Its registered Pharmacist will have undertaken appropriate training in contraception and sexual health including periodic updates that are required to maintain competency.

- its Staff are competent in all aspects of this treatment, including appropriate knowledge of the pharmacology of the medication, exclusion criteria, contraindications and warnings.

- Emergency contraception may only be supplied by a pharmacist accredited under the accompanying PGD. Medicine counter Staff must be trained to refer each request for EHC.

[11] Department of Health (2011). *You're Welcome: Quality Criteria for Young People Friendly Health Service* (http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126813)

The Provider's pharmacist must have completed the Centre for Pharmacy Postgraduate Education (CPPE) training detailed below:

- CPPE Emergency Contraception Open Learning Programme (3 Hours)
- CPPE Contraception Open Learning Programme (12 Hours)
- CPPE Chlamydia test and treatment open Learning Programme (3 Hours)
- CPPE Child Protection Open Learning Programme (1.5 Hours)
- Attended a workshop on EHC/Chlamydia treatment every three years organised or designated by the Authority's public health department
- Complete the CPPE competency self-assessment and Declaration of Competence for provision of EHC and chlamydia treatment under PGD.
- NHS: Spotting the Signs of Child Exploitation 2016 https://www.cppe.ac.uk/programmes/l/cse-e-01/

- Safeguarding Children and Vulnerable Adults: Level 2 2018
  https://www.cppe.ac.uk/programmes/l/safegrdingl2-a-02/

For CPPE accreditations the Provider's pharmacist must allow 'see all' on the CPPE website to enable audit training accreditation. If the Provider is a group pharmacy it will have contracts and accreditation managed by their group managers.

Amnesty period for those holding up to date documents provided by other training organisations:-

Some pharmacists may have certificates that are current but relate to previous training organisations, or have been acquired in other areas. Providing these documents are still up to date pharmacists can provide the Service subject to a review of documentation by the Authority. Documents should be sent to the Public Health Department of the Authority (see Contacts). Within six months of the Service Commencement Date the Provider must ensure that its pharmacist(s) complete the CPPE accredited requirements www.cppe.ac.uk

Shropshire Public Health authorise the supply of following items under Shropshire's PGD
The PGDs are accessible via the relevant section on PharmOutcomes
https://pharmoutcomes.org/pharmoutcomes/

- Supply of levonelle® under PGD
- Supply ellaOne® under PGD

The Authority will:

- ensure that an up to date PGD is available via the EHC section of PharmOutcomes;
- ensure that the EHC template, reflects clinical changes and guidance;
- conduct an annual review of this Service to determine whether the needs of the local population are being met;
- arrange at least one Provider meeting per year to promote service development and update the knowledge of the Provider's Staff;
- provide details of relevant referral points which the Provider's Staff may use to signpost Service Users who require further assistance;
- disseminate information on the Service to other pharmacies and health care professionals in order that they may signpost Service Users to the Service; and

The Provider:

- must ensure all Activity is included in their professional indemnity cover

Accredited Community Pharmacists will need to continually update their skills and knowledge effectively and attend training supplied by the Authority's Public Health department to implement this Patient Group Direction safely.

- Competencies and Training Framework 2015/16 - CPPE Emergency Hormonal Contraception Learning Pack & CPPE Safeguarding and Vulnerable Adults Training Packages that must have been completed between 1st April 2015 and 31st March 2018. CPPE. Training which was undertaken prior to 31st March 2015 is not valid.
- Hold a valid Disclosure and Barring Service (DBS) Check /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 or evidence of annual declaration made to the GPhC. (http://www.pharmacyregulation.org/raising-concerns/registrants/definition-fitness-practise/declarations)
- A signed PGD

It is the Providers responsibility to ensure that it holds up to date training and records as appropriate on the CPPE accreditation.

The Authority may from time to time request evidence of training and accreditation and this must be provided by the Provider upon written request.

The Provider will ensure that all members of Staff are aware of the scheme and full details will be made available to locum Providers to ensure continuity of provision of the Service. The Provider will introduce a Standard Operating Procedure (SOP). This must be made available to the Authority when requested.

4.2 Information Provision:

- Data must be recorded in full on PharmOutcomes Modules as part of the Service User clinical record.
- All data must be auditable and payment is conditional on receipt of accurate and full data reports for all Service Users accessing the Services.
- Patient consent must be obtained

- Data will be recorded and reported to allow:
  - Pseudonymised data for reporting local and National outcome measures
  - Audit of data for payment and outcome monitoring
  - Compliance with Data Protection Legislation
  - Follow up of Service Users where consent has been obtained by the Authority for

- Service review
- Outcome monitoring

- Service User records must be securely stored and used strictly in accordance with the terms of

this Contract.

- Data collected must be accessible to the Authority to audit payments and report outcomes

5. Location of Provider Premises

The Provider's Premises are to be located within the administrative area of the Authority. The Provider shall provide the Authority with a written schedule of the location of each of the Premises from which the Services under this Lot are to be delivered **within one month** of the Service Commencement Date

The Service will take place at the location and Provider Premises specified within this Contract.

The Provider must:

- Notify the Authority of any planned changes to service locations.
- Ensure the Service is carried out in suitable premises with facilities for private consultations and in accordance with Covid-19 Safe Working Practices
- Ensure the design and layout of the Premises are suitable for carrying out the Service or Activity with appropriate measures being in place to ensure the security of the Premises.
- Ensure the Premises protect people's rights to privacy, dignity, choice, autonomy and safety.
- Ensure the Premises have space, heating, lighting and ventilation that conform to relevant and recognised standards.
- Ensure the Premises are accessible to people who need to enter the Premises and meet the appropriate requirements of the Equality Act.
- Ensures the Premises and any grounds are adequately maintained and complies with any legal requirements relating to the Premises.
- Take account of any relevant design, technical and operational standards and manages all risks in relation to the Premises.

6. Required Insurances

Public Liability Level of cover of a minimum of 5 MILLION POUNDS (£5,000,000.00)

Professional Liability Level of cover of a minimum of 5 MILLION POUNDS (£5,000,000.00)

Employers Liability Level of cover of a minimum of 5 MILLION POUNDS (£5,000,000.00)

Product Liability Level of cover 5 MILLION POUNDS (£5,000,000.00)

Medical Mal-practice Level of cover 5 Million Pounds (£5,000,000.00)

Insurances are required to be maintained for a minimum period of 6 years following termination/expiry of this Contract

7. QUALITY OUTCOME INDICATORS

QUALITY OUTCOMES DATA			
Outcome indicator	**Threshold**	**Method of measurement**	**Consequence of breach**
Number of consultations where supply made of Levonorgestrel	n/a	PharmOutcomes report	n/a
Number of consultations where supply made of Ulipristal acetate 30mg	n/a	PharmOutcomes report	n/a
Number of consultations where EHC not supplied	n/a	PharmOutcomes report	n/a

7.2 Monitoring and Review

7.1.3 The Provider shall ensure that the necessary documentation, as detailed in this Specification, is maintained and made available to the Authority to enable the Service to be monitored and for the purpose of post payment verification.

7.1.4 The Authority may undertake a visit to the Provider's participating Premises to inspect the provision of the Service and to ensure that the Provider is meeting this Specification.

7.1.5 The Authority will undertake an annual review of all EHC Activity data.

7.2.4 The Provider will be monitored on the following data which will be accessible to the Authority from PharmOutcomes on a quarterly basis:

Issuing Pharmacy
Date of attendance:
Service User age:
Levonorgestrel/Ullipristal Acetate issued
LSOA of service use

7.2.5 **Use of PharmOutcomes**

The Provider shall ensure that all consultations are logged on PharmOutcomes to enable the Authority to monitor Activity and verify payments for Services provided

All information should be available for audit if required.

8. SERVICE USER EXPERIENCE

All Service Users must be provided with a copy of, or a link to, a Service User satisfaction questionnaire within 4 weeks of attending the Service.

9. CHARGES

The service fee will comprise the following four components:

Payment for this Service will be made on a quarterly basis in arrears.

Additional One-Off Payment:

It has been agreed between the Parties that the Authority shall, within 30 Business Days of the Service Commencement Date, calculate and make a one-off payment to the Provider to reflect the shortfall in payments made to the Provider during the period from 1st April 2021 up to and including 30th April 2022, following the agreed 20% uplift in the Consultation Fee tariff effective from 1st April 2021

Valid Invoices for payment must be submitted and sent to: ali.cartwright@shropshire.gov.uk

Payment Schedule

Activity	Price
Consultation fee Note this fee only applies to supply of EHC	£12:00
Supply of Levonelle® Levonorgestrel including drug cost.	£5.75
Supply Of ellaOne® Ulipristal Acetate including drug cost	£18.00

10. DISCHARGE OF CARE –

All Service Users issued with Emergency Hormonal Contraception should be advised to visit their GP for long term contraception management.

11. SERVICE QUALITY PERFORMANCE REPORT

Quantitative and qualitative information may be used to evaluate the Services.

Data will be collected through the PharmOutcomes clinical patient record system and should be held by the Provider according to the guidance issued by the Information Commissioner's Office in regard to the storage and handling of patient details and the terms of this Contract including Schedule 1 to this Specification (GDPR).

The Provider must submit details of complaints received on a quarterly basis throughout the duration of the Term of the Contract EXCEPT in circumstances where a complaint arises from a safeguarding issue or an issue that has a significant impact upon a Service User. In these circumstances, details of complaints received must be notified to the Authority as soon as practicably possible and in any event within 48 hours of receipt. . In all other circumstances complaints shall be dealt with in accordance with clause B.17 of this Contract.

For local data monitoring, to trigger payments and for quality monitoring purposes, quarterly submission of quantitative and qualitative data will be supplied to the Authority on a quarterly basis see **Section 7.2** Monitoring and review.

All information should be available for audit and quality reporting if required.

Qualitative information may also be gathered via informal patient feedback

12 REVIEW MEETINGS:

Reviews shall take place in accordance with section 7 above and in addition the Authority may undertake a visit to the Provider's participating Premises to inspect the provision of the Service and to ensure that the Provider is meeting this Specification.
13 NOTICE REQUIRED TO WITHDRAW DELIVERY OF THIS LOT
Either Party may serve the other with three months' prior written notice to terminate the provision of this Lot

Schedule 1 – Processing Personal Data and Data Subjects – Lot 5

1) The Provider shall comply with any further instructions with respect to processing by this Authority
2) Any such further instructions shall be incorporated into this Schedule

Description	Details
Subject matter of the processing	Processing of data collected in PharmOutcome record for Service Users receiving Sexual Health Services in community pharmacies issuing Emergency Hormonal Contraception.
Duration of the processing	For the duration of this Contract
Nature and purposes of the processing	The nature of the processing shall include any operation such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction of date (whether or not by automated means) The nature of the processing shall include any operation such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction of date (whether or not by automated means) The purpose for the processing shall be: Data is collected via secure, web-based record management programme; PharmOutcomes. Pseudonymised and is returned to the Local Authority quarterly to enable payment, audit and management of contract and monitoring of service outcomes. Processing allows local and national level analysis and reporting on the effectiveness of commissioned services. Commissioning and monitoring of contraception, prevention of sexually transmitted Infections is a mandatory Public Health function. Identifiable data may also be used should audits require and where it is of benefit to the healthcare of the individual.
Type of Personal Data	Name, address, date of birth, NI number, telephone number, demographic data, relevant sexual health data including last monthly period, number of previous pregnancies, last time of sexual intercourse, current contraception, any allergies.
Categories of Data Subject	Service Users/ Aged 13 years and over.

Plan for return and destruction of the data once the processing is complete UNLESS requirement under union or member state law to preserve that type of data	Plan will follow the Council's "Information and Records Management Standards". The records entered onto PharmOutcomes by the Provider remains its data as it forms part of a clinical record for a healthcare professional/provider. This information is held by PharmOutcomes for as long as necessary and the current NHS guidelines indicate that this is 8 years (or 8 years after an individual passes their 16th birthday), unless the contract is terminated.

Lot 6 - Issue of Chlamydia/Gonorrhoea Self-Sampling Smartkits

Service Specification No.	**Lot 6**
Service	Pharmacy Sexual Health Services Issue of Chlamydia/Gonorrhoea Self-Sampling Smartkits
Authority Lead	Ken Stringer Public Health Programme Lead
Provider Lead	
Period	**Initial Term: 1st May 2022 – 31st March 2023**
Date of Review	March 2023

For the purposes of this Service Specification for Lot 6, the following additional definitions to the main Contract apply:

EC	Means Emergency Contraception
Fraser Guidelines	The guideline to be followed to determine if a child under 16 who is considered to be of sufficient age and understanding to be competent to receive contraceptive advice without parental knowledge or consent.
Integrated Community Sexual Health Services and the term OpenClinic	Means the service provided by Midlands Partnership NHS Foundation Trust (SSSFT) and delivered as OpenClinic
IUD	Means intrauterine device
IUS	Means intrauterine systems

LARC	Means Long Acting Reversible Contraception
Medicines Management Team	Means Pharmacists, technicians and a team of staff who support GP practices and advise on anything related to medicines management in Shropshire
PGD	Means Patient Group Direction
"PharmOutcomes"	Web-based information system for Community Pharmacies
Premises	Means the premises described in section 5 where the Services are to be delivered by the Provider
"Services"	Means the Issue of Chlamydia/Gonorrhoea Self-Sampling Smartkits service further to this Specification and Lot 6
"Service Users"	Means individuals eligible to receive the Service being those persons who: Are aged 13years or over; Are resident within the administrative area of the Authority
SmartKit	means A self sampling Chlamydia and Gonorrhoea test kit
STI	Sexually Transmitted Infection

3. Population Needs

.

Unprotected sex may lead not only to an unplanned pregnancy but also the possible transmission of a Sexually Transmitted Infection, including chlamydia, the most common bacterial sexually transmitted infection, with sexually active young people at highest risk. As chlamydia often has no symptoms and can have serious and costly health consequences (e.g. pelvic inflammatory disease, ectopic pregnancy and tubal factor infertility) it is vital that it is diagnosed early and treated. As such offering tests during other healthcare consultations, i.e. Whilst accessing EC, enables early diagnosis of infections and, with effective provision of treatment and partner notification, also stops onward transmission to partners and re-infection.

Relevant policy and guidance includes::

A Framework for Sexual Health Improvement in England https://www.gov.uk/government/publications/a-framework-for-sexual-health-improvement-in-england (DH 2013)

Working together to Safeguard Children and Young People https://www.gov.uk/government/publications/working-together-to-safeguard-children (2015)

Service Standards for Sexual and Reproductive Health Care https://www.fsrh.org/standards-and-guidance/documents/fsrh-service-standards-for-sexual-and-reproductive-healthcare/ (2016)

Healthy Lives, Healthy People https://www.gov.uk/government/publications/healthy-lives-healthy-people-our-strategy-for-public-health-in-england (2010)

Teenage Pregnancy Strategy Beyond 2010 https://www.education.gov.uk/consultations/downloadableDocs/4287_Teenage%20pregnancy%20strategy_aw8.pdf (2010)

You're Welcome Quality Criteria https://www.gov.uk/government/publications/quality-criteria-for-young-people-friendly-health-Services (2011)

Safeguarding Vulnerable Groups Act http://www.legislation.gov.uk/ukpga/2006/47/contents (2006)

Recommended Standards for sexual health Services http://www.medfash.org.uk/uploads/files/p17abl5efr149kqsu10811h21i3tt.pdf (2005)

National Service Framework for children, young people and maternity Services https://www.gov.uk/government/publications/national-service-framework-children-young-people-and-maternity-Services (2004)

Every Child Matters https://www.education.gov.uk/consultations/downloadableDocs/EveryChildMatters.pdf (2004)

Sexual Offences Act http://www.legislation.gov.uk/ukpga/2003/42/contents (2003)

UK National Guideline for Consultations requiring Sexual History https://www.bashhguidelines.org/media/1078/sexual-history-taking-guideline-2013-2.pdf (2013)

BASHH UK National Guideline for the Treatment of Chlamydia Trachomatis (2018) http://www.bashhguidelines.org/media/1191/update-on-the-treatment-of-chlamydia-trachomatis-infection-final-16-9-18.pdf
Faculty of Sexual & Reproductive Healthcare Clinical Guidance – Emergency Contraception https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/ (2017)

UK Medical Eligibility Criteria for Contraceptive Use https://www.fsrh.org/standards-and-guidance/uk-medical-eligibility-criteria-for-contraceptive-use/ (2016)

2. Key Service Outcomes

The Service will deliver the following outcomes to improve the sexual health in the to those people living within the administrative area of the Authority as a whole by providing:

- Provide clear, accessible and up to date information about Services providing emergency contraception and sexual health
- Improved access to Services among those of highest risk of sexual ill health
- Reduced health inequalities amongst young people and adults
- Increased screening of sexually transmitted infections (chlamydia and gonorrhoea) The provision of accurate, high-quality and appropriate information that helps to make informed decisions about relationships, sex and sexual health
- Appropriate preventive interventions, such as condoms, literature; to help boost personal resilience, build self-esteem and promote healthy choices

- Rapid access to confidential, open-access, integrated Sexual Health Service in various settings that are accessible at convenient times
- When necessary, offer advice on where to find other sexual health service such as those at Level 2 and Level 3 e.g. Long Acting Reversible Contraception, testing and treatment for symptomatic STI's, and other gynaecological problems.

The Service will make a positive *contribution* to the following related indicators from the Public Health Outcomes Framework 2016-2019:

Domain 2: Health Improvement
Under 18 conceptions

Domain 3: Health Protection
Chlamydia Detection Rate (15 – 24 year olds)

3. Scope

3.1 Overall aims and objectives of service

- To improve access for the treatment of asymptomatic chlamydia
- To improve access to sexual health advice.
- To increase the knowledge of risk associated with STIs.
- To refer Service Users who may have been at risk of STIs to an appropriate service.
- To strengthen the local network of contraceptive and sexual health service in the community to help ensure easy and swift access to advice and treatment.

3.2 Service Description/Pathway

To offer a Chlamydia/Gonorrhoea Self-Sample Smartkit to all Services Users at risk of a Sexually Transmitted Infection,including

3.2.1 Local Standards

The Provider will ensure:

- All women accessing Emergency Contraception will be offered a Chlamydia/Gonorrhoea Smartkit.

- All 15-24year olds requesting registration or issue of condoms as part of the CDS will be offered a
- Chlamydia/Gonorrhoea Smartkit at each partner change and annually.
- The Provider will be expected to work towards achieving the 'Your Welcome' or other similar mark of quality provision certification for young people.

The Provider must take account of the following:

Those young people aged over 13years and under the age of 16 years must be seen by a worker trained to assess Fraser[12] and Gillick competence to receive sexual health advice and

[12] Available at https://www.gov.uk/government/organisations/**department-of-health**

interventions in the absence of a parent or guardian and to ensure that safeguarding issues are identified, dealt with and appropriately referred on if additional support is needed.[13]

3.2.2 Records

The Provider shall use the PharmOutcomes on-line platform to record and provide accurate information and ensure modules - Patient Registration and Consultation and Supply are completed on PharmOutcomes.

3.2.3 The Provider's Responsibilities:

- As part of good clinical governance the Provider is required to develop, implement, monitor and review the clinical quality of the Service that it delivers.

The Provider will:

- Undertake a risk assessment to ensure adequate facilities and equipment are in place to deliver the Service and identify the resources available to support the Service.
- Develop appropriate systems for record keeping including Service User assessment, follow-up/recall and an appropriate clinical record
- The Provider has a duty to ensure that its Staff involved in offering and issuing the Smartkits have relevant knowledge and are appropriately trained in the operation of the Service, including sensitive, Service User centred communication skills.
- The Provider has a duty to ensure that the Service and Staff involved in the provision of the Service are aware of and operate within local protocols and standards, including any training facilitated by Public Health Department of the Authority.

- Monitoring Safety and Reporting of Significant Events –The Provider will be responsible for operating a system for monitoring safety and reporting significant events.
- The Provider will be required to report incidents and significant events relating to the prescribing, dispensing, administration and record keeping involving medicines in relation to this scheme. Any root cause analysis following any incidents undertaken by the Provider or other parties will need to ensure input by all parties to demonstrate individual and organisational outcomes and change and should be of acceptable standard. They should be forwarded to Medicines Management Team subsequently for local learning. The Authority should also be directly informed.
- The Provider shall maintain records, in a form acceptable to the Authority, which allow measurement of the units of Activity. An anonymised summary shall be sent to the Authority alongside claims for payment for individual Activity which is a requirement before payment can be authorised.
- Promotion of the Service. The Provider is required to undertake, in participation with the Authority, promotion of Public Health sexual health campaigns. The Provider's Premises or the Provider will not promote the Service to the public without the prior approval of the Authority.

[13] Department of Health (2004). *Best Practice Guidance for Doctors and other Health Professionals on the Provision of Advice and Treatment to Young People Under 16 on Contraception, Sexual and Reproductive Health* (http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4086960)

- Where appropriate Service Users will be signposted to access a free of charge HIV self-sampling kit via https://www.test.hiv/

- Where required, arrangements must be made for a suitable chaperone, acceptable to the Service User accessing the Service, to be present. The cost of the chaperone will be borne by the Provider.

Workforce

As this is an outcomes based Specification, it will not specify workforce capacity or management. However, it is expected that all Staff will be the correct mix of clinical and other professional staff, working within safe and robust clinical governance protocols, which can help to offer better and more cost effective provision for the Authority.

Applicable national standards (e.g. NICE) and training requirements

The Provider must adhere to all national standards and training requirements. It is the Provider's responsibility to keep up to date and adhere to any changes to national training requirements, guidance and service standards.

- A DBS check must be in place for all Staff delivering this Service.

- Providers are only permitted to issue Chlamydia/Gonorrhoea Smartkits further to this Specification once they have received confirmation from the Authority.

It is the Providers responsibility to ensure that it holds up to date training and supply evidence of this to the Authority if required.

3.3 Discharge Criteria and Planning

All Service Users issued with a Chlamydia/Gonorrhoea Smartkit should be advised to access treatment services e.g. Pharmacies, GP practices, Sexual Health Services via OpenClinic

All Service Users should be notified they will received their results by text message to a mobile phone number of their choice.

3.4 Population covered

Service Users aged 13 years and over and resident in the administrative area of the Authority

3.5 Any acceptance and exclusion criteria and thresholds

Any Service User aged over 13 years resident in the administrative area of the Authority assessed to be at risk of a Sexually Transmitted Infection.

Service Users with symptoms of a Sexually Transmitted Infection should be signposted to Sexual Health Services:
http://openclinic.org.uk/
Tele: 0300 404 2996

Service Users who are not resident in the administrative area of the Authority are excluded and should be referred to Sexual Health Services:
http://openclinic.org.uk/
Tele: 0300 404 2996

The Provider has the right to refuse Service provision to Service Users*:

- For any unreasonable behaviour unacceptable to the Provider, it's Staff, or the named professional clinically responsible for the care of the Service User.

*The Provider must immediately inform the Authority of any service complaints or serious or untoward incidents.in accordance with the terms of this Contract

3.6 Interdependencies with other Services

The Provider cannot deliver the Services in isolation and is required to work with partners to address the needs of Service Users and increase the opportunity for Service Users to achieve optimum sexual health outcome and will maintain efficient working partnerships with allied services, agencies and stakeholders in order to support effective signposting and referrals, reduce transition trauma, enhance the quality of care delivered, attain best outcomes for the Service User and ensure the holistic nature of the wider sexual health provision across the administrative area of the Authority within Shropshire

Partners include:

- Shropshire Public Health Department
- Shropshire Clinical Commissioning Group (CCG) - Medicines Management Team
- National Chlamydia Screening Programme (NCSP)
- Shropshire General Practitioner and Primary Care Services
- Shropshire Community pharmacies
- The Specialist Sexual Health Service
- Safeguarding Adults and Children Provision

3.7 Any Activity planning assumptions

Activity planning assumptions are made annually by the Authority based on the previous year's Activity. Service Activity will be based on information submitted by the Provider through the relevant monitoring and Reporting Arrangements of this Specification. All fields specified in Service User Registration and Consultation modules and must be completed by the Provider and submitted on PharmOutcomes.

4. Applicable Service Standards

The Provider is required to work to the latest national standards including (this list is not exhaustive

NICE: One to one interventions to reduce the transmission of STI's and to reduce the rate of under 18's conceptions, especially among vulnerable and at risk groups (PH3) (2007 updated September 2017) https://www.nice.org.uk/Guidance/PH3

FRSH: Recommended standards for sexual health Service (2015) https://www.fsrh.org/standards-and-guidance/documents/fsrh-service-standards-for-sexual-and-reproductive-healthcare/

National Chlamydia Screening Programme Standards (7th Edition 2016) https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/574351/NCSP_Standards_7th_edition.pdf

Progress and Priorities - Working Together for High Quality Sexual Health (MEDFASH 2008) http://www.medfash.org.uk/uploads/files/p17abl1iai1e961d438j2pjl1rp7p.pdf

UK National Guidelines on Safer Sex (BASHH 2012) https://www.bashhguidelines.org/media/1080/4452.pdf

Quality Criteria for Young People's Health Service (2011) https://www.gov.uk/government/publications/quality-criteria-for-young-people-friendly-health-Services

When providing Services for young people the Department of Health's *You're Welcome* quality criteria[14] should be used as guiding principles when planning and implementing changes and improvements, in order to become young people friendly.

Service planning and improvement should always include consultation with Service Users and local populations.

4.1 Training Requirement

The Provider will ensure that:

- Its registered pharmacist(s) will have undertaken appropriate training in contraception and sexual health including periodic updates that are required to maintain competency.

The pharmacist in charge must have completed the Centre for Pharmacy Postgraduate Education (CPPE) training detailed below:

- CPPE Chlamydia Test and Treatment Open Learning Programme (3 Hours)
- CPPE Child Protection Open Learning Programme (1.5 Hours)
- Safeguarding Children and Vulnerable Adults: Level 2 2018 https://www.cppe.ac.uk/programmes/l/safegrdingl2-a-02/
- NHS: Spotting the Signs of Child Exploitation 2016 https://www.cppe.ac.uk/programmes/l/cse-e-01/
- CPPE Sexual Health learning module 2018 https://www.cppe.ac.uk/programmes/l/tlp-e-07/
- CPPE Dealing with Difficult Discussions 2018 https://www.cppe.ac.uk/programmes/l/diffdisc-e-01/
- CPPE Sexual Health in Pharmacies 2017 https://www.cppe.ac.uk/programmes/l/sexual-e-01/

For CPPE accreditations the Provider's pharmacist must allow 'see all' on the CPPE website to enable audit training accreditation. If the Provider is a Group pharmacy it will have contracts and accreditation managed by their group managers.

Amnesty period for those holding up to date documents provided by other training organisations:-

Some pharmacists may have certificates that are current but relate to previous training organisations, or have been acquired in other areas. Providing these documents are still up to date pharmacists can

[14] Department of Health (2011). *You're Welcome: Quality Criteria for Young People Friendly Health Service* (http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126813)

provide the Service subject to a review of documentation by the Authority. Documents should be sent to the Public Health Department of the Authority (see Contacts). Within six months of the Service Commencement Date the Provider must ensure that its pharmacist(s) have completed the CPPE accredited requirements www.cppe.ac.uk

The Authority will:

- conduct an annual review of this Service to determine whether the needs of the local population are being met;
- arrange at least one Provider meeting per year to promote service development and update the knowledge of the Provider's Staff;
- provide details of relevant referral points which the Provider's Staff may use to signpost Service Users who require further assistance;
- disseminate information on the Service to other pharmacies and health care professionals in order that they may signpost Service Users to the Service; and
-

The Provider:

- must ensure all Activity is included in their professional indemnity cover

Accredited Community Pharmacists will need to continually update their skills and knowledge effectively and attend Authority's Public Health Department updates to implement the Patient Group Direction safely.

It is the Providers responsibility to ensure that it holds up to date training and records as appropriate on the CPPE accreditation.

The Authority may from time to time request evidence of training and accreditation and this must be provided by the Provider upon written request..

The Provider will ensure that all members of its Staff are aware of the Service and full details will be made available to locum Staff to ensure continuity of provision of the Service. The Provider will introduce a Standard Operating Procedure (SOP). This must be made available to the Authority when requested.

4.2 Information Provision:

- Data must be recorded in full on PharmOutcomes modules registration and consultation as part of the Service User clinical record.
- All data must be auditable and payment is conditional on receipt of accurate and full data reports for all Service Users accessing the Services.
- Service User consent must be obtained
- Data will be recorded and reported to allow:
  - Pseudonymised data for reporting local and National outcome measures
  - Audit of data for payment and outcome monitoring
  - Compliance with Data Protection Legislation

- Follow up of Service Users where consent has been obtained by the Authority for

- Service User records must be securely stored and used strictly in accordance with the terms of this Contract.
- Data collected must be accessible to the Authority to audit payments and report outcomes

5. Location of Provider Premises

The Provider's Premises are to be located within the administrative area of the Authority. The Provider shall provide the Authority with a written schedule of the location of each of the Premises from which the Services under this Lot are to be delivered **within one month** of the Service Commencement Date

The Service will take place at the location and Provider Premises specified within in this Contract.

The Provider must:

- Notify the Authority of any planned changes to service locations.
- Ensure the Service is carried out in suitable premises with facilities for private consultations and in accordance with Covid-19 Safe Working Practices.
- Ensure the design and layout of the Premises are suitable for carrying out the related service or Activity with appropriate measures being in place to ensure the security of the Premises.
- Ensure the Premises protect people's rights to privacy, dignity, choice, autonomy and safety.
- Ensure the Premises have space, heating, lighting and ventilation that conform to relevant and recognised standards.
- Ensure the Premises are accessible to people who need to enter the Premises and meet the appropriate requirements of the Equality Act.
- Ensures the Premises and any grounds are adequately maintained and complies with any legal requirements relating to the Premises.
- Takes account of any relevant design, technical and operational standards and manages all risks in relation to the Premises.

6. Required Insurances

Public Liability Level of cover of a minimum of 5 MILLION POUNDS (£5,000,000.00)

Professional Liability Level of cover of a minimum of 5 MILLION POUNDS (£5,000,000.00)

Employers Liability Level of cover of a minimum of 5 MILLION POUNDS (£5,000,000.00)

Product Liability Level of cover 5 MILLION POUNDS (£5,000,000.00)

Medical Mal-practice Level of cover 5 Million Pounds (£5,000,000.00)

Insurances are required to be maintained for a minimum period of 6 years following termination/expiry of this Contract

7. QUALITY OUTCOME INDICATORS

QUALITY OUTCOMES DATA			
Outcome indicator	**Threshold**	**Method of measurement**	**Consequence of breach**
Numbers of Smartkits issued by each participating pharmacy	Following review of year 1 Activity	PharmOutcomes report	n/a
Number of positive Chlamydia tests	Following review of year 1 Activity	PharmOutcomes report	n/a
Number of positive Gonorrhoea tests by participating pharmacy	Following review of year 1 Activity	PharmOutcomes report	n/a

7.2 Monitoring and Review

7.2.1 The Provider shall ensure that the necessary documentation, as detailed in this Specificaton, is maintained and made available to the Authority to enable the Service to be monitored and for the purpose of post payment verification.

7.2.2 The Authority may undertake a visit to the Provider's participating Premises to inspect the provision of the Service and to ensure that the Provider is meeting this Specification.

7.2.3 The Authority will undertake an annual review.

7.2.4 The Provider will be monitored on the following data which will be accessible to the Authority from PharmOutcomes on a quarterly basis:

Issuing pharmacy.
Service User age:
Numbers of SmartKits issued:
Numbers of Positive tests.
LSOA of Service User.

7.2.5 **Use of PharmOutcomes**
The Provider shall ensure that all consultations are logged on PharmOutcomes to enable the Authority to monitor Activity and verify payments for Services provided.

7.2.6 Supply of Chlamydia/Gonorrhoea Self-Sampling Smartkits:
The Authority will provide the Smartkits at no cost to the provider.
Contact: ali.cartwright@shropshire.gov.uk Tel: 01743 253939

8. SERVICE USER EXPERIENCE

All Service Users must be provided with a copy of, or a link to, a Service User satisfaction questionnaire within 4 weeks of attending the Service.

9. CHARGES

The service fee will comprise the following component:

Payment for this Service will be made on a quarterly basis in arrears.

Valid Invoices for payment must be submitted and sent to ali.cartwright@shropshire.gov.uk

Payment Schedule

Activity	Price
Appropriate issue of Chlamydia/Gonorrhoea SmarKit	1.00

9.3 Claims for Payment

9.2.5 Details of the consultation must be entered on to PharmOutcomes in a timely manner to meet claims deadlines.

9.2.6 Only under exceptional circumstances will paper claims be accepted.

9.2.7 No claim shall be submitted more than one month after the Expiry Date of this Contract.

9.2.8 Claims for Activity more than 2 months old will not be paid.

9.3 This Provider will be paid on an Activity basis.

9.4 Payment for this Service will be made on a quarterly basis in arrears, based on actual Activity. Payment to each Provider will be provided according to timely and complete data submitted to Pharmoutcomes in line with the requirements included in this Specification.

9.5 Payment will be in accordance with the payment schedule set out above

9.6 Only information submitted to and reported to the Authority by Pharmoutcomes will be eligible for payments.

Initial term: 1st May 2022 – 31st March 2023

All prices exclude VAT

10. DISCHARGE FROM CARE

All Service Users issued with a Chlamydia/Gonorrhoea Smartkit should be advised to access treatment services e.g. Pharmacies, GP practices, Sexual Health Services via OpenClinic
All Service Users should be notified they will received their results by text message to a mobile phone number of their choice.

11. SERVICE QUALITY PERFORMANCE REPORT

Quantitative and qualitative information may be used to evaluate the Services.

Data will be collected through the PharmOutcomes clinical patient record system and should be held by the Provider according to the guidance issued by the Information Commissioner's Office in regard to the storage and handling of patient details and the terms of this Contract including Schedule 1 to this Specification (GDPR).

The Provider must submit details of complaints received on a quarterly basis throughout the duration of the Term of the Contract EXCEPT in circumstances where a complaint arises from a safeguarding issue or an issue that has a significant impact upon a Service User. In these circumstances, details of complaints received must be notified to the Authority as soon as practicably possible and in any event within 48 hours of receipt. . In all other circumstances complaints shall be dealt with in accordance with clause B.17 of this Contract.

For local data monitoring, to trigger payments and for quality monitoring purposes, quarterly submission of quantitative and qualitative data will be supplied to the Authority on a quarterly basis see **Section 7.2** Monitoring and review.

All information should be available for audit and quality reporting if required.

Qualitative information may also be gathered via informal patient feedback.

12 REVIEW MEETINGS:
Reviews shall take place in accordance with section 7 above and in addition the Authority may undertake a visit to the Provider's participating Premises to inspect the provision of the Service and to ensure that the Provider is meeting this Specification.

13 NOTICE REQUIRED TO WITHDRAW DELIVERY OF THIS LOT

Either Party may serve the other with three months' prior written notice to terminate the provision of this Lot

Schedule 1 – Processing Personal Data and Data Subjects – Lot 6

1. The Provider shall comply with any further instructions with respect to processing by this Authority
2. Any such further instructions shall be incorporated into this Schedule

Description	Details
Subject matter of the processing	Processing of data collected in PharmOutcome record for Service Users receiving Sexual Health Services in community pharmacies e.g. Chlamydia treatment.
Duration of the processing	For the duration of this Contract
Nature and purposes of the processing	The nature of the processing shall include any operation such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction of date (whether or not by automated means) The purpose for the processing shall be:

	Data is collected via secure, web-based record management programme; PharmOutcomes to enable safe and secure reporting of data to the Authority Following Service User consent, Service User data captured at each consultation. Pseudonymised data returned to the Local Authority quarterly to enable payment, audit and management of contract and monitoring of service outcomes. Processing allows local and national level analysis and reporting on the effectiveness of commissioned services. Commissioning and monitoring of emergency contraception, testing and treatment of sexually transmitted infections is a mandatory Public Health function. Identifiable data may also be used should audits require and where it is of benefit to the healthcare of the individual.
Type of Personal Data	Collected by provider: Name, address, date of birth, NI number, telephone number, demographic data, relevant sexual health data including last monthly period, number of previous pregnancies, last time of sexual intercourse, current contraception and any allergies.
Categories of Data Subject	Service Users Aged 15years and over.
Plan for return and destruction of the data once the processing is complete UNLESS requirement under union or member state law to preserve that type of data	Plan will follow the Council's "Information and Records Management Standards". The records entered onto PharmOutcomes by providers remain the providers as it forms part of a clinical record for a healthcare professional/provider. This information is held by PharmOutcomes for as long as necessary and the current NHS guidelines indicate that this is 8 years (or 8 years after an individual passes their 16th birthday), unless the contract is terminated prior to the end of that period

Lot 7 - Registration and Issue of Condoms as part of the Local Condom Distribution Scheme for 13-25year olds.

Service Specification No.	**Lot 7**
Service	Pharmacy Sexual Health Services Registration and Issue of Condoms as part of the Local Condom Distribution Scheme for 13-25year olds.

Authority Lead	**Ken Stringer Public Health Programme Lead**
Provider Lead	
Period	**Initial Term: 1st May 2022 – 31st March 2023**
Date of Review	March 2023

For the purposes of this Service Specification for Lot 7, the following additional definitions to the main Contract apply:

C-Card	Means a Condom Card which is a plastic, double sided, wallet sized card, with stars that indicate the number and frequency condoms can be issued to the registered holder.
CDS	Condom Distribution Scheme
EC/EHC	Means Emergency Contraception
Fraser Guidelines	The guideline to be followed to determine if a child under 16 who is considered to be of sufficient age and understanding to be competent to receive contraceptive advice without parental knowledge or consent.
Integrated Community Sexual Health Services	Provided by Midlands Partnership NHS Foundation Trust (SSSFT) and delivered as OpenClinic
IUD	Means intrauterine device
IUS	Means intrauterine systems
LARC	Means Long Acting Reversible Contraception
Medicines Management Team	Means Pharmacists, technicians and a team of staff who support GP practices and advise on anything related to Medicines Management in Shropshire
PGD	Means Patient Group Direction
"PharmOutcomes"	Web-based information system for Community Pharmacies
Premises	Means the premises described in section 5 where the Services are to be delivered by the Provider
"Services"	Means the Registration and Issue of Condoms service as part of the Local Condom Distribution Scheme for 13-25 year olds further to this Specification and Lot 7

"Service Users"	Means individuals eligible to receive the Service being those persons who: Are aged 13-25 years; Are resident within the administrative area of the Authority
STI	Sexually Transmitted Infection

4. Population Needs

Reducing the burden of unplanned pregnancy (whether this leads to maternity, miscarriage or abortion) requires a sustained public health response and requires:
easy access to high quality information for informed decision-making;
easy access to prevention and treatment Services,; and
should be delivered alongside promotion of safer sexual health and prevention campaigns and initiatives.
Including promoting safer sexual behaviours among individuals –by promoting condom use, the use of the most effective contraceptives, and easy access to regular testing – remains crucial.

Unprotected sex may lead not only to an unplanned pregnancy but also the possible transmission of a Sexually Transmitted Infection, including chlamydia, the most common bacterial sexually transmitted infection, with sexually active young people at highest risk. As chlamydia often has no symptoms and can have serious and costly health consequences (e.g. pelvic inflammatory disease, ectopic pregnancy and tubal factor infertility) it is vital that it is diagnosed early and treated. As such offering tests during other healthcare consultations, i.e. Whilst accessing emergency contraception, enables early diagnosis of infections and, with effective provision of treatment and partner notification, also stops onward transmission to partners and re-infection.

Relevant policy and guidance includes::

A Framework for Sexual Health Improvement in England https://www.gov.uk/government/publications/a-framework-for-sexual-health-improvement-in-england (DH 2013)

Working together to Safeguard Children and Young People (2015,updated 2020))
https://www.gov.uk/government/publications/working-together-to-safeguard-children--2

Service Standards for Sexual and Reproductive Health Care https://www.fsrh.org/standards-and-guidance/documents/fsrh-service-standards-for-sexual-and-reproductive-healthcare/ (2016)

Healthy Lives, Healthy People https://www.gov.uk/government/publications/healthy-lives-healthy-people-our-strategy-for-public-health-in-england (2010)

Teenage Pregnancy Strategy Beyond 2010
https://www.education.gov.uk/consultations/downloadableDocs/4287_Teenage%20pregnancy%20strategy_aw8.pdf (2010)

You're Welcome Quality Criteria https://www.gov.uk/government/publications/quality-criteria-for-young-people-friendly-health-Services (2011)

Safeguarding Vulnerable Groups Act http://www.legislation.gov.uk/ukpga/2006/47/contents (2006)

Recommended Standards for sexual health Services https://www.fsrh.org/standards-and-guidance/documents/fsrh-service-standards-for-sexual-and-reproductive-healthcare/fsrh-service-standards-for-sexual-and-reproductive-healthcare-september-2016.pdf#:~:text=Services%20should%20provide%20comprehensive%20sexual%20and%20reproductive%20healthcare,to%20the%20FSRH%20Service%20Standard%20Workload%20in%20Services.

National Service Framework for children, young people and maternity Services https://www.gov.uk/government/publications/national-service-framework-children-young-people-and-maternity-Services (2004)

Every Child Matters https://www.education.gov.uk/consultations/downloadableDocs/EveryChildMatters.pdf (2004)

Sexual Offences Act http://www.legislation.gov.uk/ukpga/2003/42/contents (2003)

UK National Guideline for Consultations requiring Sexual History https://www.bashhguidelines.org/media/1078/sexual-history-taking-guideline-2013-2.pdf (2013)

BASHH UK National Guideline for the Treatment of Chlamydia Trachomatis (2018) http://www.bashhguidelines.org/media/1191/update-on-the-treatment-of-chlamydia-trachomatis-infection-final-16-9-18.pdf

2. Key Service Outcomes

2.1 The Service will deliver the following outcomes to improve the sexual health in the administrative area of the Authority by providing:

- Provide clear, accessible and up to date information about services providing emergency contraception and sexual health for the whole population
- Improved access to Services among those of highest risk of sexual ill health
- Reduced health inequalities amongst young people and adults
- A reduction in unwanted pregnancies in all ages as evidenced by teenage conception, abortion and repeat abortion rates
- Increased screening of sexually transmitted infections (chlamydia and gonorrhoea) The provision of accurate, high-quality and appropriate information that helps to make informed decisions about relationships, sex and sexual health
- Appropriate preventive interventions, such as condoms, literature; to help boost personal resilience, build self-esteem and promote healthy choices
- Rapid access to confidential, open-access, integrated Sexual Health Service in various settings that are accessible at convenient times
- When necessary, offer advice on where to find other sexual health service such as those at Level 2 and Level 3 e.g. Long Acting Reversible Contraception, testing and treatment for symptomatic STI's, and other gynaecological problems.

The Service will make a positive contribution to the following related indicators from the Public Health Outcomes Framework 2016-2019:

Domain 2: Health Improvement
Under 18 conceptions

Domain 3: Health Protection
Chlamydia Detection Rate (15 – 24 year olds)

3. Scope

3.1 Overall aims and objectives of the Service

- To improve access for the treatment of asymptomatic chlamydia
- To improve access to free condoms as part of the Condom Distribution Scheme (CDS)
- To increase the knowledge, especially among young people, of the availability of emergency contraception and contraception from pharmacies.
- To improve access to free emergency contraception and sexual health advice.
- To increase the knowledge of risk associated with STIs.
- To refer Service Users who may have been at risk of STIs to an appropriate service.
- To strengthen the local network of contraceptive and sexual health service in the community to help ensure easy and swift access to advice and treatment.

3.2 Service Description/Pathway

The Provider will provide a free registration/distribution point of the local Condom Distribution Scheme for young people aged 15-24years. In order to provide a good introduction to broader sexual and reproductive health services, especially for younger people, and help prevent unplanned pregnancies.

Pathway

- Registration: when a Service User registers for a Condom Card (C-Card) the Provider must undertake a sexual history assessment to ensure service user is in a safe relationship, free of harm or coercion, competent to consent (Fraser Guidelines) and know how to use a condom correctly .

- Issue: once the C-Card is issued, the Service User is entitled to an agreed number of supplies free from any of the Provider's participating distribution point. Supplies and quantities vary but may include condoms and/or lubricant, depending on the age and needs of the Service User.

- The Provider must advise Service Users that: after receiving supplies an agreed number of times, the Service User must then return to the registration outlet where their circumstances, sexual health and medical needs will be reviewed.

- The Provider must provide data returns to CDS operating team at Midland Partnership Foundation Trust as per current CDS operating procedures.

3.2.1 Local Standards.

The Provider will ensure that:

- All 13-25 year olds requesting issue of condoms as part of the CDS may be offered a Chlamydia/Gonorrhoea Smartkit at each partner change and annually.
- It meets the Department of Health's You're Welcome criteria for young-person-friendly services
- treats the provision of Services as confidential
- it provides the Services in settings accessible to Service Users
- it provides the Services in locations accessible by public transport
- the Services are available at convenient times for Service Users (for example, after school, college or university and at weekends)

3.2.2 The Provider will ensure the safety of Service Users by:

- Assessing the competence of those under 16, and others from whom there is a duty of care, before providing them with condoms.
- Being alert to signs of child sexual exploitation or abuse, including intimate partner violence. See Spotting the Signs Proforma (British Association for Sexual Health and HIV and Brook) and NICE's guideline on child maltreatment.
- Agreeing with the Service User how they will use the Service, taking into account their age and circumstances and include an agreement that after a specified number of visits they will discuss their relationships and condom use again.
- Providing data returns to CDS operating team at Midland Partnership Foundation Trust as per current CDS operating procedures.

The Provider must ensure that:

Those young people aged over 13 years and under the age of 16 years must be seen by a worker trained to assess Fraser[15] and Gillick competence to receive sexual health advice and interventions in the absence of a parent or guardian and to ensure that safeguarding issues are identified, dealt with and appropriately referred on if additional support is needed.[16,17,18]

[15] Available at https://www.gov.uk/government/organisations/**department-of-health**
[16] Department of Health (2004). *Best Practice Guidance for Doctors and other Health Professionals on the Provision of Advice and Treatment to Young People Under 16 on Contraception, Sexual and Reproductive Health* (http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4086960)
[17] Gillick v West Norfolk & Wisbech Area Health Authority [1985] UKHL 7 (17 October 1985) (http://www.bailii.org/uk/cases/UKHL/1985/7.html)
[18] Sexual Offences Act 2003 (http://www.legislation.gov.uk/ukpga/2003/42/contents)

3.2.3 Records

The Provider shall use the PharmOutcomes on-line platform to record and provide accurate information and ensure modules - Patient Registration and Consultation and Supply are completed on PharmOutcomes.

CDS records as per current CDS operating procedures should also be completed

3.2.4 The Service Responsibilities:

- As part of good clinical governance the Provider is required to develop, implement, monitor and review the clinical quality of the service that it undertakes.

The Provider will:

- Undertake a risk assessment to ensure adequate facilities and equipment are in place to deliver the Service and identify the resources available to support the Service.
- Develop appropriate systems for record keeping including Service User assessment, follow-up/recall and an appropriate clinical record
- The Provider has a duty to ensure that its Staff involved in offering and issuing the condoms have relevant knowledge and are appropriately trained in the operation of the Service, including sensitive, Service User centred communication skills.
- The Provider has a duty to ensure that the Service and its Staff involved in the provision of the service are aware of and operate within local protocols and standards, including any training facilitated by Public Health Department of the Authority
- Monitoring Safety and Reporting of Significant Events – Providers will be responsible for operating a system for monitoring safety and reporting significant events. The Provider will be required to report incidents and significant events relating to the prescribing, dispensing, administration and record keeping involving medicines in relation to this scheme. Any root cause analysis following any incidents undertaken by the Provider or other parties will need to ensure input by all parties to demonstrate individual and organisational outcomes and change and should be of acceptable standard. They should be forwarded to Medicines Management Team subsequently for local learning. The Public Health Department of the Authority should also be directly informed.
- The Provider shall maintain records, in a form acceptable to the Authority, which allow measurement of the units of Activity. An anonymised summary shall be sent to the Authority alongside claims for payment for individual Activity which is a requirement before payment can be authorised.
- Promotion of the Service. The Provider is required to undertake, in participation with the Authority, promotion of Public Health sexual health campaigns. The Provider's Premises nor the Provider will promote the Service to the public without the prior approval of the Authority.

- Where appropriate Service Users will be signposted to access a free of charge HIV self-sampling kit via https://www.test.hiv/

- Where required, arrangements must be made for a suitable chaperone, acceptable to the Service User accessing the service, to be present. The cost of the chaperone will be borne by the Provider.

Workforce

As this is an outcomes based Specification, it will not specify workforce capacity or management. However, it is expected that all Staff of the Provider will be the correct mix of clinical and other professional Staff, working within safe and robust clinical governance protocols, which can help to offer better and more cost effective provision for the Authority.

Applicable national standards (e.g. NICE) and training requirements

The Provider must adhere to all national standards and training requirements. It is the Provider's responsibility to keep up to date and adhere to any changes to national training requirements, guidance and service standards.

NICE. Sexually Transmitted Infections: condom distribution schemes
(https://www.nice.org.uk/guidance/ng68/chapter/Recommendations-for-research (2017)

3.3 Discharge Criteria and Planning

Service Users issued with a Chlamydia/Gonorrhoea Smartkit should be advised of where to access treatment services e.g. Pharmacies, GP practices, Sexual Health Services.

3.4 Population covered

Service Users aged 13 -25years and resident in the administrative area of the Authority

3.5 Any acceptance and exclusion criteria and thresholds

Any Service User aged over 13 -25years assessed to be at risk of a Sexually Transmitted Infection.

Service Users with symptoms of a Sexually Transmitted Infection should be signposted to Integrated Sexual Health Services (OpenClinic)
http://openclinic.org.uk/
Tele: 0300 404 2996

Any one not resident in the administrative area of the Authority is excluded and should be referred to OpenClinic:
http://openclinic.org.uk/
Tele: 0300 404 2996

Young people under the age of 13years are excluded from CDS and should be referred to OpenClinic or a GP:
http://openclinic.org.uk/
Tele: 0300 404 2996

The Provider has the right to refuse Service provision to the Service Users*:

- For any unreasonable behaviour unacceptable to the Provider, it's Staff, or the named professional clinically responsible for the care of the Service User.

*The Provider must immediately inform the Authority of any service complaints or serious or untoward incidents.in accordance with the terms of this Contract

3.6 Interdependencies with other Services

The Provider cannot deliver the Service in isolation and is required to work with partners to address the needs of Service Users and increase the opportunity for Service Users to achieve optimum sexual health outcome and will maintain efficient working partnerships with allied Services, agencies and stakeholders in order to support effective signposting and referrals, reduce transition trauma, enhance the quality of care delivered, attain best outcomes for the service user and ensure the holistic nature of the wider sexual health provision across Shropshire.

Partners include:

- Shropshire Public Health Department
- Shropshire School Nurses
- Shropshire Clinical Commissioning Group (CCG) - Medicines Management Team
- National Chlamydia Screening Programme (NCSP)
- Shropshire General Practitioner and Primary Care Services
- Shropshire Community pharmacies
- The Specialist Sexual Health Service
- Safeguarding Adults and Children Provision

3.7 Any activity planning assumptions

Activity planning assumptions are made annually by the Authority based on the previous year's Activity. Service Activity will be based on information submitted by the Provider through the relevant monitoring and Reporting Arrangements of this Specification. All fields specified in Service User Registration and Consultation modules and must be completed by the Provider and submitted on PharmOutcomes at the time of consultation.

3.8 Supply of condoms:

Condoms and resources and CDS staff training will be provided at no cost to the Service User:

Contact: http://openclinic.org.uk/
Tele: 0300 404 2996
Email: Shropshire.Sexualhealth@nhs.net

4. Applicable Service Standards

The Provider is required to work to the latest national standards including (this list is not exhaustive

NICE: One to one interventions to reduce the transmission of STI's and to reduce the rate of under 18's conceptions, especially among vulnerable and at risk groups (PH3) (2007 updated September 2017) https://www.nice.org.uk/Guidance/PH3

NICE. Sexually Transmitted Infections: condom distribution schemes https://www.nice.org.uk/guidance/ng68 (2017)

PHE. Condom Distribution Schemes in Englandhttps://www.gov.uk/government/publications/condom-distribution-schemes-in-england (2017)

FRSH: Recommended standards for sexual health Service (2015) https://www.fsrh.org/standards-and-guidance/documents/fsrh-service-standards-for-sexual-and-reproductive-healthcare/

National Chlamydia Screening Programme Standards (7th Edition 2016)
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/574351/NCSP_Standards_7th_edition.pdf

Progress and Priorities - Working Together for High Quality Sexual Health
MEDFASH: Progress and priorities - working together for high quality sexual health | National AIDS Trust
UK National Guidelines on Safer Sex (BASHH 2012)
https://www.bashhguidelines.org/media/1080/4452.pdf

Quality Criteria for Young People's Health Service (2011)
https://www.gov.uk/government/publications/quality-criteria-for-young-people-friendly-health-Services

When providing Services for young people the Department of Health's *You're Welcome* quality criteria[19] should be used as guiding principles when planning and implementing changes and improvements, in order to become young people friendly.

Service planning and improvement should always include consultation with Service Users and local populations.

4.1 Training Requirement

The Provider must ensure that:

- Its registered pharmacists will have undertaken appropriate training in contraception and sexual health including periodic updates that are required to maintain competency.

.

its pharmacist(s) have completed the Centre for Pharmacy Postgraduate Education (CPPE) training detailed below:

- Safeguarding Children and Vulnerable Adults: Level 2 2018
  https://www.cppe.ac.uk/programmes/l/safegrdingl2-a-02/
- And accessed local training by the provider of the local CDS in order to order and be supplied with Condoms and resources: Contact: http://openclinic.org.uk/ Tel: 0300 123 0994
  Email: Shropshire.Sexualhealth@nhs.net
- NHS: Spotting the Signs of Child Exploitation 2016 https://www.cppe.ac.uk/programmes/l/cse-e-01/
- CPPE Sexual Health learning module 2018 https://www.cppe.ac.uk/programmes/l/tlp-e-07/
- CPPE Dealing with Difficult Discussions 2018 https://www.cppe.ac.uk/programmes/l/diffdisc-e-01/
- CPPE Sexual Health in Pharmacies 2017 https://www.cppe.ac.uk/programmes/l/sexual-e-01/
- EHC and Chlamydia 2017 https://www.cppe.ac.uk/programmes/l/sexualech-w-01/

[19] Department of Health (2011). *You're Welcome: Quality Criteria for Young People Friendly Health Service* (http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126813)

- Chlamydia testing and treatment 2017 https://www.cppe.ac.uk/programmes/l/chlamydia-w-06
- Patient Group Directions 2018 https://www.cppe.ac.uk/programmes/l/ptgpdir-e-01/

For CPPE accreditations the Provider's pharmacist9s) must allow 'see all' on the CPPE website to enable audit training accreditation. If the Provider is a Group pharmacy it will have contracts and accreditation managed by their group managers.

Amnesty period for those holding up to date documents provided by other training organisations: -

Some pharmacists may have certificates that are current but relate to previous training organisations, or have been acquired in other areas. Providing these documents are still up to date pharmacists can provide this Service subject to a review of documentation by the Authority. Documents should be sent to the Authority's Public Health Department (see Contacts). Within six months of the Service Commencement Date the Provider must ensure that its pharmacist(s) complete the CPPE accredited requirements www.cppe.ac.uk

The Authority will:

- conduct an annual review of the Services to determine whether the needs of the local population are being met;
- arrange at least one Provider meeting per year to promote service development and update the knowledge of pharmacy Staff;
- provide details of relevant referral points which the Provider's Staff may use to signpost Service Users who require further assistance;
- disseminate information on the Service to other pharmacies and health care professionals in order that they may signpost Service Users to the Service; and
- ensure condom supplies are delivered in a timely manner

The Provider:

- must ensure all Activity is included in their professional indemnity cover

It is the Providers responsibility to ensure that it holds up to date training and records as appropriate on the CPPE accreditation.

The Authority may from time to time request evidence of training and accreditation and this must be provided by the Provider upon written request..

The Provider will ensure that all members of Staff are aware of the Service and full details will be made available to locum Staff to ensure continuity of provision of the Service. The Provider will introduce a Standard Operating Procedure (SOP). This must be made available to the Authority when requested.

4.2 Information Provision:

- Data must be recorded in full on PharmOutcomes modules registration and consultation as part of the Service User clinical record at the time of the consultation.

- All data must be auditable and payment is conditional on receipt of accurate and full data reports for all Service Users accessing the Services.
- Service User consent must be obtained
- Providing data returns to CDS operating team at Midland Partnership Foundation Trust as per current CDS operating procedures

- Data will be recorded and reported quarterly to allow:
    - Pseudonymised data for reporting local and National outcome measures
    - Any data entered after the 15th Day of quarter end for previous quarter reporting will not be taken into account for payment.
    - Audit of data for payment and outcome monitoring
    - Compliance with Data Protection Legislation
    - Follow up of Service Users where consent has been obtained by the Authority for
- Outcome monitoring
- Service User records must be securely stored and used strictly in accordance with the terms of this Contract.

Data collected must be accessible to the Authority to audit payments and report outcomes

5. Location of Provider Premises

The Provider's Premises are to be located within the administrative area of the Authority. The Provider shall provide the Authority with a written schedule of the location of each of the Premises from which the Services under this Lot are to be delivered **within one month** of the Service Commencement Date

The Service will take place at the location and Provider Premises specified within this Contract.

The Provider must:

- Notify the Authority of any planned changes to service locations.
- Ensure the Service is carried out in suitable premises with facilities for private consultations and in accordance with Covid-19 Safe Working Practices
- Ensure the design and layout of the Premises are suitable for carrying out the Service or Activity with appropriate measures being in place to ensure the security of the Premises.
- Ensure the Premises protect people's rights to privacy, dignity, choice, autonomy and safety.
- Ensure the Premises have space, heating, lighting and ventilation that conform to relevant and recognised standards.

- Ensure the Premises are accessible to people who need to enter the Premises and meet the appropriate requirements of the Equality Act.
- Ensures the Premises and any grounds are adequately maintained and complies with any legal requirements relating to the premises.
- Takes account of any relevant design, technical and operational standards and manages all risks in relation to the Premises.

6. Required Insurances

Public Liability Level of cover of a minimum of 5 MILLION POUNDS (£5,000,000.00)

Professional Liability Level of cover of a minimum of 5 MILLION POUNDS (£5,000,000.00)

Employers Liability Level of cover of a minimum of 5 MILLION POUNDS (£5,000,000.00)

Product Liability Level of cover 5 MILLION POUNDS (£5,000,000.00)

Medical Mal-practice Level of cover 5 Million Pounds (£5,000,000.00)

Insurances are required to be maintained for a minimum period of 6 years following termination/expiry of this Contract

7. QUALITY OUTCOME INDICATORS

QUALITY OUTCOMES DATA			
Outcome indicator	**Threshold**	**Method of measurement**	**Consequence of breach**
Number of 15-25 year olds registered to the CDS scheme by month	TBA in year 1	PharmOutcomes report	n/a
Number of 13-25year olds issued with condoms by month	TBA in Year 1	PharmOutcomes report	n/a
Number of condoms issued by participating pharmacy by month	TBA in Year 1	PharmOutcomes report	n/a

7.1 Monitoring and Review

7.1.1 The Provider shall ensure that the necessary documentation, as detailed in this Specification, is maintained and made available to the Authority to enable the Service to be monitored and for the purpose of post payment verification.

7.1.2 The Authority may undertake a visit to the Provider's participating Premises to inspect the provision of the Service and to ensure that the Provider is meeting this Specification.

7.1.3 The Authority will undertake an annual review of all Activity.

7.1.4 The Provider will be monitored on the following data which will be accessible to the Authority from PharmOutcomes on a quarterly basis.

Number of CDS registrations:

Number of CDS distributions.

Ages of service users.

Numbers of Smartkits distributed

7.1.5 **Use of PharmOutcomes**

The Provider shall ensure that all consultations are logged on PharmOutcomes to enable the Authority to monitor Activity and verify payments for Services provided on a quarterly basis.

8. SERVICE USER EXPERIENCE

All Service Users must be provided with a copy of, or a link to, a Service User satisfaction questionnaire within 4 weeks of attending the Service.

9. CHARGES

9.1 The service fee will comprise of the following component:

Payment Schedule

Activity	Price
Packs of condoms issued as part of local CDS programme for each 13-25 year old accessing the Service	1.00

9.2 **Claims for Payment**

9.2.1 Details of the consultation must be entered onto PharmOutcomes in a timely manner to meet claims deadlines.

9.2.2 Only under exceptional circumstances will paper claims be accepted.

9.2.3 No claim shall be submitted more than one month after the Expiry Date of this Contract.

9.2.4 This Provider will be paid on an Activity basis.

9.2.5 Payment for this Service will be made on a quarterly basis in arrears based on actual Activity.

9.2.6 Payment will be in accordance with the payment schedule set out above.

9.2.7 Only information submitted to and reported to the Authority by Pharmoutcomes will be eligible for payments.

9.2.8 Valid Invoices for payment must be submitted and sent to ali.cartwright@shropshire.gov.uk

Term of contract: Initial term: 1st May 2022 – 31st March 2023

All prices exclude VAT

Not included in the charges listed above;
The Provider will bear the costs of cleaning any in equipment and the consultation room providing the Service,

10 DISCHARGE FROM CARE

Service Users issued with a Chlamydia/Gonorrhoea Smartkit should be advised of where to access treatment services e.g. Pharmacies, GP practices, Sexual Health Services.

11. SERVICE QUALITY PERFORMANCE REPORT

Quantitative and qualitative information may be used to evaluate the Services.

Data will be collected through the PharmOutcomes clinical patient record system and should be held by the Provider according to the guidance issued by the Information Commissioner's Office in regard to the storage and handling of patient details and the terms of this Contract including Schedule 1 to this Specification (GDPR).

The Provider must submit details of complaints received on a quarterly basis throughout the duration of the Term of the Contract EXCEPT in circumstances where a complaint arises from a safeguarding issue or an issue that has a significant impact upon a Service User. In these circumstances, details of complaints received must be notified to the Authority as soon as practicably possible and in any event within 48 hours of receipt. . In all other circumstances complaints shall be dealt with in accordance with clause B.17 of this Contract.

For local data monitoring, to trigger payments and for quality monitoring purposes, quarterly submission of quantitative and qualitative data will be supplied to the Authority on a quarterly basis see **Section 7.2** Monitoring and review.

All information should be available for audit and quality reporting if required.

Qualitative information may also be gathered via informal patient feedback

12 REVIEW MEETINGS:
Reviews shall take place in accordance with section 7 above and in addition the Authority may undertake a visit to the Provider's participating Premises to inspect the provision of the Service and to ensure that the Provider is meeting this Specification.

13 NOTICE REQUIRED TO WITHDRAW DELIVERY OF THIS LOT

Either Party may serve the other with three months' prior written notice to terminate the provision of this Lot

Schedule 1 – Processing Personal Data and Data Subjects – Lot 7

1. The Provider shall comply with any further instructions with respect to processing by this Authority
2. Any such further instructions shall be incorporated into this Schedule

Description	Details
Subject matter of the processing	Processing of data collected in PharmOutcome record for Service Users receiving Sexual Health Services in community pharmacies e.g. Chlamydia treatment.
Duration of the processing	For the duration of this Contract
Nature and purposes of the processing	The nature of the processing shall include any operation such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction of date (whether or not by automated means) The purpose for the processing shall be: Data is collected via secure, web-based record management programme; PharmOutcomes to enable safe and secure reporting of data to the Authority Following Service User consent, Service User data captured at each consultation. Pseudonymised data returned to the Local Authority quarterly to enable payment, audit and management of contract and monitoring of service outcomes. Processing allows local and national level analysis and reporting on the effectiveness of commissioned services. Commissioning and monitoring of emergency contraception, testing and treatment of sexually transmitted infections is a mandatory Public Health function. Identifiable data may also be used should audits require and where it is of benefit to the healthcare of the individual.
Type of Personal Data	Collected by provider: Name, address, date of birth, NI number, telephone number, demographic data, relevant sexual health data including last monthly period, number of previous pregnancies, last time of sexual intercourse, current contraception and any allergies.
Categories of Data Subject	Service Users Aged 15years and over.

Plan for return and destruction of the data once the processing is complete UNLESS requirement under union or member state law to preserve that type of data	Plan will follow the Council's "Information and Records Management Standards". The records entered onto PharmOutcomes by providers remain the providers as it forms part of a clinical record for a healthcare professional/provider. This information is held by PharmOutcomes for as long as necessary and the current NHS guidelines indicate that this is 8 years (or 8 years after an individual passes their 16th birthday), unless the contract is terminated prior to the end of that period

Part C – Lots10 - 12 – Drug & Alcohol Recovery Services

Lot 10

Service Specification No.	**PHARMACY: Needle and Syringe Programmes**
Service	**Pharmacy Needle and Syringe Programmes and associated harm reduction promotion.**
Authority Lead	**Jayne Randall / Ian Houghton Drug and Alcohol Strategic Commissioning Lead**
Provider Lead	
Period	**Initial Term: 1st May 2022 – 31st March 2023**
Date of Review	**March 2023**

Population Needs

1.1 Introduction

1.1.1 This Service Specification will provide open access community pharmacy Needle Syringe Programmes (**NSP**) to people who inject drugs (PWID) in Shropshire, whether they are permanent or temporarily resident in the area. People who inject drugs will require sterile injecting equipment, information and advice around changing lifestyles, minimising the complications associated with drug misuse and accessing resources within the Community.

1.1.2 The Service provided through this specification will form part of Shropshire's Drug and Alcohol Action Team overall approach to harm reduction.

1.1.3 The NSP service is for the provision of equipment to people aged 18 years and over, management of people under 18 should be referred to the appropriate Young People's Service

1.1.4 The provision of this Service shall be commissioned via a targeted approach via the local Drug & Alcohol Action team and based upon locally defined needs.

1.2 National/Local Context

1.2.1 Local Authorities are responsible for the commissioning of drug and alcohol services to meet the needs of their population. All services should be recovery focused, be ambitious for their service users and support people to recover.

1.2.2 It is recognised that not all drug and/or alcohol users are at a stage when this is an option for them. A harm reduction approach does not seek to support a drug using lifestyle but, takes a non-judgmental approach to engage and build relationships with people who are placing themselves and others at potential risk.

1.2.3 It uses a broad range of approaches which include:

- Actions to the risk of reduce drug related deaths
- Overdose awareness training
- Access to Hepatitis and HIV testing
- Access to Hepatitis A/B inoculation
- Provision of a range of sterile injecting equipment and paraphernalia
- Provision of safer injecting information and other health promotion information
- Sexual health information and condoms to prevent blood borne viruses transmitted by sexual partners
- Building trusting relationships aiming to motivate drug users towards seeking help with drugs and/or alcohol dependence.

1.2.4 All services within the Treatment System are mindful of the potential need to reinforce Harm Reduction at any part of person's treatment journey.

1.2.5 NSP delivery is based on the philosophy of providing injecting drug users with sterile hypodermic needles and associated injection equipment at no cost. The aim of these services is to reduce the damage associated with using unsterile or contaminated injecting equipment.

1.3 Local Need

A service review completed in July 2015 *"Service Review of Pharmacy-based Needle Exchange Programmes Shropshire County 2009/10 – 2013/14"* found the following:

- In 2011/12, the estimated pervalence rate of injecting opiate and crack users in Shropshire was 1.86 per 1000, this represented an estimated 361 injecting opiate and crack.
- In 2013/14 approximately 28% of service users in structured treatment were currently injecting (204). The approximate crude rate of currently injecting drug users who were in treatment in Shropshire was 0.83 per 1000 of the resident population in 2013/14.
- There were 11 pharmacies providing a Level 1 Needle Exchange Service in Shropshire in 2013/14.
- Geographically these pharmcies are dispersed across the county.
- With the exception of Market Drayton, postal districts with higher or middle level concentrations of currently injecting drug users who are known to treatment contain at least one pharmacy providing needle exchange services.
- There were no pharmacies offering needle exchange services in Bishop's Castle, Church Stretton and Craven Arms in 2013/14.

- In 2012/13 an estimated total of 747 clients accessed needle exchange services from pharmacies across Shropshire obtaining an estimated 10.88 needle exchange packs per client.
- In 2013/14 a total of 6,168 needle exchange packs were given out in Shropshire, representing a total of 61,680 syringes.
- 1,318 disposal bins were returned to pharmacies making the county's overall bin return rate 21%.
- In 2013/14, pharmacies in Ludlow and Oswestry had the best bin return rates in Shropshire, of 88% and 77% respectively.
- In 2013/14, pharmacies in Albrighton, Wem, and Bridgnorth all had return rates of 0%
- Between 2009/10 and 2012/13, the proportion of red and blue packs (designed for injecting heroin users) given out in Shropshire has remained fairly steady although showing a slight decline.
- The proportion of total packs given out which were yellow (and designed for injecting performance enhancing drugs such as steriod) has increased from 1% to 8% over five years.

1.4 Evidence Base

1.4.1 Models of Care for Drug Misusers, Department of Health
1.4.2 Drug Misuse and Dependence- Guidelines on Clinical Management, Department of Health (2007)
1.4.3 Home Office (2010) Drug Strategy 2010 Reducing Demand, Restricting Supply, Building Recovery: Supporting People to live a drug-free life'
1.4.4 National Treatment Agency 2008: Good Practice in Harm Reduction, Drug Strategy 'Reducing Demand, Restricting Supply, Building Recovery: Supporting People to live a drug-free life'
1.4.5 NICE Guidance PH4 – Interventions to reduce substance misuse among vulnerable Young People (Mar 2007)
1.4.6 NICE Clinical Guidance 51 – Drug Misuse Psychosocial Interventions (Jul 2007)
1.4.7 NICE Guidance PH18 – Needle Exchange and Syringe Programme (Feb 2009)
1.4.8 NICE Guidance PH24 – Alcohol-Use Disorder – Preventing harmful drinking (Nov 2010)
1.4.9 Department of Health 2010 - Healthy lives, healthy people: our strategy for public health in England
1.4.10 National Treatment Agency 2010 – Building Recovery in Communities
1.4.11 NICE quality standards 23 – Quality Standard for drug use disorders, 2012

2. Key Service Outcomes

The overall aim of treatment is to provide a person centred approach to drug and alcohol users and their families to support and promote recovery. All Service Users should have access to appropriate support and recovery focused interventions irrespective of their background and are actively supported to improve their health, social circumstances, and wellbeing by the provision of individually tailored care packages. As part of the ongoing development of treatment services drug and alcohol users and their carers will be given the opportunity and support to provide feedback into the commissioning and delivery of service provision. It is anticipated that through these services the following outcomes can be achieved:

- Reduction in the levels of harm to self and families

- Service user quality measures to improve outcomes
- Improved support mechanisms
- Reduce the health and social harms associated with injecting drug use
- Contribute to a reduction in discarded injecting equipment and paraphernalia and associated risks to public health.
- Facilitate access to specialist drug treatment services and generic health services to injecting drug users who may be socially excluded.
- To increase levels of controlled substance misuse or abstinence as appropriate

2.1 <u>Delivery of Substance Misuse interventions for complex clients:</u>

Delivery of treatment should be based on a care planned process of engagement, retention, planned endings and recovery. Delivery of the Services should be in accordance with good practice and an appropriate evidence base for delivery. Treatment should include seamless and continual care across all service provision. The Service should be provided in accordance with:

- Department of Health and National Treatment Agency Guidance
- DH/NHS Clinical Governance and Supervision regimes and agreements
- DH Standards for better Health (2004)
- BACP standards and accreditation purposes
- Drug Misuse and Dependence- Guidelines on Clinical Management, Department of Health

2.2 Outcomes should contribute to an:

- Increase in positive health, social and psychological outcomes
- Improved rate of successful outcomes
- Reduced levels of harm to self and families
- Reduction in offending and/or antisocial behaviour

3.Scope

3. <u>Aims and objectives of service:</u>

3.1.1 Reduce the need for people who inject drugs to share non-sterile equipment.

3.1.2 Reduce the potential harm related to blood borne virus transmission and bacterial infection amongst Service Users who inject drugs, through the provision of sterile injecting equipment.

3.1.3 Provide a pharmacy based NSP which is an easy to access and user-friendly service and which respects the confidentiality of the injecting drug user.

3.1.4 Encourage people who inject drugs to return used equipment for safe disposal.

3.1.5 Assist people who inject drugs to remain healthy until they are ready and willing to cease injecting through the provision of accurate, current and non-judgemental health advice and information. This shall include handing out written information where appropriate.

3.1.6 Minimise the risk of exposure to members of the public from contaminated needles and syringes by offering a safe used needle disposal point.

3.1.7 Proactively signpost people who inject drugs to Shropshire Recovery Partnership who can provide wider services including a broader range of injecting paraphernalia, wound checking, the promotion of safer injecting or alternative drug taking practices, blood borne virus testing and inoculation to reduce the risk of blood borne virus infection and access to overdose awareness and basic first aid training.

3.1.8 Proactively signpost people who inject drugs direct to a drug treatment service if they are ready to receive that level of intervention.

3.1.9 Provide accurate, up-to-date and non-judgemental health advice relevant to people who inject drugs.

3.1.10 Encourage multi-disciplinary working and collaboration in the provision of services within the community for drug users.

3.2 Service description/pathway

3.2.1 The community pharmacy NSP shall offer a confidential service to Service Users who inject drugs for the provision and return of injecting equipment. Pharmacies across the Shropshire (participating in the scheme), will work together to reduce the practice of sharing equipment amongst drug users.

3.2.2 Pharmacies shall provide people who inject drugs:

- the provision of sterile injecting equipment
- information and advice around changing lifestyles
- basic information on minimising the complications associated with drug misuse
- signposting information on how to access drug and alcohol open access or treatment services within the community

3.3 People Who Inject Drugs

3.3.1 The Service shall be offered as open access, low threshold services which operate during the Provider's normal opening hours.

3.3.2 The Service shall only be available to people who inject drugs over the age of 18.

3.3.3 The Service shall be strictly confidential. Service Users must be guaranteed that their dealings with the Service will at all times be kept confidential. A basic data set as detailed on the Registration Card shall be collected. Some of the information requested on the initial visit will be anonymised and shared with Shropshire Public Health Commissioner to help plan services to meet local need.

3.3.4 Service Users shall be treated with courtesy and respect, as would be the case for any other individuals within the Provider's pharmacy, and be afforded privacy when using the Service.

3.3.5 The Provider shall ensure that its Staff shall be friendly and supportive and have an understanding and professional attitude.

3.3.6 Whilst every effort should be made to engage with Service Users the Provider has the right to refuse or exclude service users at any time during the Service take up where behaviour is unacceptable in accordance with the provisions of clause B2 of this Contract.

3.3.7 There may be times when the Provider feels it is necessary to exclude Service Users from its participating Premises which would prevent Service Users accessing the NSP. This could include incidents of crime and anti-social behaviour by the Service User such as:

- Shoplifting or attempted shoplifting
- accidents and injuries
- Acts of violence towards staff or customers
- Verbal abuse including threats of violence
- Incidents of serious intoxication

3.4 It may be that the Provider no longer wishes to provide a NSP to a particular service user. In the first instance it is expected the Provider would give a verbal warning. If the incident is severe or a repeat incidents, a written warnings could be issued or a banning order. It is expected that a Service User will only be banned as a last resort when previous warnings have not been adhered to. In this case the Service User will need to be referred to another service that provides NSP services. Banning orders can have particularly negative consequences in more rural areas as there may not be another NSP operating within a reasonable travelling distance

3.4.1 If a Provider excludes or refuses to work with a Service User, the Provider must advise the service user of alternative NSPs and inform Shropshire Recovery Partnership of the Service User's registration number

3.5 <u>Working with Young People (under 18 years)</u>

3.5.1 The Services are not appropriate for the provision of NSP services for young people under the age of 18 years. The course of action for a young person presenting to a pharmacy NSP will be as follows:

3.5.2 The Provider should request proof of the young person's age before making a decision as to whether or not it should provide injecting equipment;

3.5.3 If the young person is under 18 years of age it is the Provider's responsibility to advise the young person that he/she can access a Needle Syringe Programme within specialist services and provide details and/or refer the young person to Young Addaction (the Young People's Substance Misuse Service).

3.5.4 Where there are any concerns in relation to safeguarding the Provider should where possible discuss concerns with the young person and follow the procedures set out by the Shropshire Safeguarding Children's Board

3.6 Giving Advice and Information

3.6.1 The Provider shall ensure that its employees take every opportunity to engage with Service Users and provide advice/information on general health promotion such as diet, health, exercise, smoking reduction and oral hygiene where opportunities permit.

3.6.2 Healthcare and treatment advice leaflets shall be readily available to all.

3.6.3 Signposting - as relationships of trust develop with Service Users, opportunities should be taken by the Provider to promote the contact telephone numbers of specialist drug and alcohol services, information and advice services and alternative NSP facilities.

3.7 Training and Staff Requirements

3.7.1 The Provider and its employees providing the Service shall be competent and have knowledge on the range of drugs injected, including heroin, cocaine, crack cocaine, amphetamines and steroids and in particular the local drug and alcohol service to signpost Service Users to.

3.7.2 Locum Pharmacists - All locum pharmacists engaged by the Provider must be made aware that the NSP operates within its Premises and that the Standard Operating Procedure (SOP) must be adhered to.

3.7.3 All Provider Staff delivering the Service shall be offered the initial induction training and shall be encouraged to attend the additional local training workshops organised jointly by the Authority throughout the year.

3.8 Pharmacy Induction

3.8.1 From the Commencement Date, the Provider shall receive an initial visit from a representative of the Authority (whose details shall be notified to the Provider in advance) to advise on setting up the Service and to give practical advice on how the NSP transaction can take place within a pharmacy setting.

3.8.2 An on-site induction will be arranged to ensure that the Provider's employees involved in the scheme are suitably trained in:

- The scheme context
- The ethics and principles of a NSP, blood borne virus awareness and basic awareness about substance use
- Service operation - carrying out the transaction and recording Activity.
- Confidentiality
- Safety and risk management precautions within the Provider's Premises to ensure the prevention of injury to Staff and members of the public:
- Dealing with spillage and contamination with potentially infected blood or body fluids.
- Processes of what to do in the event of needle stick injury
- Reporting of incidents/accidents

- Handling Conflict; dealing with difficult situations; what action to carry out if a Service User becomes threatening
- Safeguarding children and vulnerable adults (reference to other training)
- Signposting to specialist services available in the area
- Expected action in an overdose situation – administer basic first aid, if available administer naloxone and put service user into recovery position dial 999 for ambulance.

3.8.3 This will be complemented with onsite training as agreed with the Provider. The Provider shall be required to ensure that cascading of the training shall take place for Staff who are unable to attend training sessions.

3.9 Training Requirements

3.9.1 Locum Pharmacists - All locum pharmacists engaged by the Provider must be made aware that the NSP operates within its Premises and that the Standard Operating Procedure (SOP) must be adhered to.

3.9.2 All Provider Staff delivering the Service shall be offered the initial induction training and shall be encouraged to attend the additional local training workshops organised jointly by the Authority throughout the year

3.10 Hepatitis B Vaccination of Staff

3.10.1 All of the Provider's employees shall be encouraged to access a Hepatitis B vaccination if they are not currently vaccinated.

3.11 Premises, Equipment and Stock

3.11.1 The Provider's Premises will need to have a suitable area set aside for storage of stock and returned items.

3.11.2 The Provider's Premises layout will allow for discreet requests for packs and well as for returns of used needles, syringes and other injecting paraphernalia.

3.12 Product Details (Injecting Equipment packs)

3.12.1 The Services shall provide for sterile injecting equipment to be made available to Service Users in the form of the following pre-packed packs:

Label	Purpose	Contents
Red Pack	For heroin injecting	10x 1ml fixed needle/syringe 10x sachet of citric acid 10x Spoon and filter 1x Sharp safe Exchange Container
Blue Pack	For long time users, has longer needles to reach deeper veins	10x 2ml syringe 10x (0.5 x 25mm) needle 10x sachet of citric acid

		10x spoon and filter 1x Sharp safe Exchange Container
Yellow pack	Designed for image and performance enhancing drug users	10x 2.5 ml syringe 10x (0.8 x 40mm) needle 10x (0.6 x 30mm) needle 1x Sharp safe Exchange Container
Emergency/Green pack	Issued when service user needs equipment but has no needles to return	5x 1ml fixed needle/syringe 5x sachet of citric acid 5x Spoon and filter 1x Sharp safe Exchange Container

3.13 Carrying Out the Transaction

3.13.1 In practice, the transaction is simple and generally takes only a few minutes. Where a Service User presents to the Service for the first time, a simple registration process shall be undertaken using the Registration form on PharmOutcomes.

3.13.2 When Service Users access the Services they shall state their initial and the Provider shall carry out the following:

- Oversee and guide the Service User to place any returned 'used' equipment into the Pharmacy Yellow Sharps Container.
- Identify the pack(s) Service User requires (e.g. Red, Blue, Yellow, and Emergency).
- Enter the details of each transaction onto PharmOutcomes

3.13.3 An appropriate number of the most suitable packs are to be issued depending on the needs of the individual. According to local statistical monitoring as an average, most service users in practice tend to only request one or two packs per visit. However, there may be occasions where a service user may be collecting and distributing for friends/other members of the family and request more packs. It would be expected that equivalent numbers of the black personal sharps containers would be returned on follow up visits
https://www.nice.org.uk/guidance/PH52

3.14 Pharmacy Sharps Bins Waste Collection Disposal of injecting equipment

3.14.1 The Provider shall obtain Pharmacy Yellow Sharps Containers which are available from the Supplier and shall be ordered along with the NSP Packs. The Provider shall make the Yellow Sharps Containers available for the return of the individual sharps containers issued within the NSP Packs.

3.14.2 The Yellow Sharps Container shall be sited in a designated area of the Provider's Premises (usually agreed on the initial visit), where the Provider's employees and members of the public will not have inadvertent contact with it.

3.14.3 A 60ltr porthole clinical waste container will be supplied and removed when full by the Supplier. Smaller clinical waste containers may be supplied upon request.

3.14.4 The Supplier shall attend each of the Provider's participating Premises to assess and agree a schedule for the pickup of clinical waste. The Provider shall provide the Authority with a full understanding of the waste being produced at each of its Premises so that guidance and training on the correct product and its usage may be given.

3.14.5 The Supplier shall provide the Provider with guidance notes, and information with respect to each of the Provider's participating Premises to assist with any waste issues that may arise. In addition the Supplier shall also provide the Provider with a single point of contact to help with any waste issues or enquires.

3.14.6 The Supplier shall supply the clinical waste containers direct to each participating Premises of the Provider to ensure there is always an empty container for use.

3.14.7 Where not currently registered, each of the Provider's Premises that produces waste must complete a waste pre-acceptance audit. This audit may be completed using the following link, www.srcl-audit.com.

3.14.8 Any changes to the frequency of collections must be authorised by the Authority who shall be notified of any required increase/decrease needed.

3.15 Policy on Returning Used Equipment

3.15.1 Service Users should be advised about the risks to themselves and others which are posed by used syringes and needles. This particularly includes risks to children and young people. The Service User should be proactively encouraged to return used equipment in a properly sealed sharps container (provided within each NSP Pack) for safe disposal in the Provider's Premises. The recommendation is at "every visit".

3.15.2 Service Users shall not be refused a NSP Pack if they do not return used equipment. The Provider shall discuss the Returns Policy with the Service Users reminding them of the need to return used equipment and issue them with an emergency pack.

3.15.3 Where Service Users repeatedly fail to return used equipment, the Provider shall use its discretion subject to the recommendations in the NICE Public Health Guidance 18 for NSP to giving only one pack of injecting equipment for use, until the Service User starts returning equipment for safe disposal on a regular basis.

3.15.4 The Provider shall ensure that the Service User is instructed and directed to place their used equipment in the Yellow Sharps Container themselves. No employee of the Provider shall be expected to handle returned sharps.

3.16 Ordering, Stock Maintenance and Stock Control

3.16.1 The Provider shall be responsible for ordering directly from Supplier. The Supplier will then invoice the Authority directly.

3.16.2 Supplies of NSP packs may be ordered at the Provider's discretion based on the amount of storage space it has available at its Premises.

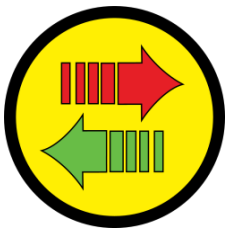
3.17 Pack delivery

3.17.1 The Provider shall oversee the collection of the clinical waste bins and shall ensure that only full bins are taken by the Supplier.

3.17.2 A schedule will be agreed with the Provider as to how often the collection visits are to be made by the Supplier. Quantity and frequency of returned equipment and available space in the Provider's participating Premises will be taken into consideration when agreeing the schedule. The Authority will agree the collection schedule with the Supplier following consultation with the Provider.

3.18 Promotion and Advertising of the Service

3.18.1 The Provider shall ensure that each of its participating Premises in the Service shall be readily identifiable to Service Users by displaying the nationally recognised window and/or wall sticker shown below:



3.18.2 The window/wall sticker will be provided by the relevant Public Health Programme Lead and further copies may be supplied to the Provider upon request.

3.18.3 The Provider may be required to display other service linked advertising at the discretion of the Authority and/or Harm Reduction Co-ordinators

3.19 Links with other Harm Reduction Services

3.19.1 The Provider shall ensure it maintains links with other Harm Reduction Services in their area to enable Service Users to access complementary Level 2 services / Central NSP who can provide more specialist harm reduction advice (such as safer injecting practices, access to Hepatitis B vaccination and Overdose Awareness Training and further equipment or the Pick and Mix service currently operating out of Crown House (Shrewsbury).

3.20 Responsibilities of the Pharmacy Contractor

3.20.1 The Provider shall offer a user-friendly, non-judgmental, person centred and confidential service.

3.20.2 The Provider shall provide support and advice to Service Users, including signposting to primary care or specialist drug and alcohol services where appropriate

3.20.3 The Provider shall comply with the Authority's Drug and Alcohol Action Team's strategies on:

- Reduction of Drug Related Deaths
- Harm Reduction
- Workforce Training

3.20.4 The Provider may on occasions be required by the Authority to take part in surveys, research or initiatives relevant to improving the accessibility, quality and effectiveness of the Services, and to distribute questionnaires to Service Users and when requested to take part in these activities, shall co-operate fully with the Authority

3.20.5 The Provider shall ensure that it has internet access in place at all times at its participating Premises and shall use PharmOutcomes to fully record all consultations and Activity and claims for payment with respect to the Service.

3.21 Service Specification Review

3.21.1 It is recognised within this Specification that the Service may be subject to change due to a range of national and local policy initiatives, such as but not by way of limitation, government guidance and legislation, industry professional standards, NICE Guidance, Public Health England or Shropshire Council Policy.

3.21.2 This Specification shall be reviewed annually and updated to reflect any changes in legislation. Adequate notice will be given to the Provider of any significant changes which may impact on the Service provided and will ensure sufficient transitional arrangements are secured to ensure Service continuity.

3.21.3 It is the responsibility of the Provider to ensure the Service achieves the following:

- Compliance with any other relevant national and local policies and guidance.
- Compliance with relevant NICE guidance.

3.22 Community Pharmacy Contractual Framework

3.22.1 The Provider must remain compliant with all the essential services under the Community Pharmacy Contractual Framework as part of this Contract.

3.22.2 No part of this Specification by commission, omission or implication defines or redefines essential or advanced services.

3.22.3 The Provider has a duty to ensure that pharmacists and dispensing staff involved in the provision of the Service have relevant knowledge and are appropriately trained and competent in the operation of the Service.

3.22.4 Providers should be familiar with the NICE guidance needle and syringe programmes and be working in compliance with this guidance at all times.

4. Applicable Service Standards

4.1 Training

The provider should ensure the completion of CPPE Declaration of Competence for Needle and Syringe service every 3 years.

Attend the Drug and Alcohol Action Team (DAAT) pharmacy updates and training meetings at least once a year.

It is the responsibility of the Provider to ensure the Service achieves the following:

- Compliance with any other relevant national and local policies and guidance.
- Compliance with relevant NICE guidance.

4.1.1 Requirements for qualification as providers

- The Provider has a duty to ensure that pharmacists and dispensing staff involved in the provision of the Service have relevant knowledge and are appropriately trained and competent in the operation of the Service.
- Providers should be familiar with the NICE guidance needle and syringe programmes and be working in compliance with this guidance at all times.

The Provider shall;

4.1.2 Review its Standard Operating Procedures and the local referral pathways for the Service on an annual basis.

4.1.3 Demonstrate that all pharmacists and employees involved in the provision of the Service have successful completion of CPD relevant to the provision of this Service.

4.1.4 National Standards

The Service should be provided in accordance with the following national standards and good practice guidance:

- Department of Health and National Treatment Agency Guidance
- DH/NHS Clinical Governance and Supervision regimes and agreements
- DH Standards for better Health (2004)
- BACP standards and accreditation purposes
- Drug Misuse and Dependence- Guidelines on Clinical Management, Department of Health

4.2 Information Provision

4.2.1 The Provider shall use the PharmOutcomes on-line platform to record and provide accurate information.

4.2.2 The Provider shall ensure that all consultations are logged on PharmOutcomes to enable the Authority to monitor Activity and verify payments for Services provided

4.2.3 If the Provider cannot enter the information onto PharmOutcomes at the time of the time of the consultation, the information shall be recorded on a photocopied Monthly Activity Sheet and entered onto PharmOutcomes as soon as possible after the consultation.

4.2.4 The Provider shall submit requests for payment in line with the Authority's requirements as set out in this Contract.

4.2.5 Participate in any audit of the Service provision within the terms of the contract.

4.2.6 Co-operate with any locally agreed assessment of Service User experience.

4.2.7 Demonstrate that clear and accurate records are kept.

5 Location of Services

5.1. Premises and equipment

The Provider shall ensure the Premises used for the provision of the service are located within the administrative area of the Authority and are sufficient to meet the reasonable needs of all Service Users and comply with Covid-19 Safe Working Practices. The Provider shall supply the Authority with a written schedule of the location of each of the Premises from which it delivers the Services under this Lot **within one month** of the Service Commencement Date

Pharmacist must provide the following:

- Appropriate consultation area that meets the national standard
- An area for display of relevant material.

6 Required Insurance

Public Liability Level of cover of a minimum of 5 MILLION POUNDS (£5,000,000.00)

Professional Liability Level of cover of a minimum of 5 MILLION POUNDS (£5,000,000.00)

Employers Liability Level of cover of a minimum of 5 MILLION POUNDS (£5,000,000.00)

Product Liability Level of cover 5 MILLION POUNDS (£5,000,000.00)

Medical Mal-practice Level of cover 5 Million Pounds (£5,000,000.00)

Insurances are required to be maintained for a minimum period of 6 years following termination/expiry of this Contract

7 Quality Outcome Indicators

7.1 During the duration of this Contract, the Provider will work with the Authority to achieve the quality outcomes below

Quality Outcome Indicators

Schedule Two Performance Requirements

Quality Indicator	Threshold (first Year)	Target	Measurement	Consequence of Breach
%Needle Bin Returns	40%	Working towards a minimum of 80%	Quarterly	Improvement action plan
% of people registered on Pharmoutcomes	40%	Working towards 100%	Quarterly	Improvement action plan
% service users signposted/referred for BBV testing	100%		Quarterly	Improvement action plan

7.3 Monitoring and Review

7.3.1 The Provider shall ensure that the necessary documentation, as detailed in this Service specification, is maintained and made available to the Authority to enable the Service to be monitored and for the purpose of post payment verification.

7.3.2 The Authority may undertake a visit to the Provider's participating Premises to inspect the provision of the Service and to ensure that the Provider is meeting this Specification.

7.3.3 The Authority will undertake an annual review.

8 SERVICE USER EXPERIENCE/STAFF, SERVICE USER AND CARER SURVEYS

All Service Users must be provided with a copy of, or a link to, a Service User satisfaction questionnaire within 4 weeks of attending the Service. In addition:

8.1 Referrals for specialist harm reduction interventions

8.1.1 Wherever possible and appropriate it will be the responsibility of the Provider to facilitate onward referrals into the integrated drug and alcohol treatment system when specialist interventions, beyond the usual scope of the NSP provision, are required. This could include care required around safer injecting practices, especially around high risk injectors, for example neck or femoral injectors, or venepuncture skills and wound management. The integrated treatment system delivers interventions that specifically aim to prevent diseases in service users due to Blood Borne Virus (BBV), and also provide:

8.1.2 Advice, information, and counselling as appropriate, for hepatitis B, C, and HIV testing (pre and post-test).

8.1.3 Testing for BBV including Hepatitis B and C and HIV screening.

8.1.4 Hepatitis B vaccinations - encourage users to complete the full course and regularly audit uptake.

8.1.5 Referrals into treatment for Hepatitis B, C, HIV, and sexually transmitted infection.

8.1.6 Referrals for these interventions should not only be opportunistic, they should be actively and regularly promoted to all Service Users and access should be facilitated by the Provider. Care pathways will be developed into the specialist treatment provider so that Service Users are able to access the above BBV interventions. Some Service Users who access the Service

will have accessed structured treatment with the specialist treatment agency and will be offered this suite of interventions but as the Provider will potentially have more contact with Service Users than any other healthcare professionals the Provider will be expected to reinforce the harm reduction messages around testing and vaccination against BBVs. Should Service Users agree to testing and/or vaccination, the Provider will be responsible for making the referral.

8.2 The Service is not available to young people aged under 18 years of age.

8.3 Referrals to non-treatment services

8.3.1 Staff delivering NSP services should promote improving health as well as harm reduction including:

8.3.2 Recognising people with physical health problems or severe mental health problems and referring them to appropriate services.
Basic health examinations, including checks on injection sites, first aid, dealing with minor infections. If health problems are identified that cannot be dealt with in the participating pharmacy, the Service User should be supported to access other appropriate services, such as GPs, walk in centres and, where appropriate, A & E

8.3.3 Risk reduction advice and health promotion including contraception and safer sex, alcohol misuse and oral health. If risks or issues are identified onward referrals should be facilitated.

8.4 Referrals into structured treatment

8.4.1 The Provider will be required to actively encourage and support motivation for change and treatment readiness. Should a Service User state that they wish to be referred for treatment the Provider should support the Service User to contact the designated single point of contact within the community drug and alcohol treatment service (Crown House, Shrewsbury 01743 294700) for assessment.

8.5 Service User

Indicator	Threshold	Method of Measurement	Period of Activity Covered	Consequences of Breach (other than clause 32)
Number of complaints received	-	The Provider must submit details of complaints received on a quarterly basis throughout the duration of the Term of the Contract EXCEPT in circumstances where a complaint arises from a safeguarding	Term of contract	Provider to submit plan to address issue raised in complaints

		issue or an issue that has a significant impact upon a Service User. In these circumstances, details of complaints received must be notified to the Authority as soon as practicably possible and in any event within 48 hours of receipt.		

- *Staff will receive an annual training needs assessment/appraisal.*

9 Charges

9.1 Payment and Reimbursement

9.1.1 An annual retainer of £50.will be paid to each provider.

9.1.2 A fee of £1 will be paid to the Provider for each NSP Pack supplied except "Emergency" packs

9.1.3 A fee of £0.50 will be paid to the Provider for each "Emergency" pack supplied

9.1.4 Only one Emergency pack per Service User may be supplied per day

9.1.5 No other NSP packs may be supplied to the same Service User in the same day unless they have registered themselves with the NSP.

9.1.6 A fee of £0.50 will be paid to the Provider for each sharp bin that is disposed of.

9.1.7 A fee of £0.50 will be paid to the provider for the supply of one NSP single pack, a payment of £1.00 will be paid to the provider for the maximum supply of three packs in one day

9.2 Claims for Payment

9.2.1 Details of the consultation must be entered on to PharmOutcomes in a timely manner to meet claims deadlines.

9.2.2 No claim shall be submitted more than one month after the end of this Contract.

9.2.3 Claims for Activity more than 2 months old will not be paid.

9.2.4 The Provider will be paid on an Activity basis.

9.2.5 Payment for this Service will be made on a monthly basis, based on actual Activity. Payment to each Provider will be provided according to timely and complete data submitted to Pharmoutcomes in line with the requirements included in this service Specification.

9.2.6 Payment will be in accordance with the payment schedule set out above.

9.2.7 Only information submitted to and reported to commissioners by Pharmoutcomes will be eligible for payments.

9.2.8 Valid Invoices for payment must be submitted and sent to ian.houghton@shropshire.gov.uk

9.3 Funding

The Provider acknowledges that the Service is funded by the Authority. This Contract is contingent upon funding from government and the Authority can in no way warrant represent or guarantee the continuation of this funding. In the event that the government withdraws funding the Provider acknowledges that the Authority may terminate this Contract in whole or in part by serving reasonable written notice on the Provider

Initial Term of contract: 1st May 2022 – 31st March 2023

All prices include VAT

10. DISCHARGE FROM CARE PROTOCOLS

10.1 It may be that the Provider no longer wishes to provide a NSP to a particular service user. In the first instance it is expected the Provider would give a verbal warning. If the incident is severe or a repeat incidents, a written warnings could be issued or a banning order. It is expected that a Service User will only be banned as a last resort when previous warnings have not been adhered to. In this case the Service User will need to be referred to another service that provides NSP services. Banning orders can have particularly negative consequences in more rural areas as there may not be another NSP operating within a reasonable travelling distance

10.2 If a Provider excludes or refuses to work with a Service User, the Provider must advise the service user of alternative NSPs and inform Shropshire Recovery Partnership of the Service User's registration number

11. Service Quality Performance Report

11.1 Quantitative and qualitative information may be used to evaluate the service. Providers will be monitored on the number of packs distributed and returned used bins. 11.2 Data will be collected on the electronic/paper record form provided which should be held by the Provider according to the guidance issued by the Information Authority's Office in regard to the storage and handling of patient details. All monitoring data to be forwarded to Ian.Houghton, Public Health Department, Shropshire Council, Abbey Foregate, Shrewsbury SY2 6ND. Ian.houghton@shropshire.gov.uk Tele: 01743 253805 11.3 It is the responsibility of the Provider to ensure the Service achieves the following: • Compliance with any other relevant national and local policies and guidance. • Compliance with relevant NICE guidance. • All staff receive an annual training needs assessment and appraisal.
12 REVIEW MEETINGS: Reviews shall take place in accordance with section 7 above and in addition the Authority may undertake a visit to the Provider's participating Premises to inspect the provision of the Service and to ensure that the Provider is meeting this Specification.
13 NOTICE REQUIRED TO WITHDRAW DELIVERY OF THIS LOT
Either Party may serve the other with three months' prior written notice to terminate the provision of this Lot

Lot 11 - Supervised Consumption of Opioid Substitution Treatment

Service Specification No.	**Lot 11**
Service	**Supervised Consumption of Opioid Substitution Treatment**
Authority Lead	**Jayne Randall/Ian Houghton Drug and Alcohol Strategic Commissioning Lead**
Period	**Initial Term: 1st May 2022 – 31st March 2023**
Date of Review	**March 2023**

For the purposes of this Service Specification for Lot 11, the following additional definitions apply:

Children's Trust	Means, a partnership of agencies and representatives of young people and parents in Shropshire who work together to ensure all young people in Shropshire are kept healthy, safe and reach their potential.

Health Improvement	Means the area of Activity the drug and alcohol agenda sits under the Public Health Outcomes Framework to improve the health and wellbeing of individuals or communities by encouraging healthy life styles
"PharmOutcomes"	Web-based information system for Community Pharmacies
Premises	Means the premises described in section 5 where the Services are to be delivered by the Provider
Public Health Outcomes Framework	Means the national framework set out to measure progress of the public health system in England.
"Services"	Means the supervised consumption of prescribed medication services to be delivered further to this Specification and Lot 11
"Service Users"	Means individuals eligible to receive the Service being those persons who: Are aged 18 years or over; Are resident within the administrative area of the Authority and been • Prescribed methadone or buprenorphine by named GPs involved in local shared care services. • Prescribed methadone or buprenorphine by the specialist substance misuse service.
Shropshire Community Safety Partnership	Means the strategic Partnership of Local Authority, Health and Police organisations responsible for tackling Crime and Disorder within Shropshire
Shropshire Recovery Partnership	Means the current treatment service provider in Shropshire
Shropshire Safeguarding Children's Board	Means the strategic Partnership responsible for the safeguarding of children in Shropshire
Standard Operating Procedure	Means step by step guidance to help carry out Activity
Treatment System	Means the organisation(s) who support people with drug and alcohol dependency.

1. Population Needs

1.1 National Policy and Local Context

Underpinning local drug and alcohol services in Shropshire is the priorities and ambitions of the National Drug Strategy 2010, the Governments Alcohol Strategy 2012 and the Social Justice Strategy 2012 to move people from a state of dependency to that of sustainable recovery that goes beyond treatment to encompass wider factors and the broader determinants of health and well-being, including housing, training, education and employment.

Reducing drug and alcohol related harm is a priority for the Shropshire Safeguarding Community Partnership and is supported through the work of the Children's Trust, the Shropshire Clinical Commissioning Group, and other relevant strategic partnerships.

The local treatment system provides the first step in which people can start to move away from dependence and towards their recovery to improve their overall health and well-being. Based on meeting individual need, the local treatment system provides a range of psychosocial and pharmacological interventions to prevent harm and support recovery from drug and/or alcohol dependency.

Opioid substitute therapy (OST) is a pharmacological intervention for the treatment of opiate dependency and is recommended by the National Institute for Health and Care Excellence (NICE TA114). Provision of OST contributes to the delivery of the Public Health Outcomes Framework to increase life expectancy and reduce health inequalities through the successful completion of drug and alcohol treatment and reduction of drug related deaths.

The Provider has a key role in the provision of OST by supporting Service Users to adhere to their prescription regime through the supervised consumption of methadone or buprenorphine; therefore, reducing the risk of overdose and illicit drug use. Through supervised consumption the Provider also minimises the risk of diversion into the community, safeguarding children and vulnerable adults from potential overdose.
As part of its drive to transform public services the Authority is committed to achieving social value outcomes through maximising the social, economic and or environmental impact of all its procurement Activity in line with the Public Service (Social Value) Act 2012. Accordingly, it is expected delivery of Services in accordance with this Specification will contribute to providing social value benefits by reducing the harm associated with illicit drug use and improving the quality of life for individuals, families and the wider community affected by substance misuse.
http://www.shropshire.gov.uk/doing-business-with-shropshire-council/social-value/

1.2 Local Need

Drug Prevalence Rates
The administrative area of the Authority within Shropshire has one of the lowest prevalence rates of problem drug use in the West Midlands when compared against other Local Authorities in the region and is comparable with other rural counties such as Warwickshire, Worcestershire and Staffordshire. However, although rates are low the levels of complexity, pockets of entrenched behaviour, transport issues and limited opportunities within some market towns bring a number of challenges to service delivery. Many of the issues encountered are connected to historic relationships between Service Users, the family and extended family networks and intergenerational substance misuse.

Treatment Overview
Unlike the national trend Shropshire saw a 4% increase in opiate presentations in 2014/2015, a 16% growth in non-opiate and a 10% growth in non-opiate and alcohol presentations. Many of those in treatment tend to be older drug users and 34% of those in treatment have been there for six years or more.

A further6% of the treatment population have an over the counter or prescribed medication dependency with an additional 3% reporting illicit use of these substances.

2. Key Service Outcomes

2.1 The delivery of the Service will contribute to the **Health Improvement** domain from the Public Health Outcomes Framework (PHOF) domain:

2.15i Successful completion of drug treatment – opiate users.
2.15iv reduction in deaths from drug misuse

In addition the delivery of the Service will support delivery of the National Drug Strategy 2010 outcomes which are:

- Freedom from dependence on drugs and alcohol;
- Prevention of drug related deaths and blood borne virus;
- A reduction in crime and re-offending;
- To enable sustained employment;
- The ability to access and sustain suitable accommodation;
- Improvement in health and well-being of the Service User

3. Scope

3.1 Aims and objectives of the Service

The principle aim of the Service is to provide supervised consumption of methadone or buprenorphine to meet the clinical needs of the Service User as part of an agreed recovery treatment plan and to support the reduction of drug related harm.

Objectives

The Provider will:

- Dispense, in specified instalments, medication as prescribed (doses may be dispensed for the Service User to take away on days the Premises are not open provided that this is explicitly stated on the prescription in accordance with Home Office wording) methadone and buprenorphine OST to Service Users living in the administrative area of the Authority as part of a planned treatment intervention.
- Calculate any missed doses from the treatment start date (not dispensing date) and inform the prescribing service of any discrepancies. Where the Service User has missed 3 consecutive doses they will need to be referred back to the specialist prescribing services GP.
- Ensure each supervised dose of prescribed medication is correctly consumed by the Service User and ensure that the Service User is the person for whom the medication was intended.
- Reduce the risk to local communities by reducing:
    - the underuse or overuse of medication.
    - Diversion of prescribed medicines onto the illicit drug market.
    - Accidental exposure to the supervised medicines
- Provide Service Users with health advice to reduce substance misuse related harm and as appropriate refer them to specialist substance misuse treatment services, health services and or other services as necessary to meet their needs.
- Promptly notify the prescribing service/other health professionals as appropriate if an incident occurs.

The delivery of the Service is based on the following principles:

- To work within national and local guidelines
- To treat Service Users as individuals and accord them respect
- To empower Service Users to make informed choices
- To provide a confidential service

- To ensure that records are securely stored.

3.2 Service description/pathway

3.2.1 The Provider shall ensure the following applicable minimum local requirements for provision of this Service:

- The Premises are open for a minimum of 40 hours per week.
- Its staffing levels are appropriate to cover the delivery of the Service
- A wide variety of relevant health promotion materials are made available for Service Users and this is promoted.
- its Premises has standard operating procedures (SOP) and that this is reviewed on a bi-annual basis or following critical incidents.
- Locum pharmacists are made aware of the delivery of the Service and the operational procedures to be in a position to carry out the role safely.

The Provider will provide the Services as a way to promote equality of access across all community groups. Special consideration should be in place where:

- the first language is not English,
- the Service User may have literacy or numeracy problems

the Service User is restricted due to culture, religion, gender, age or personal circumstances which may preclude him/her from easily accessing the Service

3.2.2 Service Pathway

a) The Provider's pharmacist or staff member deemed appropriate by the pharmacist, shall supervise the consumption of methadone and buprenorphine at the point of dispensing in the Premises which can be for titration, stabilisation, reduction or maintenance (in accordance with the prescription issued by either the specialist treatment service or those GPs who are participating in the local drug shared care initiative) ensuring the dose has been appropriately administered to the Service User.

b) The Provider will offer a user friendly, non-judgemental, service user centred confidential service. Service Users shall be treated with the same degree of courtesy as would be afforded any other customer group within the Premises.

c) The Provider shall provide support and advice to the Service User including signposting to primary care or specialist services as appropriate.

d) The Service will be provided in conjunction with either the specialist drug treatment services or GP shared care service as part of programme to manage opiate dependency.

e) The service will form part of the overall treatment system and it is therefore expected the pharmacist will forge strong links with the community substance misuse service.

f) Effective communication between all parties is vital. The Provider will ensure they are aware of the contact details of the Service Users named recovery co-ordinator in addition to the prescriber of the medication.

g) A prescribed treatment agreement should be set up between the Provider and the Service User prior to dispensing any OST medications. This will include how the Service will operate, what constitutes acceptable behaviour and what action will be taken by the Provider if the Service User does not adhere to the prescribed treatment agreement.

h) Confidentiality issues and information sharing shall be addressed in the prescribed treatment agreement, which Service Users agree to abide by when they engage with the prescribing services. The Provider shall ensure its Staff are personally aware of the terms of the agreement used by their local prescribing services and that Service Users who attend their Premises are also aware and have a current prescribed treatment agreement in place.

i) Service Users will receive information about methadone and buprenorphine, risks of overdose, loss of tolerance following missed or uncollected doses, drug interactions, an explanation of supervised consumption, where and how it will occur and opening and closing times of the Premises.

j) Service Users will receive written and verbal information about the safe storage of medicines and instructions to reduce the incidence of accidental exposure to medicines.

k) The Provider will:

- Ensure adherence to an agreed recovery plan by dispensing prescribed medication in line with the prescriber's directions specified on the prescription.
- Methadone – the Provider's pharmacist must be satisfied the dose has actually been swallowed by the Service User, for example, by water being swallowed after the dose or conversing with the Service User to ensure that the methadone is not retained in the mouth.
- Buprenorphine – the Service User must be supervised until the tablets have dissolved. The Service User's mouth must be checked before, during and after administration.
- will provide water (if required) to service users. This will be in single use, disposable cups.
- Ensure each supervised dose of medication is correctly administered to the Service User for whom it was intended (doses may be dispensed for the Service User to take away to cover days when the Premises are closed if specified on the prescription in line with Home Office policy wording).
- Liaise with the prescriber service, named recovery co-ordinator and others directly involved in the care of the Service User (where the Service User has given written permission).
- Monitor the Service User's response to prescribed treatment, for example if there are signs of overdose, especially at times when:
  - doses are changed,
  - during titration of doses,
- if the Service User appears intoxicated or when the Service User has missed doses, may, if necessary, withhold treatment if this appears to be in the interest of Service User safety and will liaise with the prescriber as appropriate.

3.2.3 Accepting new Service Users into the Service

- The prescriber/recovery co-ordinator will ask the Service User which of the Provider's participating Premises would be most convenient for daily visits and at what times.

- The prescribing service will contact the Provider before issuing the first prescription to ensure that the Provider has the capacity to accept the Service User at the Premises nominated by the Service User at the relevant time.
- The Provider's pharmacist will be responsible for verifying the Service User's identity and the Provider will not be under any obligation to provide the Service if the Service User's identity cannot be verified.
- All prescriptions will have the agreed dispensing pharmacy Premises printed on the prescription.
- The Service User will attend the named Premises with their prescription for supervised methadone or buprenorphine consumption as agreed with the prescribing service
- Service Users will be informed by the Provider in advance of what arrangements will be made for when the Premises are closed.

In addition, the Service User should be given a leaflet detailing additional services offered by the Provider to support healthy lifestyles. Health promotion is an important issue for the Service Users and the Provider is required to take every opportunity to give advice on diet, exercise and oral hygiene.

3.2.4 Identification of Service Users

- The Service User's identity must be checked to ensure the prescription being dispensed is dispensed to the correct person.
- If the Provider or any of its Staff has any uncertainty about the identity of the Service User, the prescriber/recovery co-ordinator must be contacted and the dose withheld until the individual's identity can be ascertained.

3.2.5 Missed Doses

- Missed doses may result in a drop in opiate tolerance with an increased risk of accidental overdose.
- All missed doses should be reported to the prescribing service as promptly as possible.
- To prevent Service Users from having their prescriptions stopped, the Provider's staff must alert the prescribing service by 11am on the day after the second missed dose
- Where three consecutive doses have been missed, the Service User will need to be reviewed by the prescriber prior to any medication being dispensed and the Service User may be required to restart treatment. The Provider shall ensure that where three consecutive missed doses occur, timely referrals are made to the prescriber for review.

3.2.6 Business Continuity

The Provider is responsible for ensuring that adequate arrangements are in place for continuity of the Service in the event of staffing shortages, facilities and system failures appropriate to the Service.

3.2.7 Contradictions and exclusions

Service Users have the right to choose which of the Provider's Premises they have a prescription dispensed/receive the Services from.

Dispensing supply of medication and the delivery of the Service can be refused by the Provider in certain circumstances as defined by the NHS terms of service and where the Provider or its Staff believes

- a prescription is not genuine or for the person named on the prescription form.
- the prescriber has made a clinical error or that the prescription is clinically inappropriate for the Service User concerned.
- the Service User, or anyone with them, behaves or threatens to behave, violently or commits, or threatens to commit, any criminal offence (in the Premises).

Service Users may be excluded from receiving their prescribed dose as a result of professional judgement by the Provider's pharmacist on occasions where they:

- have missed collecting their prescribed medications for a specified number of instalments and their tolerance to the drug may have been reduced.
- appear intoxicated
- are showing signs of overdose.

In the case of overdose, the Provider's pharmacist should:

i) administer naloxone,
ii) put the Service User in the recovery position and call the emergency services.

The Provider should inform the prescribing service at the earliest opportunity of the incident.

For any other reasons the prescriber or recovery co-ordinator should be informed the named individual has not received their medication and the reason why. The Service User should be directed to the specialist service to ensure continuity of care.

3.3 Criteria for participation in the Services

3.3.1 Accreditation

The accountable person for this Service is the Provider's regular pharmacist/pharmacy manager.
The Provider must ensure all Staff are managed and appropriately supported to be able to undertake their duties competently and efficiently.
The Provider's pharmacist involved in the delivery of this Service must have successfully completed or plan to complete within six months of registering to join the scheme:

- the open learning programme for 'Substance use and misuse' (2nd edition, May 2012) available from the Centre for Pharmacy Postgraduate Education (CPPE) and the CPPE e-assessment 'Substance use and misuse – delivering pharmacy services (2009) and then self-certify as required
- CPPE Consultation Skills (2009) and then self-certify as required.
- Attend an annual training and update session provided by the community drug and alcohol services.
- Undertake CPPE Safeguarding Children and Vulnerable Adults (Oct 2012) every three years.

All can be accessed via www.cppe.man.ac.uk

3.3.2 Expectations:

The Provider must ensure:

- Compliance with all legal and professional requirements.
- Appropriate insurance cover is in place,
- The Standard operating procedure is adhered to by all of its Staff
- An accredited pharmacist, as outlined above, provides the Service at all times.
- All new Staff or locums are fully aware of the local pharmacy Standard Operating Procedure and are able to enact this agreement appropriately.

3.3.3. Competences

The Provider and its Staff will:

- Offer a supportive, friendly and professional service.
- Respect Service User confidentiality at all times.
- Have the confidence to ensure and ascertain medication has been ingested by the Service User.
- Maintain Standard Operating Procedures (SOP) for the safer management of controlled drugs
- Maintain sufficient numbers of trained Staff are in place to provide good quality service.
- Provide a continuous service on all days of opening.
- Provide safe disposal of clinical waste including needles and items which may identify Service Users.

All Staff must be competent to deliver a quality recovery focused service. Staff need to be competent and able to demonstrate they are appropriately qualified to undertake the roles they do. In order to achieve this, the Provider will ensure:

- All its Staff are appropriately qualified to undertake their role and provision is in place for training updates where necessary.
- Staff attend appropriate education and training programmes to maintain their level of competency and comply with their professional body requirements.
- All Staff have the relevant professional qualifications and operate within their scope of competency, their professional body's standards, regulations and codes of conduct.
- All Staff undergo an induction process.
- A Workforce and Training Plan is in place relevant to substance misuse that is reviewed and amended annually.
- There is an appropriate skill mix of Staff in place, or plans in place to improve skill mix.
- Professional leadership is provided.
- An appropriate management structure is in place that supports Service delivery and development.
- Staff work to the Provider's employee policies.

The Provider will be responsible for ensuring all Staff professional registrations are maintained.

The Service Provider will have in place appropriate Human Resource policies to manage short and long term absences, discipline and capability policies.

3.3.4 Local Training Requirements

All Staff will be trained in local adult and children safeguarding policies and procedures, Mental Health Capacity Act 1983 and any other relevant training required to perform the Services.

The Provider should ensure that its Staff complete the CPPE Declaration for Supervised Consumption of Prescribed Medication every 3 years.

Attend the Drug and Alcohol Action Team (DAAT) pharmacy updates and training meetings at least once a year.

It is the responsibility of the Provider to ensure the Service achieves the following:

- Compliance with any other relevant national and local policies and guidance.
- Compliance with relevant NICE guidance.

Requirements for qualification as providers

- The Provider has a duty to ensure that its pharmacists and dispensing staff involved in the provision of the Service have relevant knowledge and are appropriately trained and competent in the operation of the Service.

- Providers should be familiar with NICE Guidance *Methadone and Buprenorphine for the management of opioid dependence (TA114)* and working in compliance with this and other relevant guidance at all times.

3.3 5. Population covered

The Service will be available to people aged 18 years or over who live within the administrative area of the Authority within Shropshire and have been

- Prescribed methadone or buprenorphine by named GPs involved in local shared care services.
- Prescribed methadone or buprenorphine by the specialist substance misuse service.

3.3.6. Clinical Governance

Clinical governance requirements as part of the Community Pharmacy Contractual Framework (CPCF) must be implemented by the Provider in conjunction with any regulatory standards and guidance such a:

- General Pharmaceutical Standards (GPhC) Standards for registered pharmacies 2012
- GPhC Standards of Conduct, ethics and performance 2012
- Information Governance Toolkit and its replacement Data Security and Protection Toolkit 2018
- Pharmaceutical Services Negotiating Committee (PSNC) Clinical Governance Requirements for community Pharmacists

3.3.7 Incident reporting

All incidents should be managed using internal reporting processes including informing NHS England.

The Provider is required to report in writing to inform the Authority within two working days of any incidents occurring including:

- Any clinical incidents that may cause harm or directly affect a Service User.
- Any events that may stop or disrupt the Service from operating normally or safely.

The Provider should:

investigate any incidents,

implement any action and recommendations following investigation and

share lessons learnt with the Authority.

This incident reporting is required to support Service User safety and quality assurance. In any instance of clinical incident or other events that may have a detrimental impact on the Service User should be reported to treatment services or known recovery co-ordinator in the first instance.

3.3.8 Responding to National Service User Safety Alerts

The Provider is required to respond appropriately to all relevant safety alerts issued via the National Central Alert System (CAS) and must keep a record of what has been done to implement them.

The Provider will inform the Authority within the timeframe stipulated on the alert, of any response, any actions taken or required and any risk to Service Users.

3.3.9 Risk management

- The Provider will ensure that any risks associated with the Service are identified and managed.
- The Provider will ensure appropriate risk assessments are undertaken to account for access to Premises in line with the Equality Act 2010.

- All medicine supplies should be stored as per the manufacturer's requirements.

4 Applicable Service Standards

4.1 Applicable national standards

- Clinical governance in drug treatment: A good practice guide for providers and commissioners, 2009 (NTA)
- 'Models of Care' (*National Treatment Agency, 2002 and 2006)*
- Drug Misuse and Dependence UK Guidelines on Clinical Management, 2007 (DH)
- DH 2003 NHS Code of Practice: Confidentiality
- DH 2004 Standards for Better Health (updated 2006)
- DH NICE CG51, CG52, CG100, QS23 and TA114 Guidelines

The Provider must adhere to all national standards and training requirements. It is the Provider's responsibility to keep staff up to date and adhere to any changes to national training requirements, guidance and service standards.

4.2 Information Provision

4.2. 1 Information Governance

- The Provider is required by law to ensure the Service Users identifiable data is managed in accordance with the Data Protection Legislation and the law.
- Data must be recorded in full on PharmOutcomes modules registration and consultation as part of the Service User clinical record
- Data will be recorded and reported to allow:
- Pseudonymised data for reporting local and National outcome measures
- Audit of data for payment and outcome monitoring
- Compliance with Data Protection Legislation
- Follow up of Service Users where consent has been obtained by the Authority for
- Service User records must be securely stored and used strictly in accordance with the terms of this Contract.
- Data collected must be accessible to the Authority to audit payments and report outcomes
- Breaches including prescription loss should be reported to the Authority within two working days of the incident occurring.
- In the event of a the Provider losing a prescription, the responsible pharmacist must report this to the relevant prescriber or recovery co-ordinator. If the prescriber is unavailable immediately, the Provider must contact the recovery co-ordinator to ensure the Service User's treatment is not interrupted. NHS England should be informed of the loss of any prescription and any internal controlled drugs reporting systems must be adhered to.

4.2.2 Contract Monitoring and information submission requirements

The following data shall be collected:

- Client name/address/telephone number and ID number
- Attendance records
- Prescribing/dispensing records.

A minimum data set will be required to support future needs assessment for the development and future commissioning of the Service. This will need to be available as raw anonymised data for each individual Service User transaction. All information requests will be responded to within 28 days.

Minimum Dataset (currently under review)

Field	
Unique code	
Ward Code	
Ward Name	
LSOA	
Pharmacy ID	
GP Practice	
Gender	
Age	
Ethnic Category	
Country of birth	
Main language	
Migrant /asylum status	
Employment status	
Date	
Medicine supplied	
Status (supervised consumption, DNA, Take Out Dose)	
Sexual health referral	

5. Location of Service

5.1. Premises and equipment

The Provider's Premises are to be located within the administrative area of the Authority. The Provider shall provide the Authority with a written schedule of the location of each of the Premises from which the Services under this Lot are to be delivered **within one month** of the Service Commencement Date

The Provider shall ensure the Premises used for the provision of the Service is sufficient to meet the reasonable needs of all Service Users and enable Covid-19 Safe Working Practices.

The Provider must provide the following:

- A Service User medication record
- Appropriate storage conditions for the supply of methadone and buprenorphine.
- Appropriate consultation area that meets the national standard
- An area for display of relevant material.

6 Required Insurance

Public Liability Level of cover of a minimum of 5 MILLION POUNDS (£5,000,000.00)

Professional Liability Level of cover of a minimum of 5 MILLION POUNDS (£5,000,000.00)

Employers Liability Level of cover of a minimum of 5 MILLION POUNDS (£5,000,000.00)

Product Liability Level of cover 5 MILLION POUNDS (£5,000,000.00)

Medical Mal-practice Level of cover 5 Million Pounds (£5,000,000.00)

Insurances are required to be maintained for a minimum period of 6 years following termination/expiry of this Contract

7 Quality Outcome Indicators

The Provider must demonstrate they have undertaken appropriate training to deliver the Services

The Provider will demonstrate they have a Standard Operating Procedure and this will be subject reviewed to review on an annual basis for the Service.

The Provider will remain up to date with the relevant CPPE packages in relation to the provision of supervised consumption services.

During the duration of this Contract, the Provider will work with the Authority to achieve the quality outcomes below

Quality Outcome Indicators

Quality Outcomes Indicators	Threshold	Method of Measurement	Consequence of breach
1.Keeping people safe	Reliable systems in place to protect Service Users, family members, staff and wider public	Standard Operating Procedure (SOP)	As set out in the Contract
2.Providing effective treatment	a) Prescribed treatment agreement in place for the management of prescribed medications.	100% of Service Users 100% of service users	As set out in the Contract
People are treated with dignity and respect	b) All persons to receive service within a separate consulting room	100% Service user satisfaction survey through the Drug and Alcohol Action Team No. of Complaints	As set out in the Contract

8. Service User Experience – Staff, Service User and Carer Surveys

8.1 Complaints

The Provider should ensure they have adequate policies and procedures in place to respond to complaints.

The Provider will inform the Authority in writing of the complaint within three working days of receiving it.

All Service Users must be provided with a copy of, or a link to, a Service User satisfaction questionnaire within 4 weeks of attending the Service.

9 Charges

A fee of £1.50 will be paid for each supervised dose of methadone and buprenorphine dispensed to a Service User.

The Provider will be paid on an Activity basis.

Payment for this Service will be made 30 days in arrears, based on actual activity.

Payment will be made according to data submitted to Pharmoutcomes in line with the requirements included in this Specification.

The Authority will make payments up to 3 months in arrears.

Valid Invoices for payment must be submitted and sent to ian.houghton@shropshire.gov.uk

10 Discharge from Care

Any discharge from care must be agreed with the Service User and their recovery worker to ensure continuity of treatment.

11. Service Quality

The Provider will demonstrate its Staff have undertaken appropriate training to deliver the Services.

The Provider will provide a consulting room for the delivery of the Service, ensuring the medication is completely swallowed before the Service User leaves the Premises.

The Provider will demonstrate that it has a Standard Operating Procedure and this will be subject to an annual review for the Service.

The Provider will and will ensure that its Staff remain up to date with the relevant CPPE packages in relation to the provision of the Services.

12 REVIEW MEETINGS:

Reviews shall take place in accordance with section 7 above and in addition the Authority may undertake a visit to the Provider's participating Premises to inspect the provision of the Service and to ensure that the Provider is meeting this Specification.

13 NOTICE REQUIRED TO WITHDRAW DELIVERY OF THIS LOT

Either Party may serve the other with three months' prior written notice to terminate the provision of this Lot

Schedule 1

Description	Details
Subject matter of the processing	Processing of data collected from service users to support the delivery of the Observed Consumption service from community pharmacies and to comply with the Pharmoutcomes, a web based recording system.

Duration of the processing	Processing of the data will be for the duration of this Contract
Nature and purposes of the processing	Pharmacies collect and store Service User data information through pharmacy records (Pharmoutcomes) and NHS net. Exception to sharing relevant information without consent is where it is required under the Crime and Disorder Act 1998 and subsequent Police Reform Act 2002 to prevent crime and disorder. Pseudonymised data is returned to the local authority from the pharmacist via the Pharmoutcomes system to allow payment on a monthly basis. Processed and uploaded pseudonymised data on the Pharmoutcomes system is updated daily. This allows the monitoring of performance of the service and supports both the planning and commissioning of services and contract management.
Type of Personal Data	Collected by provider - Name, Date of Birth, demographic data, GP surgery, NHS number, demographic data, medication dispensed, medication missed
Categories of Data Subject	Service Users aged 18 years plus
Plan for return and destruction of the data once the processing is complete UNLESS requirement under union or member state law to preserve that type of data	Plan will follow the Councils information and record management policy. Data collected will be retained for 8 years by the provider. Data collected by the Pharmacy will be maintained under current New Medicine Service (NMS) data management processes and kept for 10 years following either the Service Users death or if the Service User leaves the country. If there is a dispensing error paper records and associated data should be kept for one year plus the current year. Electronic data should be kept permanently. Controlled drug (CD) registers should be kept for a period of two years, but if it contains records of destruction of CD (including patient

	returns and out of date stock) it should be kept for 7 years. Requisitions, order books, orders, delivery notes and other record receipts should be kept for a period of 2 years or 2 years from the date of the last entry

APPENDIX B: CONDITIONS PRECEDENT

1. The Provider must provide the Authority with a copy of the following documents:

a) Provider's and where applicable, sub-contractor's registration with the CQC where the Provider must be so registered under the Law

b) Copies of all sub-contracts entered into by the Provider with respect to the delivery of the Services

c) Evidence of the Required Insurances

d) Provide assurance to the Authority that good information governance practices are being maintained and the Provider must demonstrate, and will allow the Authority to audit, that it meets or exceeds the NHS Information Governance Toolkit standards required for their organisation type.

APPENDIX C: QUALITY OUTCOMES INDICATORS

See section 7 in the relevant Specification for the Service (s) being delivered

APPENDIX D: SERVICE USER, CARER AND STAFF SURVEYS

See section 8 in the relevant Specification for the Service (s) being delivered

APPENDIX E: CHARGES

See section 9 in the relevant Specification for the Service (s) being delivered

Claims for payment must be submitted via Valid Invoices.

Claims for payment should not be aggregated across the Services and should clearly identify which activities have been undertaken under each Lot

Where the Commencement Date of this Contract is later than the Service Commencement Date, the Authority, unless otherwise agreed in writing between the Parties, shall be under no obligation to make payment to the Provider for any Activity undertaken by the Provider prior to the Commencement Date

APPENDIX F: SAFEGUARDING POLICIES

The Provider must have in place and adhere to appropriate Safeguarding Policies, copies of which must be provided to the Authority upon request

In addition to its own Safeguarding Policies the Provider must ensure that:

All Staff working with children, young people and vulnerable adults will have been recruited in line with Shropshire Local Safeguarding Board Standards for Safer Recruitment 2010 and will be subject to an enhanced DBS check and

The Provider and any subcontractor will comply with the local inter-agency Safeguarding Children and Young People and Adults Procedures and Practice guidelines. These are available from Shropshire Local Safeguarding Children's Board ("LSCB") websites. These guidelines relate to the protection of all children and young people and vulnerable adults residing within the administrative area of the Authority'

The LSCB definition of a vulnerable child is any child under the age of 18 including an unborn baby who can suffer from abuse. However, some children are more vulnerable than others. These include:

- "Looked after" children already in the care system
- Children with disabilities
- Homeless children
- Teenage mothers
- Children in custodial settings
- Children who live with parental drug and alcohol abuse or domestic violence.

The broad definition of a "vulnerable adult", is a person (aged 18+) who is or may be in need of community care services by reason of mental or other disability, age or illness; and who is or may be unable to take care of him/herself, or unable to protect him or herself against significant harm or exploitation.

Organisations must always follow their own Child and Adult Protection Procedures and Shropshire Safeguarding Children Board Procedures. www.safeguardingshropshireschildren.org.uk

To make a formal referral or to ask for advice contact:

	Shropshire	**Telford and Wrekin**
Monday to Friday 9.00am - 5.00pm	Initial Contact Team 0345 678 9021	Family Connect 01952 385385

Out of hours	0345 678 9040	01952 676500

For further guidance and access to the West Mercia Inter Agency Child Protection Procedures, follow the links below:

- Telford and Wrekin Safeguarding Children Board
- Shropshire Safeguarding Children Board

Safeguarding Children Guidelines for Shropshire, Telford & Wrekin, Herefordshire and Worcestershire". These can be found by visiting the West Mercia Child Protection Procedures website.

1.1 The Provider shall adopt the Authority's procedures for dealing with allegations or suspicions of Abuse including the **West Midlands Multi-Agency Safeguarding Adults Policy and Procedure** (July 2012) (as amended from time to time during the Term).and the **West Mercia Consortium Inter-Agency Child Protection Procedures for Safeguarding Children** (February 2013) (as amended from time to time during the Term).

- Any concerns can be reported online via the 'Report child abuse online - NSPCC website' or phone **the Initial Contact Team on 0345 678 9021**.
- If concerns need to be reported **out of office hours** then please contact **the Emergency Duty Team on 0345 678 9040**.
- Providers can also speak to:
  Protecting Vulnerable People (West Mercia Police): 0300 333 3000
  NSPCC: 0800 800 5000
  Childline: 0800 1111

1.2 In cases of actual or suspected abuse to a Service User who is a Vulnerable Adult the Provider must ensure strict adherence to the West Midlands Multi-Agency Safeguarding Adults Policy and Procedure in order to protect the Service User, and in so doing shall comply with requirements of any investigation carried out by the Authority or other appropriate agency.

1.3 The Authority's Representative must be notified immediately in writing by the Provider of all instances of suspected Abuse of any Service User, which comes to the attention of the Provider by any means pursuant to the operation of this Contract. For the avoidance of doubt, this includes instances which do not relate to any member of Staff or other persons engaged in the provision of the Services.

1.4 The Provider shall immediately notify the Authority in writing of any information that is required under this clause or it reasonably requests to enable it to be satisfied that the obligations of this clause have been met.

APPENDIX G: INCIDENTS REQUIRING REPORTING PROCEDURE

The Provider will be required to produce an incident report to be presented at the quarterly Contract and Performance meetings including providing details of any complaints and how they were resolved.

Any serious complaints and Serious Incidents (SIs) will be reported within 24hours to the Authority responsible contract Lead by telephone & followed up within 48hours with an email.

The Provider will include an action plan detailing any resolution to the Authority within 7 days of the SI.

All SIs will result in a root cause analysis being undertaken by the Provider and the results will be presented to the Authority within 4 weeks of final resolution of the SI

APPENDIX H: INFORMATION PROVISION

See section 4.2 in the relevant Specification for the Service (s) being delivered

APPENDIX I: TRANSFER OF AND DISCHARGE FROM CARE PROTOCOLS

See section 10 in the relevant Specification for the Service (s) being delivered

APPENDIX J: SERVICE QUALITY PERFORMANCE REPORT

See section 11 in the relevant Specification for the Service (s) being delivered

APPENDIX K: DETAILS OF REVIEW MEETINGS

Review Meetings shall be held between the parties on an annual basis and in accordance with any requirements set out in the relevant Specification for the Service(s) - Section 12

APPENDIX L: AGREED VARIATIONS

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 – Not Used
Part 3 of Appendix M - Recorded Dispute Resolutions
[*Insert*]

APPENDIX N: SUCCESSION PLAN – 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 anybody, 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. Words importing any gender include every gender
9. The headings to the clauses, schedules and paragraphs of this Agreement are not to affect the interpretation
10. Where the word 'including' is used in this Agreement, it shall be understood as meaning 'including without limitation'
11 A reference to writing or written includes faxes but not e-mail, unless otherwise specifically agreed.
12. 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 anybody or person concerned with the provision of the Service or care of a Service User

Authority Data means the data, text, drawings, diagrams, images or sounds (together with any database made up of any of these) which are embodied in any electronic, magnetic, optical or tangible media, and which are:
(a) supplied to the Provider by or on behalf of the Authority or which the Provider is required to generate, process, store or transmit pursuant to this Contract; or
(b) any Personal Data for which the Authority is the Data Controller;

Authority Representative means the person identified in clause A4.1 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

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 Activity carried out by the Provider with respect to each Lot forming the Services in accordance with the provisions of this Contract, as such charges are set out in part 9 of the respective Service Specification(s) and Appendix E (*Charges*)

Commencement Date means the date of this Contract as identified in clause A3.1.

Competent Body means anybody 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 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 has the meaning given to it in clause A1.1

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*)

Covid 19: Means all forms and mutations of the viral infection (also known as Coronavirus) being the cause of a global pandemic prior to the Service Commencement Date and continuing during this Contract

Covid 19 Safe Working Practices: Means working practices complying with all applicable guidance issued by the government from time to time with respect to safeguarding individuals from the spread of the Covid-19 virus

CQC means the Care Quality Commission

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

Data Controller: is as defined in the Data Protection Legislation

Data Loss Event: any event that results, or may result, in unauthorised access to Personal Data held by the Processor under this Agreement, and/or actual or potential loss and/or destruction of Personal Data in breach of this Agreement, including any Personal Data Breach

Data Protection Impact Assessment: an assessment by the Data Controller of the impact of the envisaged processing on the protection of Personal Data.

Data Processor: is as defined in the Data Protection Legislation

Data Protection Legislation: all applicable data protection and privacy legislation in force from time to time in the UK including the retained EU law version of the General Data Protection Regulation ((EU) 2016/679) (UK GDPR); the Data Protection Act 2018 (DPA 2018) (and regulations made thereunder) and the Privacy and Electronic Communications Regulations 2003 (SI 2003/2426) as amended and the guidance and codes of practice issued by the Information Commissioner or other relevant regulatory authority and applicable to a party

Data Protection Officer: Shall have the meaning given in the Data Protection Legislation

Data Subject: Shall have the meaning given in the Data Protection Legislation

Data Subject Request: a request made by, or on behalf of, a Data Subject in accordance with rights granted pursuant to the Data Protection Legislation to access their Personal Data.

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 the statutory rate of interest applicable to the Late Payment of Commercial Debts Regulations 2013 as may be amended from time to time

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

DPA means the Data Protection Act 2018

Domestic Law: means the Law of the United Kingdom or a part of the United Kingdom

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 a Force Majeure Event

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 upon which this Contract is terminated in accordance with its terms

First Exception Report mans 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 Event 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 but not limited to epidemic or pandemic; acts of God, earthquake, drought; collapse of buildings, accident, fire; flood; violent storm; pestilence; explosion; malicious damage; armed conflict; acts of terrorism; civil war, civil commotion or riots, war, threat of or preparation for war, imposition of sanctions, embargo or breaking off of diplomatic relations, nuclear, biological or chemical contamination or warfare, sonic boom; any law or any action taken by a government or public authority, including without limitation imposing an export or import restriction, quota or prohibition, or failing to grant a necessary licence or consent; any labour or trade dispute, strikes, industrial action or lockouts (except as set out below); interruption or failure of utility service 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

GDPR Means the General Data Protection Regulation 2016/679 as they apply and are incorporated into UK law by UKGDPR

General Conditions has the meaning given to it in clause A1

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

Initial Term means the term commencing on the Service Commencement Date and expiring on the Initial Expiry Date

Initial Expiry Date means 31st March 2023

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

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

Lots means the Public Health Services Lots 4-7 & 10-11 described in Schedule A to this Contract

NICE means National Institute for Health and Clinical Excellence being 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

Order Number: means an order reference given by the Authority to the Provider which must be quoted on all Valid Invoices submitted for payment

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

Patient: means Service User

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 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

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

Regulated Provider is as defined in section 6 of the Safeguarding Vulnerable Groups Act 2006

Relevant Transfer means a relevant transfer for the purposes of TUPE

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 section 6 of the Service Specification(s)

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

Safeguarding Policies means the Provider's 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*)

Schedule 1 – means the Schedule of Processing, Personal Data and Data Subjects annexed to each Service Specification

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. and is the date from which the Provider shall commence the delivery of the Services

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

Service User means the person or Patient 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 provided or to be provided by the Provider under and in accordance with this 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

Sub-contractor means any third party appointed by the Provider and approved by the Authority under clause B23 (*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 to deal with transfer of the Services to an alternative provider following expiry or termination of this Contract as set out at Appendix N (*Succession Plan*)

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

Valid Invoice: Means an invoice submitted by the Provider which must contain the following detail required by the Authority to enable payment as specified in section 9 of the relevant Service Specification:
1) invoices for payment of services under each Lot are to be sent to the email address specified in each Service Specification, section 9 , or to Shropshire Council at the address referred to above; and
2) submitted on the Provider's business letterhead including the Provider's name and address, and VAT registration number (where applicable); and
3) details of the Activity, Lot Number and description of Service to which payment relates; and
4) the Council's official Order Number

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*).