# **The Customer**

-and-

## **Preventx**

\_\_\_\_\_

Call-Off Contract relating to the national framework for e-sexual and reproductive healthcare

#### FORM OF CONTRACT

This Form of Contract is made on theday of
--

#### **BETWEEN**

- (1) [insert the Customer's name] of [insert Customer's address] (the "Customer"); and
  - (2) Preventx a company registered in England and Wales under company number 06603066 whose registered office is at Meadowhall Business Park, Carbrook Hall Road, Sheffield, South Yorkshire, S9 2EQ (the "Service Provider")

**WHEREAS** the Customer wishes to have supplied the e-sexual and reproductive healthcare services by the Service Provider pursuant to the PHE Framework Agreement (5607).

#### **NOW IT IS AGREED THAT**

- 1. The Service Provider will supply the goods and/or services in accordance with the terms of the Contract Documents.
- 2. The Customer will pay the Service Provider the amount due in accordance with the terms of the Contract Documents.
- 3. Subject always to paragraph 5 below, the following documents comprise the Contract Documents and shall be deemed to form and be read and construed as part of the Contract:
  - (a) this Form of Contract;
  - (b) the Order Form;
  - (c) the applicable provisions of the Framework Agreement (excluding Framework Schedules 1 and 2);
  - (d) the Call-Off General Terms and Conditions including the appendices; and
  - (e) any other documentation forming part of the Contract in the date order in which such documentation was created with the more recent documentation taking precedence over older documentation to the extent only of any conflict.
- 4. If there is an inconsistency between any of the documents listed above, the order of priority for construction purposes shall be that a higher listed document shall prevail over a lower listed document, i.e. document (a) shall prevail over all other documents; document (b) shall prevail over document (c) etc.
- 5. Where there is a conflict between the Service Provider's tender submission document (set out as part of Appendix A to the Call-Off General Terms and Conditions) and any other part of this Contract, such other part of this Contract shall prevail.

**IN WITNESS** of which the Contract has been duly executed by authorised representatives of the Customer and the Service Provider:

Signed for and on behalf of		
[INSERT CUSTOMER'S NAME]	)	Signature:
by(print name)	)	
on(date)	)	Authorised Signatory
Signed for and on behalf of		
Preventx	)	Signature:
by(print name)	)	
on(date)	)	Director

#### This document relates to and forms part of the Contract Documents

## (Document Reference **CUSTOMER'S REF NUMBER**)

#### ORDER FORM

(PHE Framework Reference 5607)

1. IERM
Service Commencement Date
[Insert the date on which the agreement for the supply of the Goods and/or Services is to commence. Any conditions precedent to the Service Commencement Date should be included here.]

## **Expiry Date**

This Contract shall expire on ...... unless terminated earlier pursuant to this Contract or in accordance with the automatic termination provisions of Section 2 below.

## [Insert the date on which the Contract is to expire.]

Subject to earlier termination of the Contract in accordance with clause **Error! Reference source not found.** of the Framework Agreement or clause B33 of the Call-Off General Terms and Conditions, the Contract shall expire on the Expiry Date provided.

#### 2. GOODS AND/OR SERVICES REQUIREMENTS

## Limit or expenditure

The Customer commits to purchase goods and services under the Framework Agreement up to a total sum not exceeding £...... expenditure during the Term defined in Section 1 above. In the event that the committed level of expenditure is reached before the Expiry Date shown above the Contract shall automatically expire at that point and the Customer shall not be liable to pay for any Goods and/or Services supplied by the Service Provider following such automatic expiry.

The Customer will use the 'Customer Information Form' (as set out in appendix 4 to the User Guide of the National Framework for e-Sexual Health and Reproductive Healthcare) to indicate the range of core and additional services to be provided.

The Goods and/or Services shall be supplied in accordance with the specification set out in Appendix A to the Call-Off General Terms and Conditions, unless and to the extent that the following variation applies:

Variation: [Either state 'None', or include a description of any special requirements, e.g. related to local initiatives or campaigns, special operational arrangements, particular messages to be conveyed to service users (e.g. about other local sexual health services) etc. If the variations are particularly detailed or complex, consider setting out this information in a separate schedule.]

#### **Geographical locations**

The Customer shall be liable to pay only for Goods and/or Services supplied to those service users who when placing their order do so using a postcode which defines their location as within the boundaries of the Customer area.

[If a more detailed geographical limitation or description is required, it may be given here.]

#### 3. CHARGES AND PAYMENT

## [Either:1

The charges made and methods of payment for Goods and/or Services supplied shall be as set out in Appendix B to the Call-Off General Terms and Conditions.

[Or, if alternative charges or payment methods are agreed between the parties, a description should be substituted here.]

#### 4. CONFIDENTIAL INFORMATION

The following information shall be deemed Commercially Sensitive Information:

[Include details of any Commercially Sensitive Information identified by the Service Provider and the duration it should be confidential for. This will assist the Customer in respect of compliance with Freedom of Information Act (FOIA) and the codes of practice issued under section 45 of FOIA from time to time on the discharge of public authorities' functions under Part 1 of FOIA.]

### 5. PERFORMANCE AND MANAGEMENT INFORMATION

[In the event that the Customer requires information in addition to that which will be supplied via PHE then those requirements should be detailed here.]

#### 6. SERVICE REVIEW AND REVIEW MEETINGS

[In the event that the Customer has a reasonable requirement for formal contract review directly with the Service Provider, in addition to the contract review process being carried out by PHE, then such requirements should be set out here, including expectations as to any review meetings which may be called for.]

#### 7. SAFEGUARDING

[In the event that the Customer has a reasonable requirement for specific safeguarding provisions to be adhered to by the Service Provider, then such requirements should be set out here, including expectations as to any review meetings which may be called for.]

#### 8. INCIDENT REPORTING

[Any arrangements for reporting, investigating, implementing and sharing the Lessons Learned from Serious Incidents, Patient Safety Incidents and non-Service User safety incidents in accordance with clause B12.3 to be referred to here.]

#### 9. NOTICES

In accordance with clause **Error! Reference source not found.** of the Framework Agreement the address for notices to the Customer shall be:

Address: [address]

For the attention of: [contact name]

Tel: [telephone number]

Email: [email address]

#### **CALL-OFF GENERAL TERMS AND CONDITIONS**

#### **B1. INTERPRETATION AND DEFINITIONS**

B1.1. 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 Customer and any body or person concerned with the provision of the Service or care of a Service User:

"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 Customer (where the Customer is a local 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;

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

"Business Continuity Plan" means the Service Provider's plan referred to in clause B35.2 (*Business Continuity*) relating to continuity of the Services, as agreed with the Customer and as may be amended from time to time;

"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 Customer to the Service Provider in respect of the provision of the Services in accordance with the provisions of this Contract, as such charges are set out in Appendix B;

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

"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 Service Provider's obligations under this Contract or for the provision by the Service Provider of the Services in accordance with this Contract:

"Contract" means the call-off contract entered into by the Customer with the Service Provider under the Framework Agreement;

## "Contract Query" means, as appropriate:

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

"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 Customer and the Service Provider held in accordance with clause B30.8 (Contract Management);

"Controller" has the meaning given in the GDPR;

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

"Customer" means the public body or contracting authority which is eligible to access the Framework Agreement and has elected to do so by means of a call-off contract (the Contract);

"Customer Representative" means the person identified by the Customer as its formal representative for the purpose of the Contract;

"Data Loss Event" means any event that results, or may result, in unauthorised access to Personal Data held by the Processor under this Contract, and/or actual or potential loss and/or destruction of Personal Data in breach of this Contract, including any Personal Data Breach;

"Data Protection Impact Assessment" means an assessment by the Controller of the impact of the envisaged processing on the protection of Personal Data;

#### "Data Protection Legislation" means:

- (i) the GDPR, the LED and any applicable national implementing Laws as amended from time to time;
- (ii) the DPA 2018 to the extent that it relates to processing of personal data and privacy;
- (iii) all applicable Law about the processing of personal data and privacy;

"Data Protection Officer" has the meaning given in the GDPR;

"Data Subject" has the meaning given in the GDPR;

"Data Subject Access Request" means a request made by, or on behalf of, a Data Subject in accordance with rights granted pursuant to the Data Protection Legislation to access their Personal Data;

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

"Default" means any breach of the obligations of the Service 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 Service Provider or the Staff in connection with or in relation to the subject-matter of this Contract and in respect of which the Service Provider is liable to the Customer;

"Default Interest Rate" means LIBOR plus 2% per annum;

- "Disclosing Party" means the Party disclosing Confidential Information;
- "Dispute" means a dispute, conflict or other disagreement between the Parties arising out of or in connection with this Contract:
- "Dispute Resolution" means the process for resolving disputes set out in clause B31;
- "DPA 2018" means the Data Protection Act 2018;
- "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 Service Provider's equipment, plant, materials and such other items supplied and used by the Service Provider in the performance of its obligations under this Contract;
- "Excusing Notice" means a notice setting out in reasonable detail the Receiving Party's reasons for believing that a Contract Query is unfounded, or that the matters giving rise to the Contract Query are:
- (i) due wholly or partly to an act or omission by the Issuing Party; or
- (ii) a direct result of the Receiving Party following the instructions of the Issuing Party; or
- (iii) due to circumstances beyond the Receiving Party's reasonable control but which do not constitute an event of Force Majeure;
- "Expiry Date" means the date identified in Section 1 of the Order Form;
- "First Exception Report" mans a report issued in accordance with clause B30.21 (*Contract Management*) notifying the relevant Party's chief executive and/or Board of Directors of that Party's breach of a Remedial Action Plan and failure to remedy that breach;
- "FOIA" means the Freedom of Information Act 2000 and any subordinate legislation made under this Act from time to time together with any guidance and/or codes of practice issued by the Information Authority or

relevant government department in relation to such legislation and the Environmental Information Regulations 2004:

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

- (i) any industrial action occurring within the Service Provider's or any Sub-contractor's organisation; or
- (ii) the failure by any Sub-contractor to perform its obligations under any Sub-contract; or
- (iii) COVID-19 and any related circumstances, events, changes or requirements but this exclusion shall only apply to the extent that the same (1) is, or ought to have been, known to the Party in question as at the Service Commencement Date; and (2) is within the reasonable control of the Party in question;

"Framework Agreement" means framework agreement reference [5607] between PHE and the Service Provider for the supply of the goods and services as further described in Appendix A of the 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 Customer;

"GDPR" means the General Data Protection Regulation (Regulation (EU) 2016/679);

"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 Customer and/or the Service 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 Service Provider to protect the safety of Services to Service Users, the public and/or Staff:

"Independent Controller" means where a Controller has provided Personal Data to another Party which is not a Processor or Joint Controller because the recipient itself determines the purposes and means of processing but does so separately from the Controller providing it with Personal Data;

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

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

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

"Joint Controller" means where two or more Controllers jointly determine the purposes and means of processing;

"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;

- "LED" means the Law Enforcement Directive (Directive (EU) 2016/680):
- "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 Service Provider's provision of the Services;
- "LIBOR" means the London Interbank Offered Rate for six (6) months sterling deposits in the London market;
- "Local HealthWatch" means the local independent consumer champion for health and social care in England;
- "Losses" means all damage, loss, liabilities, claims, actions, costs, expenses (including the cost of legal and/or professional services) proceedings, demands and charges whether arising under statute, contract or at common law but, excluding Indirect Losses;
- "NICE" means National Institute for Health and Care Excellence being the non-departmental public body 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 Service Provider under the Law and/or Guidance as amended from time to time:
- "NHS Act 2006" means the National Health Service Act 2006;
- "Parties" means the Customer and the Service Provider and "Party" means either one of them;
- "Patient Safety Incident" means any unintended or unexpected incident that occurs in respect of a Service User that could have led or did lead to, harm to that Service User;
- "Personal Data" has the meaning given in the GDPR;
- "Personal Data Breach" has the meaning given in the GDPR;
- "Personnel" means all persons employed by a Party to perform its obligations under this Contract together with the Party's servants, agents, suppliers and sub-contractors used in the performance of its obligations under this Contract:
- "PHE" means Public Health England, an executive agency of the Department of Health and Social Care;
- "Processing" has the meaning given in the GDPR;
- "Processor" has the meaning given in the GDPR;
- "Prohibited Acts" has the meaning given to it in clause B40.1 (Prohibited Acts);

- "Protective Measures" means appropriate technical and organisational measures which may include: pseudonymising and encrypting Personal Data, ensuring confidentiality, integrity, availability and resilience of systems and services, ensuring that availability of and access to Personal Data can be restored in a timely manner after an incident, and regularly assessing and evaluating the effectiveness of such measures adopted by it;
- "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 Section 5 of the Order Form or Framework Schedules 7 or 9:
- "Receiving Party" means the Party which has received a Contract Query Notice or Confidential Information as applicable;
- "Regulatory Body" means any body other than CQC carrying out regulatory functions in relation to the Service Provider and/or the Services;
- "Remedial Action Plan" means a plan to rectify a breach of or performance failure under this Contract specifying targets and timescales within which those targets must be achieved;
- "Required Insurances" means the types of policy or policies providing levels of cover as specified in the Service Specification(s);
- "Review Meeting" means a meeting to be held in accordance with clause B20 (Review Meetings);
- "Safeguarding Policies" means the Service Provider's written policies for safeguarding children and adults, as amended from time to time, and as may be referred to in Section 7 of the Order Form:
- "Second Exception Report" means a report issued in accordance with clause B30.22 (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 Service Provider's Premises or where the actions of the Service Provider, the Staff or the Customer are likely to be of significant public concern;
- "Service Commencement Date" means the date identified in Section 1 of the Order Form;
- "Service Provider Representative" means the person identified by the Service Provider formally to represent it for the purpose of the Contract;
- "Service Provider" means the organisation appointed by PHE to the Framework Agreement to provide to Customers the goods and services detailed in Appendix A to the Contract;
- "Service Provider's Premises" means premises controlled or used by the Service Provider for any purposes connected with the provision of the Services which may be set out or identified in a Service Specification;
- "Service Specification" means the description of the required services provided in Appendix A of the Contract;
- "Service User" means the person directly receiving the Services provided by the Service Provider as specified in the Service Specifications and includes their Carer and Legal Guardian where appropriate;

- "Services" means the services specified in Appendix A of the Contract;
- "Staff" means all persons employed by the Service Provider to perform its obligations under this Contract together with the Service 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 Customer between the Service Provider and a third party for the provision of part of the Services;
- "Sub-contractor" means any third party appointed by the Service Provider and approved by the Customer under clause B24 (Assignment and Sub-contracting) to deliver or assist with the delivery of part of the Services as defined in a Service Specification;
- "Sub-processor" means any third party appointed to process Personal Data on behalf of that Processor related to this Contract:
- "Succession Plan" has the meaning given to it in clause B34.2;
- "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;
- "TUPE "means the Transfer of Undertakings (Protection of Employment) Regulations 2006;
- "VAT" means value added tax in accordance with the provisions of the Value Added Tax Act 1994;
- "Variation" means a variation to a provision or part of a provision of this Contract;
- "Variation Notice" means a notice to vary a provision or part of a provision of this Contract issued under clause B23.2 (Variations); and
- "Working Day" means any day other than a Saturday, Sunday or public holiday in England and Wales.
- B1.2. The headings in this Contract shall not affect its interpretation.
- B1.3. 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.
- B1.4. References to a statutory provision shall include any subordinate legislation made from time to time under that provision.
- B1.5. References to Sections, clauses and Appendices are to the Sections, clauses and Appendices of this Contract, unless expressly stated otherwise.
- B1.6. References to any body, organisation or office shall include reference to its applicable successor from time to time.
- B1.7. 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.
- B1.8. Use of the singular includes the plural and vice versa.

#### B2. SERVICES

- B2.1. The Service Provider shall provide the Services in accordance with the Service Specification(s) in Appendix A, including any service limitations set out in them, and in accordance with the provisions of this Contract.
- B2.2. The Service Provider shall satisfy any conditions precedent set out in Section 1 of the Order Form prior to commencing provision of the Services.

#### B3. WITHHOLDING AND/OR DISCONTINUATION OF SERVICE

- B3.1. Except where required by the Law, the Service 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 Service 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 Service 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 Service 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.
- B3.2. If the Service Provider proposes not to provide or to stop providing a Service to any Service User under clause B3.1:
  - where reasonably possible, the Service 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 two (2) Working Days);
  - b) the Service Provider must tell the Service User of the right to challenge the Service Provider's decision through the Service Provider's complaints procedure and how to do so;
  - c) the Service Provider must inform the Customer in writing without delay and wherever possible in advance of taking such action:

provided that nothing in this clause B3.2 entitles the Service Provider not to provide or to stop providing the Services where to do so would be contrary to the Law.

#### B4. COMPLIANCE WITH THE LAW AND GOOD CLINICAL PRACTICE

- B4.1. The Service Provider must carry out the Services in accordance with the Law and Good Clinical Practice and must, unless otherwise agreed (subject to the Law) with the Customer 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; and
  - f) respond to any reports and recommendations made by Local HealthWatch.

## **B5.** SERVICE USER INVOLVEMENT

- B5.1. The Service 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.
- B5.2. As soon as reasonably practicable following any reasonable request from the Customer, the Service Provider must provide evidence to the Customer of the involvement of Service Users, Carers and Staff in the development of Services.
- B5.3. The Service Provider must carry out Service User surveys (and Carer surveys) and shall carry out any other surveys reasonably required by the Customer in relation to the Services. The form (if any), frequency and method of reporting such surveys shall be agreed between the Parties in writing from time to time.
- B5.4. The Service Provider must review and provide a written report to the Customer on the results of each survey carried out under clause B5.3 and identify any actions reasonably required to be taken by the Service Provider in response to the surveys. The Service Provider must implement such actions as soon as practicable. If required by the Customer, the Service Provider must publish the outcomes and actions taken in relation to such surveys.

#### B6. EQUITY OF ACCESS, EQUALITY AND NO DISCRIMINATION

- B6.1. 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.
- B6.2. The Service 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).
- B6.3. In performing this Contract the Service 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:
  - 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 Service Provider is a public authority for the purposes of section 149 of the Equality Act 2010.

- B6.4. As soon as reasonably practicable following any reasonable request from the Customer, the Service Provider must provide the Customer with a plan detailing how it will comply with its obligations under clause B6.3.
- B6.5. The Service Provider must provide to the Customer as soon as reasonably practicable, any information that the Customer reasonably requires to:
  - a) monitor the equity of access to the Services; and
  - b) fulfil their obligations under the Law.

#### **B7.** MANAGING ACTIVITY

B7.1. The Service 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 Customer to assist it with understanding and managing the levels of Activity for the Services.

#### B8. STAFF

B8.1. At all times, the Service Provider must ensure that:

- a) each of the Staff is suitably qualified and experienced, adequately trained and capable of providing the applicable Services in respect of which they are engaged;
- b) there is an adequate number of Staff to provide the Services properly in accordance with the provisions of the applicable Service Specification;
- c) where applicable, Staff are registered with the appropriate professional regulatory body;
- d) Staff are aware of and respect equality and human rights of colleagues and Service Users; and
- e) it can provide a clear DBS Certificate (Standard, Enhanced or Enhanced and DBS Barred List at the Service Provider's discretion) for each of the Staff engaged in the Services.
- B8.2. If requested by the Customer, the Service Provider shall as soon as practicable and by no later than twenty (20) Working Days following receipt of that request, provide the Customer with evidence of the Service Provider's compliance with clause B8.1.
- B8.3. The Service 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.
- B8.4. Where applicable under section 1(F)(1) of the NHS Act 2006, the Service 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.
- B8.5. The Service Provider must carry out Staff surveys in relation to the Services at intervals and in the form agreed in writing from time to time.
- B8.6. Subject to clause B8.7, before the Service 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 Service Provider must without limitation, complete:
  - a) the Employment Checks; and
  - b) such other checks as required by the DBS.
- B8.7. Subject to clause B8.8, the Service 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 Customer.
- B8.8. Where clause B8.7 applies, the Service 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 Customer.

- B8.9. Where the Customer has notified the Service Provider that it intends to tender or retender any of the Services, the Service Provider must on written request of the Customer and in any event within twenty (20) Working Days of that request (unless otherwise agreed in writing), provide the Customer 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.
- B8.10. The Service Provider shall indemnify and keep indemnified the Customer and any Successor Provider against any Losses incurred by the Customer and/or the Successor Provider in connection with any claim or demand by any transferring employee under TUPE.

#### B9. CHARGES AND PAYMENT

- B9.1. 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 Customer shall pay the Service Provider the Charges.
- B9.2. The Parties shall to the extent reasonably practicable agree the Charges in a transparent and equitable manner and the Charges shall be set out at Appendix B.
- B9.3. The Service Provider shall invoice the Customer for payment of the Charges at the end of each quarter (3 calendar month) period (or such other frequency agreed between the Parties in writing) which the Customer shall pay within ten (10) Working Days of receipt.
- B9.4. The Charges are stated exclusive of VAT, which shall be added at the prevailing rate as applicable and paid by the Customer following delivery of a valid VAT invoice.
- B9.5. In its performance of this Contract the Service 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).
- B9.6. If a Party, acting in good faith, contests all or any part of any payment calculated in accordance with this clause B9:
  - a) the contesting Party shall within five (5) Working 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.
- B9.7. If a Party contests a payment under clause B9.6 and the Parties have not resolved the matter within twenty (20) Working Days of the date of notification under clause B9.6, the contesting Party may refer the matter to dispute resolution under clause B31 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 B9.3.
- B9.8. Subject to any express provision of this Contract to the contrary each Party shall be entitled, without prejudice to any other right or remedy it has under this Contract, to receive interest at the Default Interest Rate on any payment not made from the day after the date on which payment was due up to and including the date of payment.
- B9.9. 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.

## B10. SERVICE IMPROVEMENTS AND BEST VALUE DUTY

- B10.1. The Service Provider must to the extent reasonably practicable co-operate with and assist the Customer (where the Customer is a local authority) in fulfilling its Best Value Duty.
- B10.2. In addition to the Service Provider's obligations under clause B10.1, where reasonably requested by the Customer, the Service 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 Customer and shall assist the Customer with the preparation of any Best Value Duty performance plans.
- B10.3. During the term of this Contract at the reasonable request of the Customer, the Service 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 Customer for the Services.
- B10.4. If requested by the Customer, the Service Provider must identify the improvements that have taken place in accordance with clause B10.3, by reference to any reasonable measurable criteria notified to the Service Provider by the Customer.

#### **B11. SAFEGUARDING CHILDREN AND VULNERABLE ADULTS**

- B11.1. The Service Provider shall adopt Safeguarding Policies and such policies shall comply with the Customer's safeguarding policy as amended from time to time and may be appended to the Contract.
- B11.2. At the reasonable written request of the Customer and by no later than ten (10) Working Days following receipt of such request, the Service Provider must provide evidence to the Customer that it is addressing any safeguarding concerns.
- B11.3. If requested by the Customer, the Service Provider shall participate in the development of any local multi-agency safeguarding quality indicators and/or plan.

#### **B12. INCIDENTS REQUIRING REPORTING**

- B12.1. If the Service Provider is CQC registered it shall comply with the requirements and arrangements for notification of deaths and other incidents to CQC in accordance with CQC Regulations and if the Service Provider is not CQC registered it shall notify Serious Incidents to any Regulatory Body as applicable, in accordance with the Law.
- B12.2. If the Service Provider gives a notification to the CQC or any other Regulatory Body under clause B12.1 which directly or indirectly concerns any Service User, the Service Provider must send a copy of it to the Customer within five (5) Working Days.
- B12.3. 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 Service Provider and the Customer and set out in Section 8 of the Order Form.
- B12.4. Subject to the Law, the Customer shall have complete discretion to use the information provided by the Service Provider under this clause B12.1.

#### B13. CONSENT

B13.1. The Service Provider must publish, maintain and operate a Service User consent policy which complies with Good Clinical Practice and the Law.

#### B14. SERVICE USER HEALTH RECORDS

- B14.1. The Service Provider must create, maintain, store and retain Service User health records for all Service Users. The Service 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.
- B14.2. The Service Provider must:

- a) use Service User health records solely for the execution of the Service Provider's obligations under this Contract; and
- b) give each Service User full and accurate information regarding his/her treatment and Services received.
- B14.3. The Service Provider must at all times during the term of this Contract have a Caldicott Guardian and shall notify the Customer of their identity and contact details prior to the Service Commencement Date. If the Service Provider replaces its Caldicott Guardian at any time during the term of this Contract, it shall promptly notify the Customer of the identity and contact details of such replacements.
- B14.4. Subject to Guidance and where appropriate, the Service User health records should include the Service User's verified NHS number.

#### **B15.** INFORMATION

- B15.1. The Service Provider must provide the Customer the information (if any) specified by the Customer in Section 5 of the Order Form.
- B15.2. The Service Provider must deliver the information (if any) required under clause B15.1 in the format, manner, frequency and timescales specified in Section 5 of the Order Form.
- B15.3. If the Service Provider fails to comply with any of the obligations in this clause B15 and/or Section 5 of the Order Form the Customer 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 Section 5 of the Order Form.
- B15.4. In addition to the information required under clause B15.1, the Customer may request from the Service Provider any other information it reasonably requires in relation to this Contract and the Service Provider must deliver such requested information in a timely manner.

#### **B16. EQUIPMENT**

B16.1. The Service Provider must provide and maintain at its own cost (unless otherwise agreed in writing) all Equipment necessary for the supply of the Services in accordance with any required Consents and must ensure that all Equipment is fit for the purpose of providing the applicable Services.

#### B17. NOT USED

## B18. COMPLAINTS

- B18.1. The Service Provider must at all times comply with the relevant regulations for complaints relating to the provision of the Services.
- B18.2. If a complaint is received about the standard of the provision of the Services or about the manner in which any of the Services have been supplied or work has been performed or about the materials or procedures used or about any other matter connected with the performance of the Service Provider's obligations under this Contract, then the Customer may take any steps it considers reasonable in relation to that complaint, including investigating the complaint and discussing the complaint with the Service Provider, CQC or/and any Regulatory Body. Without prejudice to any other rights the Customer may have under this Contract, the Customer may, in its sole discretion, uphold the complaint and take any action specified in clause B29 (*Default and Failure to Supply*).

## B19. SERVICE REVIEW

B19.1. If the Customer has specified in Section 6 of the Order Form that it requires a formal service review process in addition to the contract management activity conducted by PHE under the Framework Agreement, and such requirements are reasonable, then the Service Provider shall accommodate such requirements.

#### **B20. REVIEW MEETINGS**

B20.1. If the Customer has specified in Section 6 of the Order Form that as part of its service review process it has a reasonable requirement that periodic review meetings be held, then the Service Provider shall cooperate with such requirements.

#### **B21.** CO-OPERATION

- B21.1. The Parties must at all times act in good faith towards each other.
- B21.2. The Service Provider must co-operate fully and liaise appropriately with:
  - a) the Customer;
  - b) any third party provider who the Service User may be transferred to or from the Service Provider;
  - c) any third party provider which may be providing care to the Service User at the same time as the Service 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 Customer or members of the public.

## **B22. WARRANTIES AND REPRESENTATIONS**

- B22.1. The Service 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 Customer 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 Customer 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 Service 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 Service Commencement Date:
    - 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 ongoing 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 Service 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 Service Provider's assets or revenue.
- B22.2. The Customer 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;
  - 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.
- B22.3. The warranties set out in this clause B22 are given on the Service Commencement Date and repeated on every day during the term of this Contract.

#### **B23. VARIATIONS**

- B23.1. This Contract may not be amended or varied other than in accordance with this clause B23.
- B23.2. 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).
- B23.3. If a Variation Notice is issued, the Customer and the Service Provider must enter into good faith negotiations for a period of not more than thirty (30) Working 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.
- B23.4. No Variation to this Contract will be valid or of any effect unless agreed in writing by the Customer Representative (or his nominee) and the Service Provider Representative (or his nominee). All agreed Variations shall form an addendum to this Contract.

#### B24. ASSIGNMENT AND SUB-CONTRACTING

- B24.1. The Service 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 Customer 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 Subcontract as the Customer may reasonably require.
- B24.2. The Customer's consent to sub-contracting under clause B24.1 will not relieve the Service Provider of its liability to the Customer for the proper performance of any of its obligations under this Contract and the Service 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 Service Provider.
- B24.3. Any sub-contract submitted by the Service Provider to the Customer 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.

B24.4. The Customer may assign, transfer, novate or otherwise dispose of any or all of its rights and obligations under this Contract without the consent of the Service Provider.

#### **B25.** AUDIT AND INSPECTION

- B25.1. The Service 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 Service 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 Service Provider may refuse such request to enter the Service 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.
- B25.2. Subject to Law and notwithstanding clause B25.1, an Authorised Person may enter the Service Provider's Premises and/or the premises of any Sub-contractor with reasonable 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 Service Provider must not restrict access and must give all reasonable assistance and provide all reasonable facilities to the Authorised Person.
- B25.3. Within ten (10) Working Days of the Customer's reasonable request, the Service Provider must send the Customer 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 Service Provider, to which the Service Provider has access and which it can disclose in accordance with the Law.
- B25.4. The Customer shall use its reasonable endeavours to ensure that the conduct of any audit does not unreasonably disrupt the Service Provider or delay the provision of the Services.
- B25.5. During any audit undertaken under clause B25.1 or B25.2, the Service Provider must provide the Customer and any Authorised Person 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 Service Provider's Premises and/or the premises of any Subcontractor; and
  - c) access to the Staff.

#### **B26. INDEMNITIES**

B26.1. The Service Provider shall indemnify and keep indemnified the Customer against all actions, proceedings, costs, claims, demands, liabilities, losses and expenses whatsoever, whether arising in tort (including negligence), default or breach of this Contract, or breach of its statutory duty or breach of an obligation under the Data Protection Legislation, save to the extent that the same is directly caused by or directly arises from the negligence, breach of this Contract or breach of statutory duty or breach of an obligation under the Data Protection Legislation by the Customer.

#### **B27.** LIMITATION OF LIABILITY

- B27.1. 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.
- B27.2. Neither Party shall be liable to the other Party (as far as permitted by Law) for Indirect Losses in connection with this Contract.
- B27.3. Nothing in this Contract will exclude or limit the liability of either Party for:
  - a) death or personal injury caused by its negligence; or

b) fraud or fraudulent misrepresentation.

#### **B28. INSURANCE**

- B28.1. The Service Provider must at its own cost effect and maintain with a reputable insurance company the Required Insurances. The cover shall be in respect of all risks which may be incurred by the Service Provider, arising out of the Service 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 Service Provider.
- B28.2. The Service Provider must give the Customer, on request, a copy of or a broker's placement verification of the Required Insurances insurance, together with receipts or other evidence of payment of the latest premiums due under those policies.
- B28.3. The provision of any insurance or the amount or limit of cover will not relieve or limit the Service Provider's liabilities under this Contract.

#### B29. DEFAULTS AND FAILURE TO SUPPLY

- B29.1. In the event that the Customer is of the reasonable opinion that there has been a Default which is a material breach of this Contract by the Service Provider, then the Customer may, without prejudice to any other rights or remedies it may have under this Contract including under clause B30, consult with the Service Provider and then do any of the following:
  - a) require the Service Provider to submit a performance improvement plan detailing why the material breach has occurred and how it will be remedied within ten (10) Working Days or such other period of time as the Customer may direct;
  - b) without terminating this Contract, suspend the affected Service in accordance with the process set out in clause B32:
  - 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 B33 (whereupon a corresponding reduction in the Charges shall be made) and thereafter the Customer may supply or procure a third party to supply such part of the Services.
- B29.2. If the Customer exercises any of its rights under clause B29.1, the Service Provider must indemnify the Customer 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 Customer or a third party to the extent that such costs exceed the payment which would otherwise have been payable to the Service Provider for such part of the Services and provided that the Customer uses its reasonable endeavours to mitigate any additional expenditure in obtaining replacement Services.

#### **B30.** CONTRACT MANAGEMENT

- B30.1. If the Parties have agreed a consequence in relation to the Service Provider failing to meet a Quality Outcomes Indicator (as set out in Section 5 of the Order Form or Framework Schedules 7 or 9) and the Service Provider fails to meet the Quality Outcomes Indicator, the Customer may exercise the agreed consequence immediately and without issuing a Contract Query, irrespective of any other rights the Customer may have under this clause B30.
- B30.2. The provisions of this clause B30 do not affect any other rights and obligations the Parties may have under this Contract.
- B30.3. Clauses B30.19, B30.23, B30.24 and B30.26 will not apply if the Service 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 Customer.

### **Contract Query**

B30.4. If the Customer has a Contract Query it may issue a Contract Query Notice to the Service Provider.

B30.5. If the Service Provider has a Contract Query it may issue a Contract Query Notice to the Customer.

#### **Excusing Notice**

- B30.6. The Receiving Party may issue an Excusing Notice to the Issuing Party within five (5) Working Days of the date of the Contract Query Notice.
- B30.7. If the Issuing Party accepts the explanation set out in the Excusing Notice, it must withdraw the Contract Query Notice in writing within ten (10) Working Days following the date of the Contract Query Notice.

#### **Contract Management Meeting**

- B30.8. Unless the Contract Query Notice has been withdrawn, the Customer and the Service Provider must meet to discuss the Contract Query and any related Excusing Notice within ten (10) Working Days following the date of the Contract Query Notice.
- B30.9. At the Contract Management Meeting the Customer and the Service 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.
- B30.10. If a Joint Investigation is to be undertaken:
  - a) the Customer and the Service Provider must agree the terms of reference and timescale for the Joint Investigation (being no longer than four (4) weeks) and the appropriate clinical and/or non-clinical representatives from each Party to participate in the Joint Investigation.
  - b) the Customer and the Service Provider may agree an Immediate Action Plan to be implemented concurrently with the Joint Investigation.

## Joint Investigation

- B30.11. On completion of a Joint Investigation, the Customer and the Service 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.
- B30.12. Either the Customer or the Service 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**

- B30.13. If a Remedial Action Plan is to be implemented, the Customer and the Service Provider must agree the contents of the Remedial Action Plan within:
  - a) five (5) Working Days following the Contract Management Meeting; or
  - b) five (5) Working Days following the Review Meeting in the case of a Remedial Action Plan recommended under clause B30.11.
- B30.14. 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 B30.23, the consequences for failing to meet each milestone by the specified date.
- B30.15. The Service Provider and the Customer must implement or meet the milestones applicable to it within the timescales set out in the Remedial Action Plan.

- B30.16. The Customer and the Service Provider must record progress made or developments under the Remedial Action Plan in accordance with its terms. The Customer and the Service Provider must review and consider that progress on an ongoing basis and in any event at the next Review Meeting.
- B30.17. 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 Customer or the Service Provider unresolved, either may issue a further Contract Query Notice in respect of that matter.

## Withholding Payment for Failure to Agree Remedial Action Plan

- B30.18. If the Customer and the Service Provider cannot agree a Remedial Action Plan within the relevant period specified in clause B30.13, they must jointly notify the Boards of Directors of both the Service Provider and the Customer.
- B30.19. If, ten (10) Working Days after notifying the Boards of Directors, the Customer and the Service Provider still cannot agree a Remedial Action Plan, the Customer may withhold up to 2% of the monthly sums payable by it under clause B9 (*Charges and Payment*) for each further month the Remedial Action Plan is not agreed.
- B30.20. The Customer must pay the Service Provider any sums withheld under clause B30.19 within ten (10) Working Days of receiving the Service Provider's agreement to the Remedial Action Plan. Unless clause B30.25 applies, those sums are to be paid without interest.

## **Exception Reports**

- B30.21. If a Party breaches a Remedial Action Plan and does not remedy the breach within five (5) Working Days of its occurrence, the Service Provider or the Customer (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 Service Provider, the Customer may withhold payment from the Service Provider in accordance with clause B30.23.
- B30.22. 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 Customer or the Service 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

- B30.23. If the Service Provider breaches a Remedial Action Plan:
  - a) the Customer may withhold, in respect of each milestone not met, up to 2% of the aggregate monthly sums payable by the Customer under clause B9 (*Charges and Payment*), from the date of issuing the First Exception Report and for each month the Service Provider's breach continues, subject to a maximum monthly withholding of 10% of the aggregate monthly sums payable by the Customer under clause B9 (*Charges and Payment*) in relation to each Remedial Action Plan:
  - b) the Customer must pay the Service Provider any sums withheld under clause B30.23(a) within ten (10) Working Days following the Customer's confirmation that the breach of the Remedial Action Plan has been rectified. Subject to clause B30.25, no interest will be payable on those sums.

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

B30.24. If the Service Provider is in breach of a Remedial Action Plan the Customer may, when issuing any Second Exception Report retain permanently any sums withheld under clause B30.23.

## **Unjustified Withholding or Retention of Payment**

B30.25. If the Customer withholds sums under clause B30.19 or clause B30.23 or retain sums under clause B30.24, and within twenty (20) Working Days of the date of that withholding or retention (as the case may be) the Service Provider produces evidence satisfactory to the Customer that the relevant sums were withheld or retained unjustifiably, the Customer must pay those sums to the Service Provider within ten (10) Working Days following the date of the Customer'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 Customer does not accept the Service Provider's evidence the Service Provider may refer the matter to Dispute Resolution.

#### Retention of Sums Withheld on Expiry or Termination of this Contract

- B30.26. If the Service Provider does not agree a Remedial Action Plan:
  - a) within six (6) months following the expiry of the relevant time period set out in clause B30.13; or
  - b) before the Expiry Date or earlier termination of this Contract,

whichever is the earlier, the Customer may retain permanently any sums withheld under clause B30.19.

B30.27. If the Service Provider does not rectify a breach of a Remedial Action Plan before the Expiry Date or earlier termination of this Contract, the Customer may retain permanently any sums withheld under clause B30.23.

#### **B31. DISPUTE RESOLUTION**

- B31.1. The Parties shall attempt in good faith to negotiate a settlement to any dispute between them arising out of or in connection with the Contract within twenty (20) Working Days of either Party notifying the other of the dispute and such efforts shall involve the escalation of the dispute to the level of the Customer Representative and the Service Provider Representative.
- B31.2. Nothing in this dispute resolution procedure shall prevent the Parties from seeking from any court of competent jurisdiction an interim order restraining the other Party from doing any act or compelling the other Party to do any act.
- B31.3. If the dispute cannot be resolved by the Parties pursuant to clause B31.1 the Parties shall refer it to mediation pursuant to the procedure set out in clause B31.5 unless:
  - a) the Customer considers that the dispute is not suitable for resolution by mediation; or
  - b) the Service Provider does not agree to mediation.
- B31.4. The obligations of the Parties under the Contract shall not be suspended, cease or be delayed by the reference of a dispute to mediation and the Service Provider and the Staff shall comply fully with the requirements of the Contract at all times.
- B31.5. The procedure for mediation is as follows:
  - a) a neutral adviser or mediator ("**the Mediator**") shall be chosen by agreement between the Parties or, if they are unable to agree upon a Mediator within ten (10) Working Days after a request by one Party to the other or if the Mediator agreed upon is unable or unwilling to act, either Party shall within ten (10) Working Days from the date of the proposal to appoint a Mediator or within ten (10) Working Days of notice to either Party that he is unable or unwilling to act, apply to the Centre for Effective Dispute Resolution ("**CEDR**") to appoint a Mediator:

- b) the Parties shall within ten (10) Working Days of the appointment of the Mediator meet with him in order to agree a programme for the exchange of all relevant information and the structure to be adopted for negotiations to be held. If considered appropriate, the Parties may at any stage seek assistance from the mediation provider appointed by CEDR to provide guidance on a suitable procedure;
- unless otherwise agreed, all negotiations connected with the dispute and any settlement agreement relating to it shall be conducted in confidence and without prejudice to the rights of the Parties in any future proceedings;
- d) if the Parties reach agreement on the resolution of the dispute, the agreement shall be reduced to writing and shall be binding on the Parties once it is signed by their duly authorised representatives;
- e) failing agreement, either of the Parties may invite the Mediator to provide a non-binding but informative opinion in writing. Such an opinion shall be provided on a without prejudice basis and shall not be used in evidence in any proceedings relating to the Contract without the prior written consent of both Parties; and
- f) if the Parties fail to reach agreement in the structured negotiations within sixty (60) Working Days of the Mediator being appointed, or such longer period as may be agreed by the Parties, then any dispute or difference between them may be referred to the courts.

#### B32. SUSPENSION AND CONSEQUENCES OF SUSPENSION

- B32.1. A suspension event shall have occurred if:
  - a) the Customer reasonably considers that a breach by the Service 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) clauses B32.1(a) and B32.1(c) do not apply, but the Customer, acting reasonably, considers that the circumstances constitute an emergency, (which may include an event of Force Majeure) affecting provision of a Service or Services; or
  - c) the Service 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).

- B32.2. Where a Suspension Event occurs the Customer:
  - a) may by written notice to the Service Provider and with immediate effect suspend any affected Service, or the provision of any affected Service, until the Service Provider demonstrates to the reasonable satisfaction of the Customer 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.
- B32.3. During the suspension of any Service under clause B32.2, the Service Provider must comply with any steps the Customer reasonably specifies in order to remedy the Suspension Event, including where the Customer's decision to suspend pursuant to clause B32.2 has been referred to dispute resolution under clause B31 (*Dispute Resolution*).
- B32.4. During the suspension of any Service under clause B32.2, the Service 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 B32.2; and/or
- b) all or part of the suspended Service which the Service Provider continues to deliver during the period of suspension in accordance with clause B32.5.
- B32.5. 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.
- B32.6. Except where suspension occurs by reason of an event of Force Majeure, the Service Provider must indemnify the Customer in respect of any Losses directly and reasonably incurred by the Customer in respect of that suspension (including for the avoidance of doubt Losses incurred in commissioning the suspended Service).
- B32.7. Following suspension of a Service the Service Provider must at the reasonable request of the Customer and for a reasonable period:
  - a) co-operate fully with the Customer 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 Customer or members of the public; and
  - b) at the cost of the Service 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 Customer all materials, papers, documents and operating manuals owned by the Customer and used by the Service Provider in the provision of the suspended Service.
- B32.8. As part of its compliance with clause B32.7 the Service Provider may be required by the Customer to agree a transition plan with the Customer and/or any alternative Successor Provider.
- B32.9. If it is determined, pursuant to clause B31 (*Dispute Resolution*), that the Customer acted unreasonably in suspending a Service, the Customer must indemnify the Service Provider in respect of any Loss directly and reasonably incurred by the Service Provider in respect of that suspension.
- B32.10. During any suspension of a Service the Service 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.

#### **B33. TERMINATION**

- B33.1. Either Party may voluntarily terminate this Contract or any Service by giving the other Party not less than three (3) months' written notice at any time after the Service Commencement Date.
- B33.2. The Customer may terminate this Contract in whole or part with immediate effect by written notice to the Service Provider if:
  - a) the Service Provider is in persistent or repetitive breach of the Quality Outcomes Indicators;
  - b) the Service Provider is in persistent breach of its obligations under this Contract;
  - c) the Service Provider:
    - (i) fails to obtain any Consent;
    - (ii) loses any Consent; or
    - (iii) has any Consent varied or restricted,

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

- d) the Service Provider has breached the terms of clause B40 (*Prohibited Acts*);
- e) any of the Service Provider's necessary registrations are cancelled by the CQC or other Regulatory Body as applicable;
- f) the Service Provider materially breaches its obligations in clause B38 (*Data Protection*);
- g) two or more Second Exception Reports are issued to the Service Provider under clause B30.22 (*Contract Management*) within any rolling six (6) month period which are not disputed by the Service Provider, or if disputed, are upheld under Dispute Resolution;
- h) the Service Provider breaches the terms of clause B24 (Assignment and Sub-contracting);
- a resolution is passed or an order is made for the winding up of the Service Provider (otherwise than for the purpose of solvent amalgamation or reconstruction) or the Service 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 Service Provider's property or equipment;
- the Service Provider ceases or threatens to cease to carry on business in the United Kingdom; or
- k) the Service 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 Service Provider has not remedied that breach within thirty (30) Working Days following receipt of notice from the Customer identifying the breach.
- B33.3. Either Party may terminate this Contract or any Service by written notice, with immediate effect, if and to the extent that the Customer or the Service Provider suffers an event of Force Majeure and such event of Force Majeure persists for more than thirty (30) Working Days without the Parties agreeing alternative arrangements.
- B33.4. The Service Provider may terminate this Contract or any Service with immediate effect by written notice to the Customer if the Customer is in material breach of any obligation under this Contract provided that if the breach is capable of remedy, the Service Provider may only terminate this Contract under this clause B33.4 if the Customer has failed to remedy such breach within thirty (30) Working Days of receipt of notice from the Service Provider to do so.

#### **B34.** CONSEQUENCE OF EXPIRY OR TERMINATION

- B34.1. 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.
- B34.2. On the expiry or termination of this Contract or termination of any Service for any reason the Customer, the Service Provider, and if appropriate any successor provider, will agree a succession plan (the "Succession Plan") and the Parties will comply with the provisions of the Succession Plan.
- B34.3. On the expiry or termination of this Contract or termination of any Service the Service Provider must co-operate fully with the Customer to migrate the Services in an orderly manner to the successor provider.
- B34.4. In the event of termination or expiry of this Contract, the Service Provider must cease to use the Customer's Confidential Information and on the earlier of the receipt of the Customer's written instructions or twelve (12) months after the date of expiry or termination, return all copies of the Confidential Information to the Customer.
- B34.5. If, as a result of termination of this Contract or of any Service in accordance with this Contract (except any termination under clauses B33.4, B33.3 or if the Customer terminates under clause B33.1 (*Termination*)), the Customer 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 Service Provider for providing the same Service, then the Customer, acting

reasonably, will be entitled to recover from the Service Provider (in addition to any other sums payable by the Service Provider to the Customer 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 six (6) months following termination.

B34.6. The provisions of clauses B8 (Staff), B9 (Charges and Payment), B12 (Incidents Requiring Reporting), B14 (Service User Health Records), B15 (Information), B24 (Assignment and Subcontracting), B25 (Audit and Inspection), B34 (Consequence of Expiry or Termination), B37 (Confidentiality) and B39 (Freedom of Information and Transparency) will survive termination or expiry of this Contract.

#### **B35.** BUSINESS CONTINUITY

- B35.1. The Service Provider must comply with the Civil Contingencies Act 2004 and with any applicable national and local civil contingency plans.
- B35.2. The Service Provider must, unless otherwise agreed by the Parties in writing, maintain a Business Continuity Plan and must notify the Customer as soon as reasonably practicable of its activation and in any event no later than five (5) Working Days from the date of such activation.

## **B36.** COUNTER-FRAUD AND SECURITY MANAGEMENT

- B36.1. The Service Provider must put in place and maintain appropriate counter fraud and security management arrangements.
- B36.2. The Service Provider must take all reasonable steps, in accordance with good industry practice, to prevent Fraud by Staff and the Service Provider in connection with the receipt of monies from the Customer.
- B36.3. The Service Provider must notify the Customer immediately if it has reason to suspect that any Fraud has occurred or is occurring or is likely to occur.
- B36.4. If the Service Provider or its Staff commits Fraud in relation to this or any other contract with the Customer, the Customer may terminate this Contract by written notice to the Service Provider with immediate effect (and terminate any other contract the Service Provider has with the Customer) and recover from the Service Provider the amount of any Loss suffered by the Customer resulting from the termination, including the cost reasonably incurred by the Customer of making other arrangements for the supply of the Services for the remainder of the term of this Contract had it not been terminated.

## **B37.** CONFIDENTIALITY

- B37.1. 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
- B37.2. Subject to clauses B37.3 and B37.4, 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.
- B37.3. The Receiving Party may disclose the Disclosing Party's Confidential Information:
  - a) in connection with any dispute resolution under clause B31 (*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 B37.2; or
- e) to comply with a regulatory body's request.
- B37.4. The obligations in clause B37.1 and clause B37.2 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.
- B37.5. 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 B37.
- B37.6. The Parties acknowledge that damages would not be an adequate remedy for any breach of this clause B37 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 B37.
- B37.7. This clause B37 shall not limit the Public Interest Disclosure Act 1998 in any way whatsoever.
- B37.8. The obligations in clause B37.1 and clause B37.2 shall not apply where the Confidential Information is related to an item of business at a board meeting of the Customer or of any committee, sub-committee or joint committee of the Customer or is related to an executive decision of the Customer 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 Customer 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 Service Provider and where reasonably practicable shall consider any representations made by the Service Provider.

## **B38.** DATA PROTECTION

#### Status of the Controller

- B38.1. The Parties acknowledge that for the purposes of the Data Protection Legislation, the nature of the activity carried out by each of them in relation to their respective obligations under this Contract dictates the status of each party under the DPA. A Party may act as:
  - a) "Controller" in respect of the other Party who is "Processor";
  - b) "Processor" in respect of the other Party who is "Controller";
  - c) "Joint Controller" with the other Party;
  - d) "Independent Controller" of the Personal Data where the other Party is also "Controller",

in respect of certain Personal Data under a Contract and shall specify in Appendix C which scenario they think shall apply in each situation.

## Where one Party is Controller and the other Party its Processor

B38.2. Where a Party is a Processor, the only processing that it is authorised to do is listed in Appendix C by the Controller.

- B38.3. The Processor shall notify the Controller immediately if it considers that any of the Controller's instructions infringe the Data Protection Legislation.
- B38.4. The Processor shall provide all reasonable assistance to the Controller in the preparation of any Data Protection Impact Assessment prior to commencing any Processing. Such assistance may, at the discretion of the Controller, include:
  - a) a systematic description of the envisaged Processing operations and the purpose of the Processing;
  - b) an assessment of the necessity and proportionality of the Processing operations;
  - c) an assessment of the risks to the rights and freedoms of Data Subjects; and
  - d) the measures envisaged to address the risks, including safeguards, security measures and mechanisms to ensure the protection of Personal Data.
- B38.5. The Processor shall, in relation to any Personal Data Processed in connection with its obligations under this Contract:
  - a) Process that Personal Data only in accordance with [Appendix C] unless the Processor is required to do otherwise by Law. If it is so required the Processor shall promptly notify the Controller before Processing the Personal Data unless prohibited by Law;
  - b) ensure that it has in place Protective Measures, which the Controller may reasonably reject (but failure to reject shall not amount to approval by the Controller of the adequacy of the Protective Measures) having taken account of the:
    - (i) nature of the data to be protected;
    - (ii) harm that might result from a Data Loss Event;
    - (iii) state of technological development; and
    - (iv) cost of implementing any measures;
  - c) ensure that:
    - (i) its Personnel do not process Personal Data except in accordance with this Contract (and in particular Appendix C);
    - (ii) it takes all reasonable steps to ensure the reliability and integrity of any Personnel who have access to the Personal Data and ensure that they:
      - A. are aware of and comply with the Processor's duties under this clause;
      - B. are subject to appropriate confidentiality undertakings with the Processor or any Sub-processor;
      - C. are informed of the confidential nature of the Personal Data and do not publish, disclose or divulge any of the Personal Data to any third party unless directed in writing to do so by the Controller or as otherwise permitted by this Contract; and
      - D. have undergone adequate training in the use, care, protection and handling of Personal Data; and
  - d) not transfer Personal Data outside of the United Kingdom or the EU unless the prior written consent of the Controller has been obtained and the following conditions are fulfilled:
    - the Controller or the Processor has provided appropriate safeguards in relation to the transfer (whether in accordance with GDPR Article 46 or LED Article 37) as determined by the Controller;
    - (ii) the Data Subject has enforceable rights and effective legal remedies;

- (iii) the Processor complies with its obligations under the Data Protection Legislation by providing an adequate level of protection to any Personal Data that is transferred (or, if it is not so bound, uses its best endeavours to assist the Controller in meeting its obligations); and
- (iv) the Processor complies with any reasonable instructions notified to it in advance by the Controller with respect to the Processing of the Personal Data;
- e) at the written direction of the Controller, delete or return Personal Data (and any copies of it) to the Controller on termination of the Contract unless the Processor is required by Law to retain the Personal Data.
- B38.6. Subject to clause B38.7, the Processor shall notify the Controller immediately if in relation to it Processing Personal Data under or in connection with this Contract it:
  - a) receives a Data Subject Access Request (or purported Data Subject Access Request);
  - b) receives a request to rectify, block or erase any Personal Data;
  - c) receives any other request, complaint or communication relating to either Party's obligations under the Data Protection Legislation;
  - d) receives any communication from the Information Commissioner or any other regulatory authority in connection with Personal Data Processed under this Contract;
  - e) receives a request from any third party for disclosure of Personal Data where compliance with such request is required or purported to be required by Law; or
  - becomes aware of a Data Loss Event.
- B38.7. The Processor's obligation to notify under clause B38.6 shall include the provision of further information to the Controller in phases, as details become available.
- B38.8. Taking into account the nature of the Processing, the Processor shall provide the Controller with full assistance in relation to either Party's obligations under Data Protection Legislation and any complaint, communication or request made under clause B38.6 (and insofar as possible within the timescales reasonably required by the Controller) including by promptly providing:
  - a) the Controller with full details and copies of the complaint, communication or request;
  - such assistance as is reasonably requested by the Controller to enable the Controller to comply with a Data Subject Access Request within the relevant timescales set out in the Data Protection Legislation;
  - c) the Controller, at its request, with any Personal Data it holds in relation to a Data Subject;
  - d) assistance as requested by the Controller following any Data Loss Event; and
  - e) assistance as requested by the Controller with respect to any request from the Information Commissioner's Office, or any consultation by the Controller with the Information Commissioner's Office.
- B38.9. The Processor shall maintain complete and accurate records and information to demonstrate its compliance with this clause. This requirement does not apply where the Processor employs fewer than 250 staff, unless:
  - a) the Controller determines that the Processing is not occasional;
  - b) the Controller determines the Processing includes special categories of data as referred to in Article 9(1) of the GDPR or Personal Data relating to criminal convictions and offences referred to in Article 10 of the GDPR;
  - c) the Controller determines that the Processing is likely to result in a risk to the rights and freedoms of Data Subjects.

- B38.10. The Processor shall allow for audits of its Data Processing activity by the Controller or the Controller's designated auditor.
- B38.11. The Processor shall designate a Data Protection Officer if required by the Data Protection Legislation.
- B38.12. Before allowing any Sub-processor to Process any Personal Data related to this Contract, the Processor must:
  - a) notify the Controller in writing of the intended Sub-processor and processing:
  - b) obtain the written consent of the Controller;
  - c) enter into a written agreement with the Sub-processor which gives effect to the terms set out in this clause B38 such that they apply to the Sub-processor; and
  - d) provide the Controller with such information regarding the Sub-processor as the Controller may reasonably require.
- B38.13. The Processor shall remain fully liable for all acts or omissions of any Sub-processor.
- B38.14. The Customer may, at any time on not less than thirty (30) Working Days' notice, revise this clause by replacing it with any applicable controller to processor standard clauses or similar terms forming part of an applicable certification scheme (which shall apply when incorporated by attachment to this Contract).
- B38.15. The Parties agree to take account of any non-mandatory guidance issued by the Information Commissioner's Office. The Customer may on not less than thirty (30) Working Days' notice to the Service Provider amend the Contract to ensure that it complies with any guidance issued by the Information Commissioner's Office.

#### Where the Parties are Joint Controllers of Personal Data

B38.16. In the event that the Parties are Joint Controllers in respect of Personal Data under this Contract, the Parties shall implement clauses that are necessary to comply with GDPR Article 26 based on the terms set out in Appendix D.

#### **Independent Controllers of Personal Data**

- B38.17. With respect to Personal Data provided by one Party to another Party for which each Party acts as an Independent Controller, each Party undertakes to comply with the applicable Data Protection Legislation in respect of their Processing of such Personal Data as Controller.
- B38.18. Each Party shall Process the Personal Data in compliance with its obligations under the Data Protection Legislation and not do anything to cause the other Party to be in breach of it.
- B38.19. Where a Party has provided Personal Data to the other Party in accordance with clause B38.7 above, the recipient of the Personal Data will provide all such relevant documents and information relating to its data protection policies and procedures as the other Party may reasonably require.
- B38.20. The Parties shall be responsible for their own compliance with Articles 13 and 14 of the GDPR in respect of the Processing of Personal Data for the purposes of this Contract.
- B38.21. The Parties shall only provide Personal Data to each other:
  - a) to the extent necessary to perform their respective obligations under this Contract;
  - b) in compliance with the Data Protection Legislation (including by ensuring all required data privacy information has been given to affected Data Subjects to meet the requirements of Articles 13 and 14 of the GDPR); and
  - c) where it has recorded it in Appendix C.
- B38.22. Taking into account the state of the art, the costs of implementation and the nature, scope, context and purposes of Processing as well as the risk of varying likelihood and severity for the rights and freedoms of natural persons, each Party shall, with respect to its Processing of Personal

Data as Independent Controller, implement and maintain appropriate technical and organisational measures to ensure a level of security appropriate to that risk, including, as appropriate, the measures referred to in Article 32(1)(a), (b), (c) and (d) of the GDPR, and the measures shall, at a minimum, comply with the requirements of the Data Protection Legislation, including Article 32 of the GDPR.

- B38.23. A Party Processing Personal Data for the purposes of this Contract shall maintain a record of its Processing activities in accordance with Article 30 of the GDPR and shall make the record available to the other Party upon reasonable request.
- B38.24. Where a Party receives a request by any Data Subject to exercise any of their rights under the Data Protection Legislation in relation to the Personal Data provided to it by the other Party pursuant to the Contract ("Request Recipient"):
  - a) the other Party shall provide any information and/or assistance as reasonably requested by the Request Recipient to help it respond to the request or correspondence, at the cost of the Request Recipient; or
  - b) where the request or correspondence is directed to the other Party and/or relates to that other Party's Processing of the Personal Data, the Request Recipient will:
    - (i) promptly, and in any event within five (5) Working Days of receipt of the request or correspondence, inform the other Party that it has received the same and shall forward such request or correspondence to the other Party: and
    - (ii) provide any information and/or assistance as reasonably requested by the other Party to help it respond to the request or correspondence in the timeframes specified by Data Protection Legislation.
- B38.25. Each Party shall promptly notify the other Party upon it becoming aware of any Personal Data Breach relating to Personal Data provided by the other Party pursuant to this Contract and shall:
  - do all such things as reasonably necessary to assist the other Party in mitigating the effects of the Personal Data Breach;
  - b) implement any measures necessary to restore the security of any compromised Personal Data;
  - c) work with the other Party to make any required notifications to the Information Commissioner's Office and affected Data Subjects in accordance with the Data Protection Legislation (including the timeframes set out therein); and
  - d) not do anything which may damage the reputation of the other Party or that Party's relationship with the relevant Data Subjects, save as required by Law.
- B38.26. Personal Data provided by one Party to the other Party may be used exclusively to exercise rights and obligations under the Contract as specified in Appendix C.
- B38.27. Personal Data shall not be retained or processed for longer than is necessary to perform each Party's respective obligations under the Contract which is specified in Appendix C.
- B38.28. Notwithstanding the general application of clauses B38.2 to B38.15, where the Service Provider is required to exercise its regulatory and/or legal obligations in respect of Personal Data, it shall act as an Independent Controller of Personal Data in accordance with clauses B38.16 to B38.27.

#### B39. FREEDOM OF INFORMATION AND TRANSPARENCY

- B39.1. The Parties acknowledge their respective duties under the FOIA and must give all reasonable assistance to each other where appropriate or necessary to comply with such duties.
- B39.2. If the Service Provider is not a Public Authority, the Service Provider acknowledges that the Customer is subject to the requirements of the FOIA and will assist and co-operate with the Customer to enable the Customer to comply with its disclosure obligations under the FOIA. Accordingly the Service Provider agrees:

- a) that this Contract and any other recorded information held by the Service Provider on the Customer's behalf for the purposes of this Contract are subject to the obligations and commitments of the Customer under the FOIA;
- 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 Customer;
- that if the Service Provider receives a request for information under the FOIA, it will not respond
  to such request (unless directed to do so by the Customer) and will promptly (and in any event
  within two (2) Working Days) transfer the request to the Customer;
- d) that the Customer, acting in accordance with the codes of practice issued and revised from time to time under both section 45 of the Freedom of Information Act 2000, and regulation 16 of the Environmental Information Regulations 2004, may disclose information concerning the Service Provider and this Contract either without consulting with the Service Provider, or following consultation with the Service Provider and having taken its views into account; and
- e) to assist the Customer 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 five (5) Working Days of such request and without charge.
- B39.3. The Parties acknowledge that, except for any information which is exempt from disclosure in accordance with the provisions of the FOIA, the content of this Contract is not Confidential Information.
- B39.4. Notwithstanding any other provision of this Contract, the Service 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.
- B39.5. In preparing a copy of this Contract for publication pursuant to clause B39.4 the Customer may consult with the Service Provider to inform its decision making regarding any redactions but the final decision in relation to the redaction of information shall be at the Customer's absolute discretion.
- B39.6. The Service Provider must assist and co-operate with the Customer to enable the Customer to publish this Contract.
- B39.7. In order to comply with the Government's policy on transparency in the areas of contracts and procurement the Customer will be disclosing information on its website in relation to expenditure in relation to this Contract. The information will include the Service Provider's name and the monthly Charges paid. The Parties acknowledge that this information is not Confidential Information or commercially sensitive information.

## **B40.** PROHIBITED ACTS

- B40.1. 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
  - 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").

- B40.2. If either Party or its employees or agents (or anyone acting on its or their behalf) commits any Prohibited Act or commits any offence under the Bribery Act 2010 with or without the knowledge of the other Party in relation to this Contract, the non-defaulting Party shall be entitled:
  - a) to exercise its right to terminate under clause B33.2 (*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.
- B40.3. Each Party must provide the other Party upon written request with all reasonable assistance to enable that Party to perform any activity required for the purposes of complying with the Bribery Act 2010. Should either Party request such assistance the Party requesting assistance must pay the reasonable expenses of the other Party arising as a result of such request.
- B40.4. The Service 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 Customer within five (5) Working Days of the Customer requesting it and enforced by the Service Provider where applicable.
- B40.5. Should the Service Provider become aware of or suspect any breach of this clause B40, it will notify the Customer immediately. Following such notification, the Service Provider must respond promptly and fully to any enquiries of the Customer, co-operate with any investigation undertaken by the Customer and allow the Customer to audit any books, records and other relevant documentation.

#### **B41.** FORCE MAJEURE

- B41.1. Where a Party is (or claims to be) affected by an event of Force Majeure, it must take all reasonable steps to mitigate the consequences of it, resume performance of its obligations under this Contract as soon as practicable and use its reasonable efforts to remedy its failure to perform its obligations under this Contract.
- B41.2. Subject to clause B41.1, the Party claiming relief as a result of an event of Force Majeure will be relieved from liability under this Contract to the extent that because of the event of Force Majeure it is not able to perform its obligations under this Contract.
- B41.3. The Party claiming relief as a result of an event of Force Majeure must serve an initial written notice on the other Party immediately it becomes aware of the event of Force Majeure. This initial notice shall give sufficient details to identify the particular event. The Party claiming relief must then serve a detailed written notice within a further fifteen (15) Working Days. This detailed notice shall contain all relevant available information relating to the failure to perform the relevant obligations under this Contract as is available, including the effect of the event of Force Majeure, the mitigating action being taken and an estimate of the period of time required to overcome it and resume full delivery of Services.
- B41.4. 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.
- B41.5. The Customer shall not be entitled to exercise its rights to withholdings and/or deduction of payments under this Contract, to the extent that the circumstances giving rise to such rights arise as a result of an event of Force Majeure.

## **B42.** THIRD PARTY RIGHTS

B42.1. 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, save that PHE shall be entitled to exercise its rights to receive

management information from the Service Provider in respect of this Contract and the Customer acknowledges and agrees to this provision.

## B43. CAPACITY

B43.1. Without prejudice to the contractual rights and/or remedies of the Service Provider expressly set out in this Contract, the obligations of the Customer under this Contract are obligations of the Customer in its capacity as a contracting counterparty and nothing in this Contract shall operate as an obligation upon the Customer or in any way fetter or constrain the Customer in any other capacity, nor shall the exercise by the Customer of its duties and powers in any other capacity lead to any liability on the part of the Customer under this Contract (howsoever arising) in any capacity other than as contracting counterparty.

## **B44.** SEVERABILITY

B44.1. 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.

## B45. WAIVER

B45.1. 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.

## B46. PUBLICITY

- B46.1. Without prejudice to clause B39 (*Freedom of Information and Transparency*), except with the written consent of the Customer (such consent not to be unreasonably withheld or delayed), the Service Provider must not make any press announcements in relation to this Contract in any way.
- B46.2. The Service Provider must take all reasonable steps to ensure the observance of the provisions of clause B46.1 by all its staff, servants, agents, consultants and sub-contractors.

## B47. EXCLUSION OF PARTNERSHIP, JOINT VENTURE OR AGENCY

B47.1. Nothing in this Contract creates a partnership or joint venture or relationship of employer and employee or principal and agent between the Customer and the Service Provider.

## B48. GOVERNING LAW AND JURISDICTION

- B48.1. 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.
- B48.2. Subject to the provisions of clause B31 (*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.

#### CALL-OFF GENERAL TERMS AND CONDITIONS APPENDIX A

#### THE GOODS AND/OR SERVICES

## **REQUIREMENT (Specification as set out in ITT 4341)**

## National Framework for e-Sexual and Reproductive Healthcare Service specification

## 1. Introduction

- 1.1. This in an Invitation to Tender (ITT) with information, instructions and guidance provided in Part A, following consideration of which the Tender submission (Part B) should be completed and returned by all Service Providers who wish to Tender for the Framework described in the following pages.
- 1.2. Public Health England (PHE) exists to protect and improve the nation's health and wellbeing and to reduce health inequalities. It does this through advocacy, partnerships, world-class science, knowledge and intelligence, and the delivery of specialist public health services. PHE is an operationally autonomous executive agency of the Department of Health.

## 2. Background

- 2.1. In recent years, there has been an expansion of e-sexual and reproductive health services in the UK, driven by increasing demand and the rapid development of innovative testing technologies and telemedicine. E-sexual and reproductive health services have been rapidly scaled up in response to COVID-19 to maintain access to services in some areas where capacity to deliver face-to-face services has been reduced. It is for local commissioners to determine how sexual and reproductive health services should and will be delivered and organised in their area however, it is expected that many e-sexual and reproductive health services will be maintained post COVID-19 to complement local service delivery.
- 2.2. The Framework is intended to create efficiencies for the Customer by offering convenient, low cost and flexible contracting options with one or more Provider(s) appointed to provide the Goods and/or Services according to an established service specification, quality standards and Call-Off Terms.
- 2.3. The Framework is intended to support local delivery of sexual and reproductive health services. The services offered by the Provider(s) will complement local provision and have connections to sexual and reproductive health services in the participating areas to ensure that service users can access appropriate local clinical services for appropriate follow up, complex care, and a broader range and choice of services.
- 2.4. The Framework offers flexibility and choice for the Customer to opt in and out of components of the service (all of which are described in greater detail in this document). The Customer also has flexibility to define the length of the contract with the Service Provider(s).
- 2.5. Development of the current framework is based on the experience of launching a successful nation-wide HIV Self-Sampling Service co-commissioned by Public Health England (PHE) and local authorities, which has been running since 2015.

## 3. Scope

- 3.1. The national framework for e-sexual and reproductive healthcare has provision of STI self-sampling (Chlamydia, Gonorrhoea, Syphilis and HIV or T4 kits as standard), remote prescribing and dispense and supply (via post and / or collection from pharmacy) of contraception, emergency contraception and treatment for uncomplicated cases of chlamydia as the main components of service. Provision of condoms and lubricants, pregnancy tests, and chlamydia tests (T1 kits) are secondary components of service and are subject to local determination.
- 3.2. The Service, which will complement sexual and reproductive health services in participating areas, will be managed and operated by the Service Provider(s), entirely or in partnership with a local provider of sexual and reproductive healthcare. The Service Provider(s) will provide access to one or more of the components of service described below, accepting self-referrals or referrals from a local provider, or both, in line with the agreement with the Customer. All Service Users will be assessed for eligibility and then their STI testing and contraception needs will be met following an initial online consultation. Based on this assessment, Service Users will be offered the available services within this system and / or signposted to other e-services and / or local services. There are 11 main components of the Service (all of which are described in greater detail in the Requirement section of this document). The 11 are:
  - User interface and access
  - · Information and advice about sexual and reproductive health
  - T4 testing kit order fulfilment
  - Hepatitis B (HBV) and hepatitis C (HCV) testing where appropriate
  - Remote prescribing and supply (via post and/or collection) of treatment for uncomplicated chlamydia
  - Remote prescribing and supply (via post and/or collection) of EHC and other hormonal contraception options
  - Pathology
  - Results management
  - Referral to local services and agencies
  - Signposting to further support and health promotion information
  - Safeguarding management obligations
- 3.3. Framework Customers should also be able to select from a number of additional options including condom and lubricant provision, pregnancy test provision and standalone Chlamydia (T1) for certain service users.
- 3.4. The delivery models proposed by Tenderers must meet the requirement of the end to end service. The appointed Service Provider(s) will be contractually responsible for the entire Service; however appropriate sub-contracting or partnering of components of the Service is permissible. Where sub-contracting is proposed, Tenderers will be required to demonstrate in their Tender submissions how they will ensure a more complex supply chain will not jeopardise an efficient and 'seamless' Service delivery.

- 3.5. The Service will be free of charge to eligible individual Service Users electing to use it, and who have an address (or other address selected by the Service User) that falls within an area where the Service has been commissioned. The Service Provider will invoice the appropriate Customer on a price per kit/treatment/contraception method provided basis for activities undertaken.
- 3.6. It should be recognised that the appointed Service Provider(s) will need to work collaboratively across a number of national, regional and local providers and other organisations responsible for both commissioning and delivery of different elements of sexual and reproductive health pathways.
- 3.7. At a framework level, the Service and Service Provider compliance will be contract managed by PHE. Customers will however be responsible for the day to day management of their individual call-off contracts, including payment of invoices.
- 3.8. The Service Provider will be required to submit or make available quarterly performance and quality monitoring reports to each Customer and, at framework-level, to PHE
- 3.9. Tenderers should be aware that a significant aspect of the requirement will be to manage peaks in demand efficiently and effectively. Further information can be found in the next section, Requirement (including Specification).

## 4. Procurement design and Lots

4.1. This procurement has been divided into three Lots, Providers may bid for one or more of the lots detailed in table 1. Section 6 describes the requirements for each lot in more detail.

Table	1	
Lot	Lot name	Outline of requirement
1	STI testing and management	<ul> <li>Online portal assessment for and provision of postal kit for STI and viral hepatitis testing (Gonorrhoea, Chlamydia, HIV Syphilis).</li> <li>1st line treatment for uncomplicated Chlamydia infection</li> <li>Referral and support into care</li> <li>Provision of surveillance and monitoring data</li> <li>Provision of condoms and lubricant</li> <li>Sign posting, information and support</li> </ul>
2	EHC assessment and provision	<ul> <li>Online and or remote assessment for emergency contraception</li> <li>Referral/signposting for IUD if appropriate</li> <li>Remote prescribing of EHC</li> <li>Dispensing and supply of medication</li> <li>Provision of bridging contraception and home pregnancy tests</li> <li>Provision of condoms and lubricant</li> <li>Provision of chlamydia self-sample kits (for selected user)</li> <li>1st line treatment for uncomplicated Chlamydia infection</li> <li>Sign posting, information and support</li> <li>Provision of surveillance and monitoring data</li> </ul>

3	Contraception assessment and provision	<ul> <li>Online and or remote assessment for hormonal contraception</li> <li>Referral/signposting for LARC methods if appropriate</li> <li>Remote prescribing of contraception</li> <li>Dispensing and supply of medication</li> <li>Provision of condoms and lubricant</li> <li>Provision of chlamydia self-sample kits (for selected user)</li> <li>1st line treatment for uncomplicated Chlamydia infection</li> <li>Sign posting, information and support</li> </ul>
		Provision of surveillance and monitoring data

## 5. Objectives

## 5.1. The objectives of the procurement are:

- To appoint one or more qualified Service Providers to a national framework to support or complement the local commissioning of e-sexual and reproductive healthcare
- To ensure that local commissioners of sexual and reproductive healthcare (or their providers) have access to low-cost, clinically robust e-sexual and reproductive healthcare as described in this specification and to include: STI self-sampling (T4 as standard), remote prescribing and dispensing and supply (via post, and / or collection from a pharmacy) of contraception, emergency contraception and treatment for uncomplicated cases of chlamydia as the main components of service and provision of condoms and lubricants, pregnancy tests, and chlamydia tests (T1) as secondary components of service. For the purposes of this document these services will be described as e-SRH.
- To ensure that local commissioners of sexual and reproductive healthcare (or their providers)
  have a convenient and flexible method of contracting with a provider of e-sexual and
  reproductive healthcare and choice in terms of what and how components of care will be
  delivered and implemented.
- To support and complement the provision of sexual and reproductive healthcare in
  participating areas, establishing and maintaining strong and productive relationships with local
  providers and commissioners to support the management of care for patients.
- Produce a fully testable/working version demonstrated to PHE in advance of go-live within two
  weeks of contract award.
- To have the Framework available for use by Customers as soon as possible following contract award.
- Create efficiencies for the Customer by offering convenient, low cost and flexible contracting options with one or more Provider(s) appointed to provide the Goods and/or Services according to an established service specification, quality standards and Call-Off Terms.

## 6. REQUIREMENTS

## 6.1 Service outcomes

- Increase access to STI testing services
- Diagnose STIs and provide treatment for chlamydia or refer to specialist services for treatment of STIs
- Increase access to contraception through remote services primarily delivered online or through referral to specialist services

## 6.2. Relevant organisations and intended usage

- 6.2.1 The Framework will be open for use by the following:
  - Public Health England
  - any local authority in England
  - NHS England / NHS Improvement
  - · any clinical commissioning group, NHS Trust or NHS Foundation Trust in England
  - · any combined authority in England
  - any other organisation deemed suitable by a local commissioner and with the agreement of the steering group
- 6.2.2 It is anticipated that local commissioners will consider, if a need to offer e-sexual and reproductive healthcare to complement existing provision in their area has been established, purchasing one or more of the components of service described in this specification via the national framework.

## 6.3. Duration

- 6.3.1 The Framework will be in place for an initial period of 2 years, with two options to extend for a period of 12 months, taking the contract term to a maximum of 4 years. The Framework is intended to start on mid-July 2020 (see contract documentation for dates).
- 6.3.2 Any subsequent extension to the Framework will be agreed between Public Health England and the Service Provider. For any extension(s) to the Framework, discussions with Service Providers shall be conducted sufficiently far in advance of the Framework expiry date to arrive at an agreed position.
- 6.3.3 The Service Provider will ensure that Customers have the flexibility to sign-up to one or more components of service and to change these components during the course of the contract term. Customers will be able to sign up to the Framework for a minimum of 3 months.

## 6.4. Governance

6.4.1 The Service Provider is required to have robust management and governance to ensure the safe and effective delivery of all the components of service described in this specification. Robust management of all sub-contractors and / or partners is also required. Likewise, effective processes for developing and maintaining effective relationships with customers and other stakeholders is expected.

## **Clinical Governance**

- 6.4.2 The Service Provider will ensure that sufficient arrangements for clinical governance are in place to allow for the provision of safe, effective services delivered to a high standard and in line with all relevant legislation including NHS Clinical Governance Frameworks. Clinical leadership for components of service including remote prescribing of contraception and emergency contraception is required.
- 6.4.3 The Service Provider is responsible for developing and implementing clinical pathways to allow for inward and onward referral of patients e.g. for patients who request or require an emergency IUD.

- This process must include the provider(s) of specialist sexual and reproductive healthcare and the commissioner(s) in each participating area.
- 6.4.4 The Service Provider will also ensure, if any part of any component of service (e.g. results management) is delegated or sub-contracted to another organisation, that clear roles and responsibilities are defined, agreed, and that clinical and / or management oversight is maintained.
- 6.4.5 The Service Provider is required to produce an annual clinical governance report.
- 6.4.6 The Service Provider will ensure that all staff involved in the provision of clinical or laboratory services have appropriate and relevant qualifications, accreditations or registrations; competencies; and have opportunities for continuing professional development.
- The Service Provider is required to develop, implement and monitor infection prevention and control policies, procedures and practice.
- 6.4.8 The Service Provider will ensure that the e-sexual and reproductive health service is developed and delivered in accordance with relevant guidelines and standards of bodies or organisations including but not limited to BASHH, BHIVA, FSRH and other National Standards for Microbiology Investigations.
- 6.4.9 The pathology provider for the service must participate in the UK EQA schemes for HIV and syphilis serology, and molecular detection of Gonorrhoea (GC) and Chlamydia (CT)
- 6.4.10 The pathology provider must be accredited with either ISO 15189 or ISO 17025 under the United Kingdom Accreditation Service (UKAS) and shall comply with all requirements for the handling, processing and storage of samples.
- 6.4.11 The Service Provider must be able to quality assure and evidence pre-and post-analytical components of the service.
- 6.4.12 The Service Provider must have processes and procedures to allow for the identification, recording and reporting of near misses, adverse events and serious untoward incidents. Processes must take into account the work of sub-contractors or other partners if involved in the delivery of the e-sexual and reproductive health service. Customers and PHE must be informed as soon as possible of all serious incidents. Incidents must also be reported to the relevant regulator or similar if required.
- 6.4.13 The Service Provider will ensure registration with all and any relevant regulators e.g. the Care Quality Commission (CQC) and the Information Commissioner.

## Information governance

- 6.4.14 The Service Provider is required to develop and adopt a written confidentiality policy and statement. The policy and related processes should be monitored for compliance
- 6.4.15 The Service Provider will ensure that the confidentiality statement is available to service users / patients. The statement will explain how personal information will be protected and the circumstances in which information could be shared with other organisations e.g. for safeguarding.
- 6.4.16 The Service Provider is required to develop and adopt robust policies and procedures to protect the personal information of service users / patients and to inform if and how information about service users / patients will be shared between or with other organisations (including subcontractors and partners).

- 6.4.17 The Service Provider will ensure that information is not shared with others, including GPs, without the consent of the service user / patient unless a risk to the service user / patient (e.g. safeguarding need) or the wider public has been identified. Best practice guidance should be followed.
- 6.4.18 The Service Provider will ensure that service users / patients can obtain information about how their personal information is or could be used, stored and safeguarded, and the circumstances in which information could be shared with other organisations. Records should be kept in line with NHS guidance for record retention.
- 6.4.19. The Service Provider is required to appoint a senior member of staff to act Caldicott Guardian (if an NHS organisation) or to act in the manner of a Caldicott Guardian (other organisations) to protect the confidentiality and use of service user / patient information.
- 6.4.20. The Service Provider is responsible for the security of information including the personal information of service users / patients. Electronic communications and websites must be secure and protected. Requirements for data protection must be followed.

#### 6.5. Online Portal User interface and access

- 6.5.1 The Service User interface must be fit for purpose on the day it is launched (DATE) and will include, but not be limited to the following requirements:
  - Can process high volumes of requests simultaneously and be able to accept orders/requests for services from Service Users 24 hours a day, 365 days a year.
  - Comply with security standards at all times and should be registered with the Information Customers' Office (ICO).
  - Comply with the General Data Protection Regulation 2018.
  - Be accessible to all Service Users including those with visual impairments, learning difficulties and those with a preference for information in languages other than English
  - Must assure and inform Service Users of their privacy and confidentiality
  - For the Service Provider and/or relevant parties under this contract to be certified members of The Information Standard, NHS England
  - Designing, hosting, managing and maintaining a secure and accessible user-friendly interface
    that facilitates e sexual and reproductive healthcare. The security, accessibility and user
    experience will be assessed by the Framework steering group.
  - Comprehensive and appropriate signposting for individuals residing outside of the local authorities that are co-investing in the Service to obtain services from an alternative provider

     this should include signposting to sexual and reproductive health services as well as other options for free self-sampling and contraception. Signposting should exclude any paid-for services
  - Providing information in a format designed to inform and support decision making by Service Users
- 6.5.2. The platform should be accessible 24 hours a day, 7 days a week with the exception of planned downtime for maintenance. Any periods of downtime should be kept to a reasonable minimum, with prior notice to Customers and a suitable message should be displayed to Service Users visiting the site during this period. Periods of downtime should be restricted to periods of low demand where possible and records of number and duration of downtimes should be available for Customers.

- 6.5.3. Online information and guidance for all kits, treatment, contraception and other items delivered including instructional video(s).
- 6.5.4. The option for Customers to select or de-select one or more of the service options detailed below for a minimum time period of 3 months.
- 6.5.5. All platforms, service user questions, result and case management processes to be agreed, tested and signed off by the Public Health England before implementation. Public Health England will consult with a representative group of commissioners and, as far as possible, customers.

### 6.6. Referrals

- 6.6.1. The Service Provider must be able to accept a) self-referrals, b) re-directions, and / or c) professional referrals from partner sexual and reproductive health services
- 6.6.2. Local commissioners will determine which of the above options should be implemented in their area. Local commissioners are best placed to understand how and if e-sexual and reproductive healthcare can complement and support existing service provision.
- 6.6.3. Self-referral refers to service users (in participating areas) being able to access one or more of the components of service described in this specification without prior authorisation or direct referral from a sexual and reproductive health service.
- 6.6.4. Re-direction refers to providers of sexual and reproductive health services (in participating areas) signposting or re-directing service users to the e-service. This could be via a link on their website or following a local triage process.
- 6.6.5. Referral refers to providers of sexual and reproductive health services (in participating areas) referring patients to the e-service. Clinicians will be able to refer if their patient requires or could benefit from one or more of the components of service.
- 6.6.6. The Service Provider is required to develop and implement a user interface and processes to allow self-referrals, re-directions, and professional referrals. This is required to allow for maximum flexibility for local commissioners and their providers of sexual and reproductive health services.
- 6.6.7. The Service Provider should ensure that visitors to the website should be able to find out if one or more of the components of service described in this specification are available in this area and, if so, how these can be accessed (e.g. self-referral or referral from a sexual and reproductive health service)

## 6.7. Data collection and Service User journey

- 6.7.1. Appropriate information should be collected from the Service User in line with national guidance. The user journey should reflect the services commissioned by Framework Customers for the area they cover. If a component of service has not been commissioned, the Service User should be signposted to other relevant provision (e.g. the sexual and reproductive health system in the area)
- 6.7.2. Data collected should allow comprehensive data provision to the data collections listed in section 6.19
- 6.7.3. Data collected from the Service User should be sufficient to inform correct provision of service e.g. if a Service User reports condomless anal intercourse rectal swabs should be included in the test kit.

6.7.4. The data collected should reflect full patient pathways and include everything required to assess need and safely provide contraception in line with Faculty of Sexual and Reproductive Health (FSRH) Clinical Guidelines for EHC, POP, and CHC.

## 6.8. STI testing and management

- 6.8.1. The Service Provider is required to offer self-sampling of specimens for testing for selected sexually transmitted infections and related functions including results management and linkage to treatment as described in this specification. STI self-sampling is to be made available in areas that choose to purchase this service. Customers can choose whether to offer STI self-sampling service to asymptomatic individuals and/ or to limit this offer to individuals with symptoms. Customers can also choose whether to offer the STI self-sampling service to individuals based on risk and / or demographic information reported by the Service User.
- 6.8.2. The Service Provider will ensure that information about sexually transmitted infections is included on their website and in relevant communications with Service Users.
- 6.8.3. The Service Provider will provide comprehensive information to users denied this service either due to not being eligible, not residing in an area covered by the Framework or because local activity limits have been reached that includes the reason they have been denied service and signposting to other local, free to access service and support options. This could include signposting to other online services available in that area.
- 6.8.4. The Service Provider will have an online assessment process to determine if a visitor is eligible for service (based on criteria such as age and postcode of residence etc) and, if so, if self-sampling is an appropriate offer. If self-sampling is not available or appropriate, the visitor should be signposted to other services.
- 6.8.5. The Service Provider is required to collect sufficient information during the assessment process to determine if screening for certain infections is appropriate or desirable (e.g. not screening for HIV if the Service User is HIV-positive, and if triple site testing and/or screening for HBV and / or HCV is required).
- 6.8.6. Supply of self-sampling kits containing: in-date consumables for capillary or finger- tip blood sampling; 1st pass urine sampling; pharyngeal swab sampling, vulvo-vaginal swab sampling, rectal swab sampling (swab/urine collection consumables to be provided as appropriate based on information reported by the Service User)
- 6.8.7. Easy-to-read and simple to follow sampling instructions in the sampling kit (complemented by the instructional video described in 6.5.3)
- 6.8.8. Sexual health promotion messaging and Service information leaflets; branded microbiology form; prepaid postage return envelope suitable for Category B UN 3373, diagnostic and clinical specimens containing biological and infectious substances.
- 6.8.9. Delivery of a sampling kit to the Service Users' preferred address which may, given the option, differ from their place of residence (this needs to be within postcode area of 'the customer' unless directed and agreed by 'the customer), in discrete and unbranded packaging. Fulfilment of T4 self-sampling kit orders free of charge to the Service User.

## 6.9. Pathology

- 6.9.1. The Customer will only incur the costs of processing the specimens returned by the Service User. For example, if a blood sample is not provided only the costs associated with chlamydia and gonorrhoea testing should be included.
- 6.9.2. The pathology services must be fit for purpose on the day the Service is launched and will include, but not be limited to the following requirements:
  - The pathology provider must have capacity to perform high volume testing on specimens with capability to cope with surges in demand during peak times including surges linked to national and local campaigns.
  - CE marked 4th generation assay testing for HIV antibody and p24 antigens simultaneously as a minimum.
  - Antibody testing for syphilis (excluding Service Users who have previously received treatment for a syphilis infection).
  - Gonorrhoea/ chlamydia nucleic acid amplification test (NAAT) for self-collected swabs (pharyngeal, vulvo-vaginal, rectal as appropriate)
  - Gonorrhoea/ chlamydia NAAT for 1st pass urine specimens as appropriate
  - Confirm any specimen that is gonorrhoea reactive with an alternative molecular target
  - Testing algorithms that maximise Positive Predictive Value and minimize the frequency of ambiguous/ equivocal results.

## 6.10. Chlamydia treatment

- 6.10.1 The Service Provider is required to offer remote assessment and prescribing of treatment for uncomplicated chlamydia and arrange for the dispensing and supply of medication as described in this specification. Medication can be supplied via the post or for collection from a pharmacy. Customers can choose to purchase this component of service and will therefore not be available to all Service Users. If this is not available, the Service Provider will signpost to other providers of treatment in the relevant area (noting that this could include other e-services)
- 6.10.2 The Service Provider will ensure that information about chlamydia is included on their website and in relevant communications with Service Users.
- 6.10.3 The Service Provider will, if an uncomplicated case of urogenital, pharyngeal or rectal chlamydia has been diagnosed and the Service User is residing in a participating area, offer to deliver treatment of chlamydia if the prescriber considers this to be safe and appropriate. The Service Provider should ask the Service User whether they would prefer to receive their treatment via post or for collection from a pharmacy during the initial order process or post-diagnosis via text message.
- 6.10.4 First line treatment of Doxycycline 100mg twice daily for 7 days (as recommended by BASHH) to be dispatched to the registered address within 2 working days.
- 6.10.5 If 1st line treatment is contraindicated, 2nd line and alternative regimens should be provided as per BASHH treatment guidelines6.
- 6.10.6 Complicated CT cases should be identified from the information collected from the Service User and referred to local clinical services for follow-up.

## 6.11. Emergency hormonal contraception

- 6.11.1 The Service Provider is required to offer remote assessment and prescribing of emergency hormonal contraception and arrange for the dispensing and supply of medication as described in this specification. Medication can be supplied via the post or for collection from a pharmacy, however, it must be within a timeframe that enables it to be most effective. Customers can choose to purchase this component of service and will therefore not to be available to all Service Users. If this is not available, the Service Provider will signpost to other providers of emergency contraception in the area (noting that this could include other e-services)
- 6.11.2 The Service Provider will ensure that information about emergency contraception (emergency contraceptive pills and the emergency IUD) is included on their website and in relevant communications with Service Users, including how to access face to face services for emergency IUD.
- 6.11.3 The Service Provider will prescribe Emergency Hormonal Contraception (EHC) to individuals who do not meet the criteria for emergency IUD insertion, or who decline an emergency IUD: women should be advised that copper IUD is the most effective method of emergency contraception and if preferred the provider should refer / signpost to a local service. If IUD is preferred the Service User should still be provided with EHC (if not contra-indicated) as a precaution if an IUD cannot be inserted or they change their mind.
- 6.11.4. Supply of the most appropriate oral emergency contraception medication and dosage (Levonelle or EllaOne) following a detailed online assessment.
- 6.11.5. The Service Provider will provide the option of an enhanced EHC offer. If the Customer has agreed to purchase the enhanced offer this will also include one or more of the following:
  - The offer of chlamydia test kit for all service users aged 24 and under. This requirement is in line with the National Chlamydia Screening Programme (if not being provided with a T4 kit). The Service Provider is required to send the kit to the Service User and to process all kits returned to the lab. See 6.8 and 6.9.
  - The provision of chlamydia treatment as set out in 6.10.
  - A 3-month supply of POP (or combined hormonal method if continuation of current method) as a bridging contraception method
  - A home pregnancy test (provided by post or collection from pharmacy along with EHC) with accompanying advice on how and when to use so the Service User can rule out EHC failure or pregnancy.
  - The provision of condoms (provided by post or collection from pharmacy along with EHC) as set out in 6.13.
- 6.11.6. If Customers do not select the enhanced EHC offer then Service Users should be advised about other options for contraception and sign-posted to local options for accessing contraception. Service users should also be advised about pregnancy testing 3 weeks after EHC to exclude EHC failure.
- 6.11.7. If Customers do not select the provision of chlamydia test kits, service users aged 24 and under should be advised about the importance of regular screening for chlamydia in line with NCSP guidance and recommendations.
- 6.11.8. All individuals receiving EHC should be given clear advice about additional contraceptive precautions, when to start a regular method and how to use pregnancy tests including signposting

to local services that could provide these methods. Follow-up advice and care should be easily accessible, and its uptake encouraged.

## 6.12 Contraception

- 6.12.1 The Service Provider is required to offer remote assessment and prescribing of contraception and arrange for the dispensing and supply of medication as described in this specification. Medication can be supplied via the post or for collection from a pharmacy. Customers can choose to purchase this component of service and it will therefore not be available to all Service Users. If this is not available, the Service Provider will signpost to other providers of contraception in that area (noting that this could include other e-services).
- 6.12.2 The Customer should have the option of selecting the contraception methods they want to purchase: POP, COP, patch, ring, self-administered injectable
- 6.12.3 The Customer should have the option to include the offer of a chlamydia test kit for all service users aged 24 and under (if not being provided with a T4 kit). This requirement is in line with the National Chlamydia Screening Programme. The Service Provider is required to send the kit to the Service User and to process all kits returned to the lab. See 6.8 and 6.9
- 6.12.4 The Customer should have the option to include the provision of chlamydia treatment as set out in 6.10.
- 6.12.5 The Customer should have the option to include the provision of condoms (provided by post or collection from pharmacy along with contraception) as set out in 6.13.
- 6.12.6 The Service Provider will ensure that information about contraception is included on their website and in relevant communications with Service Users.
- 6.12.7 The Service Provider is required to inform users of the full range of contraceptive choices including the relative benefits of long and short-acting methods of contraception (in line with NICE and other relevant guidance) and signpost visitors / Service Users to alternative providers if they are unable to provide the preferred method choice.

## 6.12.8. Continuation of an existing method:

- 6.12.8.1. Provide Progestogen only pill (POP) to cover the next 6 months, without a review.
- 6.12.8.2. Provide progestogen only pill (POP) to cover next 12 months with online review
- 6.12.8.3. Provide continuation of combined method (pills, patch, ring) with review of any changes in health status and assessment of blood pressure and BMI for the next 3, 6 or 12 months as appropriate.
- 6.12.8.4. Changing from Depot medroxyprogesterone acetate (DMPA) to POP without a review, if started within 14 weeks of last DMPA injection to cover next 6 months or 12 months.
- 6.12.8.5. Provide continuation of self-administered injectable contraception for 6 or 12 months.
- 6.12.8.6. Remote prescribing and dispensing and supply of medication can be managed as a central function or be delegated to a sexual and reproductive health service or via local general practices in participating areas if a partnering / sub-contracting arrangement is in place and agreed with all parties including the Customer.

## 6.12.9. Initiating a new method

- 6.12.9.1. Following a detailed online assessment, prescribe and dispense and supply 3-months of POP medication to the Service User if this is deemed safe and appropriate.
- 6.12.9.2. Prescribe and dispense and supply 3 months' of CHC (pills, patch or ring) after a detailed online assessment of medical eligibility and accurate self-reported blood pressure / BMI.
- 6.12.9.3. Remote prescribing and dispensing and supply of medication can be managed as a central function or be delegated to a sexual and reproductive health service in participating areas if a partnering / sub-contracting arrangement is in place and agreed with all parties including the Customer.

## 6.13. Provision of condoms

6.13.1. If the Customer has agreed to purchase this component of the service the Service Provider will include 6 condoms and 6 lube sachets to be sent with STI test kits and contraception methods with advice about use for general contraception and STI prevention but also specific advice about protection whilst hormonal contraception methods become effective, use before receiving test results and use during STI treatment.

## 6.14. Condom distribution scheme

6.14.1. During the first year of the Framework the Service Provider will establish and maintain a mechanism to allow residents of participating areas to order free supplies of condoms and lubricants, both via self-referral (i.e. no restriction on sign-up) or via referral from / in partnership with local condom distribution schemes.

## 6.15. Results management (including clinical advice) and links to clinical services

- 6.15.1. The results management services must be fit for purpose on the day the Service is launched and will include, but not be limited to the following requirement:
- 6.15.2. The Service Provider must provide an efficient and effective method for the follow-up of Service Users with reactive and / or positive STI results. If selected by the Customer, treatment for those with positive chlamydia (uncomplicated) results should be dispatched and the Service User contacted by text to notify them of their result and that treatment has been sent.
- 6.15.3. For those whose test results are confirmed positive for gonorrhoea and / or reactive for syphilis and HIV, attempts should be made to contact them by telephone within 2 working days followed by multiple attempts should the Service User not answer the call. The Service Provider may also provide results via a secure Service User portal.
- 6.15.4. The Service Provider may use discreet text messaging and letters to contact Service Users if telephone contact proves difficult. Where specimens are reactive for HIV, text messages can only be used to assist with arranging telephone contact not to deliver the result. The Service Provider must facilitate the transfer of Service User into a clinical service most convenient for the Service User, liaising with the Service User to remove or reduce barriers to this transfer. The Service Provider will provide general support throughout this process as required. The Service Provider will request confirmation via telephone and / or text message from the Service User of their attendance and outcomes at clinical services.

- 6.15.5. Service Users must be given information on the need for partner notification and must be offered ways to arrange partner notification either through the Service Provider's service or another local service.
- 6.15.6. The pathway into clinical services will be determined by the Framework Customer.
- 6.15.7. The Service Provider can share, delegate or sub-contract some of these functions to a local sexual and reproductive health service, in consultation with and the agreement of the relevant commissioner (the Customer).
- 6.15.8. Where the Service Provider is responsible for transport services, triage and medical advice provided remotely, they will also need to seek registration under the Health and Social Care Act (HSCA) with the Care Quality Commission (CQC) and adhere to its incidence reporting policy.
- 6.15.9. Where the Service Provider is an NHS body they should participate in NHS system reporting.

## 6.16. Recording clinician confirmed attendance

6.16.1. During the first year of the Framework the Service Provider will work with PHE and provider organisations to establish and maintain a mechanism for clinicians to enter results directly into the Service Providers system and record the attendance ID code (GUMCAD) for Service Users referred into clinical services following a reactive and / or positive result.

## 6.17. Applicable service standards

- 6.17.1. Relevant UK clinical guidance covering the specialities of Sexual and Reproductive Healthcare and Genitourinary Medicine can be found at www.fsrh.org, www.bashh.org and www.bhiva.org. The Provider must ensure services reflect updates in guidance and recommendations as and when produced.
- 6.17.2. The Service should use the DHSC's You're Welcome quality criteria and local resources where available, as guiding principles when planning and implementing changes and improvements, in order for the service to be young people friendly where appropriate.
- 6.17.3. The Service is to be underpinned by the following national standards and guidelines:
  - HIV testing: increasing uptake among people who may have undiagnosed HIV (NICE 2016)
  - UK National Guidelines for HIV Testing (BHIVA 2008)
  - Guidance for the detection of gonorrhoea in England (BASHH 2014)
  - British HIV Association (BHIVA) Standards of Care for People Living with HIV (BHIVA 2018)
  - Guidelines for the Sexual and Reproductive Health of people living with HIV; Current out for consultation (BHIVA 2017)
  - Standards for the Management of Sexually Transmitted Infections (BASHH & MEDFASH 2019)
  - UK national guidelines on the management of syphilis (BASHH 2015)
  - 2018 UK national guideline for the management of infection with Neisseria gonorrhoeae (BASHH)
  - BASHH Statement on Partner Notification for Sexually Transmissible Infections (BASHH 2012)

 Interim update of the 2015 BASHH National Guidelines for the Management of the Viral Hepatitis (BASHH 2017)

## Service delivery

- Service Standards for Sexual and Reproductive Healthcare (FSRH 2016)
- All relevant FSRH guidelines and statements
- UK National Guideline on Safer Sex Advice (BASHH & BHIVA 2012)
- Standards for psychological support for adults living with HIV (British Psychological Society, BHIVA & MEDFASH 2011)
- Standards for Online and Remote Providers of Sexual and Reproductive Health Services (FSRH / BASHH 2019)
- Standards for Sexual History Taking (BASHH 2013)
- National Chlamydia Screening Programme Standards (PHE 7th Edition 2014, updated 2018)
- Progress and Priorities Working Together for High Quality Sexual Health (MEDFASH 2008)
- BASHH / Brook (April 2014) Spotting the Signs. A national proforma for identifying risk of child sexual exploitation in sexual health services

## Governance and quality

- Research Governance Framework for Health and Social Care (Department of Health 2005)
- Government Service Design Manual: Digital By Default Service Standard
- Service Standards for Risk Management (FSRH 2017)
- Information Commissioners Office; Guide to the General Data Protection Regulations

## 6.18. Estimated value and volumes

- 6.18.1. Following a brief consultation with 86 Local Authority commissioners we estimate that 45%, 69% and 66% of these commissioners would be interested in using this Framework for STI testing, EHC provision and contraception provision respectively.
- 6.18.2. The number of other categories of Framework Customers who will use this Framework is unknown at this time.
- 6.18.3. The estimates below are for indication purposes only.
- 6.18.4. According to GUMCAD 1,955,000 sexual health screens for HIV, gonorrhoea, chlamydia and syphilis were delivered by sexual health services in 2018. If 45% of Local Authority Commissioners purchase this component of the service this represents just under 880,000 tests. However, this Framework is designed to complement other local service delivery. If we estimate that between 5% and 15% of testing will move from face to face services to this service then between 44,000 and 132,000 tests will be delivered through this Framework per year.
- 6.18.5. According to CTAD around 10% of those aged 15-24 who test for chlamydia are positive. If we assume that positivity rates will be similar in this population of Service Users and apply it to the estimated number of tests being delivered (section 5.18.4) then we estimate that between 4,400 and 13,200 cases of chlamydia would require treatment under this Framework.

- 6.18.6. In 2018 91,000 doses of EHC were delivered by specialist sexual health services. If 69% of Local Authority commissioners purchase this component of the Framework this represents around 63,000 doses/year. However, this framework is designed to complement other local service delivery, if we estimate that between 5% and 15% of the total will be delivered through this Framework this represents 3,150 and 9,459 doses of EHC per year.
- 6.18.7. According to SRHAD data in 2018/19 311,000 women using sexual and reproductive health services for contraception used oral contraception as their main method. If 66% of Local Authority commissioners purchase this component of the Framework this represents 205,000 women. If we estimate that between 5% and 15% of these women will use the services delivered under this Framework then between 10,300 and 30,800 women will use the service for contraception per year. This estimate will vary significantly depending on the number and type of Customers using the Framework and the accessibility of other sources of contraception.
- 6.18.8. Demand for the Framework will vary for example whilst face to face services are restricted due to the COVID-19 response it is likely that demand will be higher. Demand for STI testing services may also be affected by any national or local testing campaigns delivered during the period of the Framework. The Service Provider must be able to manage these changes in demand whilst maintaining high levels of service quality.

## 6.19. Surveillance Data provision

- 6.19.1. Service provider(s) will be required to submit data, or ensure the submission of data by subcontracted providers, to the following routine data collection systems:
- GUMCAD, is the mandatory surveillance system for STIs and collects data on STI tests, diagnoses
  and services from all commissioned sexual health services in England. Data on all STI tests
  returned (not kits delivered) regardless of test outcome should be submitted to PHE as specified in
  the submission requirements referenced here. Following the development described in section 6.16
  the attendance ID code (GUMCAD) for clinical follow-up visits should also be included in these
  returns.
- The CTAD Chlamydia Surveillance System is a mandatory surveillance system used to provide detailed reports at national and local levels on screening coverage, the proportion of chlamydia tests that are positive and the chlamydia detection rate in England. Data on all Chlamydia tests provided through this Framework should be submitted to PHE as per the submission requirements referenced here. CTAD data should be submitted from the test laboratory directly whether that is the Framework Service Provider or a laboratory sub-contracted by the Service Provider.
- The SRHAD dataset is an anonymised, patient level, electronic collection from sexual and reproductive health (SRH) services and all contraception and SRH care services delivered through this Framework must be submitted to NHS Digital as per the submission requirements referenced here.

## 6.20. Service availability

- 6.20.1. The Service Provider is required to accept inbound calls from Service Users (e.g. to answer questions about the ordering process or for advice about how to collect and return samples).
- 6.20.2. The Service Provider is required to operate the results management / clinical consultation and follow-up / prescription functions during normal service hours as a minimum. If one of more of these functions are delegated or delivered via a partnership or sub-contracting arrangement with a local

- sexual and reproductive health service, operating hours and turnaround times should be agreed with that provider and in consultation with the relevant commissioner.
- 6.20.3. Service Users who contact the Service out of hours should be sign posted to an appropriate 24-hour service such as NHS 111 or equivalent, and in case of emergency, sign posted to where Post-exposure Prophylaxis (PEP) is available for free on the NHS.
- 6.20.4. All elements of coordination and management functions of the Service should be delivered, as a minimum, during business operating hours 9am-5pm (GMT) Monday to Friday.

## 6.21. Applicable local standards

6.21.1. Individual Customers may require the Service Provider to operate in accordance with their own (i.e. the Customer's) local standards. Unless such standards are demonstrably outside whatever would reasonably have been considered by the Service Provider in Tendering, then the Service Provider must comply with such standards.

## 6.22. Multiple orders from the same service user

- 6.22.1. The Service Provider must have mechanisms to allow for the identification and review of repeat requests from the same Service User. Where a Service User has accessed the service for STI testing more than four times in a six-month period the Service Provider is required to facilitate a one-to-one consultation for these Service Users specifically to establish the reasons for multiple use and provide further support, advice and signposting. Such Service Users should not be dissuaded from using the service and their kits requests should be processed as normal.
- 6.22.2. Service Users that access the service for EHC more than four times in a six-month period should be offered a telephone consultation to discuss the repeat use and provide information on and support to access routine contraception. Such service users should still be provided with EHC as appropriate.
- 6.22.3. Service Providers must have mechanisms to record current contraception use and last previous prescription for Service Users that access the service for non-emergency contraception. Where Service Users are identified as having a current method available the Service Provider should establish the reason for the current request and provide further advice and support if required.

## 6.23. Multiple orders from the same address

6.23.1. The Service Provider must alert the Customer concerned if a non-residential address is used multiple times to place an order for an STI test kit or EHE or contraception. Should the customer have set a service threshold of less than 500 uses no more than 10% of service orders should have the same commercial address recorded as a residential address. Should the service threshold exceed 500 per annum no more than 5% of the service orders should have the same commercial address recorded as a residential address. The purpose is not to prevent the Service being used by residents, but to encourage local conversations between Customers and the Service User about online service provisions.

## 6.24. Safeguarding

- 6.24.1. The Service Providers and any sub-contracting or partner organisations must have robust safeguarding policies, procedures and practice in relation to children, young people and vulnerable adults. Processes for responding to safeguarding or other concerns including when and how to make a referral must be in place and followed. Safeguarding policies must include clear protocols to deal with dangerous, exploitative or unsafe behaviour and practice and provide training to all of the Provider's Staff to ensure awareness of responsibilities and develop appropriate skills and knowledge. The Service Provider shall have in place and implement robust up-to-date procedures, (including, disciplinary procedures, whistle-blowing policy and recruitment checks), for preventing, avoiding and responding to actual or suspected physical, sexual, psychological, financial or material and discriminatory abuse and acts of neglect or omission. Such procedures shall be reviewed at least once every year.
- 6.24.2. The Service Provider will record all safeguarding concerns and actions and report to customers as part of the performance and quality monitoring process. Significant or serious concerns should be raised with and discussed with the customer as and when required.
- 6.24.3. The Service Provider will be required to ensure that all individuals engaged in the provision of the Services are subject to a valid enhanced disclosure check undertaken through the DBS including a check against the barred lists. The Provider will be responsible for ensuring that it has no reason to believe that any person who is or will be employed or engaged by the Provider in the provision of the Services is barred from the regulated activity as defined by the Safeguarding Vulnerable Groups Act 2006.
- 6.24.4. The service will be available to those aged 16 and above. The Service Provider should put in place reasonable steps agreed with the service steering group to facilitate the identification of under-age Service Users. In the event it is discovered a Service User is under the age of 16, practitioners also need to be aware of the specific responsibilities that they have for young people aged 13-15 and for those under the age of 13. In dealing with Service Users under the age of 16, the provider must ensure that they adhere to the Department of Health's guidance document "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".
- 6.24.5. The Provider must ensure that they adhere to Department of Health's guidance document Safeguarding adults: The role of Health Service Practitioners. The Provider should put in place reasonable steps agreed with the service steering group to facilitate the identification of vulnerable Service Users over the age of 16.
- 6.24.6. The Provider shall have in place a robust safeguarding training programme for all Staff (including volunteers) appropriate to their level of responsibility. Further the Provider shall maintain appropriate records of training for audit purposes.

## 6.25. Incidents requiring reporting procedure

- 6.25.1. All safeguarding incidents should be reported immediately to the authority under which the care was provided i.e. the Local Authority from which the kit was ordered. In participating in the framework, Customers may acquaint the Provider with their own safeguarding protocols and requirements, with which the Provider must act in accordance. A quarterly report of the number and type of safeguarding incidents along with information on status and resolution will be provided to each Customer and to PHE.
- 6.25.2. The Service Provider will produce a quarterly summary report providing full details of all complaints and how they were resolved. The Service Provider will have awareness of, and will respond to,

infectious diseases outbreaks and other threats to health. A clinical governance report will be submitted to Public Health England on an annual basis and full details of any Serious Incidents (SIs) will be communicated to the relevant Local Authority and Public Health England without delay.

## 6.26. Service users with vulnerabilities

- 6.26.1. The Service Provider will collect data on Service Users with vulnerable characteristics that may impede their use of an online SRH service and / or with characteristics that may place them at increased risk of poor sexual and / or reproductive health.
- 6.26.2. The Service Provider will report data on these characteristics to Framework Customers and to PHE as part of the routine information provision detailed in section 6.27.
- 6.26.3. The Service Provider will be expected to collect data on the following vulnerabilities, this list is not exhausted and can be added to and adapted by Framework Customers and PHE during the lifetime of the Framework.
  - Sex work
  - · Drug and alcohol use including injecting and sexualised drug use
  - Signs of Child Sexual Exploitation (CSE)

## 6.27. Information Provision and Contract Monitoring

- 6.27.1. The Service Provider will make available a brochure for prospective customers detailing service provision, pricing, sign-up and contracting arrangements.
- 6.27.2. The Service Provider is required to submit on a quarterly basis a report on progress against all performance and quality outcome indicators as detailed in sections 6.28 and 6.29 (or as otherwise agreed) for each Customer.
- 6.27.3. The service provider is required to compile and submit (or otherwise make available, e.g. via a secure web portal) a performance and quality monitoring report to each Customer no more than 6 weeks after the end of each quarter. Draft KPIs to be monitored by these data can be found at Section 6.29.
- 6.27.4. The Service Provider is also required to submit on a quarterly basis a report on progress against all performance and quality outcome indicators to PHE. Reports to PHE should cover all customers signed up to the Framework. PHE may also require data reports and extracts detailing all activity included in this Framework.
- 6.27.5. The Service Provider is also expected to provide anonymised, quarterly, disaggregate activity datasets to PHE. The content of these extracts should include all activity data, test results, SRH and contraception care services provided, and demographic and sexual history data collected.
- 6.27.6. In addition to the routine reporting requirements detailed above, the Service Provider is required to inform the relevant Customer or Customers and / or PHE of any incident or concern.
- 6.27.7. Where any Customer has stipulated a maximum level of expenditure or maximum number of test kits / services to be delivered, the Service Provider shall provide a monthly report to that Customer detailing recent and cumulative activity under the Framework payment for which that Customer is responsible. Additionally, an alert shall be sent to the Customer when such activity reached 95% of the specified maximum.

- 6.27.8. Customers shall have secure access (controlled by logins and passwords) to an online database so that they may monitor Framework usage in real-time. Levels of access shall be controlled to limit the data visible (such access shall automatically manage controls required under relevant legislation e.g. as applies to data protection and patient confidentiality). PHE shall have secure access to all data from services delivered under the Framework via an online database.
- 6.27.9. The Service Provider will meet quarterly with the Steering Group to review performance, and at least ten working days ahead of such meetings provide or provide access to disaggregate data for all Service Users to the Public Health England service manager. Five working days ahead of each such meeting the Service Provider shall also send PHE a report which includes at least the following information:
  - How the Service User had found out about the Service
  - Where there is an online Service provision:
  - · List of referrers and their volume of click-throughs to website
  - Total number of website visitors
  - Amount of time individuals spend on the site and the drop out points
  - Number of visitors denied a service through the Framework according to the reason e.g. age, resident in area not covered by the Framework.
  - Proportion of website visitors that result in a component being requested
  - Aggregate summary of where ineligible Service Users reside by Lower-tier Local Authority of residence
  - Number of first and follow up Service Users ordering a T4 testing kit and how they ordered
- 6.27.10. Membership of the Steering Group will be extended to all Customers or representatives and will be the main forum for discussion of strategic issues. However, Service Providers will need to develop their own relationship with each Customer in order to facilitate local operation and integration of the service offer.

## 6.28. Performance monitoring

- 6.28.1. Number of Service Users (for all Service Users) by:
  - Kit ordering channel (referred or self-referral)
  - Age
  - Gender identity
  - Sex at birth
  - Sexual orientation
  - Sex of partners
  - Ethnicity (as per the NHS data dictionary with the addition of Latin American)
  - Country of birth
  - English language status
  - Lower-tier Local Authority of residence
- 6.28.2. For the STI testing and treatment components of the service the Service Provider will provide data to Customers and PHE on the following:
  - All GUMCAD data items collected and reported as specified in the Sexual Risk Information section of the GUMCAD STI Surveillance System: starter pack

- The time and location for the last STI and / HIV test
- Number of T4 kits processed by the Service
- Number of reactive / confirmed positive samples
- Number of insufficient, haemolysed or incorrectly provided specimens
- Number of specimens that could not be tested due to laboratory error
- Number of referrals of individuals with reactive or positive results to sexual health services
- Total referrals by sexual health service
- Number of people receiving chlamydia treatment (including type of treatment provided)
- Number and proportion of HIV and syphilis reactive results confirmed positive or negative following confirmatory testing in sexual health services (Service User or Clinician reported)
- Outcome of referral to sexual health services for gonorrhoea positive Service Users (Service User or Clinician reported)
- · Quarterly reports from external EQA schemes

## 6.28.3. For the contraception components of the service

- All SRHAD data items collected and reported as specified in the Attendance, Contraception information and SRH activity information sections of the SRHAD Summary Guidance document
- Results of medical history questions relevant to specific methods of contraception being assessed
- Numbers of issues / supplies of POP / other methods
- If planned, numbers of continuation and numbers of initiations
- If continuation, the last source of contraception method
- If continuation, the timing of last prescription
- Number of assessments for emergency contraception
- Numbers of issues / supplies of emergency contraception (by EHC type)
- Number taking up emergency IUD in face to face services following online consultation
- If emergency, number of days / hours between exposure and online consultation
- Numbers of new and returning users
- Number accessing LARC in face to face service following consultation

## 6.29. Quality outcomes indicators

6.29.1 In order to secure maximum effectiveness from the Framework in terms of delivering against its overarching objectives, the Service Provider's performance will be monitored against relevant quality outcomes indicators. The following table sets out various such indicators, based on national standards and experience from the previous Frameworks. Reporting against these indicators will be as per the requirements section of this specification.

Table 2			_	
Quality outcomes indicator	Threshold	Technical guidance reference	Method of measurement	Consequence of breach
Percentage of Service User survey respondents reporting a positive experience	>90%	N/A	Contract monitoring	Remedial action plan
Percentage of test kits packaged and posted to Service User within 2 working days of request.	>95%	N/A	Contract monitoring	Remedial action Plan

Percentage of requests for EHC delivered within 24 hours of request	>95%	N/A	Contract monitoring	Remedial action plan
Percentage of specimens returned to the laboratory by Service User for processing within 30 days of receipt	>60%	N/A	Contract monitoring	Remedial action plan
Percentage of requests for postal contraception dispatched within 2 days of request	>95%	N/A	Contract monitoring	Remedial action plan
Percentage of specimens that could not be processed by the laboratory due to sampling error	<5%	N/A	Contract monitoring	Remedial action plan
Percentage of STI and HIV-negative Service Users receiving sexual health promotion messaging and signposting where to access information for other sexual health services	100%	N/A	Contract monitoring	Remedial action plan
Percentage of Service Users seeking contraception signposted to/receiving comprehensive information on the full range of and sources for contraception options	100%	N/A	Contract monitoring	Remedial action plan
Percentage of Service Users with negative results that received their results through their preferred method of contact within 5 working days of receiving sample	100%		Audit and feedback from Service User	Remedial action Plan
Percentage of reactive and or positive results attempted to be communicated to Service Users within 5 working days of receiving the sample	100%	N/A	Contract monitoring	Remedial action Plan
Percentage of reactive results actually communicated to Service Users within 5 working days of receiving sample.	75%	N/A	Contract monitoring	Remedial action Plan
Percentage of reactive / positive Service Users self-reporting attendance at chosen sexual health service in less than 10 working days from being informed	>80% patient confirmed	N/A	Audit	Remedial action plan
Percentage of treatment dispatched to chlamydia positive Service Users within 2 days of positive result	>95%	N/A	Contract monitoring	Remedial action plan

## 6.30. Patient satisfaction survey

6.30.1. The Service Provider will be expected to monitor Service User satisfaction and provide an easily accessible opportunity to give feedback. The Service Provider will share the outcomes from satisfaction surveys with Customers and PHE and provide updates on how user feedback is being used to improve services.

## **CALL-OFF GENERAL TERMS AND CONDITIONS**

## **APPENDIX B**

## **Pricing Information**

## Section 1: STI self-sampling (Lot 1)

Preventx offers an HIV/STI self-sampling service. Remote prescribing of medication to treat uncomplicated cases of chlamydia infection can also be provided\*.

Dispat	Dispatch of kits				
No	Dispatch of kits	Cost of kit including first class post	Cost of kit including collection	(a)	
P-A1	Dispatch of an STI self-sampling kit following an online assessment:  1 x blood test + 1 x urine / swabs	£4.50	£2.50	(b) (d)	
P-A2	Dispatch of an STI self-sampling kit following an online assessment:  1 x blood test + 2 x urine / swabs	£5.00	£3.00	(b) (e)	
P-A3	Dispatch of an STI self-sampling kit following an online assessment:  1 x blood test + 3 x urine / swabs	£5.00	£3.00	(b) (e)	
P-A4	Dispatch of a BBV self-sampling kit: 1 x blood test	£4.00	£2.50	(b) (d) (f)	
P-A5	Additional cost for: Supply of pack of condoms and lubricant	+ £5.00	+ £5.00	(c)	

- \* please refer to the brochure for the range of services available at framework launch
- a please refer to the brochure for further information about options for fulfilment of orders for self-sampling kits
- b includes all costs up to and include dispatch / supply of the self-sampling kit
- c customers can include the offer of a pack of condoms and lubricants as an optional additional service
- d kits for local distribution (supplied in cartons of 36) are subject to an additional £1 fee at activation (for digital services) and delivery charge of £7.49 per order (not per carton)
- e kits for local distribution (supplied in cartons of 18) are subject to an additional £1 fee at activation (for digital services) and delivery charge of £7.49 per order (not per carton)
- f please check brochure for further information about provision of BBV screening kits

Process	sing of returned samples			
No	Processing of returned kits	Cost including first class post for returned kits	Cost including tracking for returned kits	(a) (d)
P-B1	1 x blood test for HIV and syphilis + 1 x urine / swab test for chlamydia and gonorrhoea	£27.08	£28.58	(b) (c)
P-B2	1 x blood test for HIV and syphilis + 2 x urine / swab tests for chlamydia and gonorrhoea	£36.88	£38.38	(b) (c)
P-B3	1 x blood test for HIV and syphilis + 3 x urine / swabs to test for chlamydia and gonorrhoea	£46.68	£48.18	(b) (c)
P-B4	1 x blood test for HIV + 1 x urine / swab test for chlamydia and gonorrhoea	£23.20	£24.70	(b) (c)
P-B5	1 x blood test for HIV + 2 x urine / swab tests for chlamydia and gonorrhoea	£33.00	£34.50	(b) (c)
P-B6	1 x blood test for HIV + 3 x urine / swab tests for chlamydia and gonorrhoea	£42.80	£44.30	(b) (c)
P-B7	1 x blood test for syphilis + 1 x urine / swab test for chlamydia and gonorrhoea	£21.98	£23.48	(b) (c)
P-B8	1 x blood test for syphilis + 2 x urine / swab tests for chlamydia and gonorrhoea	£31.78	£33.28	(b) (c)
P-B9	1 x blood test for syphilis + 3 x urine / swab tests for chlamydia and gonorrhoea	£41.58	£43.08	(b) (c)
P-B10	1 x blood test for HIV, Hep B, Hep C and syphilis + 1 x urine / swab test for chlamydia and gonorrhoea	£42.58	£44.08	(b) (c)
P-B11	1 x blood test for HIV, Hep B, Hep C and syphilis + 2 x urine / swab tests for chlamydia and gonorrhoea	£52.38	£53.88	(b) (c)

P-B12	1 x blood test for HIV, Hep B, Hep C and syphilis + 3 x urine / swab tests for chlamydia and gonorrhoea	£62.18	£63.68	(b) (c)		
P-B13	1 x blood test for HIV, Hep B and Hep C + 1 x urine / swab test for chlamydia and gonorrhoea	£38.70	£40.20	(b) (c)		
P-B14	1 x blood test for HIV, Hep B and Hep C + 2 x urine / swab tests for chlamydia and gonorrhoea	£48.50	£50.00	(b) (c)		
P-B15	1 x blood test for HIV, Hep B and Hep C + 3 x urine / swab tests for chlamydia and gonorrhoea	£58.30	£59.80	(b) (c)		
P-B16	1 x blood test for syphilis, Hep B and Hep C + 1 x urine / swab test for chlamydia and gonorrhoea	£37.48	£38.98	(b) (c)		
P-B17	1 x blood test for syphilis, Hep B and Hep C + 2 x urine / swab tests for chlamydia and gonorrhoea	£47.28	£48.78	(b) (c)		
P-B18	1 x blood test for syphilis, Hep B and Hep C + 3 x urine / swab tests for chlamydia and gonorrhoea	£57.08	£58.58	(b) (c)		
P-B19	1 x blood test for HIV, syphilis, Hep B and Hep C	£32.78	£34.28	(b) (c)		
P-B20	1 x blood test for HIV and syphilis	£17.28	£18.78	(b) (c)		
P-B21	1 x blood test for HIV	£13.40	£14.90	(b) (c)		
P-B22	1 x blood test for syphilis	£12.18	£13.68	(b) (c)		
P-B23	1 x blood test for HIV, Hep B and Hep C	£28.90	£30.40	(b) (c)		
P-B24	1 x blood test for syphilis, Hep B and Hep C	£27.68	£29.18	(b) (c)		
P-B25	1 x urine / swab tests for chlamydia	£14.68	£16.18	(b) (c)		
	continued					

P-B26	2 x urine / swab tests for chlamydia	£23.18	£24.68	(b) (c)
P-B27	3 x urine / swab tests for chlamydia	£31.68	£33.18	(b) (c)
P-B28	1 x urine / swab tests for chlamydia and gonorrhoea	£15.98	£17.48	(b) (c)
P-B29	2 x urine / swab tests for chlamydia and gonorrhoea	£25.78	£27.28	(b) (c)
P-B30	3 x urine / swab tests for chlamydia and gonorrhoea	£35.58	£37.08	(b) (c)

- \* please refer to the brochure for the range of services available at framework launch
- a First class post is included as an option at framework launch but is subject to review if Royal Mail confirms a change to their terms and conditions for the carriage of biological specimens
- b includes all costs associated with receiving and processing returned kits including laboratory testing and results management
- c samples will be tested for an appropriate combination of HIV, Hepatitis B and Hepatitis C, syphilis, chlamydia and gonorrhoea, and will be based on the assessment
- d please check brochure for further information about options for return and processing of samples and related activities including results management

## **Section 2: Emergency contraception (Lot 2)**

Preventx offers remote prescribing of emergency hormonal contraception for supply via the post and / or for collection from selected pharmacies\*.

Emerg	ency contraception				
No	Product (~)	Cost including first class post	Cost including tracking	Cost including charge for collection	(a)
P-C1	Remote assessment and prescribing of: EllaOne (single supply)		£27.21	£22.54	(b) (g)
P-C2	Remote assessment and prescribing of: Levonorgestrel 1500 (single supply)		£27.21	£22.54	(b) (g)
P-C3	Remote assessment and prescribing of: Levonorgestrel 1500 (double supply)		£27.21	£22.54	(b) (g)
	continued				

P-C4	Additional cost for prescribing: Cerazette (6 month supply)		£26.58	£21.91	(b) (f) (g)
P-C5	Additional cost for prescribing: Rigevidon (6 month supply)		£23.49	£18.82	(b) (f) (g)
P-C6	Additional cost for prescribing: Evra (6 month supply)		£63.12	£58.45	(b) (f) (g)
P-C7	Additional cost for: Supply of pack of condoms and lubricant	£5.00	£6.50		(c)
P-C8	Additional cost for: Supply of pregnancy test	£3.80	£5.30		(d)
P-E	Additional cost for: Supply of a chlamydia self-sampling kit	See additional components section		(e)	

- \* please refer to the brochure for the range of services available at framework launch
- a please refer to the brochure for further information about options for delivery or collection of medication
- b includes the cost of medication as at framework launch and is subject to adjustment in line with changes to the NHS drug tariff (or equivalent)
- c customers can include the offer of a pack of condoms and lubricants as an optional additional service
- d customers can include the offer of a pregnancy test device as an optional additional service.
- e customers can include the offer of a chlamydia self-sampling kit as an optional additional service
- f customers can include the offer of a bridging method of contraception as an optional additional service
- g additional £10 applied for Sunday delivery
- ~ products can be added or removed in line with changes to guidance or practice

## **Section 3: Routine contraception**

Preventx offers remote prescribing of selected methods of routine contraception for supply via the post and / or for collection from selected pharmacies\*.

Routine contraception					
No	Product (~)	Cost including first class post	Cost including tracking	Cost including charge for collection	(a)
P-D1	Remote assessment and prescribing of: Cerazette 75mcg (1 month)		£8.95	£6.90	(f) (b) (c)
				Contir	nued

P-D2	Remote assessment and prescribing of: Cerazette 75mcg (3 months)	£1:	9.23	£17.18	(b)
P-D3	Remote assessment and prescribing of: Cerazette 75mcg (6 months)	£2	3.96	£21.91	(b)
P-D4	Remote assessment and prescribing of: Cerazette 75mcg (12 months)	£3:	3.11	£31.06	(b)
P-D5	Remote assessment and prescribing of: Rigevidon 30 / 150 (1 month)	£	8.65	£6.60	(f) (b) (c)
P-D6	Remote assessment and prescribing of: Rigevidon 30 / 150 (3 months)	£1	7.64	£15.59	(b)
P-D7	Remote assessment and prescribing of: Rigevidon 30 / 150 (6 months)	£2	0.87	£18.82	(b)
P-D8	Remote assessment and prescribing of: Rigevidon 30 / 150 (12 months)	£2'	7.06	£25.01	(b)
P-D9	Remote assessment and prescribing of: Evra (1 month)	£1	3.05	£11.00	(f) (b) (c)
P- D10	Remote assessment and prescribing of: Evra (3 months)	£3:	3.00	£30.95	(c)
P- D11	Remote assessment and prescribing of: Evra (6 months)	£6	0.50	£58.45	(b)
P- D12	Remote assessment and prescribing of: Evra (12 months)	£10	4.50	£102.45	(b)
P- D13	Remote assessment and prescribing of Nuvaring 0.12mg/0.15mg	£3	7.40	£35.35	(b)
	1			Contin	ued

P- D14	Remote assessment and prescribing of: Sayana Press 104mg / 0.65ml (3 months)		£23.38	£21.33	(c)
P- D15	Remote assessment and prescribing of: Sayana Press 104mg / 0.65ml (6 months)		£42.08	£40.03	(c)
P- D16	Remote assessment and prescribing of: Sayana Press 104mg / 0.65ml (12 months)		£79.48	£77.43	(c)
P- D17	Additional cost for: Supply of a pack of condoms and lubricant	£5.00	£6.50		(d)
P-E	Additional cost for Supply of a chlamydia self-sampling kit	See additional components		(e)	

- \* please refer to the brochure for the range of services available at framework launch
- a please refer to the brochure for further information about options for delivery or collection of medication
- b includes the cost of medication as at framework launch and is subject to adjustment in line with changes to the NHS drug tariff (or equivalent)
- c customers can agree the range of methods to be provided
- d customers can include the offer of a pack of condoms and lubricants as an optional additional service
- e customers can include the offer of a chlamydia self-sampling kit as an optional additional service
- f can be issued for safeguarding purposes
- ~ products can be added or removed in line with changes to guidance or practice

## Section 4: Chlamydia self-sampling (Lots 2 and 3)

Preventx offers opportunistic screening for chlamydia as an additional service for customers of the emergency contraception service (lot 2) and the contraception service (lot 3)\*.

Dispatch of kits				
No	Dispatch of kits	Cost of kit including first class post	Cost of kit including collection	(a)
P-E1	Dispatch of kit following an assessment:  1 x urine / swab to test for chlamydia	£4.50	£2.50	(b)
P-E2	Dispatch of kit following an assessment:  1 x urine / swab to test for chlamydia and gonorrhoea	£4.50	£2.50	(b)

<sup>\*</sup> please refer to the brochure for the range of services available at framework launch

a please refer to the brochure for further information about options for delivery or collection of self-sampling kits

b includes all costs up to and include dispatch / supply of the self-sampling kit

c customers can select P-E1 or P-E2

Processing of returned samples				
No	Processing of returned kits	Cost including first class post for returned kits	Cost including tracking for returned kits	(a)
P-E3	Processing of returned kits:  1 x urine / swab tests for chlamydia	£14.68	£16.18	(b)
P-E4	Processing of returned kits:  1 x urine / swab tests for chlamydia and gonorrhoea	£15.98	£17.48	(b)

- a First-class post is included as an option at framework launch but is subject to review if Royal Mail confirms a change to their terms and conditions for the carriage of biological specimens
- b includes all costs associated with receiving and processing returned kits including laboratory testing and results management

Remote prescribing of medication for uncomplicated cases of chlamydia is available to customers contracting with Preventx for provision of the HIV/STI self-sampling service (lot 1) and chlamydia screening (additional to lots 2 and 3)\*.

Treatment of chlamydia				
No	Product (~)	Cost including tracking	Cost including charge for collection	(a)
P-E5	Remote assessment and prescribing of: Azithromycin (single supply)	£19.80	£17.75	(b) (c)
P-E6	Remote assessment and prescribing of: Doxycycline (single supply)	£19.80	£17.75	(b) (c)

- \* please refer to the brochure for the range of services available at framework launch
- a please refer to the brochure for further information about options for delivery or collection of medication
- b includes the cost of medication as at framework launch and is subject to adjustment in line with changes to the NHS drug tariff (or equivalent)
- c customers can agree the range of medication to be provided
- ~ products can be added or removed in line with changes to guidance or practice

## **Set-up costs**

Set-up costs are not applicable. Please check the brochure for further information.

## **VAT**

Pricing is exclusive of VAT

#### **Discounts**

Discounts are not available. Please check the brochure for further information.

## CALL-OFF GENERAL TERMS AND CONDITIONS APPENDIX C SCHEDULE OF PROCESSING, PERSONAL DATA AND DATA SUBJECTS UNDER THE CONTRACT

This Appendix shall be completed by the Controller, who may take account of the view of the Processor, however the final decision as to the content of this Appendix shall be with the Customer at its absolute discretion.

- 1. The contact details of the Customer's Data Protection Officer are: [Insert contact details]
- 2. The contact details of the Service Provider's Data Protection Officer are: [Insert contact details]
- 3. The Processor shall comply with any further written instructions with respect to Processing by the Controller.
- 4. Any such further instructions shall be incorporated into this Appendix.

Description	Details
Identity of the Controller for each category of Personal Data	The Customer is Controller and the Service Provider is Processor  The Parties acknowledge that in accordance with clauses B38.2 to B38.15 (Where one Party is Controller and the other Party its Processor) and for the purposes of the Data Protection Legislation, the Customer is the Controller and the Service Provider is the Processor of the following Personal Data:  • [Insert the scope of Personal Data for which the purposes and means of the Processing by the Service Provider is determined]
	The Service Provider is Controller and the Customer is Processor  The Parties acknowledge that for the purposes of the Data Protection Legislation, the Service Provider is the Controller and the Customer is the Processor in accordance with clauses B38.2 to B38.15 (Where one Party is Controller and the other Party its Processor) of the following Personal Data:  Insert the scope of Personal Data which the purposes and means of the Processing by the Customer is determined by the
	Service Provider]  The Parties are Joint Controllers  The Parties acknowledge that they are Joint Controllers for the purposes of the Data Protection Legislation in respect of:  [Insert the scope of Personal Data which the purposes and
	means of the Processing is determined by the both Parties together]  The Parties are Independent Controllers of Personal Data  The Parties acknowledge that they are Independent Controllers for the purposes of the Data Protection Legislation in respect of:

Business contact details of Service Provider Personnel for which the Service Provider is the Controller. Business contact details of any directors, officers, employees. agents, consultants and contractors of the Customer (excluding the Service Provider Personnel) engaged in the performance of the Customer's duties under the Contract) for which the Customer is the Controller. [Insert the scope of other Personal Data provided by one Party who is Controller to the other Party who will separately determine the nature and purposes of its Processing the Personal Data on receipt e.g. where (1) the Service Provider has professional or regulatory obligations in respect of Personal Data received, (2) a standardised service is such that the Customer cannot dictate the way in which Personal Data is processed by the Service Provider, or (3) where the Service Provider comes to the transaction with Personal Data for which it is already Controller for use by the Customer1 [Guidance where multiple relationships have been identified above, please address the below rows in the table for in respect of each relationship identified] Duration of the processing [Clearly set out the duration of the Processing including dates] Nature and purposes of the Please be as specific as possible, but make sure that you cover all processing intended purposes. e.g. To facilitate the fulfilment of the Service Provider's obligations arising under this Contract including: i. Ensuring effective delivery of the service to Service Users (members of the public) ii. Ensuring accurate and timely reporting of Key Performance Indicator data Ensuring effective monitoring of the Service iii. Ensuring effective communication between the Service iv. Provider and the Customer Maintaining full and accurate records of every call-off Contract arising under the Framework Agreement in accordance with clause Error! Reference source not found. (Records and Audit Access) Type of Personal Data being e.g. Includes: Processed Personal data of Service Users registering online including but not limited to contact details, age, ethnicity, gender, sexual orientation and sexual history ii. Laboratory test results for Service Users who have returned a viable specimen iii. Medical history for the purpose of assessment and prescribing of medication iv. Contact details of, and communications with the Customer and PHE staff concerned with management of the Contract v. Contact details of, and communications with, Customer staff concerned with award and management of call-off Contract

	vi. Contact details, and communications with, Sub-contractor staff concerned with fulfilment of the Service Provider's obligations		
Categories of Data Subject	[ <mark>e.g. Includes:</mark>		
	i. Members of the public that register online to use the service (Service Users)		
	ii. Customer and PHE staff concerned with management of the Contract		
	iii. Customer staff concerned with award and management of call-off Contracts awarded under the Framework Agreement		
	iv. Sub-contractor staff concerned with fulfilment of the Service Provider's obligations arising from this Framework Agreement		
Plan for return and destruction of the data once the processing is complete	All relevant data to be deleted 7 years after the expiry or termination of		
UNLESS requirement under union or member state law to preserve that type of data			

# CALL-OFF GENERAL TERMS AND CONDITIONS APPENDIX D JOINT CONTROLLER AGREEMENT

## 1. JOINT CONTROLLER STATUS AND ALLOCATION OF RESPONSIBILITIES

- 1.1 With respect to Personal Data under Joint Control of the Parties, the Parties envisage that they shall each be a Controller in respect of that Personal Data in accordance with the terms of this Appendix D (Joint Controller Agreement) in replacement of clauses B38.2 to B38.15 (Where one Party is Controller and the other Party is Processor) and clauses B38.17 to B38.27 (Independent Controllers of Personal Data). Accordingly, the Parties each undertake to comply with the applicable Data Protection Legislation in respect of their Processing of such Personal Data as Controllers.
- 1.2 The Parties agree that the [Service Provider/Customer]:
  - 1.2.1 is the exclusive point of contact for Data Subjects and is responsible for all steps necessary to comply with the GDPR regarding the exercise by Data Subjects of their rights under the GDPR;
  - 1.2.2 shall direct Data Subjects to its Data Protection Officer or suitable alternative in connection with the exercise of their rights as Data Subjects and for any enquiries concerning their Personal Data or privacy;
  - 1.2.3 is solely responsible for the Parties' compliance with all duties to provide information to Data Subjects under Articles 13 and 14 of the GDPR;
  - 1.2.4 is responsible for obtaining the informed consent of Data Subjects, in accordance with the GDPR, for Processing in connection with the Services where consent is the relevant legal basis for that Processing; and
  - shall make available to Data Subjects the essence of this Appendix (and notify them of any changes to it) concerning the allocation of responsibilities as Joint Controller and its role as exclusive point of contact, the Parties having used their best endeavours to agree the terms of that essence. This must be outlined in the [Service Provider's/Customer's] privacy policy (which must be readily available by hyperlink or otherwise on all of its public facing services and marketing).
- 1.3 Notwithstanding the terms of paragraph 1.2, the Parties acknowledge that a Data Subject has the right to exercise their legal rights under the Data Protection Legislation as against the relevant Party as Controller.

## 2. UNDERTAKINGS OF BOTH PARTIES

- 2.1 The Service Provider and the Customer each undertake that they shall:
  - 2.1.1 report to the other Party every twelve (12) months on:
    - (i) the volume of Data Subject Request (or purported Data Subject Requests) from Data Subjects (or third parties on their behalf);
    - (ii) the volume of requests from Data Subjects (or third parties on their behalf) to rectify, block or erase any Personal Data;

- (iii) any other requests, complaints or communications from Data Subjects (or third parties on their behalf) relating to the other Party's obligations under applicable Data Protection Legislation;
- (iv) any communications from the Information Commissioner or any other regulatory authority in connection with Personal Data; and
- (v) any requests from any third party for disclosure of Personal Data where compliance with such request is required or purported to be required by Law,

that it has received in relation to the subject matter of the Contract during that period;

- 2.1.2 notify each other immediately if it receives any request, complaint or communication made as referred to in paragraph 2.1.1;
- 2.1.3 provide the other Party with full cooperation and assistance in relation to any request, complaint or communication made as referred to in paragraph 2.1.1 to enable the other Party to comply with the relevant timescales set out in the Data Protection Legislation;
- 2.1.4 not disclose or transfer the Personal Data to any third party unless necessary for the provision of the Services and, for any disclosure or transfer of Personal Data to any third party, (save where such disclosure or transfer is specifically authorised under the Contract or is required by Law) ensure consent has been obtained from the Data Subject prior to disclosing or transferring the Personal Data to the third party. For the avoidance of doubt the third party to which Personal Data is transferred must be subject to equivalent obligations which are no less onerous than those set out in this Appendix D:
- 2.1.5 request from the Data Subject only the minimum information necessary to provide the Services and treat such extracted information as Confidential Information;
- 2.1.6 ensure that at all times it has in place appropriate Protective Measures to guard against unauthorised or unlawful Processing of the Personal Data and/or accidental loss, destruction or damage to the Personal Data and unauthorised or unlawful disclosure of or access to the Personal Data;
- 2.1.7 take all reasonable steps to ensure the reliability and integrity of any of its Personnel who have access to the Personal Data and ensure that its Personnel:
  - (i) are aware of and comply with their 's duties under this Appendix D (Joint Controller Agreement) and those in respect of Confidential Information
  - (ii) are informed of the confidential nature of the Personal Data, are subject to appropriate obligations of confidentiality and do not publish, disclose or divulge any of the Personal Data to any third party where the that Party would not be permitted to do so;
  - (iii) have undergone adequate training in the use, care, protection and handling of personal data as required by the applicable Data Protection Legislation;
- 2.1.8 ensure that it has in place Protective Measures as appropriate to protect against a Data Loss Event having taken account of the:
  - (i) nature of the data to be protected;

- (ii) harm that might result from a Data Loss Event;
- (iii) state of technological development; and
- (iv) cost of implementing any measures;
- 2.1.9 ensure that it has the capability (whether technological or otherwise), to the extent required by Data Protection Legislation, to provide or correct or delete at the request of a Data Subject all the Personal Data relating to that Data Subject that the Service Provider holds; and
- 2.1.10 ensure that it notifies the other Party as soon as it becomes aware of a Data Loss Event.
- 2.2 Each Joint Controller shall use its reasonable endeavours to assist the other Controller to comply with any obligations under applicable Data Protection Legislation and shall not perform its obligations under this Appendix D in such a way as to cause the other Joint Controller to breach any of its obligations under applicable Data Protection Legislation to the extent it is aware, or ought reasonably to have been aware, that the same would be a breach of such obligations

#### 3. DATA PROTECTION BREACH

- 3.1 Without prejudice to paragraph 3.2, each Party shall notify the other Party promptly and without undue delay, and in any event within 48 hours, upon becoming aware of any Personal Data Breach or circumstances that are likely to give rise to a Personal Data Breach, providing the other Party and its advisors with:
  - 3.1.1 sufficient information and in a timescale which allows the other Party to meet any obligations to report a Personal Data Breach under the Data Protection Legislation;
  - 3.1.2 all reasonable assistance, including:
    - co-operation with the other Party and the Information Commissioner investigating the Personal Data Breach and its cause, containing and recovering the compromised Personal Data and compliance with the applicable guidance;
    - (ii) co-operation with the other Party including taking such reasonable steps as are directed by the other Party to assist in the investigation, mitigation and remediation of a Personal Data Breach;
    - (iii) co-ordination with the other Party regarding the management of public relations and public statements relating to the Personal Data Breach; and/or
    - (iv) providing the other Party and to the extent instructed by the other Party to do so, and/or the Information Commissioner investigating the Personal Data Breach, with complete information relating to the Personal Data Breach, including, without limitation, the information set out in paragraph 3.2.
- 3.2 Each Party shall take all steps to restore, re-constitute and/or reconstruct any Personal Data where it has lost, damaged, destroyed, altered or corrupted as a result of a Personal Data Breach as if it was that Party's own data at its own cost with all possible speed and shall provide the other Party with all reasonable assistance in respect of any such Personal Data

Breach, including providing the other Party, as soon as possible and within 48 hours of the Personal Data Breach relating to the Personal Data Breach, in particular:

- 3.2.1 the nature of the Personal Data Breach;
- 3.2.2 the nature of Personal Data affected:
- 3.2.3 the categories and number of Data Subjects concerned;
- 3.2.4 the name and contact details of its Data Protection Officer or other relevant contact from whom more information may be obtained;
- 3.2.5 measures taken or proposed to be taken to address the Personal Data Breach; and
- 3.2.6 describe the likely consequences of the Personal Data Breach.

#### 4. AUDIT

- 4.1 The Service Provider shall permit:
  - 4.1.1 the Customer, or a third-party auditor acting under the Customer's direction, to conduct, at the Customer's cost, data privacy and security audits, assessments and inspections concerning the Service Provider's data security and privacy procedures relating to Personal Data, its compliance with this Appendix D and the Data Protection Legislation; and/or
  - 4.1.2 the Customer, or a third-party auditor acting under the Customer's direction, access to premises at which the Personal Data is accessible or at which it is able to inspect any relevant records, including the record maintained under Article 30 GDPR by the Service Provider so far as relevant to the Contract, and procedures, including premises under the control of any third party appointed by the Service Provider to assist in the provision of the Services.
- 4.2 The Customer may, in its sole discretion, require the Service Provider to provide evidence of the Service Provider's compliance with paragraph 4.1 in lieu of conducting such an audit, assessment or inspection.

## 5. IMPACT ASSESSMENTS

- 5.1 Each Party shall:
  - 5.1.1 provide all reasonable assistance to the other Party to prepare any data protection impact assessment as may be required (including provision of detailed information and assessments in relation to Processing operations, risks and measures); and
  - 5.1.2 maintain full and complete records of all Processing carried out in respect of the Personal Data in connection with the Contract, in accordance with the terms of Article 30 GDPR.

## 6. ICO GUIDANCE

6.1 The Parties agree to take account of any guidance issued by the Information Commissioner and/or any relevant Competent Body. The Customer may on not less than thirty (30) Working

Days' notice to the Service Provider amend the Contract to ensure that it complies with any guidance issued by the Information Commissioner and/or any relevant Competent Body.

## 7. LIABILITIES FOR DATA PROTECTION BREACH

- 7.1 If financial penalties are imposed by the Information Commissioner on either the Customer or the Service Provider for a Personal Data Breach ("Financial Penalties") then the following shall occur:
  - 7.1.1 if in the view of the Information Commissioner, the Customer is responsible for the Personal Data Breach, in that it is caused as a result of the actions or inaction of the Customer, its employees, agents, contractors (other than the Service Provider) or systems and procedures controlled by the Customer, then the Customer shall be responsible for the payment of such Financial Penalties. In this case, the Customer will conduct an internal audit and engage at its reasonable cost when necessary, an independent third party to conduct an audit of any such Personal Data Breach. The Service Provider shall provide to the Customer and its third party investigators and auditors, on request and at the Service Provider's reasonable cost, full cooperation and access to conduct a thorough audit of such Personal Data Breach;
  - 7.1.2 if in the view of the Information Commissioner, the Service Provider is responsible for the Personal Data Breach, in that it is not a Personal Data Breach that the Customer is responsible for, then the Service Provider shall be responsible for the payment of these Financial Penalties. The Service Provider will provide to the Customer and its auditors, on request and at the Service Provider's sole cost, full cooperation and access to conduct a thorough audit of such Personal Data Breach; or
  - 7.1.3 if no view as to responsibility is expressed by the Information Commissioner, then the Customer and the Service Provider shall work together to investigate the relevant Personal Data Breach and allocate responsibility for any Financial Penalties as outlined above, or by agreement to split any financial penalties equally if no responsibility for the Personal Data Breach can be apportioned. In the event that the Parties do not agree such apportionment then such dispute shall be referred to the dispute resolution procedure set out in clause B31.
- 7.2 If either the Customer or the Service Provider is the defendant in a legal claim brought before a court of competent jurisdiction ("Court") by a third party in respect of a Personal Data Breach, then unless the Parties otherwise agree, the Party that is determined by the final decision of the court to be responsible for the Personal Data Breach shall be liable for the losses arising from such Personal Data Breach. Where both Parties are liable, the liability will be apportioned between the Parties in accordance with the decision of the Court.
- 7.3 In respect of any losses, cost claims or expenses incurred by either Party as a result of a Personal Data Breach (the "Claim Losses"):
  - 7.3.1 if the Customer is responsible for the relevant Personal Data Breach, then the Customer shall be responsible for the Claim Losses;
  - 7.3.2 if the Service Provider is responsible for the relevant Personal Data Breach, then the Service Provider shall be responsible for the Claim Losses; and
  - 7.3.3 if responsibility for the relevant Personal Data Breach is unclear, then the Customer and the Service Provider shall be responsible for the Claim Losses equally.

7.4 Nothing in either paragraphs 7.2 or 7.3 shall preclude the Customer and the Service Provider reaching any other agreement, including by way of compromise with a third party complainant or claimant, as to the apportionment of financial responsibility for any Claim Losses as a result of a Personal Data Breach, having regard to all the circumstances of the Personal Data Breach and the legal and financial obligations of the Customer.

## 8. TERMINATION

8.1 If the Service Provider is in material default under any of its obligations under this Appendix D (Joint Controller Agreement), the Customer shall be entitled to terminate the Contract by issuing a notice to the Service Provider in accordance with clause B33.4.

## 9. SUB-PROCESSING

- 9.1 In respect of any Processing of Personal Data performed by a third party on behalf of a Party, that Party shall:
  - 9.1.1 carry out adequate due diligence on such third party to ensure that it is capable of providing the level of protection for the Personal Data as is required by the Contract, and provide evidence of such due diligence to the other Party where reasonably requested; and
  - 9.1.2 ensure that a suitable agreement is in place with the third party as required under applicable Data Protection Legislation.

#### 10. DATA RETENTION

10.1 The Parties agree to erase Personal Data from any computers, storage devices and storage media that are to be retained as soon as practicable after it has ceased to be necessary for them to retain such Personal Data under applicable Data Protection Legislation and their privacy policy (save to the extent (and for the limited period) that such information needs to be retained by a Party for statutory compliance purposes or as otherwise required by the Contract), and taking all further actions as may be necessary to ensure its compliance with Data Protection Legislation and its privacy policy.