**SCHEDULE 2 – THE SERVICES**

**A. Service Specification**

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| **Service specification No.**  | Community Phlebotomy Service  |
| **Commissioner Lead** | NHS Enfield CCG |
| **Provider Lead** | TBC |
| **Period** | Jan 2020 – Mar 2024 |
| **Date of review** |  Yearly |

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| **1. Population needs** |
| * 1. National /local context and evidence base

Enfield faces a number of significant health challenges. Its residents experience more health inequalities than most other parts of England, have a lower life expectancy and experience higher than average deprivation. As one of the fastest growing boroughs in London, the population of Enfield is rapidly expanding and changing. The CCG is committed to commissioning services that meet the needs of the local population and strive to provide an integrated approach to care in the community.NHS Enfield Clinical Commissioning Group (CCG) is committed to ensuring it commissions sustainable, high quality, safe, effective and efficient healthcare services with a focus on improving patient experience on behalf of the population of Enfield. Enfield CCG is led by the Governing Body on behalf of the 47 member GP practices, serving a patient population of approximately 320,000. The borough is divided into 4 localities along geographical lines which align well with local demography. Each locality has elected 2 GP representatives to the Governing Body. (please refer to Enfield CCG’s website http://www.enfieldccg.nhs.uk/about-us/ccg-board-members.htmThe Community Phlebotomy service will allow for adults (over the age of 18 years) to receive routine blood tests, and domiciliary blood testing services in the community daily between the hours of 8am and 18.30pm as a minimum and on weekends if needed. This model will provide local, accessible and integrated services that are aligned with providers within the health and social care economy. The CCG would like to include offering the service to sixteen plus year olds for routine blood tests at the outset. |
| **2. Outcomes** |
| 2.1 NHS Outcome Framework Domains & Indicators

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| Domain 1 | Preventing people from dying prematurely | No |
| Domain 2 | Enhancing quality of life for people with long-term conditions | Yes |
| Domain 3 | Helping people to recover from episodes of ill-health or following injury | No |
| Domain 4 | Ensuring people have a positive experience of care | Yes |
| Domain 5 | Treating and caring for people in a safe environment and protecting them from avoidable harm | Yes |

2.2 Local defined outcomes The community based phlebotomy service will:* Improve access to blood tests across the borough of Enfield to GP practices and their patients.
* Deliver care close to home by improving phlebotomy service provision in the local community.
* Provide a timely service (within 2 working days), 6 days a week (Monday to Saturday) for routine phlebotomy of the patient booking their phlebotomy appointment.
* Provision for urgent same day appointments
* Improve access to GP request for domiciliary phlebotomy service (within 2 working days).
* Work closely with the Pathology service to ensure that samples are optimally transferred to the laboratory
* Ensure failsafe mechanisms are in place if they suffer a loss of samples whilst in their care
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| **3. Scope** |
| 3.1 Aims and Objectives of Phlebotomy serviceThe aim of the phlebotomy service is to:* Ensure routine phlebotomy tests on adults are carried out in the local community with hospital based services accessed as the last resort for routine GP requested blood tests
* Provide an efficient, safe, patient- focused and high quality phlebotomy service for all Enfield service users
* To provide a service at an appropriate time, location and environment

3.2 Service Description/ Operational Delivery of the Phlebotomy care pathway Under the Phlebotomy service specification, the provider is expected to provide all standard blood tests to the adult population of Enfield either;* Registered with a GP practice in Enfield,
* Patients living in the London Borough of Enfield but registered with a GP practice outside of Enfield, for example patients in Nursing & Residential Care Homes.
* Ensure that staff comply with the infection prevention and control procedures i.e. hands are decontaminated, clean gloves used for every procedure and that the puncture site is prepped as appropriate
* The service will also ensure the phlebotomy services are provided to vulnerable adult patient groups and that staff are appropriately trained
* If a routine phlebotomy samples is unable to be collected, the provider will be required to refer the patient to a clinically appropriate secondary care phlebotomy service and/or liaise with the clinical haematology department, of the local acute hospital provider.
* Develop a written protocol for the provision of this service. The protocol must be reviewed annually and must include infection control and needle-stick injury management.
* Maintain a stock of suitable phlebotomy containers and ensure the correct usage.
* Ensure that there is adequate back up / contingency plans in place for the continued provision of the service in the event of breakdown of equipment, staff absence or supply chain problems.

The service will include for Adult patients: * Routine Phlebotomy testing
* Glucose Tolerance Testing
* Domiciliary Phlebotomy for eligible patients

3.2.1 Service AccessThe service is expected to encompass the following requirements in relation to service provision:* The community phlebotomy services must be widely accessible for all service users during core opening hours (8.00am to 6:30pm), Monday to Saturday.
* The site for the community phlebotomy services must ensure it is accessible to patients traveling either by public transport (bus, rail, taxi) and that suitable car parking is available for patients travelling to the phlebotomy service either as a confirmed booked appointment or as a walk-in patient (without a confirmed appointment)
* The provider will ensure the phlebotomy service meets the regulatory requirements in relation to NHS premises, health and safety and infection control {need to reference relevant NHS regulations)
* Phlebotomy services must be provided by suitably trained and qualified practitioners with the appropriate equipment.
* The provider will be responsible for the storage of blood samples and other pathological samples for transportation of all blood samples or collection of other pathological samples from the provider’s phlebotomy service site to the pathology laboratories (Health Services Laboratories) in accordance with the pathology laboratories requirements, including the use of existing sample collection services provided including North Middlesex University Hospital NHS Trust, Royal Free London Hospital NHs Foundation Trust ( inc. Barnet Hospital and & Chase Farm Hospital sites) using an approved courier service for the transportation of pathological specimens.
* The provider must provide a Domiciliary Phlebotomy service at the request of GP practices, 9:00am -5:00pm, Monday to Friday, with a response time of 2 working days for those patients that are housebound or in either Nursing or Residential care in the London Borough of Enfield To work in partnership with Enfield Community Services and Adult Mental Health services provided by Barnet, Enfield & Haringey Mental Health NHS Trust to ensure patients can access community based or domiciliary phlebotomy services, when requested by their GP
* The provider MUST undertake “3 months prior to contract commencement” a review of the phlebotomy service operating model with the CCG’s 4 Primary Care Networks to ensure that service delivery meets the service specification requirements and provide evidence of delivery as part of the mobilisation plan.

3.2.2 Equipment* The service provider will hold responsibility to provide chairs and stock of equipment required to deliver the service
* The service provider is responsible for ensuring all equipment for taking bloods are disposed of appropriately

All equipment used for taking blood is single use and must be disposed of immediately after use into either a UN-approved sharps container or orange clinical waste bag, as applicable3.3 Referral Criteria * Patients must be registered with a GP in Enfield
* Patients living in the London Borough of Enfield but registered with a GP practice outside of Enfield, for example patients in Nursing & Residential Care Homes.
* The provider will require an agreed referral from an appropriate clinician to provide the service, the provider will be expected to work closely with the local pathology service providers and GP practices to develop a paperless referral option within the next 12 months.
* The provider will be expected to provide phlebotomy services that ensure the provision of the GP Direct Access blood tests to the adult population in Enfield. GP Direct Access blood tests include the majority of adult tests excluding some specialist blood tests. It is not expected that phlebotomy will provide tests on children, unless staff have a separate child phlebotomy certificate and with prior agreement with the CCG.

3.3.1 Phlebotomy Service –Patient Booking through a Single Point of Access The provider will ensure that patients accessing a community based phlebotomy service as requested by their GP, is able to either:* Book their phlebotomy appoint directly via a web based appointment which identifies availability, community phlebotomy service site/ location/ address/ postcode. The website will be use friendly and simple to use by patients (including elderly patients).
* For patients unable to book an appointment via the website, a telephone booking service will be available Monday- Friday, 9am-5:00pm
* Patients will receive confirmation of booking appointment by SMS text message (where available)

3.3.2 Referral Route The service will receive referrals from clinician’s through the agreed referral route including working towards offering appointments electronically via existing GP systems.Where the patient is identified as high risk by the referrer (i.e.HIV/MRSA positive) this should be clearly marked on the referral form/blood sample bag and the necessary precautions taken.Where the patient is identified as having known behavioural problems this should be noted on the referral form by the referrer so appropriate safety measures can be taken.3.3.3 Referral Pathway – Registered Patient Phlebotomy Primary Care Clinician requests a phlebotomy sample from patientResults sent electronically to the GP or clinicianPathology request form completed by Primary Care clinicianPatient checks availability of phlebotomy services with their Primary Care ProviderSamples taken to the local Pathology Lab for analysisPatient attends a ‘drop in’ servicePatient books an appointment with a providerPatient details checked and confirmed by the provider. Patient has venepuncture taken inCourier service collects samplesSample labelled and stored temporarily (Max of 4 hours)3.4 Exclusion Criteria* Children (the longer-term vision is that this service will include children, however this will require additional funding and outside the scope of this agreement.)
* Specialist tests
* Patients registered with a GP outside of Enfield

  3.5 Eligibility to Provide the Community based Phlebotomy Service * The provider must have a written policy/ protocol (e.g. to cover technical requirements such as ‘order-of-draw’ and protocols for incomplete referral forms). This will be required for phlebotomy, glucose tolerance testing and domiciliary phlebotomy which is to be approved by the CCG
* Staff performing the phlebotomy service must be adequately trained and supervised and undertake the relevant training to require with NHS accredited provision (including undertaking mandatory training in accordance with NHS staff requirements/ HR policies).
* Staff undertaking phlebotomy procedures must be covered by Hepatitis B protection and suitable medical defence indemnity
* The provider must have adequate mechanisms and facilities including premises and equipment as are necessary to enable the proper provision of this service
* The provider must ensure an appropriate room for taking bloods is available for privacy and dignity requirements
* The provider providing the phlebotomy service must maintain a stock of suitable testing equipment and ensure the correct usage
* Blood samples must be stored in a safe clinical environment prior to transportation to the Pathology Laboratories for analysis
* Samples must be transported via an approved courier service to ensure a safe delivery and quality conditions of the samples
* Provide access and facilities for patients with disabilities, in accordance with the Equality Act 2010
* Have a procedure for dealing with any vasovagal fainting episodes.
* Provide vinyl floor covering in the clinical area, or have an agreed, time bound action plan to meet this specification.
* Provide a clinical hand wash basin in the clinical area.
* Provide suitable storage for consumables.
* Ensure compliance with hazardous waste procedures.
* Ensure the service environment meets the patient’s requirements for dignity and privacy.
* Ensure reasonable access to appropriate translation services as required.
* Be able to demonstrate that evidence-based clinical protocols are being used e.g. Needle stick injuries.
* Be responsible for all consumables required to deliver the service, with the exception of the provision of specimen bottles.

3.6 Interdependence with other services/providers* The provider will require close working relationships with Enfield GP practices
* The local acute hospital services providers and HSL as the provider of the pathology laboratory services in North Central London

3.7 Onwards Referral* Refer patients younger than 18 years on to paediatric phlebotomy at an acute hospital

3.8 Record Keeping * Providers will be required to organise an electronic record keeping information exchange system. As a minimum it will be required to record information on phlebotomy (routine or housebound) or glucose tolerance testing that has been administered (i.e. who has had their bloods taken and when). Also, to record key performance activity to be reported to the CCG, this includes the number of tests administered, DNA and waiting times. The provider will work with the CCG to build the right template and agree what should be captured and coded.

3.9 Notification of Results * Practices will provide patients referred to the community phlebotomy service an information sheet or checklist detailing how they can be notified of the results along with the blood test request form.
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|  **National/ Local and Applicable Standards** |
| 4.1 Applicable national standards (e.g. NICE)Providers should demonstrate to what extent they adhere to national standards and that:* Staff performing the phlebotomy service should be adequately trained and supervised as determined by the provider.
* The staff undertaking the procedure must have verified Hepatitis B protection.
* Staff undertaking the procedure must have suitable indemnity.

Providers must ensure that they are aware of, compliant with, and can provide evidence if required to demonstrate compliance with any of the relevant Standards including adherence to the following NICE guidelines:* CG2 section 2 – Standard principles for the safe use and disposal of sharps
* CG2 section 2 – Standard principles for hand hygiene
* CG92 – Reducing the risk of venous thromboembolism

Providers should follow WHO guidelines on drawing blood: best practices in phlebotomy.=4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)Providers should demonstrate to what extent they adhere to guidance issued by competent bodies.It is a requirement to demonstrate that staff have undergone appropriate training and supervised practice required to undertake the role of a phlebotomist, to guarantee the delivery of effective health care.The service provider is required to ensure that all personnel involved in the clinical delivery of the Phlebotomy service can demonstrate competence, as a minimum to the levels described in the National Occupational Standard HSC376 training (**www.skillsforhealth.org.uk),** which includes a period of mentorship.4.3 Applicable Local Standards4.4 Infection Control & HygieneIt is vital that all staff working within this service(s) demonstrate good infection control and hygiene practice in accordance with The Health and Social Care Act: The Hygiene Code (2008). (<https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216227/dh_123923.pdf> )The systems required to prevent health care associated infections are as follows:* Management arrangements to include access to accredited microbiology services.
* Clinical leadership to include access to an infection control team.
* Evidence of application of evidence based policies through annual audit and observational audit for Infection Prevention and Control and Practice.
* Design and maintenance of the environment and medical devices.
* Education, information and communication
* All clinicians have attended infection control training and prevention in particular hand hygiene, and this is documented.
* GP Practices must adhere to good practice as outlined in the Infection Control Guidance for General Practice.

4.5 Safety AlertsProviders must ensure that they are aware of any safety alerts from the Medicines and Healthcare products Regulatory Agency (MHRA) <http://www.mhra.gov.uk/#page=DynamicListMedicines> and the NHS Central Alerting System (CAS) <https://www.cas.dh.gov.uk/Home.aspx> that apply to any equipment or patient safety concerns associated with this service and that these are acted upon. Details of action taken must be reported back to NHS Harrow CCG within the designated timescale.4.6 Patient SafetyIn line with national patient safety and safeguarding guidelines, the providers must ensure that all staff meet CQC requirements to continue to work.* All staff shall be trained and regularly updated in Basic Life Support, Safeguarding for Adults
* All members of staff involved in the delivery of this service to have obtained a Disclosures and Baring Service (DBS) certificate

4.7 Applicable standards set out in Guidance and/or issued by a competent body(e.g. Royal Colleges)* Procedures carried out to UKCC nursing standards

4.8 Applicable local standardsThe service(s) will adhere to all local policies, procedures and guides.Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)Providers of services should follow the recommendations in the NMC Code of Conduct (2008) Royal College of Nursing Competency framework for capillary blood sampling and venepuncture. |
| **Quality and Clinical Service Requirements** |
| 5.1 Applicable quality requirements (see schedule 4 parts A-D)* The provider will be monitored against activity across all sites through quarterly meetings. The delivery mechanism for services is for the provider to decide as long as it meets the requirements of the scope outlined in section 3.
* Performance activity data will need to be submitted on a quarterly basis via and agreed template
* The CCG will expect providers to demonstrate continued adherence to the eligibility criteria for this service contract and to meet the requirements outlined in their policy and protocol.
* The provider is required to adhere to quality NHS guidelines on confidentiality and consent
* The provider will be expected to keep waiting times to a minimum, whether an appointment system operates or not.
* The CCG will review template audit data quarterly as necessary

5.2 Applicable CQUIN goals will be developed with the provider once the contact has been awarded. It is likely to reflect the vision for a paperless referral system, point of care testing wherever possible and results direct to patients as well as Primary Care. |
| **6. Location of Provider Premises** |
| The community phlebotomy services must be delivered to ensure the service is available equitably in the 4 CCG localities, to all 47 GP practices. The provider should also consider the demands form the 8 neighbourhoods in the 4 Primary Care Networks to inform the service delivery model given the demographics of Enfield, to meet the needs of the local population.As a minimum, the community based phlebotomy services should be provided 8am-6:30pm, Monday to Saturday. The service as a minimum must be co-located with the Enfield Extended Access Hubs. In addition another site should be sourced within in each locality but a minimum of 1 mile away from the hub location.Consideration will also be given to the provision of a mobile phlebotomy service, but this must be delivered in accordance with NHS Estate regulations and policies. The provider must undertake domiciliary phlebotomy for housebound patients within the same time frames. |
| 7. K**ey Performance Indicators for the service** |
| 7.1 Data to be collected & submitted monthly:* Activity levels by service:
	+ Phlebotomy Test administered
	+ Glucose Tolerance Test administered
	+ Domiciliary Phlebotomy Test administered
* DNA rates
* Average waiting times experienced for service users
* Maximum waiting times experienced for service users
* Patient feedback on provision of services
* % of void samples - unlabelled, clotted etc.
* Number of complaints (<5)

The provider will be required to submit a schedule outlining transport arrangements (including the number of blood pick-ups per day). Any changes to the blood transport schedule will need to be immediately notified to the CCG. |
| 8. Community based Phlebotomy Service Accreditation  |
| 8.1 NHS Regulatory requirements The provider will be required to ensure the community based phlebotomy service is compliant with the required NHS regulatory requirements including Care Quality Commission regulations, etc. The service provider must have in place appropriate health and safety and risk management systems that adhere to: Department of Health Primary and Social Care Premises and Planning and Design Guidance ([www.dh.gov.uk/en/Procurementandproposals/Publicprivatepartnership](http://www.dh.gov.uk/en/Procurementandproposals/Publicprivatepartnership) ) and [www.dh.gov.uk/en/Publichealth/Healthprotection/Healthcareacquiredinfection](http://www.dh.gov.uk/en/Publichealth/Healthprotection/Healthcareacquiredinfection)  |

**Monitoring**

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| Activity Monitoring  |
| Activity Performance Indicators  | Threshold  | Method of measurement  | Consequences of breach  |
| The demand for phlebotomy services for Enfield CCG will be monitored under the following categories: This is the minimum data set requirement.Each service provider to report on:-* Number of Registered patients attended
* Number of out of district patients attended (by
* CCG)
* Difficult to bleed patients noted and recorded
* Number of patients attended where no blood sample was extracted.
* Number of spoilt tests recorded
 | Service providers must deliver a phlebotomy service for 98% of patients requesting the service from that provider }95% of data collected by end of year 1 | All activity to be captured on a suitable electronic system. Reports toBe provided quarterly in the first year. Listed by GP/ GP practice where possible. | Review meeting  |
| *Additional data requirements are set out in the Quality and performance indicators will be agreed with the providers to inform the KPI dashboard.* |  |  |  |