**Specification for Satellite Haemodialysis Services in Doncaster and Bassetlaw**

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**1 GENERAL SPECIFICATION INTRODUCTION**

**1.1** **National** **Context**

**In Centre Haemodialysis (ICHD)**

End stage renal failure (ESRF), also known as established renal failure (ERF), is an irreversible, long-term condition as a result of chronic kidney disease for which regular dialysis treatment or transplantation is required if the individual is to survive. If the kidneys fail, the body is unable to excrete certain waste products, excess water, acid and salts resulting in increasing symptoms and eventually death. When ESRF is reached, renal replacement therapy (RRT), in the form of dialysis or transplantation, is required as a life-saving and life-sustaining measure. In 2020, 139 patients per million (ppm) population in the UK started renal replacement therapy (RRT) for established renal failure.

This specification focuses on haemodialysis which takes place in main or satellite dialysis units (adults) but also includes home haemodialysis, and forms just one part of a wider portfolio of detailed specifications for RRT. In recent years there has been a growing recognition that, in patients who are not transplanted, self-care in the home or in a community centre by either peritoneal or haemodialysis should be encouraged wherever possible to enhance health and quality of life prospects. Where these treatments are inappropriate or difficult to establish and whenever patients choose it, in-centre haemodialysis (ICHD) is the mainstay of treatment. The prevalence rate for patients receiving ICHD in the UK was 457 pmp in 2020. In England in 2020 82% of patients being treated with chronic dialysis received that as ICHD.

All 49 renal referral centres in England have an integral haemodialysis unit. These are referred to as Main Renal Units (MRUs). In addition to providing an essential support function for in-patient renal care including new and unstable patients they typically also provide routine ICHD for patients who live near to the main hospital. In 2020, 41% of ICHD patients in England were treated in MRUs

In 2020 59% ICHD patients in England were treated in satellite units. At the time of writing 48 of the 49 renal referral centres have ‘satellites’ around them, some over five, the majority less than 3. Satellite renal units may be located in district general hospitals, or in other healthcare facilities (eg GP practice). Others are ‘freestanding’, often in industrial locations in towns and cities. Those in hospitals have the advantages of convenient access to other healthcare services and investigations, the latter having the advantage of ‘locality’, easy access and parking. Some years ago it was shown that there was little difference in the case-mix of patients managed in satellites or MRUs (Roderick et al). This is reflected in uniformity of tariff for ICHD patients, irrespective of dialysis location

While the majority of ICHD units are managed by the NHS a number are managed by the independent sector. This includes a small number of MRUs. Over 30% of patients are thought to be treated by the independent sector, mainly in satellite units, and this proportion has increased year on year. While the independent sector provider typically provides the building and equipment and employs the nursing staff other models exists in which the independent provider provides the non-clinical aspects of the service and the nurses remain in the NHS, accountable to the senior NHS nurse manager in the MRU. In all cases hitherto, the doctor who assumes the responsibility of continuity of care of the patient, remains an NHS employee of the Trust of the MRU. Similarly, other members of the multi-professional renal team most often are directly employed by the local NHS MRU but not exclusively so.

ICHD is a specialised service commissioned by NHS England, but this is currently in transition to commissioning by ICBs.

**1.2 Local Context**

Doncaster & Bassetlaw Hospitals NHS Foundation Trust provides renal services for a population of about 400,000. The Trust currently provides satellite haemodialysis units at Montagu Hospital in Mexborough (serving the Dearne Valley area including parts of Rotherham and Barnsley) and Bassetlaw Hospital in Worksop (covering the Bassetlaw area and neighbouring parts of Rotherham and North Derbyshire) in partnership with Fresenius Medical Care (FMC) as part of an Independent Sector Procurement (ISP) initiative, the contract for which terminates on 31st March 2024.

Acute dialysis services, home dialysis services (including peritoneal dialysis and home haemodialysis) and specialist outpatient services including transplant follow up are provided from the main unit at Doncaster Royal Infirmary.

Doncaster & Bassetlaw Hospitals NHS Foundation Trust wishes to secure a satellite haemodialysis service maintaining provision for the Bassetlaw and Dearne Valley areas which:

* Is of high quality and close to the patients’ homes;
* Is clinically and financially sustainable;
* Meets national and international clinical best practice for kidney services;
* Recognises the social and emotional dimensions of best practice in kidney care, which provide good patient experience;
* Recognises that kidney patients move from one modality of treatment to another and manage and support this process well, for example, many will go from pre-dialysis to peritoneal dialysis to haemodialysis to transplantation to haemodialysis to end of life care;
* Recognises the importance of encouraging patients to remain as independent as possible and therefore to encourage self/shared care based on local patient needs;
* Encourages access to renal care treatment;
* Improves the patient pathway and experience.

**1.2.1 Current Service Configuration**

**Doncaster Dialysis Unit:** 17 station in centre dialysis unit co-located with the acute ward and renal outpatient services.

**Bassetlaw NHS Dialysis Unit:** 20 station satellite unit on the Bassetlaw District General Hospital site in Worksop.

**Dearne Valley NHS Dialysis Unit:** 12 station satellite unit on the Mexborough Montagu hospital site.

**2 ACTIVITY AND DEMAND**

The modelling in Figures 1, 2 and 3 demonstrate historical growth and other supporting demand information.

**Figure 1: Actual number of hospital haemodialysis stations and patients per site and modality**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Location/Modality** | **Number of Stations** | **Historical Hospital Haemodialysis Patients** | | | | | |
|  | March 23 | March 18 | March 19 | March 20 | March 21 | March 22 | March 23 |
| Doncaster | 17 | 84 | 88 | 87 | 85 | 91 | 108 |
| Bassetlaw | 20 | 55 | 51 | 55 | 50 | 50 | 50 |
| Dearne Valley | 12 | 38 | 45 | 42 | 40 | 43 | 47 |
| Home Haemodialysis | n/a | 9 | 8 | 6 | 5 | 7 | 10 |

**Figure 2: Other supporting demand information**

|  |  |
| --- | --- |
| **Source** | **2023 Patient Numbers** |
| Low Clearance Patients | 199 |
| Nephrology Patients eGFR<20 | 59 |

Currently the following shifts are provided: Bassetlaw Monday/Wednesday/Friday morning (20 patients); Monday/Wednesday/Friday afternoon (20 patients); Tuesday/Thursday/Saturday morning (16 patients). Dearne Valley: Monday/Wednesday/Friday morning (12 patients); Monday/Wednesday/Friday afternoon (12 patients); Tuesday/Thursday/Saturday morning (12 patients); Tuesday/Thursday/Saturday afternoon (12 patients). Demand is reviewed regularly between the Provider and the Trust. The Provider will be expected to work with the Trust to deliver adequate capacity to dialyse all local patients who would benefit.

**3 SCOPE**

**3.1 Aims and Objectives of Service**

Key objectives of renal replacement therapy (RRT) are to extend life quality and expectancy for those with advanced kidney failure who are likely to benefit.

Services will be patient-centred and offer safe, effective, evidence based therapies in appropriate care settings and keep pace with advancements in technologies and therapies where required.

Patients will be supported to make informed choices regarding their treatment options and in managing their condition to achieve their goals and their best quality of life.

The provider agrees to provide the clinical services in a manner consistent with the standard for dialysis and in accordance with NHS requirements. The standard for dialysis sessions means a minimum of four (4) hours and five minutes, three (3) times a week for NHS patients or as alternatively specified by the supervising clinician, including, but not limited to:

* Daily dialysis (six (6) times per week), or alternate day dialysis as determined by the supervising clinician;
* Dialysis for home haemodialysis patients requiring temporary supervised support within the haemodialysis units;
* Dialysis for home haemodialysis patients requiring temporary non-supervised satellite haemodialysis, i.e. self/shared care;
* Extra dialysis/ultrafiltration sessions to prepare patients for surgery;
* The reconfiguration of resources to account for innovations in practice, including initiatives led by the local clinical governance groups;
* Longer dialysis session times beyond four (4) hours, if this is to the patient’s benefit and prescribed by the supervising clinician

The provider will need to be aware of and adopt the local care pathway for onward referral of patients who require other specialist care. The Provider must recognise that on-going team liaison and co-operation with other specialist teams is inevitable with chronic illness. For patients receiving haemodialysis, the Provider may be required to liaise and co-operate with the Diabetologists, Vascular teams, Cardiac teams and local Palliative Care Teams. The supervising Clinician is to be advised of any such referral to local healthcare/specialist care by the Provider.

**3.2 Service Description/Care Pathway**

**3.2.1** Infrastructure

The provider will deliver ICHD services that are provided in a safe and secure environment in a facility which complies with NHS Estates Building Notes and which meets all the technical standards detailed in the Renal Association Guidelines.

The centre must have systems to ensure prevention of nosocomial spread of blood borne viruses especially when returning from dialysing in areas with a high risk of blood borne virus transmission.

The provider will ensure that all equipment used in the delivery and monitoring of haemodialysis is CE marked and approved to ensure compliance with the relevant safety standards BS EN 60601-1-2:2015 ‘General safety standards for electrical equipment in clinical use’ and BS EN IEC 60601-2-16:2019 ‘Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment’ and Renal Association guidelines.

Water treatment standards must comply with all Renal Association guidelines.

The new provider will be responsible for replacing the Water treatment plant at Bassetlaw site within the duration of the new contract, they will also be responsible for the residual capital outlay for the water plant at Dearne Valley to be replaced within the existing contract duration, this is to be paid directly to the current supplier. These costs are outside of the financial envelop of the Tender and a stand alone transaction between the winning tender and Current Supplier (Fresenius)

In the event that the provider is unable to provide sufficient equipment for treating patients at any time, or in the event of technical difficulties or other emergencies, the provider shall have contingency systems in place. These should include the ability to provide or procure alternative dialysis sessions at other facilities.

**3.2.2 Clinical Management**

The service will provide a specific support for those patients who start dialysis as late presenters or unplanned from within the kidney service to ensure they receive appropriate information. These patients should be offered the same range of choices regarding their RRT modality.

Providers must offer education about access to shared care training for patients interested in contributing to their management by participating in the tasks relating to haemodialysis treatment. In particular, this should include the opportunities for health gain offered by self-care either in the dialysis facility itself or by carrying out more frequent haemodialysis/peritoneal dialysis treatment in the home.

Providers must ensure clear arrangements are in place for continuity of care by identifying the nephrologist responsible for each patient’s management and ensure that regular senior medical reviews can take place preferably at a time and location which is convenient to the patient. The provider will ensure that patients also have access to a multi-professional renal team for regular review and also for ad-hoc input into their care.

In some patients who have retained some of their natural renal function, twice weekly sessions may be possible for a period. Similarly less frequent dialysis is sometimes prescribed as part of a package of palliative care. These variations are determined by the nephrologist and they should be fully discussed with the patient and their carer and the reasons clearly recorded in the patient’s record.

A number of haemodialysis patients cannot maintain adequate fluid and blood pressure control on the normal dialysis prescription of thrice weekly sessions, often because of co-existing cardiac dysfunction. Higher frequency haemodialysis can control this condition. Patients in whom a greater frequency of treatment than three times a week is clinically indicated would normally be considering home haemodialysis. For those patients where this is impractical the provider must be able to accommodate requests from consultants for frequent haemodialysis.

The provider shall ensure that it adheres to all national policies and guidelines relating to infection control and decontamination. The provider will take all steps required to reduce the risk of the spread of infections to patients. This will include the provision of information to patients and carers regarding infection control processes, as stated in Section 4.3: Infection Control and Decontamination.

The provider will have in place a protocol for ensuring vaccination against hepatitis B virus, and screening for blood borne viruses according to national guidance.

The provider will ensure that all patients are included in the clinical governance processes of the MRU. By embedding clinical governance within day to day operations there should be a commitment to monitoring clinical quality and outcomes. Delivery of care must be safe, timely, effective, efficient, equitable, patient centred and sustainable.

As ICHD is only one component in the continuum of the renal patient pathway, the MDT review should consider the on-going suitability of this dialysis modality.

The MDT will review suitability for transplant listing for all patients not on the transplant list and the suitability for patients so listed to remain on the waiting list.

**3.2.3 Staffing Structure**

The provider will ensure that the haemodialysis station capacity and staffing is sufficient to enable patients to access haemodialysis as frequently as clinically prescribed and with sufficient flexibility of timings to allow patients minimal interruption to their work and family commitments.

The provider will ensure that the nurse staffing levels in haemodialysis units are adequate to manage the delivery of care and are adjusted for the dependency for the patient group. This will be a minimum of 1 registered nurse (RGN) for every 4 patients, with at least 2 registered nurses being available in patient areas at all times.

The provider will ensure that the renal assistant staffing levels in haemodialysis units are adequate to support the delivery of care and are adjusted for the dependency for the patient group. This will be a minimum of 1 renal assistant (RA) per shift for satellite units. Renal assistants are expected to have training in dialysis to enable them to perform dialysis treatments under the direction of a registered nurse.

Each unit shall have a Manager who is a registered nurse with dialysis skills and knowledge. The Manager will be supervisory for 60% of the time and available Monday – Friday.

Each satellite unit will require a receptionist/administrative post to support the unit. The duties of the post will depend upon the needs of the individual unit and so therefore may differ.

Staff at the units should have access to appropriate training and, where appropriate, specialist Renal trainers. The provider will ensure that training needs are identified and collated for each facility and that plans are developed to ensure that all staff are trained appropriately. This will include the delivery of formal structured study sessions, the identification and implementation of new processes and procedures, and mandatory training as appropriate.

These minimum requirements are detailed in Section 3.2.4 Minimum Staffing Requirements.

**3.2.4 Minimum Staffing Requirements**

**3.2.4.1 Clinical Requirements**

1 RGN: 4 patients

1 RA per shift

Minimum of 2 registered nurses in patient treatment areas at all times.

**Clinical Unit Manager**

The Clinical Unit Manager will be supervisory for the equivalent of 60% of the time and available Monday – Friday.

**3.2.4.2 Administration Requirements**

Receptionist cover is required at both satellite units Monday-Friday.

All reception and administrative duties are to meet the needs of the individual units and are subject to change due to capacity and demand.

**3.2.4.3 Supplier Support on Implementation**

1. The supplier will be able to demonstrate compliancy to Project Management methodology such as PRINCE2 or equivalent.
2. The chosen supplier must appoint a project manager to:
   1. Be accountable and responsible for all supplier, sub-contractor and third-party activities for the period of the implementation.
   2. Manage the supplier’s Project Team.
   3. Work with the Trust’s Project Manager and Project Team staff.
   4. Name points of contact including escalation details

|  |  |
| --- | --- |
| Project Manager | Name:  Telephone:  Email: |
| Implementation Manager | Name:  Telephone:  Email: |
| Account Manager | Name:  Telephone:  Email: |
| Escalation Contact | Name:  Telephone:  Email: |

1. The successful supplier must take responsibility for undertaking all agreed implementation activities required in order to satisfy this contract, including:
   1. Delivery of all components and associated services as agreed within the contract.
   2. Installation, configuration and testing of all components.
   3. Implementation of application software, including links to other systems as specified.
   4. Development of the system as required to meet each Trust’s stated requirements.
   5. The importing of data from the agreed Trusts systems.
   6. The exporting of data to agreed Trust systems.
   7. Training and retraining of relevant staff in agreement with the Trust.
   8. Delivery of relevant documentation as set out below in ‘Documentation’.
2. The successful supplier must prepare and agree with the Trust a detailed Implementation Plan. This will cover at least the following areas:
   1. All the critical path activities and milestones for the implementation.
   2. All tasks and activities:
      1. The roles and responsibilities of the Trust and the supplier.
      2. The effort required from individual Trust staff.
      3. The dependencies and relationships between all tasks.
      4. Details of all supplier and third party / subcontractor staff who will be involved in the project

**3.2.5 Adolescent Transition**

Specialist support, that is patient centred and enables patient choice, will be provided for young adults (age 18-25). This will include those who are in the process of transferring form paediatrics, those who have transferred from paediatrics or those who have come straight into adult services at a young age. Transition will involve a period of joint care from paediatric and adult services and it is important for multi-disciplinary teams (MDTs) to be aware that this group may have additional developmental needs, including educational and employment.

Any service provided to patients under the age of 18 will be in accordance with Annex 1 to NHS England Service Specification A06/S/a ICHD: Provision of Services to Children.

**3.2.6 Withdrawal of Dialysis Treatment**

For those patients who wish to withdraw from treatment the provider will ensure that they will receive co-ordinated support and care in accordance with the best principles of end-of-life management.

**3.2.7 The Multi-Professional Renal Team**

End stage renal failure is often a devastating life changing event which impacts on physical and mental health, employment and on relationships. Care of the dialysis patient entails far more than simply the execution of the dialytic process by specialised haemodialysis nursing staff. The following inputs are required:

**3.2.7.1**  **Pharmacy Services**

The Provider will:

* Supply and bear the cost of drugs routinely administered as part of dialysis sessions. This is to include the local anaesthetic, anti-coagulants, line locks, sodium chloride and paracetamol. The Provider is responsible for safe administration of these drugs according to agreed policies and procedures;
* Supply and bear the cost of other standard medical products/consumables required for the administration of dialysis medication;
* Provide an emergency cabinet containing medications as defined by the Trust. The Provider will be responsible for the regular checking and ordering of such medicines as per the policies and practices of the Trust. This should include an emergency drug box for resuscitation and medication appropriate for anaphylaxis treatment in line with National Guidance.

It is expected that it will be possible to administer prescribed medications orally or intravenously during dialysis, and also, that blood transfusions can be administered. If a patient requires intravenous medication or blood transfusion, the Provider nursing staff at the renal units will be expected to be trained and competent to administer this.

The Trust shall prescribe and supply blood products, as required, at the cost of the Trust. The Provider will ensure staff are able to obtain patient samples (e.g. bloods) for subsequent pathology tests.

The Trust is able to dispense drugs via prescription but not provide drugs via other methods to the Provider.

**3.2.7.2 Medicines Management**

The Provider is expected to have in place a Medicines Management Policy.

The Provider shall comply with the higher standards of:

(i) national Minimum Standards, and

(ii) the highest available Clinical Negligence Scheme for Trusts (CNST) Standard in relation to medicines management as updated from time to time.

In line with national guidance, intravenous iron will be delivered in an environment with access to medical equipment that is able to deal with potential side effects and proportionate to the risk of such side effects.

**3.2.7.3 Social Work Support**

The Provider will offer patients access to welfare and social work advice as required, but within 24 hours if necessary.

Patients receiving dialysis will have complex medical, emotional and social needs. Access to a broad range of professionals is essential for delivering renal replacement dialysis therapy. The Provider shall have sufficient clinical and support staff to ensure a multi-disciplinary approach to provision of services in respect of, and at all times in accordance with, good clinical practice.

**3.2.7.4 Psychology Services**

The Provider will offer patients access to psychology services as required

**3.2.8 Patient Support Groups**

The Provider will ensure that patients and carers are provided with information about local and national support groups and how to access them, including such groups’ involvement in patent education sessions organised by the Provider as it is recognised that these are a vital source of peer support, advice and information for patients. Signposting information will be displayed within the Provider’s facilities.

**3.2.9 Transport, Travel and Waiting Times**

The Provider will have robust and responsive relationships with the Patient Transport Service (PTS), ambulance service and local taxi firms.

The Provider should seek to provide haemodialysis services as close to the patient’s home as possible to meet Renal Association recommendations on patient travel and waiting times.

The nursing staff at the facility will undertake patient eligibility assessments for PTS as per local guidance.

Self-transporting patients should not be charged for parking and arrangements will be in place to ensure any such charges will be re-imbursed to the patient.

The Provider shall have arrangements in place to inform all patients of their entitlement (if any) under the Hospital Travel Costs Scheme (HTCS) and shall have regard to HTCS Guidance.

Where a patient is eligible under the HTCS, the Provider shall have adequate arrangements to assist the Trust in being able to check the appropriate travel costs claimed by that patient, and provide the patient with all necessary information to enable the patient to apply for reimbursement of travel costs.

**3.2.10 Dialysis Away from Base (DAFB)**

The Provider will facilitate arrangements for patients who wish to, or need to travel on a temporary basis, to other parts of the UK and those wishing to travel outside the UK in accordance with NHS England Commissioning Policy: Dialysis Away from Base (Reference: A06/P/a).

Referrals for NHS England funded patients’ haemodialysis away from base, subject to such referrals not prejudicing the treatment of any other haemodialysis patients, including (without limitation) the scheduling of their dialysis session(s), will be accepted by the Trust clinicians and referred to the Provider under the scope of this specification.

A named member of staff in each unit will be responsible for co-ordination of DAFB.

**3.2.11 Haemodiafiltration (HDF)**

The Provider shall provide haemodialysis and other modalities, including HDF, as requested by Trust clinicians or other consultants named by Trust clinicians, and there shall be no limit on the amount of HDF to be so prescribed. There will be no additional cost to the Trust for HDF.

**3.2.14 Responsibility for Patient Care**

Notwithstanding a referral for haemodialysis under this specification, it is acknowledged that the renal clinicians remain responsible for the overall clinical management of patients’ renal condition(s). As such, Clinicians shall be entitled to issue directions to the Provider for patient care which may be delivered in the main or satellite unit as appropriate.

For the avoidance of doubt, the Provider is responsible for the clinical governance, risks and overall management of the services within the scope of this specification, unless stated otherwise.

**3.2.15 Referral Management**

The Provider is expected to accept referrals from Trust Consultants or by named Consultants identified by the Trust. The Provider will obtain or check (where already obtained) the patient’s consent for treatment and finalise details of the haemodialysis required. Consent will be re-obtained on a regular basis.

**3.2.16 Non NHS England Funded Patients**

For the avoidance of doubt Non-NHS England patients are excluded from this service. Patients not eligible for NHS funded treatment are the Provider’s responsibility but must not impact upon the resources available or the services provided to NHS patients.

**3.2.17 Referral to Other Healthcare Professionals**

It is the responsibility of the Consultant and Nurse in charge of a patient’s care to order referrals to other healthcare specialists, as required. However, staff in the haemodialysis unit must have agreed a process locally with the Trust to initiate and manage such referrals

**3.2.18 Children and Young Adults**

This specification refers to adults from the age of 18 years. Some young people aged less than 18 years may be treated in an adult service, by mutual consent. When treating children, the service will additionally follow the standards and criteria outlined in the Specification for Childrens’ services (Annex 1 A06/S/a)

Specialist support that is patient centred and enables patient choice will be provided for young adults (age 18-25). This will include those who are in the process of transferring from paediatrics, those who have transferred from paediatrics or those who have come straight into adult services at a young age. Transition will involve a period of joint care from paediatric to adult services and it is important for multi-disciplinary teams (MDTs) to be aware that this group may have additional developmental needs, including education and employment.

**3.2.19 Trials**

The Provider shall co-operate in drugs and equipment trials, investigations, assessments and valuations of any dialysis-related equipment, devices and materials run by the Trust. The Provider will accept patients enlisted in the clinical trials as directed by the Trust.

The Provider shall co-operate with any audit and research activity as identified by the Trust such as in their annual clinical governance plan

**3.2.20 Technical Services**

The Provider will ensure that a comprehensive scientific and technical service is provided for all aspects of renal care at the satellite units.

This will include the provision of a 24 hour, 365 days a year technical on-call service, including essential out of hours maintenance. The service will include on-site and telephone advice and assistance for staff.

The Provider will ensure the service, maintenance and management of plant, dialysis equipment and the calibration of patient scales and arrangements for water testing as appropriate in accordance with Renal Association guidelines.

Technical horizon scanning, equipment and device evaluation and assessment, procurement and implementation of new technology will also be provided. The service will input into the optimisation and quantification of dialysis treatment, and participate in any dialysis facility development.

The Provider will ensure there is technical participation in the clinical governance and risk management process where required, including the development of policies and procedures and the interpretation and response to external standards. The Provider will contribute to problem solving as part of the multi-disciplinary renal team.

A full range of equipment management services will be provided, including but not limited to:

* Management of the equipment procurement and replacement programme
* Acceptance testing and commissioning
* Servicing and repairs of all equipment from all manufacturers
* Monitoring, sampling and calibration checks
* Infection control, decontamination and disinfection
* Upgrades and refurbishment
* Decommissioning
* Installation and removal of equipment
* Temporary dialysis installations
* Liaison with suppliers and managing activities of external contractors
* Indemnity management of loan equipment
* Managing stock levels and distribution of equipment
* Management of consumables, stock control, ordering and receipt of goods
* Management of equipment inventory, documentation and records
* Response to official technical alerts from statutory and other bodies
* Incident investigation

It is the Provider’s responsibility to ensure that vehicles are available to enable the service to be delivered and that these are managed, serviced and replaced appropriately.

**3.2.20.1 Service Availability & Reliability**

Level of service availability required:

* + 1. System availability: The system must be available for use 12 Plus per day Hours Monday to Saturday
    2. .
    3. Supplier support availability: as a minimum, the service must be supported between 8:00 and 20:00 Monday to Saturday.   
       The supplier is to offer options for the level of support ranging from the minimum to a full 24/7 365 day cover.
    4. System downtime: total downtime must not exceed 0.01% during the period of system availability where the supplied system is the sole source of the downtime.
    5. No single instance of service loss shall be in excess of one hour.

**3**

**3.2.22 Emergencies**

At all units the Provider shall ensure that sufficient staff with appropriate skills, training and competences are available to maintain patient safety at all times when patients are in the facility.

The Provider shall ensure that it has a current Business Continuity Plan in place for each unit.

The Provider will ensure that adequate equipment, drugs, medication, medical consumables, fluids and transfer arrangements to deal with medical emergencies and untoward events as agreed with the Trust and to comply with Care Quality Requirements and National Minimum Standards and regulations at each facility.

For each facility, the Provider will have procedures to deal with medical emergencies, including but not limited to, immediate treatment, stabilisation and arranging for the transfer of the patient to the appropriate facility which can provide the level of critical care required and any other steps that could reasonably be required to minimise the adverse consequences of the medical emergency, including using, where appropriate, locally agreed transfer protocols, including complying with the latest UK Resuscitation Council Guidelines (2021) and all future updates/revisions.

A safe environment will be maintained for patients, staff and visitors at each facility, employing an appropriate risk management strategy to minimise potential hazards.

Resuscitation equipment as defined by the Trust will be available.

**3.2.23 Service Exclusions**

The following are also excluded from the scope of this service specification:

Medical Staffing

Dietetic Staffing

Pharmacist Staffing

Pathology

Radiology

Drugs – EPO, other drugs not associated with dialysis such as antibiotics

Patient Transport provision

Patients Know Best provision

**3.2.24 Patient Acceptance and Exclusion Criteria**

ICHD should be offered to any patient reaching or presenting with established renal failure if it is deemed by the clinician in charge that the patient will benefit from treatment.

This specification refers to adults over the age of 18 years. Some young people aged less than 18 years may be best treated in an adult service, by mutual consent. When treating children, the service will additionally follow the standards and criteria outlined in the Specification for Children’s services (Annex 1 A06/S/a)

Satellite units should have the same acceptance criteria for patients who are stable while receiving haemodialysis as the MRU. Exclusions should not be on the basis of age (advancing age or adolescence), co-morbidity, frailty or type of vascular access.

The decision for continuing satellite dialysis for in patients admitted to their local hospital is at the discretion of the Trust renal clinician, or other named consultant identified by Trust clinicians, and the nurse in charge of the satellite unit in accordance with existing protocols.

Notwithstanding the above, patients should be accepted in accordance with Section 3.2.16 Non NHS England Funded Patients where applicable.

**3.3 Facilities and Equipment**

**3.3.1 Current Sessions**

The facilities, subject to agreement with the Trust and patient demand, will provide dialysis between the hours of 6.00 am to 11.00 pm Monday to Saturday on a three (3) dialysis shift basis. The actual hours of dialysis shifts will be dependent on local patient needs and there is no guarantee of activity within this specification.

All bank and Public Holidays are considered to be normal working days with the exception of Christmas Day. The provider will be responsible for making suitable adjustments to the dialysis schedule to ensure that all patients receive their prescribed dialysis over the Christmas week.

All opening hours are subject to change due to capacity and demand and as agreed with the Trust.

**3.3.2 Equipment**

The Provider shall:

* Provide dialysis machines with the ability to provide haemodiafiltration, equipment, medical consumables and materials necessary for patient care which shall be adequate, functional and effective.
* Ensure the water supply will be generated to standards set out in the clinical services specifications and HBN 07-01 (as updated from time to time). This is to include testing of the water to agreed standards;
* Where necessary and appropriate, ensure that patients who wish to self-care will be provided with necessary machine/equipment, as per the requirements of the Trust, appropriate for self use by the patient. This is to be as recommended by the Trust and to comply with the self-care policy of the Trust
* Provide medicines and drugs at their cost, in accordance with this specification, subject to change as clinically required;
* Ensure that all renal unit equipment complies with HBN 07-01 (as updated from time to time) the National Minimum Standards and other regulatory standards;
* Provide new equipment for providing dialysis to patients (machines, dialysis chairs) and ensure that they supply contingency equipment in the event of breakdown or routine repairs. Current equipment schedules are shown in Appendix-7 Haemodialysis Units Inventory List. Where new equipment is expected to be provided, this must be completed within 6 months of service commencement. Equipment must be maintained and replaced in accordance with the Renal Association standards and the recommendations of the manufacturer.
* For the avoidance of doubt, stand-alone monitoring equipment (eg BP, O2) does not need to be replaced for this specification as new dialysis machines will have integral capability. However, mobile BP, Pulse and O2 saturation monitoring units will need to be replaced within 6 months of the commencement of the service.
* Provide other associated facilities, equipment and supplies for the delivery of the services;
* Provide a defibrillator which follows local National Health Service hospital policy where applicable;
* Provide a hoist and selection of appropriate patient moving and handling equipment, including that needed for bariatric patients and those requiring to be dialysed on beds. At least 1 bed in each unit should have the capacity to weigh the patient to enable the weighing of patients with poor mobility;
* Replace dialysis machines, and other equipment, as recommended by the Renal Association standards and manufacturer’s guidance. Equipment should be replaced where it is non-viable for repair or new parts are not available.
* Provide equipment which may need to be sourced from other renal manufacturers as appropriate for reasons of clinical care or value for money, e.g. access flow monitoring.
* Provide IT equipment that enables bedside patient monitoring and data capture with no need for duplication
* Provide dialysis machines with the ability to perform:
* On line haemofiltration,
* On line haemodialfiltration,
* Integral BP monitoring,
* Double pump for single needle,
* Battery backup,
* Blood volume monitoring,
* On line Clearance Monitoring
* Access recirculation,
* UF profiling.
* Venous Needle Dislodgment sensing
* Body composition monitoring, including fluid status and flesh weight (dry weight)
* Ensure the ability for an interface between the information systems of the Provider, Trust and other required systems, in order to enable dialysis outcomes and weights of patients to be monitored

In the event that the Provider is unable to provide sufficient equipment for treating patients at any time, the Provider shall have appropriate systems in place to provide or procure alternative dialysis sessions to patients at other facilities in the same geographical area as the relevant facility and shall provide adequate transport for patients at the Provider's own cost. Any such referral to an alternative dialysis provider should be entirely at the cost of the Provider.

All equipment should keep pace with technological advances, including portable dialysis systems.

Equipment used in the renal units should be, at minimum, compliant with the relevant Renal Association guidelines, in particular Clinical Practice Guidelines for Haemodialysis (2019) or any subsequent version.

All equipment not agreed to be transferred or made available to the service Provider at commencement of the service is to be provided new from service commencement. However, to reduce the possible impact upon patient care, all new equipment required must be installed and operational within 6 months of service commencement.

Equipment to be transferred to the Provider upon service commencement is stated in Appendix 4 - Haemodialysis Units Inventory List. This includes clinical equipment that is expected to be replaced within 6 months of service commencement date.

**3.3.3 Patient Requirements**

The Provider shall provide the following requirements at and for each facility:

**Figure 5: Essential patient requirements in the satellite units**

|  |
| --- |
| **Essential Patient Requirements** |
| Notice boards, leaflets, range of reading material and posters to be provided in waiting area |
| Refreshments available whilst on dialysis as directed by dietetic advice |
| Each dialysis station to have access to a free individual television, communication and entertainment system, with remote control. Each patient to have their own headphones. |
| Patients to have access to either sheets or blankets in order to remain warm / comfortable |
| Wi-Fi |
| Non-fixed partial partitions/barriers to be available for increasing patient’s privacy when required during dialysis |
| Mobile tables for patients to use at each dialysis station |
| Pressure relieving equipment to be available for use on the dialysis unit |
| Beds to be available as appropriate (minimum of 2 beds in each unit, one of which should have weighing facility) |

**3.4 Support Services**

The Provider shall provide or procure all of the support services to ensure the Provider is able to provide the clinical services in accordance with the terms of this specification. The Trust may wish, or may be willing, to provide some support services to the Provider.  The Provider is therefore encouraged to discuss potential support service arrangements with the Trust at an early stage.  The Provider should also consider interfaces between all of the parties that will be delivering support services.

The Provider will have sole responsibility for ensuring that all sites, including those sites that may be supplied by the NHS Property Services, are appropriate and equipped to support the delivery of the services.

Support services will include, but not be limited to:

* Domestic/cleaning services – including the provision of toilet rolls, paper hand towels, polythene bags and neutral detergents;
* Catering services – Providers will supply patients during an ICHD session with a drink, sandwichand an appropriate snack directed by dietetic advice.
* Laundry and linen;
* Clinical and non-clinical waste disposal;
* Security
* Portering (currently an ad-hoc requirement)
* Utilities
* Oxygen cylinders as appropriate and crash boxes with host Trusts at all sites.
* Facilities Management Services, including window cleaning, pest control, grounds and gardens, interior and exterior maintenance of the building, including structure.
* Resuscitation and anaphylaxis equipment
* Offensive Waste Collection

This list is not exhaustive.

**4. GOVERNANCE AND QUALITY**

**4.1 Policies and Procedures**

The Provider will share and demonstrate evidence of robust policies that meet Registration Authority standards and Trust expectations and requirements.

To include, but not be limited to:

Delivering Dialysis Treatment sessions and associated care.

Vascular access management including use of ultrasound for needling

Blood Borne Virus management (BBV)

Patient consent

Duty of Candour

Care Quality Commission Certificate

Business Continuity

Infection Control

Human Resources

Occupational Health Policies

Clinical Governance review and reporting

Clinical Record Keeping

Medicines Management

Do Not Attempt Resuscitation

Management of a death within the unit

Emergency Procedures

Clinical Incident Reporting

Waste Management

Training

Dialysis Away From Base

Complaints

Management of Water Treatment Plant

Environmental Policy

Patient satisfaction

Safeguarding Children and Vulnerable Adults

Dress code

The provider will share Standard Operating Procedures (SOPs) for pre, during and post dialysis sessional care including:

Out of hours dialysis and patient transfer

Standard Operating Procedure for water treatment plant

Standard Operating Procedure for In-patient/Inpatient dialysis provision

**4.2 Quality Assurance**

The Provider is responsible for all clinical governance, which shall be in accordance with the Trust’s policies and requirements.

The Provider shall, in adherence with the policies and procedures of the Trust:

* Be clinically and managerially responsible and accountable for any activity carried out on the dialysis patient whilst in the facility;
* Operate an effective, comprehensive, clinical governance system with clear channels of accountability, and supervision that reduce the risk of clinical system failure;
* Put in place effective quality assurance systems to ensure clinical services are performed in a manner so as to minimise the need for repeat activity due to poor quality clinical services;
* Ensure the patient receives the clinically prescribed dialysis activity, within the appropriate time period, in accordance with the agreed care pathway and clinical specification;
* Continuously monitor clinical performance and evaluate unexpected clinical complications/adverse events arising from any activity. This shall also include, where appropriate:
  + Clinical adverse incidents and serious untoward incidents;
  + Adequacy of tissue sample (such as blood samples) and accuracy of pathological reports from procedures performed by staff;
  + An evaluation of the accuracy of investigation interpretations and the contribution of the report to answering the clinical question posed, the clinical appropriateness of examinations undertaken and any further investigations suggested; and
  + All clinical governance management in conjunction with the Trust, including attendance at the Trust’s renal clinical governance group by representatives of each unit;
* Audit clinical care against clinical standards as agreed with the Trust, and use appropriate formal methods such as root cause analysis for untoward incidents;

* Initiate any appropriate correction methods/or other rectification plans as soon as possible to reduce any clinically significant interpretation discrepancies identified by clinical audit, double reporting, or any other quality systems used by the Provider;
* Maintain records that demonstrate repair and maintenance of equipment, quality control, calibration, validation and routine testing, in accordance with manufacturers' instructions/recommendations and otherwise, in accordance with the Operating Manual for the facility, and also retain a record of all activities carried out to meet these obligations.

**4.3 Infection Control and Decontamination**

The Provider shall ensure that at all times it complies with Trust policies and procedures and:

* L8 guidance on the control of legionella <http://www.hse.gov.uk/pubns/priced/l8.pdf>
* UKKA Clinical practice guidelines: Management of blood borne viruses within the Haemodialysis Unit <https://ukkidney.org/sites/renal.org/files/FINAL-BBV-Guideline-June-2019.pdf>

The Provider will provide the name and 24 hour contact details for its Infection Control Doctor.

The Provider will give unhindered access to the Trust Infection Control Team and Facilities/Estates personnel

The Provider will use hand hygiene cleaning and disinfection products and methods consistent with the Trusts hand hygiene cleaning and disinfection products and methods.

Where there is a difference the product/system/method used in the Trust will be used.

The Provider will:

* Have procedures to control and prevent the transmission of infection;
* Ensure the cleaning of the facility and the machines are in accordance with the recommendations
* Use its best endeavours to take all steps required to prevent the spread of any infections to patients, including, but not limited to:
  + All recommendations in Part 2 of the Health Act 2006, the Health and Social Care Act 2008 and the accompanying Code of Practice for the Prevention and Control of Healthcare Associated Infection and related guidance 2008 (as amended, supplemented or updated from time to time), Safer Practice in Renal Medicine November 2007, and the latest relevant infection control guidance recommended by the Medicines and Healthcare products Regulatory Agency (MHRA) and the Health Protection Agency and any successor bodies;
  + Guidelines for the control and prevention of methicillin-resistant *Staphylococcus aureus* (MRSA), methicillin-sensitive Staphylococcus aureus (MSSA), and Carbapenemase Producing Enterobacteriaceae (CPE) in healthcare facilities – Journal of Hospital Infection (2006) 635, s1 – s44
  + Guidelines for the control and prevention of blood borne virus;
  + Guidelines for control and prevention of COVID-19
* Ensure that, apart from in exceptional circumstances, no carers or visitors will be allowed onto the dialysis area of the unit;
* Have effective decontamination protocols, including cleaning, sterilisation, disinfection and, if appropriate, destruction, of all equipment used in the delivery of the services and in accordance with manufacturer’s instructions and MHRA or Health Protection Agency, or any agency replacing it, recommendations; and Renal Association guidelines; and
* Minimise the risk of patient to patient; staff to patient or staff to staff transfer of infectious agents that may harm patients.

The Provider shall retain a record to identify sources of any infection acquired by patients at the Satellite Unit taking into account Renal Association Clinical Practice Guidelines (as may be updated from time to time).

The Provider will audit all decontamination procedures (including the unit, patients and machines) in accordance with National Minimum Standards and as agreed with the Trust from time to time.

The Provider will have written monitoring arrangements in place for the early identification of infections and infection trends, including audit mechanisms.

The Provider will have written infection control policies, as agreed with the Trust.

The Provider will seek the advice of a National Health Service Trust Specialist Microbiologist and shall ensure that the use of antibiotics and other infection control measures are in accordance with such advice and National guidelines. For the avoidance of doubt, the cost of the Microbiologist's services shall be met by the Provider.

The Provider shall, at all times, designate a member of staff at the facility who shall be responsible for all administrative tasks relating to decontamination and control of infection (the Infection Control Link Nurse). The Provider shall appoint an appropriately qualified Infection Control Nurse for each facility.

The Provider shall ensure that all infection control related incidents of transmission of infection to patients are recorded and reported as part of the reporting requirements, in accordance with this specification.

The Provider shall participate in all national infection surveillance programmes including MRSA/MSSA bacteraemia, intravenous access site infection and Clostridium difficile surveillance and blood borne virus.

Upon the occurrence of an infection event, the Provider, or the Infection Control Officer acting on behalf of the Provider, shall:

* Inform the Specialist Microbiologist and seek his/her advice;
* Initiate the necessary investigation into the event;
* If appropriate, notify the Consultant for Communicable Disease Control;
* If appropriate, register the infection in the national surveillance programme;
* Request the support of, without limitation, neighbouring National Health Service microbiology laboratories and the Health Protection Agency, or any agency replacing it, where the future management of infections is considered to require additional specialist support; and
* Take all appropriate action, including, without limitation:
* Obtaining specimens;
* Administering treatment, including prophylactic treatment, (or, procuring administration of such treatment, where it would not be Good Clinical Practice for the Provider to do so itself) to the patient (and in cases where the infection event was caused or contributed to by any act or omission of the Provider or a Provider Party, to others including without limitation, other patients, visitors, staff, contractors and the public affected by the infection event), in accordance with the advice of the Infection Control Officer and following receipt of a valid prescription;
* Ensuring and evidencing that others, including, without limitation, other patients, visitors, staff, contractors and the public affected by an infection event, receive information and advice concerning the event to enable them to receive appropriate treatment;
* Implementing appropriate isolation arrangements for the patient, or others;
* Closing the facility to further admissions in discussion with the Trust
* Procuring specialised cleaning or decontamination of the satellite unit including its contents;
* Acting in accordance with Good Clinical Practice and National Minimum Standards.
* Informing the referring Trust and the relevant supervising Clinician;
* Notifying the Care Quality Commission;
* Notifying the local NHS Body and Trust;
* Notifying any statutory body as required.

The information and advice referred to in the above shall be both written and verbal, and shall include:

* If appropriate, advice that affected persons should consult their own GP; and
* Any relevant advice from the Infection Control Officer.

Where any act or omission of the Provider or a Provider Party has been a contributory factor to the infection event or its consequences, the costs of any treatment or drugs administered to any person shall be the Provider’s responsibility. If an act or omission of the Trust has been a contributory factor, then similarly, any costs of treatment or drugs shall be the responsibility of the Trust.

Patients with HIV, Hepatitis B, Hepatitis C, MRSA/MSSA, VRE, CPE and Clostridium infections may be dialysed in the facilities. The Provider will ensure that such patients are isolated, or cohorted if appropriate and, where applicable dialysed on dedicated machines. The Provider must ensure practice, including sampling, is in accordance with the Blood Borne Virus policy of the Trust. The Provider must ensure that staffing ratios adhere to Blood Borne Virus Guidance.

The Provider will have a comprehensive occupational health policy for staff presenting with infections that could pose a risk to patients or other members of staff. Such policy to be in line with Trust policies and also relevant national guidance

**5. WORKFORCE**

As a means to delivering the required levels of clinical quality and patient safety, the Provider will recruit, develop and retain appropriately skilled and motivated clinical staff in accordance with the British Renal Society, NICE Guidance, CQC and NHS minimum standards.

**5.1 TUPE**

The service is currently provided by an existing workforce that is employed by either the Trust or the incumbent provider. The Provider will be expected to mobilise staff from the existing workforce and also ensure that sufficient appropriately trained staff are recruited and available for the service commencement date. There should be no interruption or disruption of service to the patient at any time whilst this service is being implemented.

The Trust anticipates that Transfer of Undertakings and Protection of Earnings (TUPE) will apply to some staff within the existing workforce. This includes the requirement that transferring staff on NHS terms and conditions should be offered to retain access to their NHS Pension Schemes.

A prediction of the staff volumes that potentially may be in-scope to TUPE transfer is given in Appendix 2 - Indicative TUPE Summary List. The Provider must utilise due diligence when giving consideration to this information.

The Provider is expected to work with all parties and effectively and efficiently manage differences in policies, payment dates and procedures.

All Provider staff will be expected to hold honorary contracts with the Trust.

**5.2 Training**

All staff should have appropriate training. Local training requirements, including statutory and mandatory staff training, are in accordance with Trust requirements.

* the Provider will not be allowed to actively canvass current nursing staff of the Trust in regard to the filling of vacant posts at the facility;
* if recruiting overseas staff from outside the EEA, that criteria of the International Recruitment are met and that the applicant is proficient and satisfies the English language tests. The Provider must ensure that the potential member of staff has a valid work permit and verifies the identity of the person;
* Save, as otherwise provided in this specification, it takes entire responsibility for the employment and conditions of service of the Provider’s own employees; and
* Staff are recruited in accordance with NHS requirements

**5.3 Uniforms and Protective Clothing**

The Provider shall provide and shall require their staff, at all times while on the premises of the haemodialysis unit, to be properly and presentably dressed in appropriate clean uniforms and work-wear to a standard not inferior to that of the host Trust’s own staff engaged on reasonably comparable duties. Uniforms should differentiate between staff groups – ie qualified and non-qualified nursing staff. Such uniform will include the provision and use by staff, of gloves, aprons and masks/visors. The Provider shall also ensure that visitors attending the haemodialysis unit in connection with the provision of services observe appropriate standards.

**6. INFORMATION MANAGEMENT AND TECHNOLOGY REQUIREMENTS**

**6.1** **Information Technology**

The Provider shall, at the Provider’s cost, arrange for the installation of a link to the Trust’s computing services, to include the Trust’s Patient Administration System (PAS) / Electronic Patient Record (EPR), the Trust’s intranet and the Renal Information System (currently EMedRenal). The Provider’s Information Technology (IT) systems must be able to process and load electronic information about patients sent from the IT systems of the Trust. Arrangements for any such link must comply with the Trusts local security policy as well as with any security policy required by the Department of Health/NHS mandate and must be updated by the Provider, at their cost, as such NHS policies change.

The Provider will be expected to confirm that its computing system is compatible with the Trust’s EPR and the Renal Information System. The system must be able to download data onto these systems as well as being able to upload data from the Trust’s renal clinical database and management system into the Provider’s system at the facilities. The technical arrangements, format and specifications of any download/upload mechanism will be subject to the written approval of the Trust and the Provider, at their cost, will provide an accurate specification for such download/upload mechanism.

The Provider is to ensure that data from all the Renal Units are able to be accessed remotely if not replicated in the system of the Trust. The provider is to bear of the cost of the staff at the facilities to undergo training on the use of the IT system of the Trust and vice versa. Additional clinical care data, such as co-morbidity and drug usage, required for input into the IT system of the Trust, will be the responsibility of the Provider.

**Existing Infrastructure / Technical Architecture**

* **Cloud hosting requirements –** Assurance will be required around data location and backup where services are to be Cloud hosted.
* **Local & wide area capabilities –** The Trust has a series of MPLS connections between sites offering between 10 and 1 GB/s. The Trust has an Internet connection at 1 GB/s. The Trust has an internet connection at 300MB per second via HCSN
* **Server virtualisation / hypervisor capabilities –** The Trust has a VMware virtualisation solution that encompasses servers, networks and storage. The present version of vSphere being used is 6.7.
* **Desktop –** The Trust is running Windows 10 on the desktop, with desktop build 21H2. (migrating to Windows11)
* **Mobile device –** The Trust runs a wide variety of mobile devices, all are managed using Workspace One (Vmware).
* **Virtual Desktop Infrastructure (VDI) –** The Trust uses Horizon (VMware) as a thin client solution in a number of areas, most commonly in Emergency Department (ED).
* **Microsoft Office** – The Trust is part of the Microsoft 365 shared tenant. All applications that call upon Microsoft Office **must** work within the Microsoft 365 shared tenant and Office 365 online. Including NHSmail authentication.
* **Trust Interface Engine** - The solution handles HL7 / FHIR and other inter-systems messaging. The current solution is Healthshare from Intersystems.
* **Service & hours that we cover –** Our office hours are 9 a.m. to 5 p.m. Out of hours cover is provided by IT support 24-7, 365 days a year.
* **Suppliers remote access –** Suppliers will be required to use Horizon VDI to access Trust systems remotely with OPSWAT used to ensure compliance with minimum security conditions.
* **Single sign on technologies –** The Trust uses Imprivata OneSign to provide a single sign on service.
* **Anti virus and security suite –** Windows Defender and ATP runs on all desktops. Sophos anti-virus is used to protect servers.
* **System back up arrangements –** Backup is via Veeam, Netvault and Backup Exec. The most common approach is using Veeam to backup virtual machines. A Dell Data Domain appliance offers an area for immutable backups.

**Minimum System Requirements**

**Separate our requirements / supplier requirements**

* 1. Servers required – number and roles of each
     1. Physical or virtual machine preference
     2. Windows Server Version with at least 5 years mainstream support remaining
     3. SQL (with at least 5 years mainstream support remaining) and Web requirements (if appropriate)
     4. RAM required
     5. Storage space required and access speeds required (read and write to be specified)
     6. Patching schedules (needed monthly) – *to be agreed with Division & supplier*
     7. Backup arrangements need specifying - *to be agreed with Division & supplier*
     8. Bandwidth requirements TO INCLUDE if Cloud Solution
     9. Media connection to network

Client requirements – operating system, CPU, RAM, disk space

**Cloud Hosting Arrangements**

If the system is to be accessed from outside the Trust infrastructure, then the following information is required:

* + 1. IP ranges of any external Cloud based assets
    2. Completion of the Firewall Request Form
    3. Completion of VPN Request Form (if required)
    4. Certificates for SSL
    5. DNS Records required

**Supplier Remote Access for Support of on Premises Assets**

Accessing systems to provide configuration and support for the system

* + 1. The provider must agree to use the Trust system
    2. This is Horizon VDI with a compliance checker to verify basic security on the connecting devices.
    3. If there is a client needed within the VDI desktop the supplier must provide details.
  1. **Records Management System**

The Provider will need to ensure that its record management system fits with future National Health Service developments, such as Personalised Health and Care 2020 (November 2014) and The Five Year Forward View (October 2014):

* National Minimum Standards and the requirements set out in the publication "Records Management: NHS Code of Practice 2006"; and
* The highest available CNST Standard in relation to records management, available from time to time relating to the creation, maintenance, confidentiality, security, retention and disposal of health records.

The Provider shall take into account the ongoing nature of patients' dialysis treatment and shall provide a system for storing patients' dialysis records in a locked and secure place at the facility and in accordance with the Records Management Code of Practice for Health and Social Care 2021.

. The Provider shall also have systems in place for transferring patients' dialysis records to the Trust or other NHS Service Provider at short notice, allowing twenty four (24) hour access to the facility for record retrieval. . Agreement will be required between the Provider and the Trust as to which personnel will be allowed such access.

The Provider will make available, on request from the Trust or supervising clinician, a copy of the patient's dialysis records created by the Provider relating to the activity, using interface with electronic or paper-based records. The cost of the copies will be borne by the Provider.

The Provider shall create a patient dialysis record for every patient receiving haemodialysis at the facility and this detail should be captured by the nursing staff at the patient bedside in a timely manner.

The Provider shall ensure that all entries made by healthcare professionals in the patient dialysis records are clear, accurate, unambiguous, typed (where possible), legible and proof read carefully to avoid typographical errors.

The Provider shall create, maintain, store and retain patient health records for all patients receiving treatment as part of the services. Patient health records shall be kept by the Provider in an appropriate secure location. Subject to compliance with Law, the consent policy and the common law duty of confidentiality, Authorised NHS Persons shall be granted access by the Provider to such patient health records and may inspect them and require copies to be provided by the Provider (at the Provider’s cost).

The Provider shall:

* Use patient health records solely for the execution of the Provider's obligations under this specification and for such purposes as may be set out in the Provider’s contract with the Trust; and
* Return any patient health records and any other personal data relating to a patient’s treatment to the patient’s GP promptly upon request at any time, unless such personal data is to be used for the purposes set out in the Provider’s contract with the Trust,or, where the Provider is required to retain it to comply with the law, in either of which cases, the Provider shall supply copies to the patient’s GP on request.
* Notify the Trust of the identity of its Caldicott Guardian and supply his/her contact details.
* Ensure that IT capability is in place and maintained so that patient health records and any other appropriate personal data relating to a patient's treatment is secure.

**6.2.1 Data Storage and Transfer**

1. The Supplier will ensure that a secure method for the transfer of information and data between Supplier and DBTH is available, both in electronic and hard copy formats.  The DBTH’s preferred storage method is electronic. The Supplier must be able to adhere to the current NHS encryption standard 256 bit AES encryption as a minimum which must be updated as and when required.
2. The Supplier will be expected to store all documents securely and provide the Authority or other authorised bodies with copies of documents on request in accordance with minimum performance standards stated below:
   * 1. Urgent – to be provided on the same working day
     2. High priority – to be provided within 3 working days
     3. Routine – to be provided within 7 working days or as agreed
3. The Supplier will retain all records as defined by current NHS Guidance on Maintenance and Destruction of Hospital Records.

**Physical Storage of Data and Records**

1. The Supplier is responsible for the storage and archiving of all document records that they receive throughout the duration of the contracts.
2. Archive data will be made accessible to the DBTH at all times in line with 6.2.1. above

**System Integrity**

* 1. The supplier **must** provide the appropriate system facilities and service measures to ensure that information will be retained following any form of system failure or facilities disruption procedures, including regular testing to validate them.
  2. The system **must** recover all data and all functionality to the point of failure, without re-input of data. Suppliers must describe how their proposed system can be configured to ensure this
  3. In the event of a power failure, the system **must** close down in a state which enables simple recovery to take place without losing data

**6.3 Renal Dataset and Renal Registry Information**

The Provider shall ensure that IT capability is in place, and maintained, so that the required patient, activity and outcomes data can be collected, transmitted to the Trust, and analysed in accordance with:

* The requirements of the National Renal Dataset (as defined by the NHS Information Centre). The National Renal Dataset has been approved as a Full Operational Information Standard by the Information Standards Board for Health and Social Care. The dataset is mandated for collection by the Department of Health, <http://www.ic.nhs.uk/services/datasets/dataset-list/renal>
* The requirements of the Renal Registry to ensure that the required patient, activity and outcomes data provided in accordance with the requirements of the UK

**6.4** **Overview of Information System Requirements**

The Provider is required to update data in existing IM&T systems that are provided by the Trust. These IM&T systems will include but not be limited to:

* Renal Information System (RIS); Emed
* Electronic Patient Records System EMED (EPR)

The use of the IM&T systems will include, but not be limited to:

* In the RIS, the Provider will be required to update the dialysis record, dialysis diary, pathology results etc;
* In the EPR, the Provider will be required to update all care records where appropriate.
* Electronic requesting: The Provider will be required to implement electronic biochemistry and radiology requesting utilising the Trust’s system (currently Clinisys ICE). The Provider will be responsible for procuring (at the Provider’s cost) suitable equipment including portable computers and printers.

Providers may also choose to implement their own IM&T system(s), in support of the clinical and operational processes. Such system(s) may assist the Provider achieve its obligations with respect to reporting, providing contract management information, supporting the Patient Care Pathway and the operational processes within the Facilities.

Providers may choose to implement interface(s) between their own IM&T systems and the Trust’s systems identified above for the purpose of updating information in the Trust’s IM&T systems. Providers proposing any electronic interfaces between their own systems and Trust provided systems should state clearly any assumptions that they are making as to the capabilities of Trust systems. The Main Renal Unit may require these interfaces to be processed through an Integration Engine, rather than directly with the Trust’s IT systems. Interfaces must be HL7, FHIR, NHS ITK compliant..

The Provider will be required to accommodate electronic booking systems and / or use existing scheduling systems at each site. Providers may choose to implement an electronic scheduling system to support the management and booking of dialysis sessions.

The Provider will be expected to enter into a service sub-contract with the Trust for the access of the Trust’s IM&T systems. Arrangements for access should be made via the Trust’s IT services.

The Provider will need to collect data to allow the Trust to submit data in support of the Renal Services Information Strategy supporting the Renal National Services Framework for Renal Services. The data sets to be collected will be agreed Trust.

The Provider’s IM&T solutions must support the Trust in developing its local IM&T strategy to deliver the Renal Services Information Strategy supporting the National Services Framework for Renal Services.

**Interfacing**

In computing, an interface is a shared boundary across which two or more separate components of a computer system exchange information. The exchange can be between software, computer hardware, peripheral devices, humans, and combinations of these.

Description of compatibility - HL7 version 2 standards as profiled by HL7 UK in the HL7 UK implementation guide HL7UK and FHIR version 3.0.2

**Interoperability**

Across healthcare there are a large number of computer systems and software applications being used. Through interoperability, we can help ensure information is shared between these different systems, so healthcare professionals have access to the information they need, when they need it.

The Chief Clinical Information Officer for health and care in England has outlined seven priority areas:

1. **NHS number/Citizen ID** – real-time access to the NHS Number at the point of care across the service, ensuring that the NHS Number is associated with care record elements e.g. lab tests. The Provider must ensure that, with effect from 1 April 2020, the Service User’s verified NHS Number is available to all clinical Staff when engaged in the provision of any Service to that Service User – this is stated in the 2019/20 Standard Contract
2. **Medications** – all medication messages in the NHS to be interoperable and machine readable across the service
3. **Staff ID**– ensuring that there is a consistent way to identify and authenticate staff across the service
4. **Dates and scheduling** – a consistent set of interoperability standards for dates and scheduling information that enables a consistent approach to appointment booking across venues of care and the creation of historic and forward views of appointments
5. **Basic observations** – a consistent set of interoperability standards for the sharing of a core set of structured observations
6. **Basic pathology**– a consistent set of interoperability standards for the sharing of a core set of pathology tests
7. **Diagnostic coding** – implementation of SNOMED CT across the wider service. SNOMED CT must be utilised in place of Read codes before 1 April 2018 across Primary care settings. For Secondary Care, Acute Care, Mental Health, Community systems, Dentistry and other systems used in the direct management of care of an individual must use SNOMED CT as the clinical terminology before 1 April 2020.

**Access Control / Security**

* 1. Include Trust approved antivirus product to detect, quarantine and/or delete malicious code, to prevent malware from causing damage to the Trusts devices. The Trusts preference is to incorporate its own standard antivirus and security suite and all new system implementations
  2. Include Patching to fix security vulnerabilities and other bugs.
  3. New users **must** be automatically assigned a system generated password matching National Cyber Security Centre (NCSC) recommended password strength requirements
  4. The Supplier must ensure the transmission of data is secure and in accordance with NHS Standards.
  5. All transfer of data must be encrypted using HTTPS / TLS 1.2 or better. Data at rest in the database must also be encrypted.
  6. All inbound and outbound communication, including, but not limited to, TCP, HTTP(S), FTP(S), SMTP, web services etc. All must be encrypted
  7. Supplier will have a current Information Security & Business Continuity Plan throughout the contract
  8. Security of the process is of upmost importance.  The Supplier will have a system in place to ensure they meet the requirements of the Trust and this service specification.
  9. The Supplier must ensure the transmission of data is secure and in accordance with NHS Standards.
  10. Suppliers are required to declare details of any data that will be held outside the borders of England or processed outside the borders of England and shall clearly reference this in the ‘Information Security & Business Continuity’ Plan and ‘Disaster Recovery Plan’. Countries outside of the EU are subject to:
      1. The destination has been the subject of an adequacy decision (Article 45)
      2. The transfer is subject to appropriate safeguards to protect the personal data (Article 46)
      3. Appropriate safeguards for other countries such as the US will be required; therefore this will attract a lower score.
  11. The Supplier will comply with the Authority’s security policies and in particular: [DBTH Trust Policies](file:///\\win2000.doncri.nhs.uk\dbhshared\Supplies\01.%20Procurement%20Category%20Management\10.%20All%20Projects%200-250\DBTH025-CLIN-AJ-2024-25%20Renal%20Dialysis%20managed%20service\4.%20ITT\DBTH%20Trust%20Policies)
      1. Data Protection, UK GDPR and Confidentiality Policy.
      2. IT Security Policy.
      3. Email & Internet Usage Policy

**6.5 Overview of Infrastructure Requirements**

Providers will be required to supply all hardware (including PCs), infrastructure and network connections (including connection to the Health and Social care network HSCN) at each facility in order to support the IM&T requirements of that location. Where Providers supply IT equipment for the facilities, it must meet the relevant NHS standards.

**6.6 Overview of Other General Requirements**

The Provider is required to provide proven and robust IM&T, which underpin both the delivery of care within their facilities and proper integration with the NHS both locally and nationally.

The procurement, implementation, installation, operation, maintenance and support of all the IM&T systems and infrastructure that are implemented by the Provider within and between the facilities are the sole responsibility of the Provider.

If the Provider chooses to implement its own systems, it may be required to interface them with local and national NHS systems in delivery of the Services, particularly with regard to the exchange of Activity Output and other clinically relevant information. The Provider will be required to cooperate closely with the bodies responsible for these external systems to ensure Provider systems are correctly specified, configured and interfaced.

All the patient information is owned by the Trust. Therefore, at the end of the contract period, the Provider will be required, at their cost, to supply the Trust with all patient information in the original format that it was recorded, and all relevant computer equipment including but not limited to the Computers and Servers to assist with task as necessary.

**6.7 Required Data Flows**

Figure 6 shows the information flows required to and from external systems. Systems within the Provider’s IM&T solution box are the responsibility of the Provider in terms of provision and implementation. The systems and processes identified outside of the Provider’s IM&T solution box are the responsibility of the NHS, or other bodies, to deliver. The Provider must however, provide and support processes and any interfaces between the Provider’s IM&T solutions and NHS systems in line with the appropriate NHS interface and messaging standards. The Provider will be responsible for modifications to its own systems to meet these interface requirements.

**Figure 6: Information flows for renal services**

Contract Management

Information

Information to support

Renal Data Set Returns

Information for  
Patients / Public

**Multiple Pathology Feeds from the differing host sites**

Stock/Order

Management

**Management**

**Information**

**Contract**

**Management**

Communication /

Email System

Accounting /

Billing

**Haemodialysis Unit**

Patient

Records

Local Management

Information

Central Management

Information

Bookings and Scheduling

Master Patient

Index

HD Slot Management

Transport

Booking

Information to Support Renal Registry

Typical  
Provider System

Renal Information System (based at the Main Renal Unit)

Drug Management

**6.8 Renal Information System Infrastructure**

Haemodialysis Services care is provided on a “hub and spoke” model, where the hub (Main Renal Unit) provides the consultant-led care and the renal information system.

It is important that the information related to the provision of the clinical services is updated in the Main Renal Unit's systems on a regular basis, as during the provision of haemodialysis services patients remain under the care and supervision of a designated consultant nephrologist employed by the Trust. Providers will be required to comply with the Trust’s local requirement regarding the frequency and timeliness of data entry (for example this might require the Provider to enter clinical information relating to the dialysis session into the Main Renal Unit’s IM&T systems within one (1) hour of the completion of the dialysis session).

Satellite dialysis units are connected to their hubs via the NHS network (although The Providers should note that some different configurations exist). Where Providers are taking over existing units it will be their responsibility to re-establish the NHS network connection (N3) using their own registration. New facilities will need an HSCN network connection as part of the infrastructure set up. This infrastructure set up will be agreed with the Trust.

Providers will need to liaise with IT departments at the Trust where the RIS is based to arrange for their firewalls to be configured to allow access to the Trust network and the RIS. Access to other IM&T systems that belong to the Trust will be organised in a similar manner.

Providers are required to support the current IM&T Systems and the required interfaces between haemodialysis locations and the RIS at all times. Within the opening times of the units, response time to an issue must be within 2 hours and fix time of an issue must be within 8 hours. An on-call service must be available for out of hour’s issues.

Providers are required to support all hardware (including PCs), infrastructure and network connections at each facility at all times.

**6.9 Information Requirements**

Providers must support and enhance the Trust’s efforts in developing patient information services that comply with the requirements identified in the Renal Services Information strategy supporting the National Services Framework for Renal Services which underpins the Renal NSF.

The Provider shall make specified information available to prospective patients, through the NHS Gateway website at [www.nhs.uk/](http://www.nhs.uk/), and other specified media, about the Facility and the services offered.

Patient knows best was created to allow renal patients greater access to information on their condition and help them make better informed choices about their own care, in line with the Renal NSF. The Provider will be expected to support and promote the use of ‘Patient knows best ‘by patients within the satellite dialysis units. Such support might involve the education of staff and patients, providing patient access within the Facilities etc. This support will be at the Provider’s cost and will be agreed with the Trust.

**6.10 Booking of Haemodialysis Slots**

The Provider shall book new end stage renal failure patients for a firm dialysis session by the next working day of receipt of referral for that patient. Date of dialysis commencement to be discussed and agreed between the patient and provider unless specified by the Consultant, but in any case will commence within 2 weeks of referral.

The Provider will be required to provide electronic bookings systems and / or existing scheduling systems at each relevant site which will deliver a service which is flexible and responsive in meeting haemodialysis volumes. The Provider‘s system for dialysis session management must be able to facilitate frequent changes that may occur to sessions depending on, for example, patient condition etc. The haemodialysis pattern can deviate according to the patient needs and Providers must ensure that their system for the management of slots is flexible but also provides an audit trail which can be used to review session management.

Audit Trail records must include the following minimum information: (minimum requirements to be confirmed. Patient record / staff accessed/changed)

* + 1. a record of the user identity. This is the User ID, Name, Role profile (including Role and Organisation, URP id when Smartcard authenticated) attribute values, obtained from the user’s Session structure
    2. the ability to identify from an audit trail any person or persons who have access to a personal or sensitive data record for this system (if different from the user);
    3. the date and time on which the event occurred;
    4. details of the nature of the audited event and the identity of the associated data (e.g. patient ID, message ID) of the audited event;
    5. a sequence number to protect against malicious attempts to subvert the audit trail by, for example, altering the system date.

While being processed, stored, and in backup and archive storage, all personal data and sensitive personal data and audit logs must be physically protected from loss or theft in line with the security policy published by NHS Digital.

Archive copies of personal data and sensitive personal data and audit logs must be retained in line with the retention policy published by NHS Digital.

If the system produces data archives, then the supplier must ensure that the encryption key for each archive is of an appropriate strength and complexity as detailed in the Approved Cryptographic Standards

If an electronic scheduling system is provided, it must be able to accommodate the following requirements:

* An electronic scheduling system must allow the Trust to see availability of haemodialysis sessions and any changes that have been made to sessions in real time (including the reasons for those changes). This will ensure that the Trust retains an accurate picture of haemodialysis session availability.
* An electronic scheduling system must be capable of providing reports which can be used by the Trust and other stakeholders to review current and future capacity etc.
* Providers will be required to provide information about haemodialysis session capacity and availability in a format provided by the Trust (for example, this could be by entry to one of the Trust’s IT systems, or by Excel spreadsheet). This will allow all facilities’ information to provide an overall picture of haemodialysis capacity across the health community. Providers will be required to provide this information according to timescales and frequency requested by the Trust to be locally agreed (typically weekly).
* The Provider will also be required to accommodate traditional booking methods for haemodialysis sessions which are reliant on the receipt of paper, email, fax, telephone (which must be confirmed in writing) or electronic message format.

**6.11 Data Entry**

The Provider will be responsible for informing the Trust of any changes to the patient demographics using an electronic method defined by the Trust. This could be, for example, by entering this onto one of the Trust’s IT systems, or by secure email, or both. The Trust will initially enter the patient demographics onto the RIS at the time of the first outpatient appointment for the Patient or first Referral to the Renal Service, but once the patient is receiving haemodialysis services, the Provider must put in place proactive systems to ensure that the Trust are aware of any demographic changes.

The Provider is responsible for maintaining a system for recording the NHS number, or equivalent, as defined by the Trust.

Providers must update the dialysis records in the RIS for the patient. This must be done on a timely basis and all data fields defined by the Trust must be completed.

Other information appropriate to the clinical pathway must be entered and maintained by the Provider in the IT Systems in use at the Trust.

The Provider must ensure that any other information that is a specific requirement of the facility is entered into the RIS in a timescale agreed with the Trust.

The Main Renal Unit may develop new facilities in the RIS during the lifetime of the service contract. Providers will be expected to implement these facilities on request from the Trust within the timescales.

The Trust may implement one or more new IT systems during the lifetime of the service contract. The Provider will be responsible for making any changes to any interfaces that are necessitated by these system changes. The Provider will also be responsible for supporting the staff within the facilities in changing over to the new system and ensuring that the new system is used appropriately to manage the outpatient process. Support of the staff will include ensuring that they are appropriately trained to use the new system and where necessary involve changing operational procedures to fit with the new system.

**6.12 Information Requirements**

It is the Provider’s responsibility to implement any information systems required to support the operational processes within the facility. There will be an obligation to ensure data integrity across any systems and any information recorded in a supplier system must match that which is held in an NHS system.

The Provider is responsible for the management and ordering of stock levels. The Provider must be able to provide audit information about stock.

The Provider must put in place adequate systems and processes to manage the prescribing of drugs to patients and management of drugs. Any drug prescribing for patients must be entered into the Trust’s Renal Information system. Providers must ensure that they maintain accurate drug information that can be audited and inspected when required. Information must be to a sufficient level of detail to support investigation into patient drug history and prescribing.

**6.12.1 Information Reporting & Data Extraction**

The Trust requires electronic read-only access to all of the Trusts data held in third party supplier systems. Access will be provided via SQL Server. Where technically possible this is to be achieved by a direct connection to a storage mechanism such as a copy or replicated database to provide near-live data. Where a direct connection is not possible alternative methods such as database backups or extracts may be used after further discussion with the Trust. All connection or extract mechanisms must be fully automatic and require no manual processes on a day-to-day basis.

All data must be able to flow easily into the Trusts established data warehouse. All data entry will confirm with the NHS Data Dictionary and must be maintained in line with the appropriate national guidance. DBTH would require technical documentation containing schema table structures and how the data links together in order for a full and comprehensive Extract, Transform and Load (ETL) process to occur.

**6.12.2 Documentation**

General documentation **must** include:

1. A systems’ overview.
2. Full configuration & process documentation.
3. Operational Management Report.
4. Monitoring / compliance reports
5. Data Dictionary.
6. Instructions / User Guides of full system functionality.
7. Data available in database, structure of data, and codes.
8. Screen based data entry functions and encoding.
9. Local user administrator functions.
10. Report and analysis.
11. The creation and use of queries.
12. Error codes and messages.
13. Fault finding, problem solving, and access to audit trail.
14. All documentation **must** be updated for any changes made to the application during implementation
15. Subsequent releases of software **must** include documentation changed for any site specific software changes made and be provided as part of the software license agreement
16. The supplier **must** provide the Trust with a skeleton document outlining controls and procedures, which must be implemented within the Trust to ensure the continual functioning of the system and integrity and security of its data
17. User documentation **must** be available prior to system implementation and be in a format to support all user types during training

**6.13 Activity Outputs**

The Provider will be required to ensure effective communication of clinically relevant information between the Provider, and the Trust. Increasingly, communications will be via electronic messages and the Provider will be required to support both paper and electronic communication mechanisms to meet the Trust’s requirements.

Electronic clinical communication: The Provider will be required to adopt the prevailing content, syntax and protocol standards when involved in electronic clinical communication with the NHS.

The Provider shall remain flexible in its approach to adopting new developments in clinical communication standards for the duration of the services contract.

**6.14 Patient Information**

It is a requirement of registration with the Care Quality Commission (CQC), that the Provider maintains comprehensive patient information appropriate to the service being delivered for the patients they treat.

The Provider must maintain patient information in line with the NHS data standards and those described within this specification.

The Provider is required to retain the majority of patient information in an electronic format. Providers should note that it may be a requirement in the future that patient administration systems are capable of being made compatible with the new NHS Care Records Service (CRS) specifically the Personal Spine Information Service (PSIS) which is a component part of the CRS. The Provider may be required, in due course, to submit electronic messages to the PSIS for each Session provided including pathology results acquired, but this will be in discussion with the Trust.

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**6.15 Clinical Data Sets**

The Provider will be required to submit data relating to clinical data sets depending on the services being provided.

For pre and post dialysis these will include as a minimum, but are not limited to:

* Patient details
* Patient GP
* Date
* Time
* Type of access used
* Blood pressure
* Actual weight
* Target weight
* Heparin doses
* Dialysis unit location

**6.16 NHS IM&T Use**

Providers will be required to utilise existing NHS IM&T Services under a local arrangement with NHS organisations. The Provider should note that where there is an intention to utilise any part of a NHS IM&T Service including any physical IT infrastructure or information system, the responsibility for delivery of IM&T Services and the use of any IM&T Infrastructure will remain with the Provider, including the costs of using NHS services or infrastructure.

If NHS IM&T infrastructure is to be used under subcontract to support the Provider’s service, the Provider will be responsible for ensuring that all network security requirements are met, and that the terms of the NHS organisation’s Code of Connection are not breached.

**6.17 NHS Provided Equipment and Services**

**6.17.1 National Network (HSCN)**

The Provider must connect to the Health and Social care network which is currently provided by BT. This connection is required to link the satellite HD dialysis unit to Renal Information System based in the hub. Further details are available at

The Provider will be expected to bear the cost of establishing a connection to HSCN and the ongoing charges that apply.

The current security standards that user organisations must achieve and maintain for HSCN are detailed in the NHSnet Code of Connection which reflects the requirements of the NHS Data Networking Security Policy.

The Provider will be required to submit its network architecture and Information Governance arrangements for security audit in line with this security policy in order to gain the necessary authority to order an HSCN connection.

The following services will be available to the Provider once HSCN connectivity has been achieved, subject to service-specific approvals:

* NHS Electronic email - ‘Contact’ - which is described below;
* Access to specific sites on the NHS-wide web, with agreement by their maintainers;
* Access to the internet via NHSnet secure gateways;
* Access to NHS Health and Social Care information Centre Services;
* Access to the CDS; and
* Access to the NSTS NHS number tracing service.

**6.17.2 NHSmail**

NHSmail is a secure, national, centrally managed directory and e-mail service, which is available to all 1.2 million NHS staff in England. It is a web-based e-mail service, also accessible from e-mail clients such as Outlook, which will provide the staff operating the Services a secure NHS e-mail address. This will enable patient-specific information to be communicated between the Provider and the NHS.

Providers should assume that NHSmail will be free at the point of use for the Provider and will be fully supported with a twenty four (24) hours a day, seven (7) days a week helpdesk.

As users of NHSmail, the Provider’s staff will have access to the NHS Directory. The Directory includes lists of NHS organisations and sites, the departments within those sites, the people working within those departments and their contact details. The Provider will be required to ensure that their own entries in the Directory are kept up to date in accordance with the prevailing Contact standards and procedures.

**6.17.3 Software Licences**

The Provider will be responsible for purchasing any additional software licences required to access the Renal Information System or other appropriate systems provided by the Trust. The Provider will also be responsible for any hardware upgrades that may be required to support additional users on the systems.

The Provider will be responsible for all software licences for those applications which are part of their submitted bid. Where the Provider opts to use a system already deployed within the NHS under a subcontract arrangement, the costs associated with any licensing or implementation requirements will be a matter for the potential Provider to determine and include in its Bid after local discussion and agreement. Potential Providers should discuss any specific requirements with the respective NHS organisations concerned.

**6.17.3.1 Software maintenance and support**

The Supplier will provide Software maintenance and support services to correct any Software material defect, fault, loss of, or failure of, System functionality or performance. The Supplier will also provide regular application Software / Security Upgrades / Updates (refer to section on System Upgrades)

**3.2.20.4 Hardware Operating System Refresh**

‘Hardware Operating System Refresh’ may need to be factored in dependant on length of contract

**3.2.20.5 System Upgrades**

The Supplier will release system upgrades against a pre-determined schedule. Upgrades to be available every 12-18 months as part of the Support Contract at no additional charge. A Software Update is a software release that incorporates improvements or needed changes/fixes to previously released software, including bug fixes and patches, feature enhancements, and database modifications. Software Updates into the UAT environment are completed within normal working hours (Monday-Friday 09:00-17:00) and Software Upgrade into the Live environment are completed out of working hours (Monday- Friday).

System upgrades will initially be released and applied to the UAT environment to enable local testing to take place. Once this has been completed the Live environment will be upgraded following all relevant change control processes.

Release notes will be provided in respect of the upgraded versions. The Supplier will update the UAT environment at least one month before the upgrade.

Suppliers must ensure that during upgrades to systems, any manual steps are documented in advance and any automated steps must involve the production of one or more logs which describe each step being taken and whether or not it has been processed successfully. Logs that cover a sequence of steps must also indicate whether the overall sequence has been a success or failure.

**6.18 IM&T Standards**

The Provider will be required to implement IM&T services that meet, as minimum, applicable IHE standard profiles and the prevailing NHS IM&T Standards

The NHS has an Information Standards Board (ISB) whose role it is to approve and review NHS Information Standards for adoption within the NHS. The scope of standards covered by ISB includes all health informatics standards within the NHS and those required by the NHS in relating to other agencies. Further information on the ISB, and on current and proposed standards, can be found at [www.isb.nhs.uk/](http://www.isb.nhs.uk/). Potential Providers may also find it helpful to access the new Health and Social Care Information Centre (IC) website at [www.ic.nhs.uk/](http://www.ic.nhs.uk/). The IC is the new Special Health Authority set up to co-ordinate and streamline the collection and sharing of health and adult social care data and works in conjunction with NHS Health and Social Care information Centre .

The Provider will be required to comply with standards approved by ISB and IHE where appropriate to the service being provided.

**6.19 Information Governance**

Information Governance provides a framework for handling personal information in a confidential and secure manner to appropriate ethical and quality standards. The Provider will be required to comply with specific information governance requirements which relate to all NHS service providers.

The Provider will be required to meet prevailing NHS standards and follow appropriate NHS guidelines for Information Governance. The “*Data Security and Protection Toolkit (dsptoolkit.nhs.uk)*” is available to NHS bodies to summarise information governance standards. It will be made available to the Provider;

Providers must not allow any patient information that they have access to or collect as part of the process of providing haemodialysis to be used for any other purpose other than the clinical management of patients. Any information that is collected for audit process must be appropriately anonymised and this includes the removal of all personally identifiable information including the patient’s postcode. Any use of patient information for any purpose other than providing the services under the services contract must be authorised by the Trust. This includes any internal company audits.

Providers will be required to comply with the following Information Governance requirements:

* [Confidentiality: NHS Code of Practice](https://www.gov.uk/government/publications/confidentiality-nhs-code-of-practice)
* [Data Protection Act 2018](https://www.gov.uk/data-protection) [Protecting and Using Patient Information - Caldicott Guardian’s Manual (2017)](https://www.google.co.uk/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwjDlLOztuGBAxVCTEEAHa0lA0YQFnoECA4QAw&url=https%3A%2F%2Fassets.publishing.service.gov.uk%2Fgovernment%2Fuploads%2Fsystem%2Fuploads%2Fattachment_data%2Ffile%2F581213%2Fcgmanual.pdf&usg=AOvVaw1NcQn7VJc9Dm5GS0LTdjAu&opi=89978449)
* The Department of Health’s Independent Health Care National Minimum Standards and Regulations- in particular the IM&T standards C1, C29, C30, C31, A1, A2, Schedule 1, 2 & 3 [Minimum Standards Regs](https://assets.publishing.service.gov.uk/media/6152d0b78fa8f5610b9c222b/Waste_classification_technical_guidance_WM3.pdf)
* BS 1S0/IEC 27001:2005 and BS ISO/IEC 17799:2005, for Information Systems Management;
* The Care Records Guarantee https://www.cqc.org.uk/; and [Reference guide to consent for examination or treatment](https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition) It is a requirement of registration under the Care Standards Act 2000 that Providers have in place appropriate systems for the management of information, not least in relation to ensuring Patient confidentiality.

**6.20 Information Quality Assurance**

The Provider will be required to comply with the Information Quality Assurance process managed by NHS Health and Social Care information Centre. This will include the requirement to undergo regular clinical coding audit to ensure consistency of clinical coding on which HRGs are based.

Information Quality Assurance is a process of self-assessment according to a detailed set of structured criteria set out in the Information Governance Toolkit.

Data submitted by the Provider, especially data submitted through may be subject to quality measurement. Data quality measures may form part of published NHS performance indicators.

**6.21 Data Protection Act and Access to Health Records Act**

The Provider will be required to comply with the Data Protection Act 1998 in its own right and to assist Health Service Bodies to comply with their obligations under the Act, in accordance with Clause 33 of the Services Contract.

Similarly, the Provider will be required to comply with, and assist Health Service Bodies to comply with, the Access to Health Records Act 1990.

**6.22 Management of Patient Records**

In maintaining Patient Records, the Provider will be expected to follow Good Clinical Practice. In compliance with law the Provider will be required to make available copies of its patient-related information in response to legitimate requests from Healthcare Professionals. Where the Provider is to be supplied with patient records and other Patient-identifiable information by Health Service Bodies, it will be required to comply with locally determined protocols for the transfer, storage, security and return of those records.

The Provider will be required to maintain largely electronic patient records, accepting that some incoming documents may be paper based (e.g. pathology results) and require retention and storage as a paper record. An appropriate and secure archiving system must therefore be used.

**6.23.1 NHS Data Standards, Datasets and Data Definitions**

The Provider must ensure that systems and procedures deployed for recording Patient or Service related information must be in accordance with NHS Data Standards which are currently recorded in the NHS Data Dictionary and the NHS CDS Manual. NHS Health and Social Care information Centre advises on the adoption of NHS Data Standards as well as providing access to written guidance and training material.

NHS data standards are periodically reviewed and updated to meet Department of Health and NHS requirements. The Provider will be required to adopt any changes to these data standards approved by the independent Information Standards Board. Notification of changes will typically be provided via a Information Standards Notices (previously known as Data Set Change Notices - DSCN).

There is a National Renal Dataset which was published under DSC notice 27/2008. The Provider will be required to collect appropriate data and return it to the Trust to enable it to meet all the relevant requirements of the National Renal Dataset. DSC Notice 02/2002 (March 2002) also identified the requirement to provide haemodialysis datasets. DSC 06/2004 (January 2004) also identified the change to site codes to enable ISTC activity to be identified. The Provider is expected to implement local arrangements to ensure the Trust can submit the CDS.

Potential Providers will be required to provide information in appropriate format for haemodialysis datasets submission. This may be through direct entry of activity into the PAS system or through a file upload into the PAS. This will be agreed with The Trust.

Providers should be aware that further National Data Sets are currently in development. The Provider will be required to implement relevant new datasets as they are adopted across the NHS.

**6.23.2 Data Quality**

Must:

1. Meet NHS Digital Data Standards
2. Meet Local and National rules, i.e. referral to treatment (RTT)
3. Interface appropriately with other Trust systems
4. Only allow staff to access modules they have been trained on

Include escalation & alerts functionality – e.g. to manage patient pathways

**6.24 National Administrative Codes Service**

The Provider will be required to register with the National Administrative Codes Service (NACS), which issues codes that uniquely identify healthcare providers and their facilities. Registration means the Provider is recognised as an independent provider of services to the NHS.

Separate codes will be required for the Provider itself and for each Facility from which it delivers the Services.

**6.25 Clinical Coding and HRGs**

The recording of high quality clinical data is essential for the proper assignment of HRGs which are used as part of the billing of electives procedures performed as part of the Services Contract. NHS Health and Social Care information Centre provides guidance and training on clinical coding standards. The clinical coding required for haemodialysis is a limited dataset and the Trust will provide guidance to the provider on how the haemodialysis sessions should be coded.

Providers must note that they may be required to use SNOMED CT to define clinical terms during the term of the Services Contract.

**6.26 Training**

The Provider will be responsible for the provision of all training required to enable the IM&T Services to be delivered (this includes both the IM&T services provided by the Trust and the Provider). This will include the appropriate training for Clinical Staff to enable all IM&T systems to be incorporated into their operational processes to support optimum efficiency and clinical effectiveness. The Provider will also be required to engage in training programmes associated with NHS Health and Social Care information Centre [www.hscic.gov.uk/systems](http://www.hscic.gov.uk/systems) or other relevant NHS IM&T requirements for which the Provider may incur a charge.

The Provider must ensure that staff that have access to any of the IM&T Systems used in the Renal Units (whether they are provided by the Trust or the Provider) and input and update data are trained to an appropriate level, at the Provider’s cost, that will be set by the Trust.

Training on the RIS may be provided via a service sub-contract with the Trust for the supply of these training services. This will be agreed locally.

Training may be provided on a “train the trainer” basis so the Trust expects to train one trainer at each facility. This trainer will then be responsible for cascade training within the facility.

The Trust will provide regular update training (at a frequency to be agreed in the service sub-contract). The Provider must ensure that all staff receive refresher/ update training as specified by the Trust.

The Trust may undertake regular data audits to ensure that the quality of data being entered into the IM&T systems that they are providing to the Provider meet local standards. Providers will be expected to implement any actions that arise from data audits which may include additional training of staff. This training must be undertaken, at the Provider’s cost, within a timescale agreed between the Trust and the Provider.

**6.27 Exit Strategy**

Supplier to provide the Trust with an exit plan (within 12 months of contract signature) which ensures continuity of service

1. Plan to include arrangements as part of a data taken-on exercise from the system to a standard format at contract end, or for migration into the replacement system. Data may vary by patient, age and group at the time of the work.
2. The Supplier must ensure that the exit plan clearly sets out the Supplier’s methodology for achieving an orderly transition of the Services from the Supplier to the Trust or its Replacement Supplier at the expiry or if the contract ends before the scheduled expiry.
3. The exit plan must set out full details of timescales, activities and roles and responsibilities of the Parties for:
   * + 1. the transfer to the Trust of any technical information, instructions, manuals and code reasonably required by the Trust to enable a smooth migration from the Supplier
       2. the strategy for export and migration of Trust data from the Supplier system to the Trust or a Replacement Supplier, including conversion to open standards or other standards required by the Trust
       3. the transfer of project- specific IPR items and other Trust customisations, configurations and databases to the Trust or a replacement supplier
       4. the testing and assurance strategy for exported Trust data
       5. if relevant, TUPE-related activity to comply with the TUPE regulations
       6. any other activities and information which are reasonably required to ensure continuity of Service during the exit period and an orderly transition
4. If relevant, data not included in the data taken-on to be extracted for the population in a secondary system, such as a data archive for use with a web-viewer or data warehousing applications
5. In limited cases, the Trust may wish to retain and maintain the outgoing application of a read-only basis for a limited number of users.
6. When requested, the Supplier will support the Trust to migrate the Services to a Replacement Supplier in line with the exit plan.
7. Costs for Professional Service will be in line with those confirmed in the contract. Scope of support to be agreed as per the Exit Plan
8. Server Hardware & Software Licensing will remain with the Trust at the point of termination (latest server software installed)
9. At a jointly agreed point in the exit process, post transfer of data to the Trusts custody, the supplier must provide:
   * 1. Destroy all Trust data including backup and archive copies of such data such that it is irrecoverable
     2. Provide written assurance to the Trust that this action has been taken

**6.28 Contract Management and Information**

1. The Supplier will have a system which will enable them to monitor, trace and audit the contract during the life of the agreement.
2. The Authority in accordance with their Duty of Care principles will agree a formal monitoring system with the Supplier, to commence at the start of the contract and be based on a continuous assessment process throughout the life of the contract.
3. The Authority reserves the right to inspect with or without prior notice, all records relating to the performance of the contract.
4. All reasonable requests for management reports or other similar information shall be adhered to as agreed by both parties.  In reference to this term reasonable is considered to be the following:
5. Urgent – to be provided on the same working day
6. High priority – to be provided within 3 working days
7. Routine – to be provided within 7 working days
8. The Supplier will provide a Service Review Report on a monthly basis which will confirm performance details against the agreed Key Performance Indicators.
9. The Supplier will provide the Authority with monthly detailed statistical data on operational activity. As part of the Bid response the Supplier is required to confirm all monthly statistical data that will be provided to the Authority.  The report will include as a minimum:

* Incident Overview
* Monthly breakdown of calls raised and call history
* Aged Incidents
* Open Incidents
* Problems

1. Contract Management meetings will be held on a quarterly basis to discuss strategic, service development issues, outstanding actions, contract variations, key performance issues, service quality/outcomes monitoring, invoicing issues, due diligence checklist (annually), sub-contractors, efficiency proposals & future developments

The Supplier will document the minutes and actions from the meeting and distribute them accordingly.

The format and frequency of meetings shall be subject to review between the Trust and the Supplier during the Contract period.

**7. FUTURE DEVELOPMENTS**

**7.1 Sites and Locations**

If the Provider chooses to deliver the services from alternative premises to those stated in Section 10.1 Location of Provider Premises which have an economic life beyond the life of the contract, and should the initial successful provider be unwilling to bid for a subsequent contract or be unsuccessful in securing a subsequent contract the Trust will have the option to require the transfer of assets at expiry of the services contract to the successful Provider of the subsequent contract (to be known as the New Provider). The New Provider will be required to pay the residual value payment to the outgoing service Provider, the residual value to be calculated by the District Valuation Office in accordance with the specific property contract under which the Provider is in occupation.

It is the Provider’s responsibility to determine if existing capacity is sufficient and to ensure that sufficient capacity is provided throughout the life of the contract. Historical growth and other supporting demand information is given in Section 2 Activity and Demand, although the Provider is expected to utilise due diligence when determining capacity and demand.

**8. APPLICABLE SERVICE STANDARDS**

The Provider is expected to comply with the legislative provisions of renal replacement therapy and the Care Standards Act (2000), and to provide services in accordance with regulations as defined by, but not limited to, the following authorities and organisations which may change over time:

**8.1 NHS England Service Specification A06/S/a – In Centre Haemodialysis (ICHD): main and Satellite Units**

**8.1.1 Regulatory bodies and legislation**

* Care Quality Commission and any successor organisations
* All applicable law on Health and Safety at work
* Anti-discrimination and equal opportunities legislation
* General Medical Council

**8.1.2 Professional bodies with an interest and national guidance**

* UK Kidney Association Clinical Practice Guideline for Haemodialysis 2019
* UK Renal Registry
* British Transplantation Society including all relevant clinical practice guidelines
* National and local health service bodies and relevant local government authorities
* Strategic Clinical Networks
* NICE guideline NG8: Chronic kidney disease: managing anaemia (2015).
* NHS Employment Check Standards
* CNST General Clinical Risk management standard appropriate to the service being delivered;
* National Service Framework for Renal Services
* Royal College of Physicians Clinical Standards for Renal Services

**8.4 Infection Control**

The Provider will comply with:

* L8 guidance on the control of legionella <http://www.hse.gov.uk/pubns/priced/l8.pdf>
* UKKA Clinical practice guidelines: Management of blood borne viruses within the Haemodialysis Unit <https://ukkidney.org/sites/renal.org/files/FINAL-BBV-Guideline-June-2019.pdf>

**8.5 Other Standards, Principles and Guidance**

* Safer Sharps **- EU Directive 2010/32/EU**
* The principles of Green Nephrology
* The NHS Standard Contract
* The British Renal Society: National Home Adaptation and Reimbursement Guidance for People undertaking Dialysis at Home

**9. REPORTING REQUIREMENTS**

In line with the requirements set out in this specification and the National Renal Contract, the Provider will be required to submit regular performance monitoring information. This will include both clinical and operational performance indicators associated with delivery of the services, for example, quality of care, speed of access, the Friends and Family Test, a Carers survey and the timeliness of reporting.

Indicative Local Contract Reporting Requirements are set out in Appendix 3 – Local Contract Reporting Requirements.

**10. PROPERTY**

**10.1 Location of Provider Premises**

It is expected that the Provider will be responsible for the provision of comprehensive haemodialysis care for patients under the care of the Trust within the following current locations:

**Figure 7: Location of provider premises**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Unit** | **Address** | **Land Owner** | **Building Owner** | **Status** |
| Bassetlaw | Bassetlaw District General Hospital, Blyth Road, Worksop  S81 0BD | Doncaster & Bassetlaw Hospitals NHS Foundation Trust | NHS Property Services | Satellite unit |
| Dearne Valley | Montagu Hospital, Adwick Road,  Mexborough  S64 0AZ | Doncaster & Bassetlaw Hospitals NHS Foundation Trust | NHS Property Services | Satellite unit |

**10.2 Site Requirements**

Access will be given to Trust staff to outpatient clinics, office accommodation and treatment rooms at no cost. Current requirements are:

**Bassetlaw**

2 clinical rooms

**Dearne Valley**

2 clinical rooms

**10.3 Property Agreements**

All locations will be maintained in accordance with the Lease Agreements that will be entered into on or before 1st April 2024. Basic heads of terms that will form the basis of the Lease Agreements for each individual property can be found as provided via the eu-supply portal. For the avoidance of doubt, no changes or additions should be made to the properties or locations without the prior written consent of the Trust.

**11. FINANCE**

For the avoidance of doubt, there is no guarantee of a level of dialysis activity at any unit or facility. The risk related to actual level of dialysis activity lies with the Provider.

**11.1 Pricing**

Providers’ unit prices should be inclusive of all input costs whether supplied directly by the Provider or subcontracted from other organisations, including the NHS.  The Trust will charge separately for any agreed service level agreements and these costs should be incorporated in the unit prices.

Prices will be based on 1st April 2024 levels and will be adjusted in accordance with the 2025 annual adjustment as detailed below to derive the price effective from 1st April 2025.

**11.2 Inflation**

An annual adjustment will be made to the unit price paid to the Provider. The mechanism that will apply will take account of the NHS efficiency requirement, as well as the inflation cost uplift factor included within the NHS National Tariff which is set each year.