Step 10: Contract
Tool 2: Commissioning Contract Schedules
This tool is for use in conjunction with Step 10 of the Commissioning Toolkit document

Doc No	Date	Title

[DN: THIS IS THE DRAFT COMMISSIONING CONTRACT – SCHEDULES 2 TO 20 - TO ACCOMPANY THE COMMISSIONING GUIDANCE/TOOLKIT]

PATHOLOGY SERVICES – COMMISSIONING GUIDANCE

COMMISSIONING CONTRACT

SCHEDULES 2 TO 20 (INCLUSIVE)

SCHEDULE 2

The Services

Part 1: Services Specification

1 General

1.1 The Clinical Requirements of the specification require the Provider to deliver three key services to support and enable the care provided by Community Users to their patients:

(a) Consultant-led Integrated Blood Sciences service for Clinical Biochemistry, Haematology, Immunology;

(b) Consultant-led Microbiology (including Virology and Mycology) service;

(c) Consultant-led Histopathology; and

(d) Community phlebotomy service (including domiciliary phlebotomy service) to improve access and convenience for patients (where GP Practices cannot or do not wish to provide this service for their patients themselves).

1.2 The Provider shall provide a Community Pathology Service that is accessible to Community Users every weekday, at a minimum, from 08.00 to 20.00 with appropriate on-call access to haematology, clinical biochemistry, immunology and microbiology (including virology and mycology) specialist expertise to:

(a) undertake urgent test analysis when clinically indicated in the community; or

(b) provide appropriate clinical advice within 30 minutes of the request at all other times.

1.3 The Integrated Blood Science service shall include the provision of a comprehensive haematology, clinical biochemistry and immunology service which includes microscopy, blood coagulation, anticoagulation monitoring and dosing where required, specialist investigations and the review of abnormal results including blood films and results.

1.4 The Provider shall have consultant-reviewed protocols in place for:

(a) follow on investigations where clinically appropriate; and

(b) amendments to test requests depending on the clinical indications after discussion with the requestor; and

(c) supporting Community Users to manage demand and ensure appropriate test requests.

1.5 The Provider shall have a pathway in place for onward referrals to specialist laboratories for specialist investigations.

1.6 The Provider shall:

(a) Ensure that any reorganisation of pathology services takes account of:

(i) the requirement for adequate laboratory test support for the various

infection control obligations that exist for all organisations within the Cluster; and

(ii) existing and anticipated community infection control obligations across the organisations within the Cluster including, but not limited to, SLAs for community infection control services or expertise in the form of ICD or ICN.

(b) Improve, where possible, the system of communication between the organisations within the Cluster and consistency of infection prevention and control services including the standardisation of practices.

(c) Provide a comprehensive microbiology service to meet the microbiology needs of Community Users and their patients which must include the provision of bacteriology, virology and mycology testing.

(d) The microbiology service shall provide laboratory support to Community Users and provide advice on infection control, prevention and the management of healthcare associated infections in the community.

(e) Provide an on-call medical and infection control service outside core hours and to support the needs of the laboratory service for clinically important specimens processed outside core hours.

(f) The microbiology service should have provisions in place to deal with emergency service response and increase capacity due to unplanned operational demand variations e.g. communicable disease outbreaks.

2 Analytical Service

Test Requirements

2.1 The Provider shall:

(a) Deliver the consultant-led analytical service from a single multidisciplinary laboratory for routine and urgent test requests from Community Users for each of the following disciplines:

(i) Integrated Blood Sciences including Clinical Biochemistry, Haematology and Immunology;

(ii) Microbiology including Bacteriology, Virology and Mycology;

(b) Provide the analytical service for the whole repertoire of tests that may legitimately be requested by Community Users for all of their clinical needs including screening, diagnosis, monitoring and therapeutic management of patients.

(c) deliver an analytical service which includes the full range of activities from the collection of the sample to the issue of the validated result and must include relevant interpretive clinical advice to the requestor;

(d) supply all request forms, or electronic requesting documentation, and the necessary consumables including, but not limited to, all appropriate sample containers.

(e) supply Community Users with centrifugation equipment and training for its use where these users are in remote areas and where there is, in exceptional

circumstances, an increased of potential delays in transporting

(f) validate and authorise all test results by a consultant or appropriately qualified specialist, or have a process in place to validate and authorise test results that has been approved by a consultant or appropriately qualified specialist, prior to the secure issue to the requestor or patient if agreed and appropriate;

(g) have appropriate and necessary facilities and equipment for the safe, effective, efficient and timely delivery of the analytical service;

(h) agree test naming conventions across Cluster members in accordance with current guidelines and future National Laboratory Medicine Catalogue;

(i) have standardised test profiles, scientific units, methodologies and reference ranges, in accordance with the National Laboratory Medicine Catalogue and the DH HARMONY project, across the Cluster and consistent with other Clusters in the region;

(j) have a robust plan in place to ensure service continuity and service resilience across all pathology disciplines, in the event of an unexpected service failure and transportation issues;

(k) participate in a joint process between the Provider, Community Users and Commissioners to agree the provision of new tests, previously not provided , and for the removal and decommissioning of obsolete and redundant tests;

(l) provide Community Users with a single point of contact for all enquiries relating to the Community Pathology Service;

(m) monitor against NICE guidance and other relevant national, regional and local standards of best practice to ensure appropriate use and pattern of test requesting from Community Users; and

(n) advise and report to Community Users and Commissioners when test request trending data suggests inappropriate use of tests.

Sample Handling

2.2 The Provider shall:

(a) have a robust system in place for the proper handling, storage and security of all samples and documentation at all times in accordance with national guidelines and regulatory and legal requirements;

(b) store blood samples for a sufficient period of time to reduce the need for re-sampling patients:

(i) To enable addition of further tests by the requestor or other clinicians;

(ii) In the case of errors and shall analyse repeat samples in this case without charge; and

(c) have a robust system in place for the proper handling and disposal of waste at all times, meeting at least the minimum national standards for their handling and disposal.

Results

2.3 The Provider shall:

(a) provide written interpretation of abnormal results or trends in results and advice on further tests where clinically appropriate;

(b) telephone unexpected or unusual results to the requestor and/or the responsible clinician where clinically indicated in a timeframe that is clinically appropriate and follow up by electronic communication as per reporting requirements;

(c) telephone unexpected or unusual results to the appropriate Out of Hours provider, in accordance with the Royal College of Pathologists guidance "Out of hours reporting of lab results requiring urgent clinical action to primary care: advice to pathologists and those working in laboratory medicine (November 2010), when there are results that require urgent clinical action outside the core hours of routine general practice;

(d) flag clearly any abnormal results and provide interpretive comments, where possible, on all issued written reports; and

(e) provide interpretive comments in addition to reference ranges which could be standardised if validated after consultant review.

Reports

2.4 The Provider shall:

(a) issue reports for routine test results in accordance with the maximum turnaround times in Annex C from the sample being taken from the patient to the issue of the report to the requestor;

(b) issue reports for urgent test requests within 1 hour of receiving the sample , or where this is not possible due to time taken for analysis the report shall be issued as a matter of urgency as soon as practicable;

(c) provide monthly exception reports for all breaches in the turnaround times for each Reporting Time Category in Annex C;

(d) undertake authorisation of all test results issued by the Provider after technical validation and clinical validation, when appropriate, and including the addition of comments to aid clinical interpretation and patient management;

(e) combine individual results or groups of results on issue of the final report;

(f) indicate clearly where results are provisional or interim reports are issued and provide the expected date of the final report;

(g) inform and update the requestor about their responsibility to take appropriate clinical decisions or actions as a consequence of receiving the test result;

(h) inform and update the requestor about the need for the issued test result to be incorporated into the patient health care record;

(i) issue cumulative tests results where the tests are repeated to view trends.

(j) issue all test results and reports electronically to the requester (by paper report if requestor cannot receive electronic reports) or by telephone if an urgent request;

(k) report results of tests requested urgently or abnormal results to the requesting clinician as soon as is practicable within the requested timeframe; if the requesting clinician is unavailable these results must be reported to a designated alternate;

(l) report a provisional result without delay when it is considered that its immediate availability may impact on the management of a patient whilst making clear that this result may change in the final report;

(m) confirm provisional results as soon as practicable and ensure any significant change to a provisional or final report likely to alter the management of the patient must be notified to the user by telephone followed up by the issue of an amended report;

(n) issue interim reports in lieu of a final report when waiting to confirm one or more test results requested as a set; this shall be superseded by a final report once all of the results are available; and

(o) issue amended reports that are clearly labelled and include the reason for the amendment when:

(i) provisional results have changed;

(ii) results previously reported are subsequently found to be erroneous; or

(iii) results and/or clinical comments are added or deleted.

Critical Reporting

2.5 The Provider shall have a robust system in place to manage critical reporting including:

(a) establishment and implementation of a list of critical results which might need immediate action according to clinical need;

(b) telephoning critical results to the requestor or responsible healthcare professional including out-of-hours providers when outside core hours of general practice;

(c) providing clinical advice to help the requestor and other Community Users including clinician in out-of-hours services to interpret the critical results; and

(d) telephoning results when there is a trend suggestive of patient deterioration requiring immediate action;

(e) working with GPs and commissioners to have robust referral pathways in place clearly identifying where patients shall be referred urgently for further opinion, if clinically indicated and in accordance with patient choice.

Errors

2.6 The Provider shall have a robust system in place to monitor and learn from laboratory based errors which shall include, but not be limited to:

(a) logging and categorisation of all errors based on Good Industry Standards; and

(b) review errors and demonstrate actions taken to reduce the chance of similar future errors; and

(c) issuing an annual report of laboratory errors and the actions taken to reduce subsequent risk of same reason repeating the error.

Onward test referrals

2.7 Where Community Users requests tests that the Provider is unable to analyse the Provider shall:

(a) refer specimens for testing by a CPA accredited (or equivalent) third party laboratory;

(b) send the tests which require a second clinical opinion or analytical qualification to a Reference Laboratory that is approved by the Provider and the respective lead consultant pathologist (or equivalent) for that pathology discipline;

(c) ensure that the third party pathology provider meets the same quality and performance criteria as the Provider as outlined in the Contract;

(d) review the contracts for esoteric analysis on an annual basis to ensure appropriate quality standards are continually met and compliance with national accreditation requirements and best practice;

(e) inform Community Users and Commissioners about all third party providers in partnership with the Provider and gain agreement for any changes to these partners.

Specimen collection & transportation

2.8 The Provider shall:

(a) have a transport and logistics service in place with the necessary capacity and capability to support the delivery of the Community Pathology Services;

(b) collect specimens from designated collection points identified by Community Users, including, GP practice sites and the community-based phlebotomy centres and transport them to the relevant analytical laboratory or laboratories within 4 hours of sampling; and

(c) offer at least two sample collections per day to each Community User from their designated collection site(s) at a time which is agreed with, and is suitable for, the Community User and which:

(i) meets their clinical requirement;

(ii) maintains the viability of individual samples; and

(iii) delivers the results within the required turnaround times.

(d) agree additional sample collections with Commissioners on behalf of Community Users when clinically appropriate and improves care delivered to patients;

(e) be responsible for sorting the specimens after collection and delivering to the appropriate Hub or site other than the Hub where the test is requested as urgent;

(f) deliver all consumable supplies required by Community Users to take specimens for the Community Pathology Service;

(g) transport specimens in suitable vehicles with the appropriate temperature

controlled environment and in accordance with statutory requirements and Good Industry Standards and which maintain the integrity of samples and data confidentiality;

(h) ensure that samples are delivered within a timeframe appropriate to the nature of the requested investigations and protects the sample from deterioration;

(i) employ drivers that are suitably trained to handle biological specimens in accordance with best practice and statutory legislation;

(j) make equipment and training available at community-based collection sites for on-site pre analytical processing prior to the sample transportation if this is required to ensure sample integrity;

(k) have an electronic tracking system in place to enable the tracking of specimens in real time;

(l) have robust contingency plans in place to ensure continuity of specimen collections; and

(m) monitor and report incidents during sample transportation that may have affected the quality of the sample.

3 <u>Specialist pathology support for Community Users</u>

3.1 The Provider shall:

(a) provide consultant-led (or Specialist-led where appropriate) advice to Community Users on the appropriate use of tests (pre-analytical advice) and on the appropriate interpretation of results (post analytical advice) to ensure best practice;

(b) operate Specialist-led clinics or virtual clinics to explain laboratory results to Community Users;

(c) provide advice on the most appropriate use of pathology testing within clinical pathways and agree protocols with users to ensure appropriate test requesting;

(d) use evidence-based practice, national and local guidance with senior Specialist review to develop recommendations for pathology testing;

(e) offer clinical interpretation of results and advice on suitable further testing if appropriate to benefit patients;

(f) suggest relevant additional tests to pre-received specimens where clinically appropriate or as part of an agreed clinical pathway;

(g) agree standardised test profiles for investigations with Community Users to ensure clinical and cost effectiveness;

(h) provide liaison with Community Users, interpretation of results and other clinical advice for Integrated Blood Sciences and Microbiology; and

(i) provide on-call advice to Community Users available 24 hours per day, 7 days per week, for Integrated Blood Sciences and Microbiology by a registered clinical scientist or consultant pathologist, appropriately trained and qualified in the

specialty, within 30 minutes of the request;

3.2 The Provider shall:

(a) provide expert guidance to Commissioners on the commissioning of new tests based on an evaluation of their analytical and clinical validity as well as its clinical utility;

(b) monitor the efficacy and impact of the introduction of all new tests to assess the benefit to patients;

(c) implement appropriate mechanisms for quality control and assurance before introducing a new test;

(d) advise Community Users and Commissioners to review the use of tests that are outdated and have no clinical utility and suggest appropriate alternative tests;

(e) audit the usefulness of all outdated tests that do not deliver clinically useful results to inform Community Users of their use in clinical practice; and

(f) advise Community Users and Commissioners on appropriate retesting frequencies for patients with long term conditions

(g) have measures in place to monitor Community Users against appropriate retesting frequencies for managing patients with long term conditions and feedback significant variances in practice to Community Users and Commissioners.

3.3 The Provider shall:

(a) Provide Community Users through the single point of contact (see Para 2.1k) across the Cluster responses to queries and to access results for their patients by telephone;

(b) provide access to specialist telephone advice to supplement the user guide and deal with specific clinical queries;

(c) have an Cluster-wide protocol for handling urgent requests at all times including from out-of-hours providers and results that require immediate action outside core hours;

(d) the Provider shall agree with Commissioners to support community care provision thorough specialist outreach clinics and domiciliary visits where this provides benefit for patients and is agreed with Commissioners; and

(e) provide specialist microbiology medical advice through telephone discussions.

3.4 The Provider shall:

(a) produce a comprehensive pathology user handbook for Community Users which includes, but is not limited to:

(i) key contact information;

(ii) sampling instructions;

(iii) guidance on choice of appropriate container;

(iv) reference ranges for tests;

(v) advice on maintaining sample integrity;

(vi) advice on common interferences;

(vii) appropriateness and timeliness of tests; and

(viii) any special handling needs;

(b) produce regular educational and training updates for Community Users and Commissioners on the use of pathology services.

3.5 The Provider shall provide specialist advice to Community Users and public health teams relating to, but not limited to:

(a) infection prevention and control;

(b) surveillance for infectious disease and monitoring of communicable disease outbreaks;

(c) health and safety in the use of diagnostic testing and equipment; and

(d) education and training in the use of pathology services

3.6 The Provider shall:

(a) establish links with Community Users, academic institutions and other centres for research and development;

(b) carry out appropriate research and development to facilitate service development and staff training such as participation in clinical trials and the evaluation of new technologies; and

(c) ensure that staff, who participate in research projects, have been properly resourced and the project has been agreed by local and other appropriate clinical research ethics committees.

3.7 The Provider shall ensure that evidence based research findings, appropriate to their pathology services, which have been generated locally or from other sources are evaluated for future local pathology service development.

4 <u>Community based phlebotomy service</u>

4.1 The Provider shall provide for patients of those GP Practices that do not or cannot provide their own phlebotomy service, a community based phlebotomy service for patients across the Cluster which consists of:

(a) community-based walk-in phlebotomy centres in accessible and convenient locations within 30 minutes driving time of every GP practice across the proposed Cluster area and agreed with the Commissioners;

(b) domiciliary phlebotomy service for housebound patients or those with mobility challenges identified by Community Users;

(c) The community-based walk-in phlebotomy centres: shall:

(i) operate between 07.30 and 19.30 on weekdays and at least four hours on each day of the weekend and bank holidays;

(ii) see patients that walk-in to the community-based phlebotomy centre within 30 minutes of attendance;

(iii) act as a collection centre for all types of specimens collected by patients and Community Users; and

(d) be responsible for maintaining the integrity of samples that are collected from the service and from patients.

4.2 the Provider shall:

(a) provide advice on sample collection to Community Users that undertake phlebotomy in community settings to ensure safe delivery in accordance with national guidelines;

(b) undertake blood collection by professional staff trained and competent in phlebotomy in accordance with national and regional guidance;

(c) provide users with guidance and advice on the sample collection, timing of sample, appropriateness of specimen container and any special patient preparation, if required;

(d) provide all of the necessary equipment for phlebotomy to Community Users that undertake phlebotomy including but not limited to sample tubes, bottles, containers and blood collection kits; and

(e) utilise a standardised Cluster-wide test request form until a common system for electronic ordering is in place across the Cluster.

5 Electronic systems to support users in test ordering and receipt of results

[DN: To be updated]

6 Information about usage, costs and outcomes

6.1 The Provider shall provide comprehensive monthly reports to Commissioners and Community Users on the use of the Community Pathology Service. This shall include, but is not limited to:

(a) information about use, activity levels by location and spend for the phlebotomy service;

(b) information about use, activity levels and spend by Community User and GP practice for the Community Pathology Service;

(c) benchmarking information comparing Community Users and Commissioners within the region; and

(d) information about the use of pathology services against key outcomes to be agreed with Commissioners e.g. mapping pathology usage to prevalence of long term conditions, prescribing data, clinical outcomes and urgent admissions.

6.2 The Provider shall undertake annual benchmarking of its service against other providers within the region and nationally, through both a recognised national industry benchmarking service such as the National Pathology Benchmarking Service, and benchmark against the Key Performance Indicators that are applicable to the service commissioned.

6.3 The provider shall undertake to provide a report at least 2-3 times a year, on an agreed set of Key Performance Indicators (KPIs), such as either those detailed in Schedule 3 Part 2A, or on another set of agreed Indicators, such as those published by the Royal College of Pathologist. It is expected that the Provider will meet the standards required by the KPIs.

7 <u>Support on the use of diagnostics and development of care pathways</u>

7.1 The Provider shall work with Community Users and Commissioners to:

(a) work with Community Users to agree care pathways to ensure the most appropriate, safe and cost-effective use of pathology testing;

(b) work with Commissioners and Community Users to optimise the patient pathway and, where possible, improve accessibility and convenience for patients, reduce the number of patient interactions with healthcare professionals and improve patient experience;

(c) support Commissioners and Community Users to audit the effectiveness of care pathways in relation to the use of pathology tests and implement relevant service improvements as recommended;

(d) provide expert, professional advice and guidance on the withdrawal of those tests considered to be obsolete or of limited clinical utility; and

(e) explore opportunities where the Provider operates registers for long term conditions.

7.2 The Provider shall work with Community Users to ensure appropriate utilisation of pathology services across the Cluster and reduce the inappropriate use of tests by measures including, but not limited to, providing:

(a) feedback about requesting behaviour to Community Users;

(b) targeted clinical education for Community Users through guidelines and protocols for appropriate testing;

(c) use information technology solutions to support evidence-based decision making by Community Users on the appropriate use of tests within local care pathways; and

(d) benchmarking information to Community Users and their use of pathology tests especially when tests have been identified to have limited or no clinical utility.

7.3 The Integrated Blood Science service shall support Community Users to:

(a) Optimise care for patients with long term conditions including, but not limited to, diabetes mellitus, thyroid disease, heart failure, lipid disorders and osteoporosis;

(b) Diagnose and manage patients with cancer, where appropriate in conjunction with the specialist/secondary care centre and include appropriate tumour markers for monitoring cancers in accordance with national and international best practice

guidelines;

(c) Innovate to improve the clinical service provided by Community Users to their patients in the community; and

(d) Care for patients receiving total parenteral nutrition.

8 Support for point of care testing

8.1 The Provider shall:

(a) support Community Users and Commissioners in the introduction of POCT in appropriate community settings;

(b) provide independent advice and guidance on the suitability and appropriateness of third party point of care testing (POCT) equipment and the process used to deliver the POCT service;

(c) oversee equipment maintenance, training and quality assurance / quality control for POCT;

(d) advise Commissioners and Community Users on the following key areas:

(i) provision of safe, effective and high-quality POCT service in the community;

(ii) undertaking of POCT in accordance with professional, national and regulatory guidance to meet best practice;

(iii) monitoring of POCT use and equipment within a robust quality management system;

(iv) promote the use of POCT where they provide similar results to laboratory methods; and

(v) compliance of POCT equipment and practices with professional, national and regulatory standards including, but not limited to, MHRA and appropriate accreditation standards and guidance; and

(e) Support Commissioners to audit the use of POCT to ensure POC tests are used appropriately.

9 User and patient experience

9.1 The Provider shall:

(a) Offer all Community Users that user the Community Pathology Service to participate in a standardised user experience survey, such as the Royal College of Pathologists User Satisfaction Survey, to highlight strengths and weaknesses of service provision from a user perspective;

(b) Offer all patients that use the community phlebotomy service and domiciliary phlebotomy service to participate in a standardised patient experience survey, such as the Royal College of Pathologists Patient Satisfaction Survey, to highlight strengths and weaknesses of service provision from a user perspective; and

(c) Review the outcomes of the user and patients biannually to identify areas of service development and improvements.

(d) Offer the results of their annual and biannual benchmarking exercises to both Community Users and all patients that use the community and domiciliary phlebotomy service.

Part 2: Major Incidents

[DN: Not used.]

Part 3: Prices

[DN: Prices/pricing mechanism to be inserted once tender process has been completed and Preferred Provider has confirmed firm prices at ITT stage agreed with the Provider. This Part 3 should set out the tests and corresponding price per test]

Part 4: Frequency of Review Meetings

[DN: Not used as dealt with in Clause 10.]

SCHEDULE 3

Managing Activity, Resource Utilisation Techniques and

Retention of Payment Scheme

Part 1: Managing Activity and Requests

[DN: To be reviewed by commissioners for relevance to pathology services being commissioned.]

In this Schedule 3:

"Capacity Review"	means a review carried out in accordance with paragraph 7 of this Schedule 3 Part 1; and
"Capacity Review Criteria"	means the criteria to be satisfied for a Capacity Review to be performed, and set out in Annex 2 to Schedule 3 Part 1.

Activity Plan

1 General

1.1 The Parties have a mutual responsibility to respond to the health needs of their populations. They shall co-operate to ensure that the Activity Plan is constructed, regularly monitored and reviewed to reflect the changing health needs of their populations, changes in the distribution profile of activity, the capacity requirements of national and local requirements and standards, and any innovative treatment or clinical practice recommended by a Clinical Network or agreed as part of the Service Development and Improvement Plan.

1.2 The Commissioners shall manage external demand for all the Services and the Provider will be expected to support the Commissioner in managing the demand for pathology services.

1.3 The Provider shall manage internal demand so as to achieve the requirements and performance standards identified in the Commissioners' Local Commissioning Plans, and the Provider shall assess capacity to respond to such demand so as to ensure that all Services are provided within the time limits set out in this Agreement.

1.4 The Co-ordinating Commissioner and the Provider shall monitor actual demand against forecast levels in accordance with this Schedule 3, and shall act in accordance with such responsibilities.

1.5 The Parties acknowledge that the Activity Plan is essential to the effective operation of the Agreement and shall reflect key national and local priorities and national and local performance requirements.

1.6 The Provider shall comply with any applicable Quality Requirements set out in Schedule 3 Part 2.

1.7 Prior to the start of each Contract Year each Commissioner and the Provider shall agree the

Activity Plan for that Contract Year in accordance with the NHS Operating Framework.

2 Contents and Thresholds

2.1 The Activity Plan (Schedule 3 Part 1 Annex 1A and 1B) shall comprise:

(a) monthly forecast levels of activity necessary for the Provider to meet the forecast levels of demand;

(b) each type of activity forecast at specialty level where appropriate;

(c) activity forecasts at HRG level (as defined from time to time by the NHS Information Authority) or equivalent;

(d) activity forecasts for groups of specialties, where specialties are not specified individually; and

(e) all commissioned activity.

2.2 The Activity Plan (Schedule 3 Part 1 Annex 1A) will specify each type of activity being commissioned, including without limitation:

(a) the Analytical Services which includes:

(i) the Specialist Pathology Support for Community Users;

(ii) support Commissioners in the use of diagnostics and the development of care pathways;

(iii) support for point of care testing;

(b) the Community Phlebotomy Services;

2.3 The agreed Activity Plan shall specify a forecast threshold or tolerance for each activity to function as an early warning of where the actual level of demand exceeds the forecast threshold, with the intent that any breach of the forecast threshold will be reviewed by the relevant Parties without delay.

2.4 The Activity Plan shall comprise the aggregated Activity Plan of all of the Commissioners and also each individual Commissioner's Activity Plan.

3 Resource Utilisation

3.1 The Commissioners shall:

(a) manage demand for all the Services to the forecast thresholds set out in the Activity Plan and will use reasonable endeavours to notify the Provider within 10 Operational Days of receiving any confirmed information demonstrating any anticipated changes in such numbers of Requests; and

(b) require their agents and practitioners to adhere to any Request and treatment protocols as may be agreed with the Provider.

3.2 The Provider shall manage demand and associated costs for all the Services in accordance with the Activity Plan, Commissioning Ambitions, the Local Commissioning Plans and the

provisions of this Schedule, and shall in particular, but without limitation:

(a) comply with the reasonable requests of the Commissioners to assist the Commissioners in understanding and managing Requests; and

(b) require its agents, sub-contractors and employees to adhere to any Request protocols that may be agreed between the Parties.

3.3 **[**Utilisation Management

3.4 The Co-ordinating Commissioner and the Provider shall agree the terms of a Utilisation Management Scheme, and when the terms of the Utilisation Management Scheme have been agreed the Co-ordinating Commissioner shall give to the Provider one month's notice in writing of the date on which the Utilisation Management Scheme is to be implemented by the Provider.

3.5 The Provider shall comply and co-operate with the agreed Utilisation Management Scheme, in particular (but without limitation) in sharing data, and allowing access for review teams and access to Patient Health Records.

3.6 If the Co-ordinating Commissioner requires any amendment to be made to the Utilisation Management Scheme, it shall consult with the Provider on the proposed amendment, and when the amendment has been agreed by the Co-ordinating Commissioner and the Provider, the Co-ordinating Commissioner will give the Provider one month's notice in writing of the date on which the amendment to the Utilisation Management Scheme is to be implemented by the Provider.

4 Monitoring and Reporting of Activity

4.1 The Provider shall submit to the Co-ordinating Commissioner an agreed monthly activity report which shall without limitation include:

(a) activity volumes by Test by Community User;

(b) spend by Test by Community User;

(c) benchmarking the utilisation of Tests by Community Users by Test;

(d) benchmarking the spend by Community Users by Test,

and shall, immediately the Provider becomes aware notify the Co-ordinating Commissioner if the Provider forecasts that there will be over-performance of activity in any of the Services compared to the levels set out in the Activity Plan.

5 Activity management following activity variations

5.1 Without prejudice to paragraphs 4 and 7 of this Schedule 3 Part 1, if the Provider breaches:

(a) the forecast threshold set out in the Activity Plan for any activity; or

(b) a Utilisation Management Scheme,

then the Provider shall notify the Co-ordinating Commissioner of such breach, and the Co-ordinating Commissioner and the Provider shall agree an Activity Management Plan comprising without limitation the matters set out in paragraphs 5.2, 5.5, and 5.6.

5.2 The Activity Management Plan may, without limitation, include an analysis of the following matters for the period in which a forecast threshold has been breached:

(a) activity levels;

(b) right-coding.

5.3 The Provider undertakes to work collaboratively with the Co-ordinating Commissioner on the development, implementation and operation of service redesign programmes and improvements to the Services Specification, and actively to engage with, support and cooperate with redesign, recording and coding policies, and demand management activities as deemed necessary in the Activity Management Plan.

5.4 The Activity Management Plan shall specify any thresholds which have been breached, and the Party in breach shall make proposals to remedy the relevant breach, including the findings of any Review insofar as they relate to the breach.

5.5 The Activity Management Plan will include specific locally-agreed requirements and timescales within which requirements shall be achieved.

5.6 Within 5 Operational Days of:

(a) any breach by the Provider of an Activity Management Plan; or

(b) a failure by the Provider to implement an Activity Management Plan,

and provided that the Provider has not referred the matter to dispute resolution under clause 26 (*Dispute Resolution*), the Co-ordinating Commissioner may, without prejudice to any other rights that it may have under this Agreement, in its absolute discretion and acting reasonably, require the Provider by written notice to take such steps as the Co-ordinating Commissioner considers necessary or expedient to mitigate or rectify the breach or implement the Activity Management Plan, and the Provider shall use its best endeavours to comply with the Co-ordinating Commissioner's requirements as soon as practicable.

6 <u>Financial Adjustment for variations in activity</u>

6.1 Subject to clauses 9.4 to 9.8 inclusive, the Co-ordinating Commissioner may initiate a joint process with the Provider to determine whether any financial adjustment should be applied in relation to any activity which has in the relevant month breached:

(a) forecast thresholds set out in the Activity Plan, where no relevant Activity Management Plan has been implemented owing to an omission by the Provider to notify the Co-ordinating Commissioner under paragraph 5.1(a); or

(b) forecast thresholds set out in the Activity Plan, and an Activity Management Plan has been implemented and breached; and

(c) Quality Requirements 7, 13, 14, 15, 16 and 17 set out in the table at Part 2A of this Schedule,

and such joint process shall take account of any relevant matters identified in the Reviews conducted, or in any Service Quality Performance Report produced under clause 29.1 relating to that month.

6.2 Initiation of the joint process under paragraph 6.1 above is at the discretion of the Co-ordinating Commissioner. If, as a result of the joint process under paragraph 6.1 above, the Co-ordinating Commissioner determines that the Provider is responsible for having provided activity which has in the Contract Year breached:

(a) forecast thresholds set out in the Activity Plan, where no relevant Activity Management Plan has been implemented owing to an omission by the Provider to notify the Co-ordinating Commissioner under paragraph 5.1(a) above; or

(b) forecast thresholds set out in the Activity Plan, and an Activity Management Plan has been implemented and breached;

(c) Quality Requirements 7, 13, 14, 15, 16 and 17 set out in the table at Part 2A of this Schedule,

then, notwithstanding the provisions of clause 9 (*Prices and Payment*) of this Agreement, the relevant Commissioner may in its reasonable discretion choose not to pay the Provider in respect of the activity or (as the case may be) part of the activity that caused the breach or to which the breach relates.

7 Capacity Review

7.1 Where:

(a) the Capacity Review Criteria set out in Annex 2 of this Schedule 3 Part 1 are satisfied; and

(b) it is not practically feasible for the Provider to take such action as is required for it to increase its capacity so as to meet an increase in demand for the relevant Service(s); and

(c) the Provider acting reasonably considers that it will be unable to meet the Turnaround Times in respect of the relevant Service(s),

the Provider shall by notice in writing require the Co-ordinating Commissioner to participate in a Capacity Review of the activity specified in the notice in order to determine whether the Provider should be exempted from any financial adjustment which the Co-ordinating Commissioner may otherwise be entitled to apply under paragraph 9 of this Schedule.

7.2 The Co-ordinating Commissioner shall commence the Capacity Review within 10 Operational Days of receipt of the said notice.

7.3 The Capacity Review shall consider:

(a) any constraints on the physical capacity or resources, including Staff of the Provider; and

(b) whether the Provider is delivering the most efficient care pathways for the activity the subject of the Capacity Review as informed by Good Health and/or Social Care Practice.

7.4 The Co-ordinating Commissioner shall, upon conclusion of the Capacity Review, report its findings and any recommendations to the Provider.

7.5 If the findings of the Capacity Review are that there is a limit on the activity in excess of the levels set out in the Activity Plan that the Provider can reasonably undertake so as to meet the Turnaround Times, and the Provider has taken all reasonable steps to increase capacity, then the Provider shall not be made the subject of any financial adjustment pursuant to paragraph 9 of this Schedule in respect of any activity which is over and above the levels set out in the relevant Activity Plan, or any higher level set by the Capacity Review. In such circumstances, the Provider and the Co-ordinating Commissioner shall agree and submit a report to the relevant SHA, to CQC (or other relevant regulatory body) and where appropriate to Monitor detailing the reasons why the Provider shall not be made the subject of any financial adjustment pursuant to paragraph 9 of this Schedule 3 Part 1 and describing any action agreed to be taken.

7.6 Where the findings of the Capacity Review are that there is a limit on the activity in excess of the levels set out in the Activity Plan that the Provider can reasonably undertake so as to meet the Turnaround Times, the Provider and the Co-ordinating Commissioner shall agree a plan to enable the Provider to comply with the Turnaround Times in respect of all such activity as soon as is reasonably practicable.

7.7 The Provider and the Co-ordinating Commissioner shall keep under review at every Review held under clause 10 (*Review*) of this Agreement the findings and recommendations of any Capacity Review, and the progress of any capacity expansion plan implemented under paragraph 7.6 above.

7.8 The Provider and the Co-ordinating Commissioner shall at all times act reasonably and in good faith in relation to any Capacity Review.

8 Dispute Resolution

8.1 In relation to any dispute concerning the matters set out in this Schedule 3 Part 1 the Parties shall follow the dispute resolution procedure set out in clause 26 (*Dispute Resolution*) of this Agreement.

Annex 1A – Activity Plans

[DN: Activity Plans to be inserted]

Annex 1B – Commissioning Ambitions based on Activity Plan

[DN: To be agreed and inserted]

Annex 2 – Capacity Review Criteria

[DN: To be agreed and inserted]

Annex 3 – Expected Annual Contract Values

[DN: To be agreed and inserted]

Part 2: Quality Requirements

Part 2A: Quality Requirements

No	Technical Guidance Reference	Quality Requirement	Threshold	Method of Measurement	Consequence of breach
1		Percentage of days in which duty clinical biochemists/haematologists/ microbiologists/virologists respond to all responses to requests for clinical advice within 30 minutes (including out of hours).	97%		
2		Percentage of Consultants in clinical biochemistry / haematology / microbiology / virology providing laboratory oversight and clinical advice who have completed appraisal	100%		
3		Percentage of staff who perform clinical work with completed clinical appraisal	100%		
4		Percentage of Consultants in clinical biochemistry / haematology / microbiology / virology registered with Royal College of Pathologists or Royal College of Physicians, or equivalent, for Continuing Professional Development	100%		
4		The percentage of Community Users that are asked to participate in a standardised user satisfaction survey.	95%		
5		The proportion of the aggregate of staff in training in BMS, clinical scientist and medical staff groups, to be between 15 and 30% of the aggregate of fully-qualified BMS, clinical scientist and medical staff.	90%		
6		The percentage of validated test results for tests in reporting time category 3 for Integrated Blood Sciences	95%		

No	Technical Guidance Reference	Quality Requirement	Threshold	Method of Measurement	Consequence of breach
		(Clinical Biochemistry) reported within 8 hours of the sample being taken from the patient.			
7		The percentage of validated test results for tests in reporting time category 3 for Integrated Blood Sciences (Haematology) reported within 8 hours of the sample being taken from the patient.	95%		
8		The percentage of validated test results for tests in reporting time category 5 for Microbiology (Bacteriology) reported within 72 hours of the sample being deposited at a collection site	95%		
9		The percentage of validated test results for tests in reporting time category 5 for Microbiology (Virology) reported within 72 hours of the sample being deposited at a collection site	95%		
10		The percentage of patients that have had their blood sample taken within 30 minutes of registering with the community-based walk-in phlebotomy service.	95%		
11		The percentage of patients that are asked to participate in a standardised patient satisfaction survey at the time of attendance at the community phlebotomy centre	95%		
12		The percentage of Integrated Blood Sciences samples requested by Community Users that are analysed at the Integrated Blood Sciences Hub	90%		
13		The percentage of Microbiology samples requested by Community Users that are analysed at the Microbiology Hub	90%		

Part 2B: Nationally Specified Events

[DN: Not used.]

Part 2C: Never Events

[DN: Not used]

Part 3: Patient, Carer and Staff Surveys

[DN: Not used.]

SCHEDULE 4

Transformation

Part 1: Conditions Precedent

[DN: To be amended/updated to reflect the specific CPs required from the Provider.]

1 The Provider shall deliver to the Co-ordinating Commissioner on or prior to the Service Commencement Date the following (Conditions Precedent) documents, or where appropriate copies of them:

(a) the Provider's Terms of Authorisation (where the Provider is an NHS Foundation Trust);

(b) CQC's registration of the Provider;

(c) Evidence of accreditation for the provider pathology services;

(d) any Consents required for the provision of the Services by the Provider;

(e) Business Continuity Plan;

(f) confirmation that all Indemnity Arrangements (acceptable to the Co-ordinating Commissioner) required under clause 24.2 are in place; and

(g) agreed rectification plan for any performance issues relating to previous contracts.

2 It shall be a condition precedent to commencement of the delivery of the Services that the Provider adopts the Safeguarding Policy.

Part 2: Documents to be delivered by the Co-ordinating Commissioner

1 Pursuant to clause 3.3, the Co-ordinating Commissioner shall deliver to the Provider the following documents, or where appropriate copies of them:

(a) [executed Consortium Agreement] OR [executed Establishment Agreement]; and

(b) Local Commissioning Plans.

Part 3: Transformation Arrangements

[DN: Transformation Plan to be agreed and inserted]

SCHEDULE 5

Information Requirements

All information gathered for the purposes of reporting is subject to the requirements set out in clause 25 (*Data Protection, Freedom of Information and Transparency*) and clause 51 (*Compliance with the Law*).

Part 1: National Requirements Reported Centrally

1 The Provider and Commissioner shall comply with the reporting requirements of SUS and UNIFY2. This includes compliance with the required format, schedules for delivery of data and definitions as set out in the Information Centre guidance and all Information Standards Notices (ISNs) (being a notice of an Information Standard approved by the Information Standards Board), where applicable to the service being provided.

2 The Provider shall ensure that each dataset that it provides under this Agreement contains the Organisation Data Service (ODS) code for the relevant Commissioner, and where the Commissioner to which a dataset relates is a Specialised Commissioning Group, or for the purposes of this Agreement hosts, represents or acts on behalf of a Specialised Commissioning Group, the Provider shall ensure that the dataset contains the ODS code for such Specialised Commissioning Group.

3 The Provider shall collect and report to the Commissioner on the patient-reported outcomes measures (PROMS) in accordance with applicable Guidance.

Part 2: National Requirements Reported Locally

1 Monthly activity report, as described in Schedule 3, Part 1 paragraph 4.1 ***[DN: Format and method for delivery to be determined locally]***.

2 Monthly Service Quality Performance Report, as described in clause 29.1, and details of performance against the Quality Requirements, including without limitation details of all Quality Requirements satisfied, and details of and reasons for any failure to meet the Quality Requirements ***[DN: Format and method for delivery to be determined locally]***.

3 Equality monitoring report ***[DN: Frequency, format and method for delivery to be determined locally]***.

4 Complaints monitoring report ***[DN: Frequency, format and method for delivery to be determined locally]***.

5 In light of the requirements of the Climate Change Act 2008, the Department's Sustainability Strategy "Taking the long term view", and in line with the national NHS Strategy: "Saving Carbon, Improving Health", the Provider shall, as applicable, demonstrate their measured progress on climate change adaptation, mitigation and sustainable development, including performance against carbon reduction management plans ***[DN: Frequency, format and method for delivery to be determined locally]***.

6 Report and provide monthly data and detailed information relating to violence-related injury resulting in treatment being sought from Staff in Walk in Centres to the local Community Safety Partnership (CSP) in accordance with applicable Guidance (College of Emergency Medicine Clinical Guideline Information Sharing to Reduce Community Violence (July 2009)) ***[DN: Format and method of delivery in accordance with the applicable Guidance]***.

7 Monthly summary report of all incidents requiring reporting ***[DN: Format and method for delivery to be determined locally]***.

8 Where appropriate, report of progress against milestones in Data Quality Improvement Plan ***[DN: Frequency, format and method for delivery to be determined locally as part of the plan]***.

Part 3: Local Requirements Reported Locally

1 The Provider will provide an electronic report on a monthly basis, or on request in exceptional circumstances, in database or spreadsheet form with the following data field completed with the pathology activity for the previous month and the year to date, for each Commissioning organisation:

(a) Commissioning Organisation code;

(b) Requesting Consultant/GP;

(c) Date sample requested;

(d) Date sample received in lab;

(e) Date reported;

(f) Discipline;

(g) Patient DOB;

(h) Practice Code;

(i) NHS number;

(j) Hospital Number (if NHS number not available);

(k) HRGC (where available);

(l) Patient post code;

(m) Patient sex;

(n) Test Name;

(o) Test Code;

(p) Test result; and

(q) Interpretation of the Test result.

Part 4: Data Quality Improvement Plan

Data Quality Indicator	Data Quality Threshold	Method of Measurement	Milestone Date	Consequence
[DN: To be agreed]	***[DN: To be agreed]***	***[DN: To be agreed]***	***[DN: To be agreed]***	***[DN: To be agreed]***

SCHEDULE 6

Variations

Part 1: Variation Procedure

1 Where clause 34.4 applies, the Parties shall follow the procedure set out in this Schedule 6 Part 1.

2 The Party proposing the Variation (the **"Proposer"**) shall make a proposal in writing to the other Party (a **"Variation Proposal"** or **"VP"**) setting out the Variation proposed and the date upon which the Proposer requires it to take effect.

3 Upon receipt of a VP, the receiving Party (the **"Recipient"**) shall respond to it in writing within 10 Operational Days from the date of the VP, or if it is marked "urgent" within 5 Operational Days of the date of the VP.

4 The Parties shall then meet within 10 Operational Days of the date of the Recipient's response to discuss the VP and acting reasonably and in good faith shall use reasonable endeavours to agree the Variation.

5 If, notwithstanding paragraph 4 above, the Recipient does not agree the Variation, the Recipient shall give notice in writing to the Proposer that the Variation is refused and shall set out reasonable grounds for such refusal. The Proposer may then:

(a) withdraw the VP; or

(b) refer such refusal to dispute resolution under clause 26 (*Dispute Resolution*); or

(c) serve notice to terminate this Agreement in accordance with clause 31.1 or 31.2, as appropriate.

Part 2: Recorded Variations and Dispute Resolutions

[DN: Intentionally left blank]

SCHEDULE 7

Service Development and Improvement Plan

[DN: Not used.]

SCHEDULE 8

Exit Arrangements and Agreements Relating to Termination Costs

[DN: To be discussed and agreed.]

SCHEDULE 9

Dispute Resolution

Part 1: Details of Mediator and Independent Binding Pendulum Adjudicator

1 The Parties have agreed to appoint ***[insert name and details of organisation/body agreed between the Parties to mediate Disputes]*** pursuant to clause 26.2(b).

2 The Parties have agreed to appoint ***[insert name and details of organisation/body agreed between the Parties to act as independent binding pendulum adjudicator]*** pursuant to clause 26.9(a)(ii).

Part 2: Procedure for Disputes between Divisions Of The Same NHS Body

[DN: unlikely to be required and therefore can be deleted.]

SCHEDULE 10

Provider's Material Sub-contractors

Material Sub-contractors

[DN: To be agreed]

SCHEDULE 11

Consortium Agreement, Local Commissioning Plans, Notices to Aggregate/Disaggregate Payments, Safeguarding Policy, Associates

Part 1: Consortium Agreement/Establishment Agreement

[DN: To be inserted if applicable]

Part 2: Local Commissioning Plans

[DN: To be inserted]

Part 3: Notices to Aggregate/Disaggregate Payments

[DN: To be inserted]

Part 4: Safeguarding Policy

[DN: To be inserted]

Part 5: Associates

[DN: To be inserted]

SCHEDULE 12

Incidents Requiring Reporting Procedure

[DN: To be agreed and inserted]

SCHEDULE 13

NHS Counter-fraud and Security Management

1 For the purposes of this Schedule 13, all references in the NHS Fraud and Corruption Manual to "NHS Body" shall be read as "the Provider", and "Secretary of State directions" shall be read as "provisions of, and matters to be done pursuant to this Agreement".

2 For the purposes of this Schedule 13, all references in the NHS Security Management Manual to "NHS Body" shall be read as "the Provider", and "Secretary of State directions" shall be read as "provisions of, and matters to be done pursuant to this Agreement".

3 The Provider shall:

(a) take all necessary steps to counter fraud relating to all functions in connection with the provision of healthcare to NHS patients (including Patients); and

(b) promote and protect the security of its staff and patients (including Staff and Patients), NHS property, assets and information in connection with the provision of healthcare to NHS patients (including Patients),

in accordance with this Schedule 13.

4 The Provider shall co-operate with the CFSMS at all times to enable the CFSMS efficiently and effectively to carry out its functions in relation to countering fraud and security management and for those purposes shall (subject to paragraph 7, below):

(a) enable CFSMS to have reasonable access to the Provider's Premises;

(b) put in place arrangements which will enable CFSMS to have reasonable access to, and to interview Staff; and

(c) supply such information, including files and other data (whether in electronic or manual form) as the CFSMS may require.

5 In the case of information required under paragraph 4(c) relating to CFSMS's responsibility for quality inspection, fraud measurement, national proactive exercises in fraud prevention, reviews and inspections, or relating to quality assurance (including inspection) and risk assessment for security measures, the Provider shall respond to any reasonable request from CFSMS as soon as practicable.

6 In the case of information required under paragraph 4(c) relating to CFSMS's counter fraud or security investigation functions, the Provider shall respond to any request from CFSMS, as soon as practicable, and in any event within 7 days after the date on which the request was made.

7 Nothing in paragraph 4(b) shall contravene any right any Staff may have to refuse to be interviewed and nothing in paragraph 4(c) obliges or permits the Provider to supply any information, disclosure of which is prohibited by law, contract or obligation of confidentiality.

8 The Provider shall act in accordance with:

(a) the NHS Counter Fraud and Corruption Manual;

(b) the NHS Security Management Manual:

(c) "A Professional Approach to Managing Security in the NHS" – NHS CFSMS 2003;

(d) "Tackling Violence Against NHS staff" – NHS CFSMS 2007;

(e) the policy statement "Applying appropriate sanctions consistently" published by the CFSMS; and

(f) all other reasonable guidance or manuals of CFSMS,

as they may from time to time be amended or issued.

9 Without prejudice to the generality of paragraph 8 (but subject to paragraph 7), the Provider shall comply with the requirements specified in the NHS Counter Fraud and Corruption Manual concerning:

(a) the arrangements for reporting fraud cases to its LCFS and to its audit committee and its auditors;

(b) the arrangements for agreeing to undertake a criminal prosecution and to refer the matter to the police;

(c) the confidentiality of information relevant to the investigation of suspected fraud;

(d) the arrangements for its LCFS to report weaknesses in fraud vulnerable systems to CFSMS and the Provider's audit committee and auditors; and

(e) the arrangements for gathering information to enable the Provider's Director of Finance to seek recovery of money lost through fraud.

10 Without prejudice to the generality of paragraph 8 (but subject to paragraph 7), the Provider shall comply with the requirements specified in the NHS Security Management Manual concerning:

(a) the arrangements for reporting security breaches to its LSMS;

(b) the arrangements for agreeing to undertake a criminal prosecution and to refer the matter to the police;

(c) the confidentiality of information relevant to the investigation of suspected security breaches;

(d) the arrangements for its LSMS to report weaknesses in security management measures; and

(e) the arrangements for gathering information to enable the Provider's Security Management Director to seek, where appropriate, recovery of money lost through security breaches.

11 The Provider shall ensure that its Chief Executive, Director of Finance and Security Management Executive Director shall monitor and ensure compliance with the Provider's obligations under paragraphs 3 to 10 inclusive.

12 The Provider shall (if it has not previously done so) within 6 weeks after the Effective Date,

designate:

(f) one of its non-Executive Directors to promote security management measures; and

(g) one of its Executive Directors to undertake specific responsibility for security management measures.

13 A further designation shall be made within 3 months of the date on which the Provider first anticipates that there is to be a vacancy for any person referred to in paragraph 12.

14 The Provider shall ensure that each person so designated receives appropriate training initially and from time to time, as appropriate, in connection with security management and countering fraud, as provided by the CFSMS.

15 The relevant information regarding details of the persons designated under paragraphs 12 and 13 shall be notified to CFSMS within 7 days after each designation.

16 The Provider shall nominate at least one person whom it proposes to appoint as its LCFS within 6 weeks after the Effective Date, and:

(h) the person so nominated may be either employed by the Provider or a person whose services are provided to it by an outside organisation; and

(i) the name of the nominee shall be notified to the CFSMS together with the information specified in the NHS Counter Fraud and Corruption Manual, within 7 days after the nomination; and

(j) before making a nomination, the Provider shall take into account any guidance issued by the CFSMS relating to:

(i) the suitability criteria for an LCFS;

(ii) where an LCFS is to be employed by the Provider, the terms on which an LCFS is to be employed; and

(iii) where the services of an LCFS are to be provided to the Provider by an outside organization, the terms on which those services are to be provided.

17 The Provider shall nominate at least one person that it proposes to appoint as its LSMS within 6 weeks after the Effective Date, and:

(k) the name of the nominee shall be notified to the CFSMS within 7 days of that nomination; and

(l) before making any such nomination, the Provider shall take into account any guidance issued by CFSMS on the suitability criteria for a LSMS.

18 After a person nominated by the Provider has:

(a) been approved by the CFSMS as a person suitable for appointment as LCFS or LSMS;

(b) successfully completed any training required by the CFSMS; and

(c) has been appropriately accredited by the Counter Fraud Professional Accreditation Board being the training organisation having that name or any successor

organisation or the NHS Security Management Accreditation Board,

the Provider may appoint the person as its LCFS or LSMS in accordance with such approval.

19 If the Provider nominates a personas its LCFS whose services are provided by an outside organisation, it shall comply with the requirements of CFSMS as to the suitability of the nominee, and satisfy itself and the CFSMS that the terms for the provision of the services will enable the nominee to carry out LCFS or LSMS functions effectively (and in particular that the nominee will devote sufficient time to these functions), and give to the CFSMS a copy of the contract under which the services of the LCFS or LSMS are provided to it.

20 Further nomination shall be made within 3 months of the date on which the Provider first anticipates that there is to be a vacancy for its LCFS or its LSMS and the provisions of paragraphs 16 to 19 inclusive shall apply to any such nomination and subsequent appointment.

21 The Provider shall specify a job description for its LCFS which includes the operational and liaison responsibilities specified by the CFSMS, and an LCFS:

(a) shall report directly to the Provider's Director of Finance; and

(b) shall not undertake responsibility for, or be in any way engaged in, the management of security.

22 The Provider shall specify a job description for its LSMS which includes the operational and liaison responsibilities specified by the CFSMS (a generic job description may be found on the CFSMS website), and an LSMS:

(c) shall report directly to the Provider's Executive Director designated under paragraph 12(b) and have the responsibilities set out in his work plan completed under paragraph 23(b); and

(d) shall not undertake responsibility for, or in any way be engaged in any counter fraud activities.

23 The Provider shall put effective arrangements in place to:

(a) ensure that in addition to the job description mentioned in paragraph 21 the LCFS and the Director of Finance agree a written work plan which outlines the LCFS's projected work for that Contract Year, and within 1 month after the beginning of each Contract Year, by reference to the seven generic areas of counter fraud activity set out in the NHS Counter Fraud and Corruption Manual;

(b) ensure that its LSMS and its Executive Director designated under paragraph 12(b) agree a written work plan for the LSMS projected work for that Contract Year, and within 1 month after the beginning of each Contract Year; by reference to the seven generic areas of security management activity set out in the NHS Security Management Manual;

(c) enable its LCFS to attend the Provider's audit committee meetings and its LSMS to attend its risk management and audit committee meetings;

(d) ensure that its LCFS provides a written report, at least once in each Contract Year, summarising the LCFS's counter fraud work by reference to the seven generic areas

of activity set out in the NHS Counter Fraud and Corruption Manual;

(e) ensure that its LSMS provides a written report to the Provider's Executive Director, designated under paragraph 12(b) at least once in each Contract Year, summarising the LSMS's security management work for that Contract Year by reference to the seven generic areas of activity set out in the NHS Security Management Manual;

(f) ensure that full and accurate records are kept, by the LCFS, of any instances of fraud and suspected fraud;

(g) ensure that full and accurate records are kept by the LSMS of any security breaches or adverse security-related incidents;

(h) ensure that any weaknesses in fraud-related systems and any other matters which may have fraud-related implications for the Provider are reported to its LCFS and that its LCFS reports them to CFSMS;

(i) ensure that any weaknesses in security-related systems of the Provider or other matters which may have implications for security management are reported to its LSMS and that its LSMS reports them to CFSMS;

(j) ensure that breaches in security and weaknesses in security-related systems are reported to:

(i) the Provider's LSMS; and

(ii) where appropriate, and having regard to CFSMS guidance, to CFSMS and to the Provider's audit committee, auditors and risk management committee;

(k) ensure that, where cost effective, it seeks to recover money lost by the Provider through breaches of security;

(l) ensure that its LCFS and its LSMS have all necessary support, including access to the CFSMS secure intranet site to enable them efficiently and effectively to carry out their responsibilities;

(m) subject to paragraph 7, ensure that all its Staff co-operate with the LCFS and the LSMS and, in particular, that those responsible for human resources disclose information which arises in connection with any matters (including disciplinary matters) which may have implications in relation to the investigation, prevention or detection of fraud or breaches of security;

(n) enable its LCFS and its LSMS to receive training recommended by the CFSMS;

(o) ensure that its LCFS, its LSMS and its Staff or any person whose services are provided to the Provider in connection with counter fraud or security management work, has regard to guidance and advice on media handling of counter fraud matters or security management matters which may be issued by the CFSMS;

(p) participate in activities in which the CFSMS is engaged, including national anti-fraud measures and security management matters, where requested;

(q) enable its LCFS and its LSMS to work in conditions of sufficient security and privacy to protect the confidentiality of their work; and

(r) enable its LCFS and its LSMS generally to perform their functions effectively, efficiently and promptly.

24 This paragraph applies where a provider has appointed as its LCFS a person whose services are provided to it by an outside organisation.

(a) The Provider must ensure that the terms on which those services are provided to it continue to be such as to enable its LCFS to carry out the LCFS's functions effectively and efficiently and in particular that the LCFS is to devote sufficient time to that provider.

(b) The Provider must notify CFSMS if:

(i) it considers that its LCFS has failed to carry out the LCFS's functions effectively and efficiently, or

(ii) if there is a material change in the terms on which the services of its LCFS are provided to it.

25 In the event of physical or non-physical assault on a member of Staff, as described in the Security Management Manual and guidance on tackling physical and non-physical assault issued by the CFSMS, the Provider's Executive Director designated under paragraphs 11 and 12(b) shall ensure that the instructions contained in the Manual are complied with, that is to say he shall put in place effective arrangements to ensure that:

(a) in all cases, he and the LSMS are informed of the incident;

(b) in all cases of physical assault, the police are contacted immediately, where appropriate, either by the person assaulted or by an appropriate manager or colleague and that full co-operation is given to the police in any investigation;

(c) in cases of physical assault, CFSMS is informed of the incident and that full co-operation is given to it in any investigation or subsequent action which it considers appropriate;

(d) in appropriate cases of non-physical assault, the police are contacted as soon as reasonably practicable and that full co-operation is given to the police in any subsequent investigation;

(e) in any case of physical or non-physical assault, where the police decide not to prosecute, the Provider considers what action, if any, it should take and in particular considers whether private prosecution or civil proceedings would be appropriate, in conference with the NHS Security Management Service Legal Protection Unit (LPU);

(f) in all cases, the details are recorded in accordance with the Provider's incident reporting system; and

(g) in all cases, the victim of the assault is informed of the investigation's progress and offered any necessary support.

SCHEDULE 14

Documents Relied On

[DN: To be discussed and agreed – should include Provider's responses to PQQ, ITPD/ISOS (if any) and ITT]

SCHEDULE 15

Change in Control Notification Pro Forma

Name of Provider	
Name of Commissioner	
Date of Agreement	
Description of Agreement	
Date of Change in Control	
Date of Change in Control Notification	
Name of body to whom Change in Control relates	
Position of affected body Provider Material Sub-contractor (If Material Sub-contractor, state services provided)	*(delete as appropriate and give further details as required)* Provider / Provider's Holding Company *(state relationship)* Material Sub-contractor / Material Sub-contractor's Holding Company *(state relationship)*
Details of Change in Control and transaction effecting Change in Control	
Regulatory approvals required and confirmation of receipt Name of all regulators whose consent is required by Law	Care Quality Commission / Charity Commission / Other (*give details*)

Confirm that, from each relevant regulator whose consent is required by Law that consent has been obtained Details of approval *(give further details as required)*	
Adverse impact on Services?	*(Either state 'No adverse effect on Services' (in the Provider's reasonable opinion) or give further details)*
Variations required as a result of Change in Control	*(Insert all relevant details of any intention or proposal to:* • *change the Staff and/or the management of the Provider involved with the delivery of the Services; and/or* • *sell or otherwise dispose of the legal or beneficial interest in any Provider Premises; and/or* • *change the corporate and/or clinical governance procedures related to the Services, including any changes of the medical director, clinical director and or nursing director of the Services; and/or* • *propose any other Variations)* *(N.B. Note effect of clauses 45.4 and 45.5)*

Notification completed by [Chief Executive/Director]:

Name: ……

Position: ……

SCHEDULE 16

Intellectual Property

Part 1: Provider IPR

[DN: To be agreed]

Part 2: Commissioner IPR

[DN: To be agreed]

SCHEDULE 17

Notices

1 For the purposes of clause 36, the address for the service of notices on the Co-ordinating Commissioner is:

Co-ordinating Commissioner:

[Insert name of Co-ordinating Commissioner]

[Insert name of contact person]

[Insert postal address]

[Insert e-mail address]

2 For the purposes of clause 36, the address for the service of notices on the Provider is:

Provider:

[Insert name of Provider]

[Insert name of contact person]

[Insert postal address]

[Insert e-mail address]

3 For the purposes of clause 36, the addresses for service of notices on the Commissioners are:

Each Commissioner

[insert name of Commissioner]

[insert name of contact person]

[insert postal address]

[insert email address]

SCHEDULE 18

Incentive Schemes

[DN: Not used]

SCHEDULE 19

Part 1 [Commissioning Region]

[DN: To be agreed]

Part 2 Provider's Premises

[DN: To be agreed]

SCHEDULE 20

Clinical Networks and Screening Programs

SCHEDULE 21

Contract Management

[DN: To be discussed]