Department of Economic Affairs

Green Book for Healthcare Sector

Guide for Practitioner's for PPP in Diagnostic Centre

CONTENTS

GUIDE FOR PRACTITIONERS FOR DIAGNOSTIC CENTRE

1. INTRODUCTION

Both Central and State governments have identified several important needs and taken initiatives to strengthen the health and medical care services for greater benefit of the people. Amongst various needs, greater access to essential investigation facilities, round the clock, for the patients at affordable cost is one of the critical aspects of modern healthcare services; there is also need to cope with the increasing load of the patients in essential investigation facilities situated within the government hospitals. In addition, round the clock investigation facilities would also enable the doctors to introduce proper and timely treatment protocol for the benefit of the patients.

To improve the health and well-being of the people has there is need to leverage resources from private sector to improve the modern healthcare services, one of the major components of the same is access to high-end diagnostic facilities, radiology facilities including CT scan.

Medical diagnosis presents a truer picture of the nature of disease, status of penetration of the disease, degree of cure and the health of the cellular components of the body. Medical treatment procedures have become highly dependent on diagnostic service to provide measured and accurate inputs. Keeping in view the requirement of evidence based medicine it is not surprising that more than 80% of the medical treatment is dependent on proper diagnostic inputs. Already, several states have started implementing projects under Public Private Partnership ("**PPP**"), for establishment of, diagnostic facilities, radiology facilities including CT scan facilities at district hospitals as well as essential diagnostic facilities in some of the rural hospitals.

Philosophically, the key objective of implementing healthcare projects on PPP basis would be to provide access to modern healthcare services to vulnerable and targeted sections of society such as economically weaker section patients/below poverty line patients ("**BPL Patients**"). In order to achieve the objectives set out hereinabove, the government ("**Implementing Agency**")proposes to develop/implement either greenfield or brownfield diagnostic centre in various Hospitals of the country which may include development of building and support infrastructure; installation of equipment's; and may provide clinical laboratory services, imaging services, support clinical services and facility management services (such as housekeeping and maintenance, etc.) to inpatients and outpatients of the concerned hospital.

With the intent to provide access to modern healthcare services to BPL Patients, the Implementing Agency proposes to implement diagnostic centre ("**Diagnostic Centre**") in various hospitals of the country where there are no diagnostic services or

the existing diagnostic capacity of the hospitals is insufficient to serve the entire population of such BPL Patients within the specified area.

- **Capacity of Diagnostic Centre:**

  - A Diagnostic Center can have a wide variance in terms of minimum capacity; it can be as low as one MRI or CT scan machine to a complete set up including radiology, imaging and clinical laboratory services. Thus the minimum capacity of the Diagnostic Center will be dependent on feasibility study which would take into account the technical and commercials aspects of a project facility, covering the required diagnostic services, usage requirements and the type of healthcare provided in the hospital

- **Services to be provided in Diagnostic Center:**

  - Clinical Services: The clinical services would cover both clinical laboratory services and imaging services in respect of healthcare diagnosis requirement.

    - Clinical laboratory services: The clinical laboratory services are conventionally divided into two, anatomical pathology and clinical pathology. Anatomical pathology includes histopathology, cytopathology, electro-microscopy etc. and clinical pathology includes microbiology, bio chemistry, hematology, genetics, reproductive biology etc.

    - Medical imaging services: Similarly medical imaging services comprise different imaging modalities and processes to image human body for diagnostic and treatment purposes. These may include plain radiography, fluoroscopy, angiography, mammography, computed tomography (CT), ultrasound, magnetic resonance imaging and nuclear medicine.

  - Support clinical services: The support clinical services would include services to support the clinical services and may include, help desk management, data and report capturing and integration with the existing hospital etc.

  - Facility management services: The facility management services would include help desk services, housekeeping services, material services (management of goods and supplies), plant services including facility maintenance, repair, and replacement, patient portering,

utilities management, etc.

A diagnostic centre may provide some of the abovementioned services or all, depending upon the project objective, hospital requirements, epidemiological assessment and budgetary outlay. Thus it is imperative that a detailed study is done before deciding upon the clinical services scope of the project.

- **Alternative models for development:**

  - *Alternative 1 – Development in clusters:* Under Alternative 1, the state government may appoint concessionaire for development of diagnostic centres for group of hospitals. Unlike other asset classes in healthcare sector where a project constitute a single site, normally, the PPP projects in diagnostic centres can involve the bundling of various projects by state government under one common umbrella and offering the collective package for private sector participation. Firstly at a state level all district hospitals where diagnostic centre development is required are identified (say 20 hospitals). Thereafter, district hospitals are packaged into clusters which typically constitute 3-6 district hospitals. Each package is treated as an individual project. The bidders can bid for any or all the packages. The bidders would need to submit single technical proposals for all the packages and separate financial proposals for each package.

  - *Alternative 2 – Development in single hospital:* This Alternative involves authority appointing concessionaire for development of diagnostic centres for an individual hospital.

  - *Recommended Approach:* The key advantages of alternative 1 over alternative 2 are:

    - Uniformity and Standardization: The clustering of projects under alternative 1 will enable uniformity and standardization of service level across hospitals in terms of diagnostic services. On the other hand under alternative 2separate services could be provided for different hospital as per the individual requirement.

    - Scale of investment and return: As investment and return levels for a single diagnostic centre can below, alternative 1 may provide an optimal scale of investment and return to attract private sector investment from established players. Under Alternative 2, the scale of investment and return may remain low, especially if the project is single service based, to attract established players.

- Combined Bidding Processes: Alternative 1 would involve a combined bidding process which would be less time consuming and cumbersome while alternative 2 would involve separate bidding process for development of their respective diagnostic centres.

- Increasing Affordability: Due to clustering of several projects better economies of scale may be achievable by the private player, under Alternative 1.Thus service prices may be more competitive than under Alternative 2.

In view of the inherent advantages available under alternative 1 over alternative 2 in respect of uniformity and standardization of service levels, scale of investment and return, combined bidding process, affordability, alternative 1 can be the preferred mode for development of diagnostic centres on PPP mode.

- **Nature of project:**

  - *Greenfield or Brownfield:* As Diagnostic Center are typically required to be set up within the existing hospital, usually built up space is provided for the setting up of Diagnostic Center. Thus the Diagnostic Center projects are by and large brown-field project. However, depending upon the non-availability of required built-up space within the existing hospital this may not always be the case, thus a vacant site within the hospital premises, may be provided to set up the Diagnostic Center. In such cases the Diagnostic Center project will be a green-field project. In the case of brown-field project concessionaire is required to upgrade the existing built-up space, whereas in case of green-field project the concessionaire will have to construct the facility also. The green field project will have there for higher cost than a brownfield project.

  - *Factors to Consider:* Thus the authority has to decide upon the nature of the project based on availability of built up space, lifecycle cost and benefit of upgrading such available built up space in contrast to constructing new facility, availability of vacant land within the site of the hospital, functional integration achievable with ongoing hospital operation in respect of the location of such vacant land and the services to be provided by the Diagnostic Center.

2. SCOPE OF THE PROJECT

- **Components of Diagnostic Centre:** The project scope will vary according to the objectives of the Implementing Agency, however the key components of scope of Diagnostic Centre project can be categorized into following:

    - *Design:* This includes all designs, drawings, calculations and documents pertaining to the development of project facilities. Based on the nature of the project i.e. whether greenfield or brownfield, design of infrastructure for Diagnostic Center at the provided site or design for upgradation of the existing built up space to establish the Diagnostic Center. The concessionaire would need to prepare the designs for the project facilities in accordance with the standards & specifications prescribed by the Implementing Agency (please refer to para 8.1) and submit the same with the Implementing Agency. The Implementing Agency will review the same and provide comments to the Concessionaire. If the designs are not in conformity, then the concessionaire would need to revise and resubmit the same with the Implementing Agency. Notwithstanding the review and comments of the Implementing Agency, complete responsibility for designs would vest with the concessionaire.

    - *Infrastructure:* The concessionaire would be required to develop the infrastructure of the Diagnostic Center. Based on the nature of the project i.e. whether greenfield or brownfield, development of infrastructure may include construction of the building of Diagnostic Center at the provided site or upgradation of the existing built up space to establish the Diagnostic Center. The Implementing Agency should provide a detailed explanation of the infrastructure scope and standards & specifications in the schedule to the concession agreement in terms of the off-site, on-site development, building components, construction responsibilities, testing and commissioning of the structure (please refer topara8.1).Any sub-contract by the Concessionaire should be granted through open tender process in order to maximize competitiveness, to ensure greater transparency and maximizing financial efficiency.

    - *Equipment's:* This includes procurement, installation and testing of the equipment and standards & specifications for the same (please refer to para. 8.2).Any sub-contract by the Concessionaire should be granted through open tender process in order to maximize competitiveness, to ensure greater transparency and maximizing financial efficiency.

- *Clinical services:* This will include as required clinical laboratory services and Imaging services for inpatients as well as outpatients.

  - Clinical laboratory services: The clinical laboratory services are conventionally divided into two, anatomical pathology and clinical pathology. Anatomical pathology includes histopathology, cytopathology, electro-microscopy etc. and Clinical pathology includes microbiology, bio chemistry, hematology, genetics, reproductive biology etc.

  - Medical imaging services: Similarly Medical imaging comprises different imaging modalities and processes to image human body for diagnostic and treatment purposes. These may include plain radiography, fluoroscopy, angiography, mammography, computed tomography (CT), ultrasound, magnetic resonance imaging and nuclear medicine.

- *Clinical support services:* This includes include IT and telecommunication services, health information management services, materials management services, systems and processes for integration with the hospital etc.

- *Facility Management services:* This includes general management services, help desk services, patient portering, housekeeping services, laundry and linen services, material services, plant services, protection services, utilities management etc.

- **Key issues to be address while defining project scope:** In defining the scope of the project, the concession agreement should clearly bring out the following:

  - *Capacity of Diagnostic Centre:* The infrastructure requirements of Diagnostic Centre to be as required based on usage requirements for various services envisaged.

  - *Specifying the Tests:* The schedule to the scope should elaborate the diagnostic test under each of the clinical service viz. the clinical laboratory service and imaging service as required.

  - *Addressing the usage risk:* A critical factor which the implementing agency will have to ensure is that all the inpatients and outpatients served by the hospital are referred by the hospital doctors to the Diagnostic Center so that optimal utilization of capacity can be

achieved. A corollary to this is that adequate provisions should be there in case of non-availability of service or emergency, such that patients can be referred to alternate service provider(s).

- *Segmentation of the Capacity:* Different categories of patients or distinction between the BPL Patients and any other patients, and reserving the capacity for BPL Patients. Segmentation of the capacity may be made by reserving (i) different time slot for BPL Patient and Private Patient or (ii) a percentage of the annual capacity of each of the equipment (x-ray, mammography, USG, CT Scan, MRI etc.) for BPL Patient. The Implementing Agency may also consider providing services at par to both BPL Patients and Private Patients on first come first serve basis. Such segmentation should be arrived at by factoring in the feasibility study; annual budget outlay of the Implementing Agency, regional demographics, socio-economic composition and such other relevant factors as may be considered.

- *Sub-contracting:* Any sub-contract by the Concessionaire should be granted through open tender process in order to maximize competitiveness, to ensure greater transparency and maximizing financial efficiency.

3. TERM OF THE AGREEMENT

- **Factors to be considered while deciding duration:** The concession agreement should specify the duration of the project. The factors to be taken into account while deciding upon the duration of the contract shall include:

  - Based on the scope of the project and services, cost and revenues from the project, the implementing agency will be required determine the optimal duration for the financial viability of the project.

  - The service requirements of the Implementing Agency and the required quality and quantity outputs in the longer term; the expected life of the assets underpinning the service; any possible residual value; and the need for and timing of major refurbishment or asset refreshment programme during the concession agreement.

  - The factors such as service requirements, forecast quality and quantity, expected life of assets, construction and maintenance requirements, forecast of the base cost, option to extend the term of the concession.

  - The importance of continuity in the delivery of the service, including

the degree of transition difficulties and inefficiencies that might be caused by changing/substituting the concessionaire. The affordability of the payments to be made by the Implementing Agency for the project.

- **Recommended Approach:** Given these factors the option for duration of agreement has to be arrived at by the authority which provides best value for money the project. The concession period in general for Diagnostic Centre project is 7-15years. On basis of whether the project is a brownfield or greenfield project development period may range from 0.5-1.5 years, the rest being the operation period.

4. PATIENT MIX

- **Options for Patient Mix:** In order to achieve to the key objective set out herein above, the Implementing Agency may provide differential benefits to BPL Patients and other patients. Based on the aforesaid, the term 'patient' may be divided into two categories under the concession agreement:

  - BPL Patients: This would include the vulnerable and targeted sections of society who falls under the definition of BPL Patient (as may be defined by the Implementing Agency).

  - *Non BPL patients:* This would include the patients who do not fall under the definition of BPL Patient ("**Private Patients**").

- **Recommended option for Patient Mix:** The concession agreement may provide for such segmentation/ categorisation of patients based on feasibility study, annual budget outlay of the implementing agency, regional demographics, socio-economic composition and such other relevant factors as may be considered.

- **Key issues to address:** The categorisation of patients requires concession agreement to address following issues:

  - *Mechanism for identification of BPL patients:* Where there is a segmentation of different classes of patients, the concession agreement should clearly specify the institutional mechanism for identification of BPL Patients. This may be in the form of Implementing Agency constituted cell.

  - *Specifying proportion of healthcare infrastructure for different category of patients:* Where there is a segmentation of different classes

of patients, the concession agreement should clearly specify a percentage of capacity or usage level which is to be achieved for BPL Patients for in-patient services. For out-patients service, a time variance approach can be adopted for different categories of patients.

5. PRICING MECHANISM[1]

- **Options for pricing:** The pricing of the services is one of the critical aspects in a Diagnostic Centre PPP as it impacts both the affordability and accessibility of diagnostic services. In this context, various options to determine pricing have been outlined below:

  - *For BPL Patients*: The following options may be followed for pricing of services to BPL Patients:

    - Option 1 - Benchmarked to CGHS prices: The concession agreement can specify that the pricing applicable under Central Government Health Scheme ("**CGHS**") to be followed by the concessionaire in pricing the healthcare services. CGHS provides comprehensive health care facilities for Central Government employees, pensioners and their dependents residing in CGHS-covered cities. Generally, two models are adopted for application of CGHS pricing: (a) city pricing at applicable rates, and (b) city pricing at a discounted rate, or where city pricing is not available, CGHS rates applicable for a nearby city are discounted and used.

    - Option 2 - Benchmarked to SGHS prices: The concession agreement can specify that the pricing applicable under the State Government Health Scheme ("**SGHS**") to be followed by the concessionaire in pricing the healthcare services.

    - Option 3 – Agreement specified pricing: A detailed pricing structure can be included in the concession agreement, wherein the prices for all services which are to be delivered under the project can be specified in the concession agreement. This approach requires a thorough working out of the services to be

[1] ***Note**: The pricing model adopted should be sensitive to Section 9(ii) of the Clinical Establishment (registration and regulation) Act, 2010 which provides that the clinical establishment shall charge the rates for each type of procedure and services within the range of rates determined and issued by the Central Government from time to time, in consultation with the State Governments.*

delivered and the prices for each of the service. Alternatively, the prices can be benchmarked to state hospital diagnostic service charges, whereby the services to users can be provided as per the prevailing prices for such services in a benchmark state hospital.

- *For Private Patients (Non - BPL Patients)*:The following options can be followed for pricing of services to Private Patients:

  - Option 1 - Benchmarked to CGHS prices: The concession agreement can specify that the pricing applicable under CGHS to be followed by the concessionaire in pricing the healthcare services. CGHS provides comprehensive health care facilities for Central Government employees and pensioners and their dependents residing in CGHS-covered cities. Generally, two models are adopted for application of CGHS pricing: (a) city pricing at applicable rates, and (b) city pricing at a discounted rate, or where such city pricing is not available, CGHS rates applicable for a nearby city are discounted and used.

  - Option 2 - Benchmarked to SGHS prices: The concession agreement can specify that the pricing applicable under the SGHS to be followed by the concessionaire in pricing the services.

  - Option 3 – Agreement specified pricing: A detailed pricing structure included in the concession agreement, wherein the prices for all services which are to be delivered under the project can be specified in the concession agreement. This approach requires a thorough working out of the services to be delivered and the prices for each of the service. Alternatively, the prices can be benchmarked to state hospital diagnostic service charges, whereby the services to users can be provided as per the prevailing prices for such services in a benchmark state hospital.

  - Option 4- Market pricing: The concession agreement will provide freedom to concessionaire to determine and charge the patients market determined prices for services. This approach is suitable where there is adequate competition for healthcare service delivery; else it would lead to a monopoly pricing.

- **Recommendation for pricing standards:** In order to implement the options

set out hereinabove, there are two approaches for pricing the services:

- *Option 1 - Uniform pricing*: Under this approach, there is no differentiation in pricing among different categories of patients (such as BPL Patients and Private Patients), and single price regime should be followed for health services provided to BPL Patients and Private Patients.

- *Option 2 - Mixed Approach*: Under this approach, there is differentiation in pricing among different categories of patients (such as BPL Patients and Private Patients), and different price regime should be followed for health services provided to BPL Patients and Private Patients.

Thus, there can be two kinds of approach for pricing within which there can be two different options specified above (such as specified CGHS pricing for BPL Patients coupled with market pricing for Private Patients or uniform pricing for both). The primary issue associated with mixed pricing approach is that it leads to discriminatory treatment towards BPL Patients, as the pricing fixed for these patients is typically lower than the pricing fixed for Private Patients. Hence, it is recommended that the uniform pricing approach should be adopted.

- **Key issues to address:** In defining price regime, following issue need to be addressed;

  - *Revision of Prices:* The PPP agreements usually have a long tenure in such cases, so the cost of the service delivery is likely to go up during the concession period. To provide for such eventuality, the concession agreement needs to provide for a mechanism for revision of prices, which can be done in following ways:

    - Market Pricing Regime: Under market pricing regime, there is no need to incorporate price revision or indexation provisions. However, in such cases it is prudent to have an Implementing Agency check point to ensure that the health care services prices do not become arbitrarily high.

    - Specified Pricing Regime: In cases where prices for services are specified in the concession agreement, the concession agreement should also provide for the revision procedure for such prices. The revision procedure should incorporate the principles for inflation indexation.

- *Non-Inclusion of free services:* In setting up a pricing regime, the Implementing Agency should refrain from obliging the concessionaire from providing free services (no reimbursement to concessionaire for such delivery of services) to BPL Patients, as it may create potential for discrimination by the concessionaire against BPL Patients. A better approach is to price the services for all and develop a payment mechanism for such services which benefits the BPL Patients.

6. USER FEE/PAYMENT FOR THE SERVICES

- **Introduction:** Collection of User Fee and the payment mechanism lies at the heart of the concession agreement and forms the consideration for which parties have entered into the concession agreement.

- **Options for Payment for Diagnostic services:** For payment of healthcare services provided to BPL Patients the following options can be adopted in the concessionagreement:

  - *Option 1 - Reimbursement by the Implementing Agency for diagnostic services to BPL Patients:* Under this approach, the Implementing Agency would reimburse the concessionaire for the diagnostic services provided to the BPL Patients.

    Cap on Reimbursement: The objective of the Implementing Agency is to extend affordable diagnostic benefits to BPL Patients being treated at government hospital. While pursuing such objective, it is equally important that the total consideration to be paid/ reimbursed by the Implementing Agency for the services given to BPL Patients should be within the budget of such agency. Accordingly, concession agreement may provide for caps on such reimbursement. Typically, there are two approaches within the healthcare sector to sustain the affordability:

    - *Budgetary cap on reimbursements*: In this approach, a budgetary cap is fixed by the Implementing Agency in respect of the maximum reimbursements to be made to the concessionaire for services to BPL Patients.

    - *Cap on number of BPL patients*: In this approach, a maximum limit is fixed on the total number of patients for whom the Implementing Agency will reimburse the charges.

    The above stated models should be based on a thorough analysis of the

Implementing Agency's budget outlay, projected demand for diagnostic services, regional demographics and socio-economic assessment. Such budgetary cap should have adequate built in margins, to factor the increase in population. Further, the concession agreement should provide suitable safeguards to go above and beyond the reimbursement caps in case of emergency, natural calamities, epidemics etc.

- *Option 2 - Reimbursement through central/state insurance schemes for treatment of BPL Patients:* Under this approach, central/state insurance provider would reimburse the concessionaire for the treatment provided to the BPL Patients. For e.g. an insurance scheme may specify surgical/non-surgical services in respect of which the entire sum (as set out under such insurance cover) would be paid by the central/state insurance provider. Such payment will cover the payments for the diagnostic services. In this case, there would not be any reimbursement from Implementing Agency.

- *Option 3 – Partial reimbursement through Central/State Insurance Scheme and the balance Implementing Agency:* This approach can be used in conjunction with the reimbursement by Implementing Agency i.e. central/state insurance provider, through the government insurance scheme, would reimburse the concessionaire for the treatment provided to the BPL Patients to the extent of insurance cover and shortfall, if any from applicable tariff structure would be reimbursed by the Implementing Agency. For example, an insurance scheme could involve a fixed cover of say Rs. 150,000 (Rupees One Lakh Fifty Thousand only) per family per annum and in case the medical expenditure exceeds the specified limit, such excess shall be reimbursed by the Implementing Agency to the hospital.

For payment of diagnostic services provided to Private Patients, the concessionaire should directly collect charges from Private Patients for services provided to them.

- **Recommended Option:** Among the above models of reimbursement, reimbursement via government health insurance schemes could work out as the most effective tool for ensuring payment for the health care services. However, this model has limitations as many states do not have state insurance policies. Thus, the optimal option is to provide for reimbursement by the Implementing Agency for the health care services in states, where the state insurance policies are non-existing. This option fulfills the objective of providing accessible and affordable health care to BPL Patients.

7. PAYMENT SAFEGUARDS

- **Options for payment safeguard:** A critical area of concern is that concession agreement defined timelines for payments of service fees may not be adhered to by the authorities. This can lead to the problem of liquidity and reduce the project viability. To resolve this issue, the concession agreement can follow two options:

    - *Option 1 No payment safeguard:* No safeguards are provided to the private partner. However, the concession agreements may provide for penal interest for delay in payment by the Implementing Agency, which is linked to SBI PLR + 2-4% per annum.

    - *Option 2-Payment safeguards:* Typically, two types of payment safeguards are available for protecting the interest of the concessionaire:

        - **Payment reserve account**: The concession agreement can provide for a payment reserve account (PRA), wherein the Implementing Agency has to deposit specified months revenue. In the event of any default or delay in payment by the Implementing Agency, the concessionaire can withdraw such amount from the PRA without notice. The Implementing Agency has to replenish the PRA within specified number of days.

        - **Letter of credit**: The concession agreement can provide that the Implementing Agency provides for an irrevocable and revolving letter of credit equivalent to specified months revenue to the concessionaire, as a security for payment of service fee. In the event of any default or delay in payment by the Implementing Agency, the concessionaire can invoke the letter of credit without notice. The Implementing Agency has to replenish the letter of credit within specified number of days.

- **Recommended option:** Though interest provisions intend to compensate the aggrieved party for the delay in payment, by far this has failed to prove as a standalone safeguard mechanism, and it can lead to dispute over payment of interest. On the other hand, option 2 of providing the payment safeguard such as a payment reserve account or a letter of credit can be an effective safeguard mechanism which can ensure payment discipline on the part of the Implementing Agency and protect the interest of the private player.

8. PERFORMANCE SPECIFICATION

To effectively manage performance and optimise risk transfer, the concession agreement should contain, at a minimum, the following elements:

- **Performance specifications:** Describing the requirement in terms of measurable outcomes rather than by prescriptive or input methods.

- **Measurable performance standards:** To determine whether performance outcomes have been met and define acceptable performance.

- **Performance assessment plan:** Describing how the concessionaire's performance will be measured and assessed against performance standards. (Quality Assurance Plan or Quality Assurance Surveillance Plan).

- **Remedies to poor performance:** Describe procedures that address how to manage performance that does not meet performance standards (please refer to para. 8.5). While not mandatory, incentives should be used, where appropriate, to encourage performance that will exceed performance standards. Remedies and incentives complement each other.

The project scope varies from project to project, based on the scope PPP arrangement in the healthcare sector, specifications would typically fall into the following categories:

8.1 Infrastructure specification

- **Design specification:** The concession agreement should elaborate the design specifications, depending upon the nature of project i.e. whether a greenfield or a brown field project. Where the project is a greenfield project, construction of facility would be required, thus detailed specifications may be arrived at on the other hand such detailed design specifications may not be required for upgradation in a brownfield project. Specifications as far as possible should be in terms of the output required where in the following approach can be taken:

    - Design as per the applicable regulations/frameworks: Where applicable design of the Diagnostic Centre can be required to follow the applicable regulations.

    - In addition, the concession agreement can provide for output based specifications for the design of the Diagnostic Centre. Where this approach is followed, the concession agreement shall provide for the following to ensure design quality:

- Technical standards and requirements which are to be achieved, to ensure optimal functioning of the project facility. This should be achieved not by specifying the design but by describing the output required from the structure and other structural elements as well as and functional integration, with existing hospital, of the diagnostic services to be delivered.

- Design quality plan, wherein the concessionaire should be required to submit its strategy along with timelines for formulation of design, including consultation with stakeholders, experts involved, internal review mechanism and submit the same to the independent monitor and Implementing Agency for review. The concessionaire should carry out revisions in the design quality plan based on the comments of the independent monitor and the Implementing Agency and also demonstrate achievement of the optimal functional integration of the services delivery with the hospital.

- **Development performance requirements:** In case of greenfield project where the concessionaire is required to construct the facility on the site provided, the construction performance specifications are also to be provided in the concession agreement. For the brownfield project, where the built up space is being provided, the upgradation performance requirement will have to be provided. The following framework can be utilized for specifying the performance requirement.

  - Defining the development scope: The concession agreement should specify all the structural elements and components of the project facility which is to be constructed or upgraded. This will have close correspondence with the design specifications. The development scope should clearly bring out the work required to be carried out for different components of the project facility.

  - Development Standards: In defining the scope of development, the second aspect is to define the standards which have to be adhered to, in creation or upgradation of different components, including the regulated standards which have to be achieved.

  - Construction Timelines: The concession agreement should clearly specify the timelines for various stages of the construction. Delay in achievement of such timelines should be penalized.

  - Development Quality Plan: The concessionaire should be required to

submit a development quality plan. Such a plan should be submitted prior to start of the construction or the upgradation and should be approved by the independent monitor. The plan should outline the approach to and adherence to the design, applicable quality standards, time lines and tests. Tests to be conducted at different stages of construction or upgradation should be elaborated along with the rectification measures required in case of failure of such test.

8.2 Equipment Specification

In outlining the equipment specification the following framework can be adopted, wherein there is an equipment list and an individual equipment data sheet for equipment of the diagnostic centre. This has to be supplemented by the equipment maintenance plan to be submitted by the concessionaire. The Equipment Specification should be divided into two parts wherein, these elements are described below.

- **Equipment List:** A list may be provided enumerating the equipment's in following format:

Equipment identification Number	Reference	Item Description	Further Description	Quantity	Procurement Category
	To Clinical/ Clinical Support/ Facility management service for which equipment would be utilized.	The Name of the equipment	The description of attachment and ancillaries		By the Concessionaire/ Implementing Agency

- **Equipment Data Sheet:** These would need to be developed by the Implementing Agency for all equipment's, as described in the equipment list. This would detail out the minimum acceptable performance requirement as per the current standards of technology and anticipated project requirements**.** Here, the approach can be either to provide a detailed specification for each of the equipment, as required. However, this approach can be constraining as there may be a possibility that at same cost, the concessionaire may be able to procure better equipment. Thus, an optimal approach is to set the minimum standards by referring to a manufacturer and model number for the equipment, as it would be available at the time. The data sheet should provide detailed specification of the equipment identified. The Concessionaire in its procurement must meet or exceed the specifications of the referenced manufacture or model number. The equipment data sheet format can be as below:

Particulars	Description
Item description	Matching the description on the equipment list
Equipment number	Matching the description on the equipment list
Reference Manufacturer-Model Number	Provide reference to manufacturer(s) and model number(s) for equipment.
Detailed description	Here detailed specifications should be provided for the referenced equipment.
Performance Standards	Installation and tests Daily and monthly minimum utilization levels for the equipment Uptime requirement of the equipment Problem rectification timelines Standby arrangements in case of equipment failure for services delivery

- **Equipment Maintenance Plan:** As the third aspect of the performance requirement the Concessionaire should be required to submit equipment maintenance plan, where in the concessionaire should list out:
    - The schedule for routine or planned maintenance for each of the equipment.
    - The planned replacement of the equipment depending upon the equipment life
    - Reactive maintenance plan, where in the equipment should be categorised into rank order of importance/criticality for delivery of different health services. Based on this categorisation adequate timelines for rectification of problems should be mandated in the concession agreement. Non-rectification within the timeline should be regarded as quality failure.
    - Where service failure is being monitored and service standards are in place, separate penalty for equipment failure should not be warranted. However, adequate protection should be there for continued non-availability of the mandated number of equipment's. This will constitute a quality failure.

8.3 Performance specification of clinical and clinical support services:

- **Introduction:** The key objective of the Diagnostic Centre project is to provide diagnostic services to different types of patients. Depending on the project scope, the Diagnostic Centre may have to provide wide range of services to inpatients and outpatients.

    - *Clinical services:* This will include as required clinical laboratory services and Imaging services for inpatients as well as outpatients.

        - Clinical laboratory services: The clinical laboratory services are conventionally divided into two, anatomical pathology and clinical pathology. Anatomical pathology includes histopathology, cytopathology, electro-microscopy etc. and Clinical pathology includes microbiology, bio chemistry, hematology, genetics, reproductive biology etc.

        - Medical imaging services: Similarly, Medical imaging comprises different imaging modalities and processes to image human body for diagnostic and treatment purposes these may include plain radiography, fluoroscopy, angiography, mammography, computed tomography (CT), ultrasound, magnetic resonance imaging and nuclear.

    - *Clinical support services:* This includes include IT and telecommunication services, health information management services, pharmacy services, materials management services, systems and processes for integration with the hospital etc.

- **Service Specification:** It is important that a comprehensive detailing of the services to be delivered in the project facility is carried out and service specifications are developed for each service. The concession agreement should bring out the output services specification for each of the clinical and support clinical services in detail. The framework for performance specification of clinical and clinical support services is provided below:

S.N	Parameter	Detail
1.	Service Description	The service description should provide as applicable, an overview of the clinical scope of the service. It should also bring out any specific service exclusion that is either provided as part of other services or is not provided at the facility at all.
2.	Operational Description	Operational parameters for each service should be defined in terms

S.N	Parameter	Detail
		of the following elements
(a)	Minimum hours of operation	The availability of the service in terms of hours and days. Unavailability of service during mandated hours will constitute service failure.
(b)	Patient Management Process	The patient flow process can be worked out from entry into the service system to exit. Based on this patient flow process service standards can be established for services.
(c)	Patient Information Management	This section will describe the information and record management for the patient. Ready availability and processing of the patient information will constitute service performance standard.
(d)	Staff Work Process	On the basis of the patient management process the staff work process can also be developed. Service level standards based on the staff work process can be established.
(e)	Linkage to non-clinical services	Here linkage to non-clinical service in terms of material services required, housekeeping services required and equipment required can be elaborated.
3	Projected Handling Capacity	Here minimum expected level of the patient traffic that the services should be able to handle should be provided. Inability to meet the minimum patient traffic will serve as service failure
4	Staff Requirements	Here the minimum staff required for the optimal performance and delivery of the services may be stated. Inadequate availability of staff would constitute service failure.
5.	Service Standards	For each element of the service as discussed above the service standards should be specified along with monitoring frequency. Non-achievement of service standards should comprise a service failure event.
6	User satisfaction Survey	Provision can be made for quarterly survey of the user satisfaction survey for the services delivered.

- **Example of Performance specification for Ultrasonography (USG)Services:**

S.N	Parameter	Performance Requirement	Indicative Service Standards
1.	Service Description	Scope of USG Services will include: 1. Provision of facilities for the examination, Ultrasound, abdomen/pelvis USG; KUB USG; Thorax USG/Orbit USG/skull/neck USG ; Obstetric((Routine, Advanced Scan) / TIFFA; Trans Vaginal/ Trans Rectal	

S.N	Parameter	Performance Requirement	Indicative Service Standards
		Sonography; Thyroid/ Parotid; Follicular study; Knee joint/ Hip joint/ Ankle joint USG; Shoulder joint USG/ Local USG; USG as specified. 2. Provision for patient to consult the Radiology-USG consultant,	
2.	Operational Description		
(a)	Minimum hours of operation	The USG services will operate from 0600 to 2200 hours, 365(6) days annually. Emergency Cases 24 hours service	Unavailability of the USG services
(b)	Patient Management Process	1. Reception/registration/booking 2. Scheduling the examination 3. Pre-examination preparation 4. Examination 5. Post –Examination care	Time taken for patient registration Waiting time for patients at different stages
(c)	Patient Information Management	Patient registration, billing information for services provided, security and confidentiality of information, diagnostic report preparation, Report delivery	Time taken in registering patient. Time taken in processing the insurance formalities. Time taken in delivering the diagnostic report to the patients
(d)	Staff Work Process	1. Reception/registration/billing Functions 2. Appointment booking 3. Preparation of chart 4. Consultation/Examination 5. Post Examination care 6. Diagnostic report delivery	Time taken in completion of various stage of process Minimum number of faults in execution of each stage Development of defined consultation/examination protocol for various ailments and adherence to it.
(e)	Linkage to non-clinical services	Information Capture and management Integration with Hospital Housekeeping services Equipment requirement	As per the performance standards mentioned in Clinical support and facility management service specification
3	Projected Handling Capacity	1. New patient consult 2. Follow up visits	At minimum 200 new patients daily or 6,000 patients monthly At minimum 50 follow up

<table>
<tr><th>S.N</th><th>Parameter</th><th>Performance Requirement</th><th>Indicative Service Standards</th></tr>
<tr><td></td><td></td><td></td><td>patients daily</td></tr>
<tr><td>4</td><td>Staff Requirements</td><td>An indicative approach to specifying number of staff required:
<table>
<tr><td>Diagnostic service</td><td>Nurse</td><td>Technical Attendant</td><td>Specialist</td></tr>
<tr><td>USG</td><td>4</td><td>2</td><td>2</td></tr>
</table></td><td>Availability of requisite staff at all times of USG service operation</td></tr>
</table>

8.4 Outcome Indicators for Clinical Performance

- **Introduction:** In addition to the service performance indicators above the concession agreement may also include outcome based indicators to monitor the outcome of the diagnostic services.

- **Indicative Framework for Specifying Outcome Indicator:** An ideal outcome indicator would capture the effect of diagnostic processes on the delivery of relevant and accurate diagnostics. An example of framework for specifying outcome indicators is shown in table below.

Category	S. No	Indicators
Clinical Service Specific Outcome Indicators (compiled for each inpatient Clinical Service offered at the project)	GO1	Number of patients provided diagnostic services
	GO2	% of patient serviced within service standards
	GO3	% on time Delivery of Diagnostic Report
	GO4	% emergency request responded within service standard
	GO5	% Post examination patient treatment protocol adherence
	G06	% Patient Satisfaction

- Outcome of care is determined by several factors related to the demography, patient, the illness, and health care. Differences in outcome may be due to case mix and other confounding factors. Standardized data collection and risk adjustment are therefore important for interpreting outcomes data.

- The Concessionaire should be obliged to provide data and reports on the specified outcome indicators on regular basis to the authority. Authority upon any deterioration overtime in any of the indicators may be empowered to take suitable remedial action.

8.5 Performance Indicators with respect to the BPL patients

- The authority may define a composite set of performance indicators to monitor the service delivery to the target vulnerable segment including the BPL patients. Here a twofold approach can be adopted;

    - Separate indices for the specified standards: under this approach the service performance for the BPL patient can be separately tracked and maintained for the specified service standards, as developed based on the methodology outlined in the section 8.3. Similarly performance pertaining to BPL patients can be tracked for the outcome indicators as developed based on the methodology indicated in the section 8.4. Such performance monitoring will allow a comparison on the performance standards achieved for the BPL patients with the overall performance on service delivery to patients.

    - BPL patient specific Indicators: The concession agreement may supplement above or as standalone define BPL patient specific indicators for monitoring service delivery to such patients. Such Indicators may include as below;

`		Indicators
Service Access and Quality Indicators	BAQO1	% of BPL patient to total patients
	BAQO2	Average waiting time for BPL patients
	BAQO3	% Adherence to defined treatment protocol for BPL patients
	BAQ04	BPL complaints rectification rate

8.6 Performance Specification of non-clinical services

- **Introduction:** The concession agreement schedule should bring out in detail all the non-clinical services which are to be performed by the Concessionaire. The non-clinical services in a hospital project will comprise of general management services, help desk services, food services, patient, housekeeping services, laundry and linen services, material services, plant service, protection services, utilities management, parking services, etc.

- **Facility management service performance specification framework:**

<table>
<tr><th></th><th></th><th></th></tr>
<tr><td>1.</td><td>Services Specification</td><td>For example if we take the House keeping service</td></tr>
<tr><td>(a)</td><td>General Requirement</td><td>This Section should include the general performance requirements for the service in terms of delivery, general standards, obligation under the concession agreement, integration with other clinical and non-clinical services etc.</td></tr>
<tr><td>(b)</td><td>Elements of Service</td><td>House Keeping service consist of three main elements as follows
Cleaning and waste management services
Pest Control services
Quality Monitoring</td></tr>
<tr><td>(c)</td><td>Element wise facility management service specific performance requirements</td><td>These are specific performance specifications for each element of the service. Where required the regulations and standards to be met for each component are can also be included. The service requirements also include as applicable the required service standards.For example for cleaning and waste management the specific service requirements may include
ESP-1: Cleaning to the standards as required under the concession agreement and as required under the applicable quality standards
ESP-2: Provide a routine cleaning service on a 24 hour a day, 365(6) days per year basis to meet the requirements of this concession agreement in all areas of the project facility.
ESP-3: Provide a reactive cleaning service on a 24 hour a day, 365(6) days per year basis to address the ad-hoc emergency, urgent/or routine cleaning requirements within the service response time specified for such categories(emergency, urgent, routine).</td></tr>
<tr><td>(d)</td><td>Define Performance Indicators and FM service benchmarks</td><td>For each element of the service the key performance specifications (service requirements) should be taken as the performance indicators. Where the Parameter is defined, type of service failure (quality failure event or delivery failure event), category (high, medium low for quality failure) or (A-E for service failure based on facility component where such failure takes place) may be defined and monitoring frequency is defined. Service standards should be set up for performance parameter as applicable. Example of Performance Indicators for Cleaning and Waste Management.
<table>
<tr><th>Ref</th><th>Parameter</th><th>Failure type</th><th>Category</th><th>Monitoring Frequency</th></tr>
<tr><td>ESP-1</td><td>All components of the different functional areas of facility cleaned to the standard as</td><td>Quality Failure</td><td>High</td><td>Weekly/Monthly</td></tr>
</table></td></tr>
</table>

			specified in appendix		
		ESP-2	Routine Cleaning service completed to quality standards and infection control policies as per the schedule	Delivery Failure	A-E	Weekly/Monthly
		ESP-3	Reactive Cleaning services completed to the quality standards and infection control policies within the specified response time	Delivery Failure	A-E	Weekly/Monthly
e)	Provisions for customer feedback and User satisfaction survey for the service	The concessionaire should also provide for system of recording and acting on customer feedback and satisfaction through customer service survey conducted quarterly which can also be one of the performance parameter.				

8.7 Options for Remedies of Poor Performance

The poor performance of the concessionaire has to be disincentivized through concession agreement provisions. The concession agreement should set up a defined performance regime in respect of the service delivery and based on such performance standards service failure event should be defined. The implementation of the remedies for poor performance in monetary terms is as follows:

- **Service failure event deductions:** Service Failure events are service performance failures related to services to be delivered by concessionaire within the facility including clinical, clinical support and facility management services, for example non-availability of CT scan equipment constitutes service failure. Service Failure events can be recorded and deductions calculated on a daily basis. Service Failure event deduction can be based on:
    - **Criticality factor**: The relative importance of the service affected by the failure event. The criticality factor can be the Rupees amount per service, detailed in the schedule and is based on significance weighting of zero to five of the service.
    - Number of days affected by the failure event
    - The severity of the failure event, i.e., the failure event category. The failure event category can be assessed based on the inconvenience,

remaining functionality and incapacity of the service delivery resulting from the failure event and in accordance with the output specifications. Percentage deductions range from 10% for category "A" failure event or routine failures to 100% for a category "E" failure event or "unavailable or unused."

- For most failure events, a rectification period may be allowed within which the failure can be corrected in which case it would not be marked as a failure event.

- Relief measures can also be provided against failure events, such as providing suitable alternative accommodation to carry out the services.

- **Quality failures deductions:** Service performance failures are not related to delivery of services but the quality of such services, where in the services fail to meet the quality standards outlined in the service specifications; for example the CT scan equipment is available but the cleanliness and sterile environment is not up to specified standards. Herein a service quality failure has occurred which can be recorded and deductions can be calculated as per the specified formula. Such performance failures can be monitored either on a daily basis or as in the case of quality satisfaction failures, on periodic basis. A quality failure deduction is based on three factors:

  - Relative importance of the service in delivery of which the quality failure occurs. Each service can be given a weighting in proportion to the criticality factor.

  - Severity of the quality failure, and the quality failure category, ranging from 1% for a low priority failure to 2% for a high priority failure

  - The time period over which the quality failure occurred

  - Quality satisfaction failures can be assessed based on a survey of services' users; failure deduction percentage ranges from 0.5% for a minor failure to 2% for a significant failure.

- **Incorporation in payment mechanism:** Both the deductions have to be incorporated in the calculation for payment due for the period in which the failure event occurs. In cases where the concessionaire is not being paid by the Implementing Agency in any form, the penalty will be recovered by the Implementing Agency on a monthly basis.

9. PERFORMANCE MONITORING

- **Introduction:** There must be a mechanism under the concession agreement which enables the Implementing Agency to monitor the concessionaire performance against the performance requirements so that the project can operate effectively. The Implementing Agency should also be able to identify performance problems so that remedies for poor performance can be pursued if necessary. This entails a need for mechanism to ensure monitoring of the project.

- **Levels of Performance Monitoring:** Depending on the project magnitude, the monitoring should occur at five levels:

    a. *Independent Monitor:* The concession agreement must provide for an independent monitor to review the performance against the performance indicators. There may be a need to appoint following independent monitors during the construction phase and the operations phase of the project.

        - Independent Engineer: An independent engineer can be appointed for monitoring during the construction phase to inspect, test and monitor the construction works. In the operations phase the independent engineer would be responsible for inspection, verification and testing for building and equipment maintenance requirements.

        - Independent Health Consultant: In the operations phase, the independent health consultant will be required to monitor clinical, support clinical services and facility management services as per the required performance standards. Such Consultant should be appointed prior to operations date so that they can be part of testing of equipment's prior to issue of completion certificate.

        - Nature of Project: Where the project is a brownfield one, requiring upgradation of existing built up space, the need for having an independent engineer may not be there. Thus the implementing agency in such cases may not provide for an independent engineer in the agreement. The testing of equipment's in such cases can be sole responsibility of the independent health consultant.

    b. *Concessionaire:* A systematic self-monitoring by the concessionaire through a quality management system, measuring availability and

performance of services to the specified performance standards. The concessionaire should report the outcome of such monitoring on a periodic basis (monthly) to the independent monitor.

c. *User Satisfaction Survey:* The ability for users to report failures by way of including the complaint mechanism and user survey provisions.

d. *Accreditation Requirement:* The concession agreement will provide provisions for requirement of accreditation from specific agencies, such as National Accreditation Board for Medical Imaging Services (the "NABMIS") or National Accreditation Board for Laboratories (NABL). NAMBIS accreditation would be applicable when the diagnostic center is providing Medical Imaging Services and NABL accreditation would be required when the diagnostic centre is providing clinical laboratory services.

e. *Disclosure on Website*: The concession agreement will provide that the Diagnostic Centres should update on its website on weekly basis the facilities used by and available for BPL Patients. Further, in order to provide transparency, all reports should be published at the website of the Hospital or Diagnostic Centre.

- **Recommended performance monitoring mechanisms:** There is no single best option; the most optimal approach is to have a multi-layered monitoring framework. In the multi-layered framework the key elements will be the Independent Monitor and the user satisfaction survey. Around these elements other options can also be included in the concession agreement. The layered approach to monitoring provisions needs to be in line with the magnitude and scope of the project. This will ensure that where it is possible to have a less onerous system, it will be in the interest of all parties to do so. Equally, where the scope is large and project magnitude demands, a rigorous monitoring system needs to be specified in the concession agreement.