

SELF DECLARATION FORM for CLINICAL ESTABLISHMENT ACT 2010

1	Name of Clinical establishment	
2	Address	
A.	House/Plot no	
B.	Street / Mohalla	
C.	Ward no	
D.	Pincode	
3	E-mail Id	
4	Phone No	
5	Name of owner	
6	Mobile	
7	Name of Medical incharge	
8	UPMCI Registration no	
9	Mobile no	
10	Name of person responsible for reporting	
11	Mobile no	
12	Total ICU Beds	
13	Total oxygen supported beds (Except ICU Beds)	
14	General beds (Except ICU & Oxygen support beds)	
15	Facility of birth & death registration	

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1. Legal/Statutory Requirements:

S No	Documents	Valid till	Send for renewal	Remark
1	Registration under Nursing Home Act/ Medical Establishment Acts			
2	Bio-medical Waste Management Licenses Authorization of HCO by PCB MOU with Vendor			
3	AERB Licenses			
4	NOC from Fire Department			
5	Ambulance Commercial Vehicle Permit Commercial Driver License Pollution Control Licenses			
6	Building Completion License			
7	Lift license for each lift			
8	DG Set Approval for Commissioning			
9	Diesel Storage Licenses			
10	Retailandbulkdruglicense(pharmacy)			
11	FoodSafetyLicenses			
12	NarcoticDrugLicenses			
13	MedicalGasesLicenses/ExplosivesAct			
14	ClinicalEstablishmentsandRegistration(ifapplicable)			
15	BloodBankLicenses			
16	BoilersLicenses			

17	MoU/agreement without sourced human resource agencies as per labor laws			
18	Spirit Licence			
19	Electricity rules			
20	Provident fund /ESI Act			
21	MTP Act			
22	PNDT Act			
23	Sales Tax registration			
24	PAN			
25	No objection certificate under Pollution Control Act(Air/Water)			
26	Wireless operation certificate from Indian P&T			
27	Arms Act, 1950 (if guards have weapons)			

SELF ASSESMENT FORM & CHECK LIST

S. No.	Particulars	Yes/No		
1	Legal/Statutory Requirements			
2	Available clinical services			
3	Support services			
4	Infrastructure			
5	Equipments			
6	Human Resource			
8	Record Maintenance and Reporting			
9	Basic Processes			
10	Annexure 1 (Minimum space requirements)			

2. Clinical Services:

1.1	General Medicine	YES	NO	
1.2	General Surgery	YES	NO	
1.3	Obstetrics and Gynaecology	YES	NO	
1.4	Paediatrics including new born care	YES	NO	
1.5	Orthopaedics	YES	NO	
1.6	Anaesthesiology	YES	NO	
1.7	Emergency Medicine & Trauma	YES	NO	
1.8	Critical Care Medicine (e.g. HDU, ICU)	YES	NO	
1.9	ENT	YES	NO	
1.10	Ophthalmology	YES	NO	
1.11	Psychiatry	YES	NO	
1.12	Dermatology	YES	NO	
1.13	Community Health	YES	NO	
1.14	Palliative Medicine	YES	NO	
1.15	Geriatric Care	YES	NO	
1.16	Family Medicine	YES	NO	
1.17	Dentistry including sub specialities	YES	NO	

1.18	Physical Medicine & Rehabilitation	YES	NO	
1.19	Transfusion Medicine/Blood Storage Centre/Blood Bank	YES	NO	
1.20	Other emerging sub-specialities in any of the above	YES	NO	
3. Support services:				
2.21.	Registration / help desk and billing	YES	NO	
2.22.	Diagnostic Services:	YES	NO	
a.	Laboratory	YES	NO	
b.	Imaging Services	YES	NO	
c.	Non-imaging services	YES	NO	
2.23.	Pharmacy and Stores	YES	NO	
2.24.	CSSD / Sterilization Area	YES	NO	
2.25.	Linen management	YES	NO	
2.26.	Kitchen & Dietary Services	YES	NO	
2.27.	Waste Management Services (General and Biomedical)	YES	NO	
2.28.	Medical Gas Supply, Storage & Distribution	YES	NO	
2.29.	Ambulance services	YES	NO	
4. Infrastructure Requirements:				
3.1	Signage			
3.1.1	The Hospital shall display appropriate signage which shall be in at least two languages	YES	NO	
3.1.2	The building shall have a board displaying the name of the hospital at a prominent location	YES	NO	
3.1.3	Directional signage shall be placed within the facility to guide the patient.	YES	NO	
3.1.4	Name of the care provider with registration number	YES	NO	
3.1.5	Registration details of the hospital as applicable.	YES	NO	
3.1.6	Availability of fee structure of the various services provided (refer to CEA 2010 rules & regulation CG 4	YES	NO	
3.1.7	Timings of the facility and services provided.	YES	NO	
3.1.8	Mandatory information such as under PNDT Act etc. prominently as applicable.	YES	NO	
3.1.9	Important contact numbers such as Blood Banks, Fire Department, Police and Ambulance Services available in the nearby area.	YES	NO	
3.1.10	Patients' rights & responsibilities.	YES	NO	
3.1.11	Safety Hazard and Caution signs, for e.g. hazards from electrical shock, inflammable articles, radiation etc. at appropriate places, and as applicable under law.	YES	NO	
3.1.12	Appropriate Fire exit signage.	YES	NO	
3.1.13	Signage for "No Smoking".	YES	NO	

3.2.	Other requirements			
3.2.1	Access to the hospital shall be comfortable for the patient and/or attendants/visitors.	YES	NO	
3.2.2	Access shall be provided within the requirements of "Persons with Disabilities Act" and shall be easy for all those whose mobility may be restricted due to whatever	YES	NO	
3.2.3	The hospital shall be developed and maintained to provide safe, clean and hygienic environment for patients, their attendants, staff and visitors	YES	NO	
3.2.4	The hospital shall have 24hr provision of potable water for drinking & hand hygiene. It shall also have 24hr supply of electricity, either through direct supply or from	YES	NO	
3.2.5	The building shall be planned as such that sensitive areas, such as wards, consulting and treatment rooms and operation theatres are placed away from the outdoor source of noise. The hospital shall be well illuminated	YES	NO	
3.2.6	The hospital shall have clean public toilet(s) separate for males and females.	YES	NO	
3.2.7	The hospital shall have mechanism for timely maintenance of the hospital building and equipment.	YES	NO	
3.2.8	The hospital shall have appropriate internal and external communication facilities.	YES	NO	
3.2.9	Furniture and fixtures shall be available in accordance with the activities and workload of the hospital. They shall be functional and properly maintained.	YES	NO	
5. Medical Equipment and Instruments:				
4.1	The hospital shall have adequate medical equipment and instruments, commensurate to the scope of service and number of beds	YES	NO	
4.2	There shall be established system for maintenance of critical Equipment	YES	NO	
4.3	All equipment shall be kept in good working condition through a process of periodic inspection, cleaning and maintenance. An equipment log-book shall be maintained for all the major equipment.	YES	NO	
6. Drugs, Medical devices and Consumables:				
5.1	The hospital shall have adequate drugs, medical devices and consumables commensurate to the scope of services and number of beds	YES	NO	

5.2	Emergency drugs and consumables shall be available at all times.	YES	NO	
5.3	Drug storage shall be in a clean, well lit, and safe environment and shall be in consonance with applicable laws and regulations.	YES	NO	
5.4	The facility has defined procedures for storage, inventory management and dispensing of drugs in pharmacy and patient care areas	YES	NO	
7. Human Resource Requirements:				
6.1	The hospital shall have qualified and/or trained medical staff as per the scope of service provided and the medical care shall be provided as per the requirements of professional and regulatory bodies	YES	NO	
6.2	The hospital shall have qualified and/or trained nursing staff as per the scope of service provided and the nursing care shall be provided as per the requirements of professional and regulatory bodies	YES	NO	
6.3	The support/paramedical staff shall be qualified and/or trained as per the scope of services provided, and as per the requirement of the respective professional or regulatory bodies.	YES	NO	
6.4	For every staff (including contractual staff), there shall be personal record containing the appointment order, documentary evidence of qualification and/or training (and professional registration where applicable).	YES	NO	
6.5	Periodic skill enhancement/updation/refresher training shall be provided for	YES	NO	
	all categories of the staff as relevant to their job profile, as prescribed by professional bodies and as per local law/regulations.	YES	NO	
8. Support Services:				
Registration/Help desk and Billing:				
7.1	The Hospital shall have a Registration/ Help-desk & Billing counter, and the scope of this shall also include	YES	NO	
Diagnostic Services:.				
7.2	Diagnostic services may be in-house or outsourced. For minimum standards for diagnostic services refer to CEA standards for Imaging and laboratory services.	YES	NO	
7.3	Whether in house or outsourced, the services shall fulfil the requirements of safe and timely patient care.	YES	NO	

7.4	The diagnostic services, whether in house or outsourced, shall be commensurate with the scope of services	YES	NO	
Pharmacy Services				
7.5	Pharmacy services in a hospital can be in-house or outsourced.	YES	NO	
7.6	All applicable legal requirements shall be complied with.	YES	NO	
7.7	Medicine storage shall be in a clean, well lit, and safe environment and as	YES	NO	
CSSD / Sterilization Area				
7.8	Provision for instrument and linen sterilization and storage of sterile items shall be made available as per the scope of services.	YES	NO	
7.9	Validation of Sterilization shall be done for ensuring the effectiveness of sterilization process	YES	NO	
Linen management:				
7.1	Soiled linen shall be collected, transported and washed separately in clean and hygienic environment.	YES	NO	
7.11	Where linen is contaminated, appropriate decontamination shall be carried prior to despatch for	YES	NO	
Waste Management Services:				
7.12	Segregation, collection, transportation, storage and disposal of biomedical waste shall be as per Bio medical waste handling rules.	YES	NO	
7.13	Waste management guidelines shall be followed in the case of Mercury & other toxic materials as per applicable local laws.	YES	NO	
7.14	Segregation, collection, transportation, storage and disposal of general waste shall be as per applicable local	YES	NO	
Medical Gas				
7.15	Oxygen for medical use shall be available. In addition other gases like Nitrous oxide, Carbon dioxide etc. may be available in consonance with the scope of services and bed strength.	YES	NO	
7.16	Medical gases shall be stored and handled in a safe	YES	NO	
7.17	All applicable legal requirements shall be complied with.	YES	NO	
7.18	Appropriate back-up and safety measures shall be in place to ensure patient safety at all times.	YES	NO	
Ambulance services				
7.19	The establishment shall have provision of transporting patients for transfer/referral/investigations etc in safe manner.	YES	NO	

7.2	Ambulance Services may be in-house or outsourced. The Ambulance services shall comply with the applicable local laws, even if they are outsourced.	YES	NO	
9. Record Maintenance and reporting:				
9.1	The minimum medical records to be maintained and nature of information to be provided by the Hospitals shall be as prescribed in CG 2 Annexe as per Section 12 (1) (iii) of this Act	YES	NO	
9.2	Medical Records may be maintained in physical or digital format.	YES	NO	
9.3	Confidentiality, security and integrity of records shall be ensured at all times	YES	NO	
9.4	The medical records of IPD patients shall be maintained in consonance with National or local law, MCI guidelines, and court orders.	YES	NO	
9.5	Every Hospital shall maintain health information and statistics in respect of national programmes, notifiable diseases and emergencies/disasters/ epidemics and furnish the same to the district authorities in the prescribed formats and frequency.	YES	NO	
10. Basic Processes:				
Registration / help desk and billing services				
10.1.	The hospital shall register all patients who visit the hospital except if the required services are not available in the facility, in which case the patient is guided to the appropriate nearest facility. (Please also see Emergency	YES	NO	
10.2.	Once registered, depending on the clinical need, patient is guided to appropriate service area like OPD,	YES	NO	
10.3.	Patient shall be guided and informed regarding Patients' rights & responsibilities, cost estimates, third party services (e.g. Insurance) etc.	YES	NO	
10.4.	The billing shall be as per the Hospital tariff list, which shall be available to patients in a suitable format.	YES	NO	
Assessment and Plan of care				
10.5.	Each patient shall undergo an initial assessment by qualified and/or trained personnel.	YES	NO	

10.6.	Further management of patient shall be done by a registered medical practitioner on the basis of findings of initial assessment; for example, OPD treatment, admission, transfer/referral, investigation etc.	YES	NO	
10.7.	At the time of admission of patient, General Consent for admission shall be taken. Attach content of Consent for admission (Annexure -).	YES	NO	
10.8.	In case of non-availability of beds or where clinical need warrants, the patient shall be referred to another facility along with the required clinical information or notes. There shall be appropriate arrangement for safe transport	YES	NO	
10.9.	Reassessments of the admitted patients shall be done at least once in a day and/or according to the clinical needs and these shall be documented.	YES	NO	
10.10.	Any examination, treatment or management of female patient shall be done in the presence of an employed female attendant/female nursing staff, if conducted by male personnel inside the hospital and vice versa.	YES	NO	

Informed Consent Procedure

10.11.	Informed consent shall be obtained from the patient/ next of kin/ legal guardian as and when required as per the prevailing Guidelines / Rules and regulations in the language patient can understand (for e.g., before Invasive procedures, anaesthesia, Blood transfusion,	YES	NO	
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Care Of Patient

10.12.	The Hospital shall provide care of patient as per the best clinical practices and reference may be made to Standard Treatment Guidelines that may be notified by the Central /State Government/National & International professional bodies.	YES	NO	
10.13.	Patient and/or families shall be educated on preventive, curative, promotive and rehabilitative aspects of care either verbally, or through printed materials.	YES	NO	
10.14.	All the relevant documents pertaining to any invasive procedures performed shall be maintained in the record, including the procedure safety checklist.	YES	NO	
10.15.	Monitoring of patient shall be done during and after all the procedures and same shall be documented (for example, after anaesthesia, surgical procedures, blood	YES	NO	
10.16.	Staff involved in direct patient care shall receive basic training in CPR	YES	NO	

Emergency Services:				
10.17.	Emergency patients shall be attended on priority. The Emergency department shall be well equipped with trained staff.	YES	NO	
10.18.	If emergency services are not available in the hospital, the hospital shall provide first aid to the patients and arrange appropriate transfer/referral of the patient.	YES	NO	
Medication Prescription, Administration And Monitoring				
10.19.	Prescription shall include name of the patient, date, name of medication, dosage, route, frequency, duration, name, signature and registration number of the medical practitioner in legible writing	YES	NO	
10.20.	Drug allergies shall be ascertained before prescribing and administration; if any allergy is discovered, the same shall be communicated to the patient and recorded in the Case sheet as well.	YES	NO	
10.21.	Patient identity, medication, dose, route, timing, expiry date shall be verified	YES	NO	
	prior to administration of medication	YES	NO	
10.22.	Safe injection practices shall be followed as per WHO guidelines.	YES	NO	
10.23.	High Risk Medicines shall be identified and verified by two trained healthcare personnel before administration.	YES	NO	
10.24.	Patients shall be monitored after medication administration and adverse drug reaction/events if any shall be recorded and reported (please refer	YES	NO	
Infection Control				
10.25.	The hospital shall follow standard precautions like practicing hand hygiene, use of personal protection equipment, etc to reduce the risk of healthcare associated	YES	NO	
10.26.	The hospital shall ensure adequate and proper spacing in the patient care area so as to prevent transmission of	YES	NO	
10.27.	Regular cleaning of all areas with disinfectant shall be done as per prescribed & documented procedure.	YES	NO	
10.28.	Prescribed & documented Infection Control Practices shall be followed in High risk areas like Operation theatre, ICU, HDU, etc as per good clinical practice	YES	NO	
10.29.	Housekeeping/sanitary services shall ensure appropriate hygiene and sanitation in the establishment.	YES	NO	
Safety of the patient, staff, visitors and relative in a hospital				

10.30.	Security and safety of patients, staff, visitors and relatives shall be ensured by provision of appropriate safety installations and adoption of appropriate safety measures. E.g. identification of mother and baby in	YES	NO	
10.31.	The Hospital shall undertake all necessary measures, including demonstration of preparedness for fire and non-fire emergencies, to ensure the safety of patients, attendants, staff and visitors. (Please also see section on Infrastructure and Security and Fire)	YES	NO	
10.32.	All applicable fire safety measures as per local law shall be adopted. This includes fire prevention, detection, mitigation, evacuation and containment measures. Periodic training of the staff and mock drills shall be conducted and the same shall be documented.	YES	NO	
10.33.	In case of any epidemic, natural calamity or disaster, the owner/keeper of every Hospital shall, on being requested by the designated supervising Authority, cooperate and provide such reasonable assistance and medical aid as may be considered essential by the supervising authority at the time of natural calamity or disastrous situation	YES	NO	
Patient Information and Education				
10.34.	The patient and/or family members shall be explained about the disease condition, proposed care, including the risks, alternatives and benefits. They shall be informed regarding the expected cost of the treatment. They shall also be informed about the progress and any change of	YES	NO	
10.35.	Patient and/or family are educated about the safe and effective use of medication, food drug interaction, diet, and disease prevention strategies.	YES	NO	
Discharge				
10.36.	A Discharge summary shall be given to all patients discharged from the hospital. Attach content of discharge summary (Annexure -)	YES	NO	
10.37.	The discharge summary shall include the points as mentioned in the annexure in an understandable language and format	YES	NO	
10.38.	Discharge summary shall also be given to patient and/or attendant in case of transfer LAMA/DAMA or death.	YES	NO	

ANNEXURE 1

Minimum space requirements in a hospital shall be as follows:

Total Area		Available	Not available	REMARK
1	Total Area of hospital level 1 including 30% area for circulation space for corridors, lobby, reception area - 40 sq mt/bed as carpet area			
Wards				
2 a.	Ward bed and surrounding space - 6sq mt/ bed; in addition circulation space of 30% as indicated in total area shall be provided for Nursing station, Ward store,			
b.	The ward shall also have designated areas for nursing station, doctors' duty room, store, room, store, clean and dirty utility, janitor room, toilets and this shall be provided from circulation			
c.	For a general ward of 12 beds, a minimum of 2 WC and 1 hand wash basin shall be provided.			
d.	Distance between beds shall be 1.0 metres			
e.	Space at the head end of bed shall be 0.25 metres.			
f.	Door width shall be 1.2 metres and corridor width 2.5 metres			
Intensive Care Unit (if available)				
3 a	For medical/surgical ICU/HDU bed and surrounding space - 10.5 sq mt/ bed; in addition circulation space of 30% as indicated in the total area shall be provided for nursing station, doctors' duty room, store, clean and dirty utility, circulating area for movement of staff,			
b.	The unit is to be situated in close proximity of operation theatre, acute care medical and surgical ward units.			
c.	Suction, oxygen supply and compressed air should be provided for each bed.			
d.	Adequate lighting and uninterrupted power supply shall be provided.			
e.	Adequate multi-sockets with 5 ampere and 15 ampere sockets and/or as per requirement to be provided for each bed.			
f.	Nurse call system for each bed.			
g	ICU shall have designated area for nursing station, doctors' duty room, store, clean and dirty utility, circulating area for movement of staff, trolley, toilet, shoe change, trolley bay, janitor closet etc			
Minor Operation Theatre/Procedure room				

4	OT for minor procedures (where applicable) 10.5 sq mt; in addition circulation space of 30% as indicated in total area shall be provided for nursing station, scrub station, clean and dirty utility, dressing room, toilet etc.			
Labour room				
5	Labour Table and surrounding space 10.5 sq mt/ labour table			
6	Other areas- nursing station, doctors' duty room, store, Clean and dirty utility, Circulating area, 10.5 sq mt for clean utility and store and 7 sq mt for dirty utility and 3.5 sq mt for toilet.Toilets			
b	The obstetrical unit shall provide privacy, prevent unrelated traffic through the unit and provide reasonable protection of mothers from infection and from cross-			
c	Measures shall be in place to ensure safety and security of neonates.			
d	Resuscitation facilities for neonates shall be provided within the obstetrical unit and convenient to the delivery			
e	The labour room shall contain facilities for medication, hand washing,charting, and storage for supplies and equipment.			
f	The labour room shall be equipped with oxygen and			
Operation Theatre (OT)				
7	Operating Room Area - 24.5 sq mt per operating room.			
b	The operation theatre complex shall have appropriate zoning.			
c	The operation theatre complex shall provide appropriate space for other areas- nursing station, doctors' duty room, scrub station, sterile store, Clean and dirty utility, Dress change room, Toilets:-			
	a. Sterile area – consists of operating room sterile store and anesthesia room			
	b. Clean zone- consists of equipment/medical store, scrub area, pre and/or post-operative area and linen bay			
	c. Protective zone- consists of change room, doctors room and toilets			
	d. Dirty area			
	e. Due considerations are to be given to achieve highest degree of asepsis to provide appropriate environment for staff and patients.			
d	Doors of pre-operative and recovery room are to be 1.5 m clear widths.			

e	Air Conditioning to be provided in all areas. Window AC and split units should preferably be avoided as they are pure re circulating units and become a source of			
f	Appropriate arrangements for air filtration to be made.			
g	Temperature and humidity in the OT shall be monitored.			
h	Oxygen, Nitrous Oxide, suction and compressed air supply should be provided in all OTs.			
i	All necessary equipment such as shadow-less light, Boyle's apparatus shall be available and in working			
j	Uninterrupted power supply to be provided.			
Emergency & Casualty (if separate):				
8	Emergency bed and surrounding space - 10.5 sq m/ bed			
9	Other areas- nursing station, doctors' duty room, store, Clean and dirty utility, Dressing area, Toilets - Nurse station out of circulation. Doctor duty room of 7sqm and a toilet of 3.5sqm. Store of 7sqm			
Pharmacy				
10	Pharmacy - The size should be adequate to contain 5 percent of the total clinical visits to the OPD in one session at the rate of 0.8 m2 per patient.			
Bio-medical Waste				
11	<50 beds - 5 sqm			
12	50-100 beds - 10 sqm			
13	>100 beds - 20 sqm			
Clinical Laboratory				
14	The laboratory area shall be appropriate for activities including test analysis, washing, biomedical waste storage and ancillary services like Storage of records, reagents, consumables, stationary etc eating area for			
Imaging				
15	The department shall be located at a place which is easily accessible to both OPD and wards and also to emergency and operation theatre.			
16	As the department deals with the high voltage, presence of moisture in the area shall be avoided.			
17	The size of the department shall depend upon the type of equipment installed.			
18	The department/room shall have a sub-waiting area preferably with toilet facility and a change room facility, if required.			

Central Sterilization and Supply				
18	Department (CSSD) — Sterilization, being one of the most essential services in a hospital, requires the utmost consideration in planning.			

On behalf of myself and the company/ society/ association/ body hereby declare that the statements above are correct and true to my knowledge and I shall abide by all the rule and

I further declare that this clinical establishment is not and will not be used for immoral purpose. I undertake that I shall intimate to the Licensing Authority any change in the particulars

Place

Date

Signature of Applicant

FOR ANY QUERIES PLEASE CONTACT – Shri Vineet Srivastava 8887145800

