

A Study On The Mandatory Licences Required To Establish An Healthcare Center In Hyderabad, Telangana With Special Emphasis On District Medical And Health Office (DMHO) Registration Under The Clinical Establishment Act.

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I. Introduction

To establish any business in India, getting the required mandatory licences and permissions is considered the toughest work. And these are more important and stringent in the health sector as it deals with the life and death of patients. These days, most of the hospitals employ Hospital Consultants or Hospital Administrators to get this work done. But in the Indian system which is famous for its Red Tape Bureaucracy, it is important for the hospital management to know all the applicable acts and rules pertaining to hospitals and the process for getting the same. There are also many approvals which need to be obtained from the local civic body which are mandatory for any commercial establishment. This article studies the various acts, licences and approvals that are required to establish an inpatient healthcare center in Hyderabad, Telangana.

II. Objectives Of The Study

- To enlist the various Government Acts pertaining to Hospitals and the associated Mandatory licenses and approvals which are required to establish an inpatient healthcare center in Hyderabad.

III. Methodology

- Latest textbooks and literature was reviewed to identify the various acts pertaining to healthcare establishment.
- Docpro Healthcare Pvt Ltd, a healthcare consulting agency was contacted to get the requisite information about the processes to get the required licences.

Observations:

There are multiple acts which govern the healthcare system in India. These acts directly or indirectly control the healthcare system in India. As healthcare is a state subject it is the prerogative of the various state governments to either adopt the central acts or formulate acts of their own in order to regulate healthcare. The various acts, licenses and approvals required to establish a healthcare centre in Hyderabad, the capital of the state of Telangana are (The acts are listed in chronological order from the initiation stage)

Director Index No (DIN NO) for each individual director

- This is under the purview of Ministry of Corporate Affairs, Govt of India.
- It is a mandatory registration required for each director who wants to be a part of a company.
- It is a one time registration for each director. It is not required for individual proprietors and for partnership firms.

Private ltd company registration / Partnership firm registration / Proprietorship

- This is under the purview of Ministry of Corporate Affairs, Government of India. It depends on the corporate structure of the proposed entity.
- The firm can be registered as a private ltd company or a partnership firm if there are multiple partners/owners or as a proprietorship firm or single limited liability company in case of a single owner.

- Companies come under Ministry of Corporate Affairs while proprietorship and partnership firms do not require registration under the same.

Rental Lease agreement registration

- This is mandatorily required if the building is leased.
- This comes under the purview of Registration Dept of the state government.
- It is preferable to have the lease taken for a long period (minimum of 8 years lease agreement is generally asked by the banks for issuing a loan).

Plan approval and Occupancy certificate of the building

- The building be it own or leased should have an approved Building plan and an occupancy certificate before the center starts its operations.
- This comes under the purview of Greater Hyderabad Municipal Corporation (GHMC). Plan approval is taken prior to construction of the building.
- Occupancy certificate is issued after completion of the construction. It is issued if there are no deviations from the approved plan.
- Penalty is issued for minor deviations and OC is rejected in case of major deviations.

Electricity Dept and CEIG (Chief Electrical Inspector to Government) approval for High Tension Transformer:

- Healthcare setups have a high consumption of electricity due to the use of medical equipment and HVAC system.
- Most hospitals require a transformer size of a minimum of 165 KV and High Tension wires.
- These require the approval of Dept of Electricity, Govt of Telangana and CEIG (Chief Electrical Inspector to Government) who approve the transformer and panel board design.

Fire Department NOC

- This comes under the purview of the State Disaster Response and Fire services department. Fire dept NOC is mandatory before the center starts operations.
- To get this clearance, the building should be constructed as per approved plans and should have fire detector and water sprinkler systems along with a separate fire exit.
- As per GO Rc.No. ISOO9IMSBB/CR/RR120L3 of Govt of Telangana, fire NOC is required only for hospital buildings which have an height of more than 15 mtrs.

Pollution Control board CFE/CFO (Consent For Operation)

- This comes under the purview of Telangana State Pollution control board under the State Ministry of Environment.

Bio medical waste authorization from PCB

- This comes under the purview of Telangana State Pollution control board under the State Ministry of Environment.
- A tie-up with a CBWTF (Common Biomedical Waste Treatment Facility Operator) is required to obtain this authorization.
- Each area has a designated CBWTF who are authorized by the government to handle bio medical waste.

Udyog Aadhar for MSME registration

- This comes under the purview of Ministry OF micro, Small and medium enterprises, Govt of India.
- Udyog Aadhar registration is required for health setups coming under the MSME scope.
- For it to be eligible under MSME , the budget of the center should be less than 1 crore for micro, < 2 crores for small and < 5 crores for medium.

Trade License registration

- This comes under the purview of Greater Hyderabad Municipal Corporation(GHMC).
- There is ambiguity over the requirement of trade licence for nursding homes and hospitals. Telangana Nursing Home Association had approached court for cancelling the same and the matter is subjudice.

Pharmacy registration for medical shop

- This is under the purview of Office of the Drug Controller. There are different licences for medical shops attached to hospitals (IP) and stand alone medical shops.

- There are a few minimum requirements for the registration like the minimum size of the shop (250 – 300 sft) and requirements of Air conditioner and Refridgerator.
- The license is valid for a period of 5 years.

Blood Bank license

- This is under the purview of the Office of the drug controller.
- This is not required if there is no attached blood bank in the hospital.
- The validity is for 5 years.

FSSAI license for operating a kitchen

- This is under the purview of of Food Safety and Standards Authority of India under the Ministry of Health and Family welfare, Govt of India.
- The license is required if the health centre runs an in house kitchen for the patients and attendants.

Trademark registration; Indian Trademarks Act 1999.

- This is not a mandatory act and is required only if the company wants to trademark its logo or name.

Provident Fund and ESI act

- This comes under the purview of Ministry of labour, Govt of Telangana.
- It's a mandatory license for the welfare of the employees.

Vehicle registration for ambulances

- The ambulance purchased by the hospital should be registered under RTO, Transport Department, Govt of Telangana.
- Benefits such as exemption of vehicle tax are provided for ambulances

Income Tax PAN and Professional Tax registration

- These come under the purview of Income Tax Department, Govt of India.
- IT PAN no is mandatorily required for the centre to file its annual returns and pay the required tax.
- Professional Tax registration is also a mandatory requirement and allows the centre to deduct tax from source (TDS) from its employees.

Radiation Protection certificate from BARC and Atomic Energy regulatory body (AERB) approvals

- This are under the purview of Atomic Energy Regulatory body, Govt of India.
- They are required for running a radiology and nuclear medicine dept.
- The license is valid for a period of 2 years.

PNDT act license

- This is the under the purview of Commisioner of Family Welfare, Ministry of Health, Govt of Telangana.
- This license is required for the use of the Ultrasonography machine.

DMHO (District Medical and Health Office) registration:

- This comes under the purview of Director of Health, Ministry of Health and Family Welfare, Government of Telangana.
- This is the single point registration and identity for hospitals. District Medical and Health Office (DMHO) of each district is the concerned authority for granting this license.
- The center should apply for a provisional DMHO registration before the start of the center. This provisional license is applicable for a period of 3 months. Application form should be filled and a set of documents have to be submitted.
- Permanent registration should be applied for after the center starts operations. The registration is given after a physical inspection of the center by a team from DMHO.
- DMHO registration is based on the Clinical establishments act of the Govt of India and AP Nursing Home Establishment Act.

The Clinical Establishments (Registration and Regulation) Act, 2010: An Act to provide for the registration and regulation of clinical establishments in the country and for matters connected therewith or incidental thereto. Whereas, it is considered expedient to provide for the registration and regulation of clinical establishments with a view to prescribe minimum standards of facilities and services which may be provided by them so that mandate of article 47 of the Constitution for improvement in public health may be achieved;

However in the state of Telangana there is a AP Nursing Home Establishment Act which is mandatory for all healthcare establishments to get registered under. The DMHO is the local authority authorized to grant license for running any medical establishment in the state of Telangana. Though last year Telangana govt has accepted to implement the provisions of the Clinical Establishment Act but the guidelines are still awaited.

DMHO is the major registration required for establishing a hospital. The various requirements for this are:-

- Rs 10,000/- DD
- Application Form*
- Photo Copy of Lease Document*
- Doctor Particulars in Annexure A*
- Nursing Staff Particulars in Annexure B*
- Paramedical Staff Particulars in Annexure C*
- Supporting Staff Particulars in Annexure D*
- Details of Specialties Available*
- Details of Equipments and Furniture*
- Audit Report of Last Two years*
- Declaration on Stamp paper*
- One set of photographs of the premises with its functional areas (hard copy and Soft copy)*
- Self addressed envelope, acknowledgement and affixed
- Registered postage fee stamps*
- Certificates

Validity period of the registration – 5 years

Cost incurred – Depends on the kind of facility and no of beds. The charges are different for outpatient centers and inpatient centers. There is a separate category for diagnostic centers. Charges vary for No of beds < 50, 50-100 and >100.

IV. Conclusion

Establishing a hospital requires understanding of the various acts, licenses and approvals as listed above. Every person/ organization taking up the task of establishing and running a hospital should have a thorough knowledge as to how the above licenses and approvals can be obtained so that the project once started can be completed on time.

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