

TRIPURA GAZETTE

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**PART--I-- Orders and Notifications by the Government of Tripura,
The High Court, Government Treasury etc.**

**GOVERNMENT OF TRIPURA
HEALTH & FAMILY WELFARE DEPARTMENT**

No.F.4(2-58)-DFWPM/GNL/19(SUB-II)

Dated, Agartala, the 24th August, 2021.

NOTIFICATION

In exercise of the powers conferred under Sections 8(2), 11, 12, 15, 16, 20, 21 & 22, read with Sections 2(g) & 2(p) of the Tripura Clinical Establishment (Registration & Regulation) Act, 2018 (the 'Tripura Act No. 16 of 2018) and of all others powers enabling it in that behalf, the State Government hereby makes the following rules, for the purpose of carrying out the provisions of the said Act:-

1. Short Title and commencement:-

- (1) These rules may be called 'The Tripura Clinical Establishments (Registration & Regulation) Rules, 2021';
- (2) They shall come into force, on the date of publication in the Tripura Gazette.

2. Definitions: -

- (1) In these rules, unless there is anything repugnant in the subject or context,-
 - (a) 'Act' means the Tripura Clinical Establishments (Registration & Regulation) Act, 2018;
 - (b) 'Allied Health professions' means any health professions distinct from Medicine, Dentistry, Pharmacy and Nursing. It includes Audiology, Behavioral health (counseling, marriage and family therapy etc.), Exercise Physiology, Nuclear Medicine Technology, Medical Laboratory Scientist, Dietetics, Occupational therapy, Optometry, Orthotics, Orthotics and Prosthetics, Osteopathy, Paramedic, Podiatry, Health Psychology/ Clinical Psychology, Physiotherapy, Radiation Therapy, Radiography / Medical Imaging, Respiratory Therapy, Sonography, Speech Pathology.
 - (c) 'Alternative system of medicine' means and includes AYUSH, an acronym for Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homeopathy represents the alternative systems of medicine recognized by the Government of India.
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(d) ‘Clinics’ means a Clinical establishment providing examination, consultation, prescription to outpatients including dispensing of medicines by a single or general practitioner or specialist doctor or super-specialist doctor.

(e) “Clinic or Polyclinic with Diagnostic Centre” means a clinical establishment with support services (pharmacy, injections, family planning facility, dressing room, sample collection facility, basic laboratory, X- ray, USG with or without color Doppler, ECG or any other) which offers health care services of examination, consultation, prescription, to outpatients by a single or general practitioner or specialist doctor or super specialist doctor.

(f) “Day care Facility”(Medical/Surgical) means and includes any Clinical establishment on its own premises or as extension, outside its premises, which offers health care services not exceeding 24 hours with a dedicated ambulance and referral mechanism.

(g) “Diagnostic Centre” means and includes stand alone organized facility to provide simple to critical diagnostic procedures such as radiological investigation supervised by a radiologist and clinical laboratory services by laboratory specialist usually performed through referrals from physicians and other health care facilities.

(h) ‘Hospital’ means and includes any health care institution that has residential establishment which provides short term and long term medical care consisting of observational, diagnostic, therapeutic, round the clock emergency services, for any patient, including or excluding educational, rehabilitative with inpatient facilities, which may be categorized in any of the followings:-

(i) *Hospital Level 1 (A)* – General Medical services with OPD and indoor admission facility provided by recognized allopathic medical graduate(s) and may also include general dentistry services provided by recognized BDS graduates. Example: PHC, CHC, SDH, Government and Private Hospitals.

(ii) *Hospital Level 1 (B)* – This level of hospital shall include all the general medical services provided at level 1(A) above and specialist medical services being provided (Full Time) by Doctors from one or more basic specialties namely General Medicine, General Surgery, Pediatrics, Obstetrics & Gynaecology and Dentistry, providing indoor and OPD services.

Level 1(A) and Level 1(B) Hospitals shall also include support systems required for the respective services like Pharmacy, Laboratory, etc.

Example: General Hospital, Single/Multiple basic medical Specialties provided at Community Health Centre, Sub Divisional Hospital, and Private Hospital of similar scope, Civil/District Hospital in few places etc.

(iii) *Hospital Level 2 (Non-Teaching)* -This level may include all the services provided at level 1(A) and 1(B) and services through other medical specialties given as under, in addition to basic medical specialty given under 1(B) like:-

Orthopedics / ENT / Ophthalmology / Dental / Emergency with or without ICU /Anesthesia / Psychiatry /Skin /Pulmonary Medicine /Rehabilitation, etc. And support systems required for the above services like Pharmacy, Laboratory, Imaging facilities, Operation Theatre etc. Example: District Hospital, Corporate Hospital, Referral Hospital, Regional/State Hospital and Private Hospital of similar scope etc.

(iv) *Hospital Level 3 (Non-Teaching) Super-specialty services* – This level may include all the services provided at level 1 (A), 1(B) and 2 and services of one or more of the super specialty with distinct department and/or also Dentistry if available. It will have other support systems required for services like Pharmacy, Laboratory, Imaging facility, Operation Theatre etc. Example: Corporate Hospitals, Referral Hospitals, Regional/State Hospital and Private Hospital of similar scope etc.

(v) *Hospital Level 4 (Teaching)* This level will include all the services provided at level 2 and may also have Level 3 facilities. It will however have the distinction of being teaching/training institution and it may or may not have super specialties. Tertiary healthcare services at this level can be provided through specialists or super specialists (if available). It will have other support systems required for these services. It shall also include the requirement of NMC/other registering body for teaching hospitals and will be governed by their rules. However registration of teaching Hospitals will also be required under Clinical Establishment Act for purpose other than those covered under NMCI such as, records maintenance and reporting of information and statistics, and compliance to range of rates for Medical and Surgical procedures, etc.

(i) ‘Hospital bed’ means a bed that is regularly maintained and staffed for the accommodation and full-time care of a succession of inpatients and is situated inwards or a part of the hospital where continuous medical care for inpatients is provided.

(j) “Inpatients” mean persons hospitalized for indoor care across all types of hospital beds.

(k) “Outpatients” means patients who is provided health care services without admission/hospitalization.

(l) “Polyclinic” means a Clinical establishment providing examination, consultation, prescription to outpatients including dispensing of medicines by more than one doctor or general practitioner or specialist doctor or super-specialist doctor.

(m) “Systems of Medicine” means Allopathy (modern medicine) or any other alternative system of medicine as defined by the GOI.

(2) Words and expressions, used herein but not defined in these rules or in the Act, shall have the same meaning as assigned to them in the Tripura State Medical Council Act, 2010, The National Medical Commission Act, 2019 and The Pre-conception and Prenatal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994.

3. Condition for Registration, as required under Section 11:

For registration or carrying on any clinical establishment, the conditions, as prescribed in **Annexure – II and III** of these rules, shall be fulfilled, on and from the commencement of these rules.

4. Procedure for Registration:-

- (a) Any person intending to establish or carry on a clinical establishment, shall make an application, in prescribed **Form-A** of **Annexure–I**, through online or offline mode, with detailed information contained in such application, along with online uploading or submission of valid supporting documents as per check list given in **Annexure -VI** and shall also deposit required fee prescribed under rule 8, to the District Registering Authority, for Provisional Registration, at least thirty days prior to the date on which he intends to commence such clinical establishment;
- (b) The Chairperson of the District Registering Authority, if satisfied, that the application is complete in all respect shall, issue provisional registration certificate in **Form-C** of **Annexure–I**, within a period not exceeding twenty five days from the date of application, so that the establishment can start from the intending date;
- (c) If the District Registering Authority finds any material defect in the application, he shall within a period not exceeding fifteen days from the date of application, inform the applicant about the defects and shall direct the applicant for necessary correction;
- (d) On receipt of the information about the defects, the applicant shall take steps for correction of such defects and inform the District Registering Authority about the correction, in writing and the District Registering Authority shall issue the Provisional Registration, within a period not exceeding fifteen days from the date of receipt of the corrected information;
- (e) If any further defect is found in the application, the provision of the forgoing sub-rules shall mutatis mutandis be followed;
- (f) The District Registering Authority shall provide the District Supervising Team, a copy of the Provisional Registration Certificate, along with all necessary available information about the application and the District Supervising Team shall make an inspection of the Clinical Establishment and submit its report to the District Registering Authority, in prescribed format in **Annexure–IV**, within a period not exceeding ninety days from the date of provisional registration;

- (g) On receipt of the report from the District Supervising Team, if the District Registering Authority is satisfied that all the required standards and conditions are fulfilled, he shall within a period not exceeding fifteen days from the date of receipt of such inspection report, ask the applicant to submit application for registration in **Form-B of Annexure-I**, at least thirty days prior to the date of expiry of the provisional registration and on receipt of such application, the District Registering Authority shall issue the certificate of Registration in **Form-D of Annexure-I**, within a period not exceeding twenty five days from the date of such application;
- (h) On receipt of the report from the District Supervising Team, if the District Registering Authority is not satisfied with all the required standards and conditions, he shall within a period not exceeding fifteen days from the date of receipt of such inspection report, endorse a copy of the inspection report to the applicant, with a direction to take necessary corrective measures, within a period not exceeding ninety days from the date of receipt of such direction;
- (i) If a direction is issued under the preceding rule, the District Registering Authority may extend the period of validity of the provisional registration, for a further period not exceeding six months and a copy of all these directions shall be endorsed to the District Supervising Team, which shall make a further inspection within a period of thirty days after the date on which the stipulated period of ninety days for taking corrective measures by the applicant expires;
- (j) If the applicant fails to take the corrective measures within the stipulated period of ninety days, the provisional registration of the clinical establishment will be revoked and his application will be treated as cancelled;
- (k) A clinical establishment, the provisional registration of which has been revoked, shall not be eligible for further provisional registration within a subsequent period of one year of such revocation and an applicant, whose application has been cancelled, shall not be eligible for making any application for registration for a subsequent period of one year from the date of cancellation.
- (l) An application for renewal of Registration shall be made through online or offline mode, in **Form-B of Annexure-I**, accompanied with such fee as prescribed in rule 8, at least ninety days prior to the date of expiry of the registration;
- (m) On receipt of the application for renewal of registration, the procedure prescribed in the foregoing sub-rules, relating to registration, shall mutatis mutandis be followed and if the District Registering Authority is satisfied that the application is in order, he shall issue a certificate of renewal of registration in **Form-E of Annexure -I**;

Provided that, failure to submit application in prescribed time and deposition of the fee as prescribed in rule 8 shall be charged with penalty as prescribed in rule 8;

Provided further that, if any defect is found during inspection by the District Supervising Team, for the purpose of renewal of the registration, the clinical establishment shall be given ninety days time for correction and if those defects are not corrected within the stipulated time, the registration will be cancelled;

(n) In case the certificate is lost, destroyed, mutilated or damaged, an application to the District Registering Authority shall be made by the applicant for a duplicate certificate, through online or offline mode, along with a fee of Rupees Five hundred and on receipt of such application, the District Registering Authority shall issue a duplicate certificate of registration in **Form-F** of **Annexure –I**, within a period not exceeding thirty days.

5. Casual Vacancy in the Supervising team: If a casual vacancy occurs, whether by reason of death, resignation, transfer, retirement or inability to discharge function owing to illness or any other in capacity of a member, such vacancy shall be filled by making a fresh appointment, within one month of occurring such vacancy.

6. Transfer of registration and ownership of clinical establishment: In case of any change in the owner ship, proprietorship or re-arrangement of any clinical establishment, the transferor and the transferee shall jointly communicate the fact of such change by an Affidavit, within fifteen days from the date of such change and within the said time the transferee shall also make an online or offline application for registration, in accordance with the provision of rule 4 and the District Registering Authority shall, on being satisfied about such change, issue a fresh registration certificate within fifteen days from the date of such application.

7. Changes in Address:- In case of any change in the address or location of the clinical establishment, the owner or proprietor shall make an application to the District Registering Authority, with detail information about the new address and location, through online or offline mode, at least thirty days prior to such change and on receipt of such application, the District Registering Authority may inquire into the facts of the application, in the manner he thinks proper and or on the basis of the inspection report of the District Supervising Team, grant permission to such change, if he is satisfied that such change will not adversely affect the conditions of registration, within a period not exceeding twenty five days from the date of application;

Provided that, any such change of address or location shall be endorsed in the registration certificate by the District Registering Authority and no such change shall be made without the permission from the District Registering Authority.

8. Fees for registration and penalty for delay:-

The fees to be paid for registration and renewal of registration shall be charged as under:-

Sl. No	Type of Clinical Establishment		Provisional Registration		Registration/Renewal	
			Non ADC area	ADC area	Non ADC area	ADC area
1.	Govt. establishment		NA	NA	NA	NA
2.	Clinical establishment having not more than 10 beds.		2000	1500	5000	3500
3.	Clinical establishment having 10 to 25 beds		2500	1750	6000	4000
4.	Clinical establishment having 26 to 50 beds		3000	2000	7000	5000
5.	Clinical establishment having 51 to 100 beds		5000	3000	8000	5500
6.	Clinical establishment having 101 to 150 beds		8000	4000	10000	6000
7.	clinical establishment having more than 150 beds		10000	6000	12000	8000
8.	Diagnostic Center		1000	500	1500	1000
9.	Collection Centre		800	350	1000	600
10.	Physical therapy establishment		1000	500	1500	1000
11.	Practicing Doctor	Non-specialist clinic	400	300	600	500
		Specialist clinic including all system of medicine	500	400	1000	700
		Poly Clinic	800	500	1200	900
		Ayush	300	200	500	400
		Dental	300	200	500	400
12.	Clinic with Diagnostic Center		1500	1000	2000	1500
13.	Poly Clinic with Diagnostic Center		1700	1200	2200	1700
14.	Others which does not fall in this category		800	500	1200	900

Note: - Penalty is applicable @ 20% for every month over and above the prescribed fee.

9. Format of Register, to be maintained under Sections 20, 21 and 22 of the Act:-

The State Council, the District Registering Authority and a Clinical Establishment shall maintain register, according to the format in **Annexure –V**;

Form-A
[See Rule 4 (a)]
Application for Provisional Registration of Clinical Establishment

1. Name of the Clinical Establishment _____

2. Address: _____ Village/Town/City: _____ Block: _____ District: _____
State: _____ Pincode _____ Tel.No(withSTDcode) _____ Mobile: _____
EmailID _____ Website(if any): _____

3. Name of the owner/ Proprietor _____

Address: Village/Town/City: _____ Block: _____ District: _____ State _____ Tel
No (with STD code): _____ Mobile: _____ Email ID: _____

4. Name of the Person In charge _____ Qualification(s): _____ Registration
Number: _____ Name of Central/State Council (with which registered): _____

TelNo(withSTDcode): _____ Mobile: _____ E-mailID: _____

5. Ownership a) Government/Public Sector: Central Government /State Government/ Local
Government/ Public Sector Undertaking/ Any other (please specify): _____ b)
Private Sector /Individual Proprietorship /Registered Partnership /Registered Company
/Cooperative Society /Trust / Charitable Any other (please specify):

6. System of Medicine: (please tick whichever is applicable) Allopathy /Ayurveda /Unani/ Siddha/
Homoeopathy/ Yoga/ Naturopathy /Physical Therapy Unit.

7. Type of Clinical Services: General /Single /Specialty /Multi Specialty /Super Specialty /Any
other(please specify): _____

8. Type of Clinical Establishment: (please tick whichever is applicable.

Sl No.	Establishment	Tick (√)	SL. No.	Establishment	Tick (√)
1.	Clinic (Outpatient)		8.	Diagnostic Imaging centers	
2.	Polyclinic		9.	Collection centers	
3.	Polyclinic with Diagnostic Center		10.	AYUSH	
4.	Day Care facility		11.	Physical Therapy Unit	
5.	Hospitals including Nursing Home		12.	Other (Specify)	

6.	Dental Clinics and Dental Hospital				
7.	Medical Diagnostic Laboratories				

9. Number of Beds (Inpatient): _____

10. Outpatient: Single practitioner /Dispensary /Polyclinic /Dental Clinic /Physiotherapy/Occupational Therapy Clinic/ Infertility Clinic/ Sub-Centre/Mobile Clinic Any other (please specify): _____

11. Laboratory: Pathology/ Hematology /Biochemistry /Microbiology /Genetics /Any other (please specify): _____

12. Imaging Centre: X ray/ Electro Cardio Graph (ECG)/ Ultrasound /CT Scan/ Magnetic Resonance Imaging (MRI) /Any other (please specify): _____

13. Any other (please specify): _____

I hereby declare that the statements made above are correct and true to the best of my knowledge. I shall abide by all the provisions of the Clinical Establishments (Registration and Regulation) Act, 2018 and the rules made there under. I shall intimate to the District Registering Authority, any change in the particulars given above.

Place:

Signature of the Owner

Signature of the Person in charge

(Name: _____). (Name: _____).

Date:

Office Seal

From-B

[See Rule4 (g) & (1)]

Application Form for Registration/ Renewal of Registration

I. ESTABLISHMENT DETAILS:

1. Name of the establishment: _____

2. Address: _____ Village/Town: _____ Block: _____ District: _____ State: _____
Pin code _____ Tel No (with STD code): _____ Mobile: _____ Fax: _____ Email ID _____
Website (if any): _____

3. Month and Year of starting: _____

(From 4 to 11 mark all whichever are applicable)

4. Location:

TTADC / NON TTADC

5. Ownership of Services

Government / Public Sector/ Central government /State government/ Local government (Municipality, Zillaparishad, etc)/Public Sector Undertaking /Other ministries and departments (Railways, Police, etc.)/Employee State Insurance Corporation/ Autonomous organization under Government / Private Sector /Individual Proprietorship /Partnership /Registered companies (registered under central/provincial/state Act) /Society/trust (Registered under central/provincial/state Act)

6.Name of the owner of Clinical Establishment: _____

Address: _____ Village/Town: _____ Block: _____ District: _____ State: _____

Pin code _____ Tel No (with STD code): _____ Mobile: _____ Fax : _____ Email ID: _____

7. Name, Designation and Qualification of person- in-charge of the clinical establishment:

Qualification(s) _____ Registration Number: _____ Name of Central/State Council (with which registered): _____ Tel No (with STD code): _____ Fax: _____ Mobile: _____ E-mail ID: _____

8. Name of visiting consultant with details*:-

9. Systems of Medicine offered: (please tick whichever is applicable)

Allopathy _____ Ayurveda _____ UnaniSiddha _____ Homoeopathy _____ Yoga _____ Naturopathy _____ Physical Therapy Unit _____ Others _____.

10. Type of establishment: (please tick whichever is applicable)

Sl No	Establishment	Tick	Sl No	Establishment	Tick
1.	Clinic (Out patient)		7.	Diagnostic Imaging centres	
2.	Polyclinic		8.	Polyclinic with Diagnostic Center	
3.	Day Care facility		9.	Collection centers	
4.	Hospitals including Nursing Home		10.	AYUSH	
5.	Dental Clinics and Dental Hospital		11.	Physical Therapy Unit	
6.	Medical Diagnostic Laboratories		12.	Other (Specify)	

II. INFRASTRUCTURE DETAILS:

10. Area of the establishment (in sq ft):

a) Total Area: _____ b) Constructed area: _____

11. Out Patient Department:

11.1 Total no. of OPD Clinics:

11.2 Specialty-wise distribution of OPD Clinic:

Sl No.	Specialty

12. In Patient Department:

12.1. Total number of beds: _____

12.2. Specialty-wise distribution of beds, please specify:

Sl No.	Specialty	No. of Beds

13. Internal Electrification: Yes No

14. Biomedical waste Management.

14.1 Method of treatment and /or disposal of Bio-medical waste.

Through Common Facility Onsite Facility

Any other (please specify): _____

14.2. Whether authorization from Pollution Control Board/Pollution Control Committee obtained?

Yes No Applied For

15. Fire Safety certification (Dept. of Fire Service)

Yes No Applied For

16. . FSSAI license for operating a kitchen:

Yes No Applied For

17. Pharmacy registration for medical shop:

Yes No

18. Vehicle registration for ambulances:

Yes No

19. Atomic energy regulatory body approvals:

Yes No

20. License for the Blood Bank:

Yes No

III. HUMAN RESOURCES:

21. Total number of Staff (as on date of application): (Name & Designation)

No. of permanent staff: _____ No. of temporary staff: _____

Please furnish the following details:-

Category of staff/Name /Qualification /Registration No /Support Staff (Certified copy to be attached).

Disposition list of human resource is to be displayed in the Clinical Establishment.

22. Payment options for Registration Fees:

Demand Draft Bank Challan

Amount (in Rs): _____ Details: _____

Receipt No.

I,.....on behalf of myself and the company/society/association/body hereby declare that the statements above are correct and true to the best of my knowledge and I shall abide by all the provisions made under the Tripura Clinical Establishments (Registration and Regulation) Act 2018. I undertake that I shall inform the District Registering Authority of any changes in the particulars given above. I shall comply with the standards prescribed under Clinical Establishments Act for the services provided by us and also all other conditions of registration as stipulate under the aforesaid Act and Rules there under.

Place:

Signature of the Authorized Signatory

Date:

Official Seal

FORM – C

[See Rule 4(b)]

Provisional Registration No.

GOVERNMENT OF TRIPURA

District Registering Authority (Name of the District)

CERTIFICATE OF PROVISIONAL REGISTRATION

This is to certify that..... (Name of Clinical Establishment).....located at..... (Full Address)..... owned by..... (Name of the owner/Proprietor) has been granted provisional registration as a clinical establishment under section 12 of **The Tripura Clinical Establishments (Registration and Regulation) Act, 2018**, on this the ____/____/____ and will remain valid till ____/____/____.

The Clinical Establishment is registered for providing medical services as a..... (Type of clinical establishment viz. Hospital, Diagnostic Centres etc)..... (Allopathic/ Homocopathic/ Ayurvedic etc.).....system of medicine.

Registering Authority.

Place-

Date of Issue-

Copy to:-

The Chairman, District Supervising Team.

FORM –D

[See Rule 4(g)]

Registration No.

GOVERNMENT OF TRIPURA

District Registering Authority

(Name of the District)

CERTIFICATE OF REGISTRATION

This is to certify that..... (Name of Clinical Establishment).....located at..... (Full Address)..... owned by..... (Name of the owner)has been granted Certificate of Registration as a clinical establishment under section 12 of **The Tripura Clinical Establishments (Registration and Regulation) Act, 2018** on this the ____/____/____ and will remain valid till ____/____/____.

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The Clinical Establishment is registered for providing medical services as a..... (Type of clinical establishment viz. Hospital, Diagnostic Centres etc.)..... (Allopathic/ Homoeopathic/ Ayurvedic etc.).....system of medicine.

Registering Authority.

Place-

Date if Issue

FORM –E

[See Rule 4(m)]

GOVERNMENT OF TRIPURA

District Registering Authority

(Name of the District)

RENEWAL OF REGISTRATION

This is to certify that, the **Registration No.**_____ **dated**___/___/___ of..... (Name of Clinical Establishment).....located at..... (Full Address)..... owned by..... (Name of the owner), which was granted the registration as a clinical establishment under section 12 of **The Tripura Clinical Establishments (Registration and Regulation) Act, 2018** has been granted the Renewal of its Registration Certificate on this the___/___/___ and will remain valid till___/___/_____. The Clinical Establishment is registered for providing medical services as a..... (Type of clinical establishment viz. Hospital, Diagnostic Centres etc.)..... (Allopathic/ Homoeopathic/ Ayurvedic etc.).....system of medicine.

Registering Authority.

Place-

Date if Issue

FORM –F

[See Rule 4(n)]

Registration No.

GOVERNMENT OF TRIPURA

District Registering Authority

(Name of the District)

CERTIFICATE OF REGISTRATION (Duplicate)

This is to certify that..... (Name of Clinical Establishment).....located at..... (Full Address)..... owned by..... (Name of the owner)has been granted Certificate of Registration as a clinical establishment under section 12 of **The Tripura Clinical Establishments (Registration and Regulation) Act, 2018** on this the___/___/_____ and will remain valid till___/___/_____. The Clinical Establishment is registered for providing medical services as a..... (Type of clinical establishment viz. Hospital, Diagnostic Centres etc)..... (Allopathic/ Homoeopathic/ Ayurvedic etc.).....system of medicine.

Registering Authority.

Place-

Date of Issue

ANNEXURE - II

(See Rule 3)

Minimum Standards of facilities and Services for Clinical Establishment

(1) STANDARDS FOR OPD/CLINIC/POLYCLINIC:

- a. Infrastructure: Separate toilet and separate waiting area should be available for the patient. The area shall be well illuminated, well ventilated and clean with adequate water supply.
- b. Patient's Right: The facility shall have uniform and user friendly signage system. Every facility shall display the services and entitlements available in its departments. There shall be availability of enquiry desk with dedicated staff or attendants. Availability of female attendant for female patient should be there. All the information shall be available in local language and easily understandable. Adequate visual privacy should be provided at every point of care.

- c. **Support Services:** The facility ensures that drugs prescribed preferably in generic name (especially for govt. Doctors). There shall be process for storage of vaccines and other drugs, require controlled temperature. OPD slip/prescription shall be given to the patient. Availability of power backup in OPD/private chamber shall be there.
- d. **Clinical Services:** The facility shall establish procedure for registration of patients. Register or Records to be maintained as proposed in rules.
- e. **Infection Control:** There shall be provision of Annual periodic medical checkup and immunization of staff. Hand washing facility shall be provided at every point of use. Facility shall ensure availability of standard materials for cleaning and disinfection of patient care areas. Facility shall ensure segregation of Bio medical waste as per recent BMW Management rules.

(2) STANDARDS FOR LABORATORY:

- a. **Infrastructure:** The laboratory space shall be adequate for carrying out activities and Minimum Floor space area should be at least 200sqf. Availability of adequate waiting area, drinking water and functional toilets shall be there. There shall be demarcated sample collection area, testing area, report writing area shall be there. Demarcated washing and waste disposal area shall be there. The physical condition of buildings shall be safe for providing patient care and there shall be availability of adequate fire fighting equipments.
- b. **Service Provision:** There shall be availability of hematology services, bio chemistry services, microbiology, urine analysis, stool analysis etc.
- c. **Patient's Right:** The facility shall have uniform and user-friendly signage system. User charges shall be displayed & communicated to patients effectively. Information shall be available in local language and easy to understand.
- d. **Support Services:** All equipments shall be covered under AMC including preventive maintenance.
- e. **Infection Control:** There shall be provision of periodic medical checkups and immunization of staffs. Facility ensures segregation of bio medical waste as per recent guidelines.

(3) STANDARDS FOR NURSING HOME/HOSPITAL:

A) Requirements of nursing home:

- i. **Location and surroundings;** the nursing home shall be situated in place having clean surroundings and shall not be adjacent to an open sewer drain or public lavatory or to a factory emitting smoke or obnoxious odour.

- ii. Building: (a) The building used for the nursing home shall comply with the relevant municipal bye laws in force from time to time. The rooms in the nursing home shall be well ventilated and lighted and shall be kept in clean and hygienic conditions. Arrangements shall be made for cooling them in summer and heating them in winter. The walls of the labour room and operation theatre up to a height of four feet from the floor shall be of such construction as to render it water proof. The flooring shall be such as not to permit retention or accumulating of dust. There shall be no chinks or crevices in the wall on floors.

(b) A septic condition shall be maintained in labour room and the operation room with proper periodical sterilization/ fumigation. Adequate arrangements shall be made for isolating septic and infectious cases. Space accommodation for the patients etc: The floor space in a nursing home shall be 120 square feet for one bed and additional 80 square feet for every additional bed in the room. For Lab minimum 150 sqft. A labour room/operation theatre shall be provided with minimum floor space of 180 square feet. There shall be the facilities for blood transfusion services. Adequate space for storage of medicines, articles, equipments etc shall be provided. The water used in the nursing home shall be pure and drinkable quality.
- iii. Health, clothing and sanitary requirements of staff: The staff employed shall be free from contagious disease and shall be provided with clean uniforms suitable to the nature of their duties. The workers shall be medically examined at the time of employment and periodically so examined thereafter.
- iv. Equipments and linen etc: There shall be adequate number of commodes, bedpans and slop sinks with flushing arrangements. High pressure sterilizer and instrument sterilizer and oxygen cylinder B Type (1 for every four beds) and necessary attachment shall be there.
- v. Admission: Admission shall be restricted to the number of beds to be maintained. The scale of diet shall not be below the standard norms in the Nursing home provide diet to the patient. The diet shall prepare and served in hygienic condition.
- vi. Nursing Staff: One nurse shall be on duty at all times on every 10 beds or a fraction thereof in the nursing home.
- vii. Records: Separate stock register shall be maintained by the nursing home for equipment, instruments and linens.
- viii. Referral: Must have a referral mechanism with higher center with availability of Ambulance round the clock.

B) Requirements of Hospital:

1. Infrastructure-

The Hospital shall display appropriate signage which shall be in at least two languages. A board stating “24 hours emergency available” is essential. The building shall have a board displaying the name of the hospital at a prominent location. Directional signage shall be placed within the facility to guide the patient(s). The directional signage’s shall be permitted outside in the nearby vicinity of the hospital/Nursing Home to facilitate easy access.

Following informative signage shall be displayed: Name of the care provider with registration number /Registration details of the hospital as applicable/Availability of fee structure of the various services provided /Timings of the facility and services provided/Mandatory information such as under PNDDT Act etc/Important contact numbers such as Blood Banks, Fire Department, Police and Ambulance Services available in the nearby area.

Following safety signage shall be displayed: Safety Hazard and Caution signs, for e.g. hazards from electrical shock, inflammable articles, radiation etc shall be displayed at appropriate places, and as applicable under law. Appropriate Fire exit signage. Signage for “No Smoking” at prominent places.

Other requirements: Access to the hospital shall be comfortable for the patient and/or attendants/visitors. 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 cause. The hospital shall be developed and maintained to provide safe, clean and hygienic environment for patients, their attendants, staff and visitors. The hospital shall have 24hr provision of potable water for drinking & hand hygiene. It shall also have 24 hr supply of electricity, either through direct supply or from other sources. The hospital shall have clean public toilet(s). Furniture and fixtures shall be available in accordance with the activities and workload of the hospital. They shall be functional and properly maintained.

2. The minimum space requirements shall be as per the mentioned criteria:

(a) Hospital level 1 (A) and (B) shall be as follows:

- I. Area (Desirable) . Ward bed and surrounding space 6sqm/ bed; Desirable: in addition circulation space of 30% as indicated in total area shall be provided for Nursing station, Ward store, Sanitary etc Minor Operation Theatre/Procedure room
- II. OT for minor procedures (where applicable) 10.5sqm (Desirable).
- III. Labour room- Labour Table and surrounding space 10.5 sqm/ labour table.
- IV. Other areas- nursing station, doctors’ duty room, store, Clean and dirty utility, Circulating area, Toilets 10.5 sqm for clean utility and store and 7 sqm for dirty utility and 3.5 sqm for toilet.

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- V. Bio-medical Waste 5 sqm other functional areas (laboratory, diagnostics, front office/reception, waiting area, administrative area etc.) shall be appropriately sized as per the scope of service and patient load of the hospital.

(b) Hospital level 2 shall be as follows:

Total Area		
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.	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, Sanitary etc.
Intensive Care Unit (if available)		
3.	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, trolley, toilet 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, Toilets	10.5 sq mt for clean utility and store and 7 sq mt for dirty utility and 3.5 sq mt for toilet.
Operation Theatre (OT)		
7.	Operating Room Area	24.5 sq mt per operating room.
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.

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Bio-medical Waste		
10.	< 50 beds	5 sq m
11.	50 – 100 beds	10 sq m
12.	> 100 beds	20 sq m

(c) Hospital level 3 shall be as follows:

Total Area		
1.	Total Area of hospital level 1 including 30 % area for circulation space for corridors, lobby, reception area	50 sq mt/bed as carpet area.
Wards		
2.	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, Sanitary etc.
Intensive Care Unit		
3.	For ICU/CCU/Neuro ICU/HDU/Trauma ICU/Renal ICU 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, trolley, toilet 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, Toilets	10.5 sq mt for clean utility and store and 7 sq mt for dirty utility and 3.5 sq mt for toilet.
Operation Theatre (OT)		
7.	Operating Room Area	30.5 sq mt per operating room.
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
Bio-medical Waste		
10.	< 50 beds	5 sq m
11.	50 – 100 beds	10 sq m
12.	> 100 beds	20 q m

Note: Structural changes shall be applicable to the Nursing home / Hospitals constructed after the implementation of CEA since it is not possible to change the existing structures, especially with restrictions of building bye-laws.

3. Medical Equipment and Instruments: The hospital shall have adequate medical equipment and instruments, commensurate to the scope of service and number of beds. There shall be established system for maintenance of critical equipment. Equipment shall be kept in good working condition through a process of periodic inspection, cleaning and maintenance along with availability of Pressure Swing Adsorption (PSA) plants.

List of Emergency Equipment for different level hospital:

Hospital level 1 (A) & (B)	Resuscitation equipment including Laryngoscope, endotracheal tubes, suction equipment, xylocaine spray, oropharyngeal and nasopharyngeal airways, Ambu Bag- Adult & Paediatric (neonatal if indicated) ,Oxygen cylinders with flow meter/ tubing/catheter/face mask/nasal prongs 3 Suction Apparatus , Defibrillator with accessories (Desirable) , Equipment for dressing/bandaging/suturing , Basic diagnostic equipment- Non mercury Blood Pressure Apparatus, Stethoscope, weighing machine, thermometer (Non mercury) , ECG Machine 8 Pulse Oximeter (Desirable) , Nebulizer with accessories.
Hospital level 2	Resuscitation equipment including Laryngoscope, endotracheal tubes, suction equipment, xylocaine spray, oropharyngeal and nasopharyngeal airways, Ambu Bag- Adult & Pediatric (neonatal if indicated) , Oxygen cylinders with flow meter/ tubing/catheter/face mask/nasal prongs , Suction Apparatus ,Defibrillator with accessories , Equipment for dressing/bandaging/suturing , Basic diagnostic equipment- Blood Pressure Apparatus, Stethoscope, weighing machine, thermometer , ECG Machine 8 Pulse Oximeter , Nebulizer with accessories.

Hospital level 3	Resuscitation equipment including Laryngoscope, endotracheal tubes, suction equipment, xylocaine spray, oropharyngeal and nasopharyngeal airways, Ambu Bag- Adult & Pediatric (neonatal if indicated) , Oxygen cylinders with flow meter/ tubing/catheter/face mask/nasal prongs , Suction Apparatus , Defibrillator with accessories. Equipment for dressing/bandaging/suturing ,Basic diagnostic equipment- Blood Pressure Apparatus, Stethoscope,, weighing machine, thermometer 7 ECG Machine , Pulse Oximeter ,Nebulizer with accessories.
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4. **Drugs, Medical devices and Consumables:** The hospital shall have adequate drugs, medical devices and consumables commensurate to its scope of services and number of beds. Emergency drugs and consumables shall be available at all times. Drug storage shall be in a clean, well lit, and safe environment and shall be in consonance with applicable laws and regulations. The facility shall have defined procedures for storage, inventory management and dispensing of drugs in pharmacy and patient care areas.

5. **Support Services:** The Hospital shall have a Registration/ Help-desk & Billing counter. The diagnostic services, whether in house or outsourced, shall be commensurate with the scope of service of the hospital. Segregation, collection, transportation, storage and disposal of general waste shall be done as per applicable local laws. Segregation, collection, transportation, storage and disposal of biomedical waste shall be done as per Bio medical waste handling rules. The Hospital shall arrange transportation of patients for transfer/referral/investigations etc. in safe manner. The arrangement can be out sourced or self owned.

6. **Basic-Processes:** The hospital shall register all patients who visit the hospital except if the required service is not available in the facility, in which case the patient is guided to the appropriate nearest facility. Patient shall be guided and informed regarding Patients' rights & responsibilities, cost estimates, third party services (e.g. Insurance) etc. The billing shall be as per the Hospital tariff list, which shall be available to patients in a suitable format. Each patient shall undergo an initial assessment by qualified and/or trained personnel. 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.

The Hospital shall ensure adequate and proper spacing in the patient care area so as to prevent transmission of infections. Regular cleaning of all areas with disinfectant shall be done. Housekeeping/sanitary services shall ensure appropriate hygiene and sanitation in the establishment. At the time of admission of patient, general consent for admission shall be taken. 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.

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. 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 . The patient and family shall be treated with dignity, courtesy and politeness. The Hospital shall provide care of patient as per Standard Treatment Guidelines that may be notified by the Central /State Government (Desirable).The Clinical Establishment shall undertake to provide within the staff and facilities available, such medical examination and treatment as may be required to stabilize the emergency medical condition of any individual who comes or is brought to such clinical establishment.

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. 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. Patient identity, medication, dose, route, timing, expiry date shall be verified prior to administration of medication. Patients shall be monitored after medication administration and adverse drug reaction/events if any shall be recorded and reported.

The hospital shall follow standard precautions like practicing hand hygiene, use of personal protection equipment etc. so as to reduce the risk of healthcare associated infections. Security and safety of patients, staff, visitors and relatives shall be ensured by provision of appropriate safety installations and adoption of appropriate safety measures. The patient and/or family members are explained about the disease condition, proposed care, including the risks, alternatives and benefits. They shall be informed on the expected cost of the treatment. They shall also be informed about the progress and any change of condition. 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, Blood transfusion, HIV testing, etc.). A Discharge summary shall be given to all patients discharged from the hospital. Discharge/Death summary shall also be given to patient and/or attendant in case of transfer LAMA/DAMA or death .The discharge summary shall include the points an understandable language and format.

4 STANDARDS FOR LABOUR ROOM:

1. Infrastructure: The physical condition of building shall be safe for providing patient Care. There shall be availability of adequate space for labour room (10.5 sq mt/ labour table and 10.5 sq mt for clean utility and store and 7 sq mt for dirty utility and 3.5 sq mt for toilet.).

There shall be availability of attach toilet with labour room. The area shall be earmarked for newborn care corner with dedicated nursing station in proximity with labour room.

2. Patient's Right: Service provision and entitlements shall be displayed at the entrance of labour room and relative's waiting area. The written informed consent shall be taken before procedure. The services shall be provided in manner that is sensitive to gender.
3. Support Services: There shall be facility for maintenance of critical equipment. The operating and maintenance instruction shall be available with the users of equipment. Patient care area shall be clean and hygienic. There shall be availability of power backup in labour room.
4. Clinical Services: The recording and reporting of clinical history and current labour details shall be maintained. Patient shall be referred with referral slip. Referral in or referral out register shall be maintained. Every medical advice and procedure shall accompany with date time and signature. Identification tags for mother and baby shall be there. Footprint shall be used for identification of newborn babies.
5. Infection Control: The availability of hand hygiene facility and running water shall be present. Equipment and instruments shall be sterilized after each use as per requirement. All the staffs shall be trained for spill (Blood and Mercury) management. The facility shall ensure segregation of bio medical waste as per guidelines and on site management of waste is carried out as per guidelines.
6. Quality Management: Work instruction of the staffs shall be displayed at point of use.

5 STANDARDS FOR RADIODIAGNOSTIC CENTRE:

1. Service Provision: Facility shall provide diagnostic services like x ray services for chest, bones, skull, spine and abdomen; dental x ray services- dental x ray, OPG etc, ultrasound of various body parts, prenatal USG; CT scan, PET CT, MRI services wherever applicable.
2. Patient Rights: There shall be availability of departmental signage's, display of PCPNDT notice at USG clinic, display of cautionary signage, sex determination and asking the same is also prohibited and punishable as per PCPNDT Act, radiation hazard sign and caution for pregnant women and children. All the information shall be available in local languages. Female attendant shall accompany for female patient. Confidentiality of patient's records shall be maintained. Form F for USG under PC-PNDT act shall be maintained.
3. Infrastructure: Room size of x-ray unit shall be as per AERB safety code: room housing shall not be less than 18sqm, any dimension not less than 4m.

The distance between control panel and x ray unit shall not be less than 3m and corridors are wide enough for movement of trolleys and stretchers approx. 2-3 meters. Stabilizers shall be there for x-ray machine. X-ray department shall not be located adjacent to patient care area. Department shall have adequate space. Room housing x-ray equipment shall have appropriate area to facilitate easy movement of staff & proper patient positioning. Attached toilet facility and waiting area shall be there. Physical condition of building shall be safe. Periodic quality assurance check-up of equipments by AERB is needed.

4. Clinical Services: Unique identification number shall be given to each patient. The patient demographic details shall be recorded in radiology/USG records. Requisition of all x-ray and USG examination shall be done in request form. The department shall identify high risk patient i.e. department shall ask every female to inform radiographer/radiologist whether she is likely to be pregnant or not. Requisition and reports shall mark with MLC and reports shall be handed over to authorized personnel.
5. Support services: All equipments shall be covered under AMC including preventive maintenance. The protective apron and gloves shall be provided to relative of the child patient who escorts the child for x-ray examination/immobilization support shall be provided to children. Lead aprons and other protective equipments shall be available with radiation workers. Availability of power backup in radiology and USG room shall be there. TLD badges shall be available with all staff of radiology department.
6. Infection Control: There shall be the provision of periodic medical checkups and immunization of all the staffs. Facility shall ensure segregation of biomedical waste as per guidelines. TLD badges shall be checked periodically as per AERB guidelines.
7. Legal /Statutory Requirements: All statutes and regulatory requirements mandated through prevalent acts like AERB & PC PNDDT shall be complied with as per the scope of service. Refer to current AERB safety code and PC PNDDT act for further details.

6 STANDARDS FOR IPD:

1. Infrastructure: There should be distance between centres of two beds- 2.25meter. There shall be availability of drinking water, separate toilet for patient and visitors. Availability of dedicated nursing station examination room, doctor's duty room, and store room shall be present. There shall be available of dirty utility room, functional toilets with running water. Space between two beds shall be at least 4ft and clearance between head end of bed and wall shall be at least 1ft. and between side of bed and wall shall be 2ft. Ward shall have fire exit to permit safe escape of its occupant at time of fire. IPD shall be install fire extinguish which will be capable of fighting A, B&C type of fire.

2. Patient Rights: Availability of departmental signage shall be there. Visiting hours and visitor policy shall display. Contact details of referral transport/ ambulance shall display. Relevant IEC material shall be display in wards. Signage and information shall be available in local language. Separate male and female wards shall be there. Availability of wheel chair or stretcher shall be there for easy access to the ward. There shall be available of ramps with railing and disable friendly toilet. General consent shall be taken before admission. Patient shall be informed about clinical condition and treatment being provided. There shall be availability of complain box and display of process for grievance redressed and with contact detail.
3. Support Services: 24 hours security, housekeeping and laundry services shall be available here.
4. Clinical Services: Unique identification number shall be given to each patient during registration. Patient demographic shall be recorded in admission records. Admission shall be done by written order of a facility of doctor present in establishment .Time of admission shall record in patient record and treatment chart shall be maintain. Register/records shall be maintained as per guidelines.
5. Infection Control: There shall be procedure for immunization of all the staff. Availability of hand washing facility and availability of running water shall be there. All the staffs shall be trained for spill management. The facility shall ensure segregation of bio medical waste as per guidelines and onsite management of waster shall carry out as per guidelines. The facility shall ensure transportation and disposal of waste as per guidelines. There shall be periodic collection & examination of samples from different sites of the IPD to prevent hospital acquired infections.
6. Quality Management: There shall be a designated nodal person for coordinating quality activities.

7 STANDARDS FOR OPERATION THEATRE:

1. Infrastructure: There shall be adequate space for accommodating surgical load (as per the level of hospital and Nursing home). There shall be present of waiting area for attendants. Demarcated protective zone, clean zone, sterile zone, disposal zone shall be present in the establishment. Availability of changing room, pre and post operative rooms shall be there. There shall be available scrub area. Availability of autoclave room/TSSU; dirty utility area; store room shall be there. Corridors shall wide enough for movement of trolleys: 2-3 meters. OT should have fire exit to permit safe escape to its occupant at time of fire.

2. Patients Right: Signage for restricted area shall be display. Signage and information shall be available in local language. Wheel chair or stretcher for easy access to the OT shall be available here. Informed/ written consent shall be taken before any surgery. Anesthesia consent shall be taken for OT.
3. Support Services: All equipment shall cover under AMC including preventive maintenance. Narcotic and psychotropic shall be kept in lock and key. Anesthetic Agents shall keep at secured place. Adequate illumination at pre and post Operative area should present. The facility shall have provision of restriction of visitors in patient area. There shall be availability of 24 hours running and portable water. Availability of power back up in OT shall be there. Centralized/local piped oxygen, nitrogen and vacuum supply shall present there.
4. Infection Control: There shall be procedure for immunization of the staffs. There shall be availability of hand washing facility at point of use. All the staff shall trained for spill management. Facility shall ensure segregation of bio medical waste as per guidelines. Facility shall ensure transportation and disposal of waste as per guidelines.

8 STANDARDS FOR ICU/MICU/SICU:

1. Service Provision: The facility shall provide general medicine i. e. major medical cases like CVA, Hematomas, CAD, Haemoptysis, snake bite, br. asthma, poisoning etc, availability of general surgery: major surgical cases including trauma. The facility shall provide obstetrics, neonate and pediatric services i.e. incubation tracheotomy, CPR, mobilization, chest tube, ventilator etc. The facility must have portable X ray, ECG, USG machine and functional side laboratory. There shall be availability of cardiac care unit.
2. Patient Rights: In ICU there must be proper signage. There shall be availability of signage and information in local languages. Service provision and which services will not be available in ICU shall be display. There shall be availability of female staff for attending female patients. Availability of wheel chair or stretcher shall be available here. Confidentiality of patient's record shall be maintained. There shall be taken consent before taking admission, intubation, and blood transfusion.
3. Inputs: Space requirement in ICU is 100 – 125sq feet area per bed in patient care area including space for storage and duty room etc. There shall be availability of adequate waiting area, availability of drinking water and functional toilets. All monitor /patient must direct or throw central monitoring system. Separate doctor and nurse change room shall be available here.

Availability of general duty doctor in 1:5 ratios. Availability of nursing staff as per guidelines. There shall be sufficient space between two beds. ICU must have the equipment and instrument required i.e. bed side monitor, pulse oximeter, thermometer, BP apparatus, Glucometer, ventilator, infusion pump etc. Availability of ancillary area: Nursing station, clean and dirty utility area, unit stores, Hand washing and gowning area. ICU shall have sufficient fire exit.

4. Support Services: Adequate illumination in patient care is (200 – 50 lux), the temperature of ICU (20 – 25`c) shall be maintained. Patient care area shall be clean and hygienic. Facility shall ensure 24 hours water and power as per requirement. Dietary service shall be available as per service provision.
5. Clinical Services: Unique identification number shall be given to the patients. All the demographic details like name, age and sex, chief complaint etc. shall be maintain. Facility shall provide appropriate referral linkage. Facility shall have a procedure to identify high risk and vulnerable patients. There shall have process for identifying and high alert drugs availability in department. The facility shall defined and established procedure for blood bank/ storage management and transfusion.
6. Infection Control: Facility shall provide regular monitoring of infection control. The availability of hand hygiene and running water shall be there. Equipment and instrument shall be sterilized after each use as per requirement. Staff shall be trained for spill management. The facility shall ensure segregation of bio medical waste as per guidelines.
7. Out Come: Facility shall measures efficiency indicators on downtime critical equipments i.e. transfer rate, re admission rate.

9 STANDARDS FOR PATHOLOGICAL COLLECTION CENTRE:

1. Service Provision: There shall be availability of hematology services, bio chemistry services, Microbiology, urine and stool analysis.
2. Patient's Right: The facility shall have uniform. Information shall be available in local language and easy to understand.
3. Infection Control: There shall be provision of periodic medical checkup, and immunization of staffs, facility ensures segregation of bio medical waste as per recent guidelines.
4. Support Services: All equipments shall be covered under EQAS/ internal quality control including preventive maintenance.

10. STANDARDSFOR PHYSIOTHERAPY:

1. Service Provision: Facility shall provide various therapies like electro therapy (Adult/ pediatrics) – hydro collator, ultrasound therapy, electrical energy, electrical muscle stimulator; exercise therapy – shoulder exercise unit, wrist and hand exercise unit, abduction ladder etc; machine therapy- cervical and lumber traction system, hydrotherapy, manual therapy.

2. **Infrastructure:** The physical facility shall be developed and maintained to provide safe and secure environment for patients, their families, staff and visitors. The area shall be well illuminated, ventilated and clean with adequate water supply. The total area requirement shall be broadly classified in to two categories; common area and treatment area. There shall be portable water supply and toilet attach with the establishment. The physiotherapy centre shall be prominent board/ signage displaying the name of the centre in local language at the gate or on the building. Other physiotherapy equipments as per the scope of service and work load requirement shall be available. Periodic inspection, cleaning, maintenance of equipments shall be done.
3. **Support Service:** Support services like registration, billing, waste management etc can be shared with the hospital, the physiotherapist card/ slip of every registered patient shall bear the minimum legibly at every visit. Working diagnosis as provided by the treating medical doctor who has referred the patient.
4. **Infection Control:** The physiotherapy centre shall take all precautions to control infection like practicing, hand hygiene etc. Bio medical waste shall be managed in accordance with the BMW management and handling rules, 1998.

11 STANDARDS FOR PHYSICAL THERAPY CENTRE:

1. **Service Provision:** Care and treatment shall provide in a uniform manner. Facility shall have appropriate staff, facilities, protocols and procedures in consonance with the scope of service. Patients with special needs and disabilities shall be identified and treated accordingly. A documented procedure exists for obtaining informed consent from the appropriate legal representative. The physical therapy clinic shall support appropriate assessment and management of pain. These services are commensurate with the clinic requirements.
2. **Patients Right:** Patient and family right and responsibilities shall be displayed. Staff shall aware of their responsibilities in protecting patient's right. The care plan as decided by the staff on duty or the patient management team to be discussed with the patient and family member .signage and information shall be available in local language. Female staff shall be available for attending female patients.
3. **Infrastructure:** Separate toilet and separate waiting area shall be available for the patient. The area shall be well illuminated, well ventilated and clean with adequate water supply.
4. **Infection Control:** There shall be provision of periodic medical checkups and immunization of staffs. Facility ensures segregation of bio medical waste as per recent guidelines.

ANNEXURE - III

(See Rule 3)

Minimum number of required personal, technical or non-technical

1. **Hospital:** The hospital shall have qualified and trained medical and nursing staff as per the scope of service provided and the medical or nursing care. The support or paramedical staff shall be qualified or trained as per the scope of services provided, and as per requirement. For every staff (including contractual staff), there shall be personal record containing the appointment order, documentary evidence of qualification or training (and professional registration where applicable).

A) For Hospital level 1(A) & (B) :

Doctor	Qualified doctor shall be available round the clock on site (Desirable for 1A). Level 1A shall have a MBBS qualified doctor. (Qualified doctor is a MBBS approved as per state government rules & regulations as applicable from time to time). Level 1B shall have MBBS doctor with required post-graduation qualification.
Nurses	Qualified nurses per unit per shift shall be available as per requirement laid down by “The Indian Nursing Council, 1985”, occupancy rate and distribution of bed (Desirable). The details placed in the separate table.
Pharmacist (If in house pharmacy available)	1 in a hospital
Lab Technician (if in house laboratory service available)	1 in a hospital (minimum DMLT) BSc, MSc ,MLT(Desirable)
X-ray Technician (if in house X-ray facility available)	1 in a hospital (minimum Diploma in X Ray Technician course)
Multi Task staff	Minimum 1

B) Hospital level 2 :

Doctor	MBBS doctor shall be available round the clock on site per unit. And 1 Doctor with specialization in the subject concerned as per scope of service (Full-Time / Part-Time or visiting)
Nurses	Qualified nurses per unit per shift shall be available as per requirement laid down by “The Indian Nursing Council, 1985”, occupancy rate and distribution of bed (Desirable). The details placed in the separate table.

Pharmacist (If in house pharmacy available)	1 in a hospital
Lab Technician (if in house laboratory service available)	1 in a hospital (minimum DMLT)
X-ray Technician (if in house X-ray facility available)	1 in a hospital (minimum Diploma in X Ray Technician course)
Multi Task staff	Minimum 2 (minimum 12th pass)
Doctor	MBBS doctor shall be available round the clock on site per unit 1 Doctor with specialization in the subject concerned as per scope of service (Full-Time / Part-Time or visiting) In ICU, 1 MBBS for every 6 beds , on- site for 24X7
Nurses	Qualified nurses per unit per shift shall be available as per requirement laid down by “The Indian Nursing Council, 1985”, occupancy rate and distribution of bed (Desirable). The details placed in the separate table.
Pharmacist (If in house pharmacy available)	2 in a hospital
Lab Technician (if in house laboratory service available)	2 in a hospital (minimum DMLT)
X-ray Technician (if in house X-ray facility available)	2 in a hospital (minimum Diploma in X Ray Technician course)
Security Guard	Minimum 1 in every department in every shift.
SCA	Minimum 1 in every department in every shift.

Note: *Requirement of other staff (Support and administrative) will depend on the scope of the hospital.

C) Hospital level 3 :

Doctor	MBBS doctor shall be available round the clock on site per unit. And 1 Doctor with specialization in the subject concerned as per scope of service (Full-Time / Part-Time or visiting)
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Nurses	Qualified nurses per unit per shift shall be available as per requirement laid down by “The Indian Nursing Council, 1985”, occupancy rate and distribution of bed (Desirable). The details placed in the separate table.
Pharmacist (If in house pharmacy available)	4 in a hospital
Lab Technician (if in house laboratory service available)	6 in a hospital (minimum DMLT)
X-ray Technician (if in house X-ray facility available)	4 in a hospital (minimum Diploma in X Ray Technician course)
Multi Task staff	Minimum 20 (minimum 12th pass)
Public Relation Officer	Minimum 2
Biomedical Engineer	Minimum 1
Nutritionist	Minimum 1
Driver	Minimum 4
Medical Record Officer	Minimum 1
Security Guard	Minimum 1 in every department in every shift.
SCA	Minimum 1 in every department in every shift.

Note: *Requirement of other staff (Support and administrative) will depend on the scope of the hospital.

D) Hospital level 4: As per National Medical Commission (NMC) recent norms/any other norms.

*** Nurse Position as per recommendation of Indian Nursing Council (INC):**

1.	Normal Wards	1 Staff Nurse/Nursing Sister for every 6 beds
2.	Special Wards: I) Paediatrics II) Burns/Burns Plastic III) Neuro Surgery IV) Cardiac Thoracic V) Neuro Medicine VI) Nursing Home VII) Tetanus VIII) Spinal Injury IX) Emergency Wards attached to casual	1 Staff Nurse/Nursing Sister for every 4 beds
3.	Nursery	1 Staff Nurse/Nursing Sister for every 2 beds
4.	ICU/CCU/ICCR Nephrology (AK Dialysis)	1 Staff Nurse/Nursing Sister for every bed
5.	Labour Room	1 Staff Nurse/Nursing Sister for every labour table

6.	O.T. I) Major II) Minor	2 Staff Nurse/Nursing Sister for every functional operation table including recovery room. 1 Staff Nurse/Nursing Sister for every functional operation table.
7.	Casualty (Main) Attendance up to 100 patient per day. Thereafter for every additional attendance of 35 patients per day. Burns Attendance up to 15 Patient per day Thereafter for every additional attendance of 10 patients per day Orthopedics Attendance up to 45 patient per day. Thereafter for every additional attendance of 15 patients per day a) Gynac/Obstetrics Attendance up to 40 patients per day. Thereafter for every additional attendance of 15 patients per day.	3 Staff Nurse/Nursing sister for 24 hours i.e. 1 per shift 1 Staff Nurse/Nursing Sister 3 Staff Nurse/Nursing Sister for 24 hours i.e. 1 per shift 1 Staff Nurse/Nursing Sister 3 Staff Nurse/Nursing Sister for 24 hours i.e. 1 per shift 1 Staff Nurse/Nursing Sister For every additional attendance of 15 patient per day 1 Staff Nurse/ Nursing Sister
8.	O.P.D. (Injection Room) Attendance up to 100 patients per day Attendance up to 120-220 patients per day Attendance up to 221-320 patients per day Attendance up to 321-420 patients per day	1 Staff Nurse 2 Staff Nurse 3 Staff Nurse 4 Staff Nurse
9.	Name of Deptt. O.P.D. Blood Bank Paediatric Immunization work Eye ENT	 1 2 2 1 1

Pre-Anaesthetic	1
Cardiac Lab.	1
Bronchoscopy	1
Lab	1
Vaccination Anti Rabic	2
Family Planning	1
Medical	1
Surgical	1
Dental	1
Central Sample Collection Centre	2
Orthopaedic	2
Gynae Obstetric	3
Skin	2
V.D. Centre	2
Chemotherapy	2
Neurology	1
Microbiology Infection Control	2
Psychiatry	1
Burns	2

2. Other Clinical Establishment: The Clinical Establishment registered under the Act shall have qualified and trained medical and nursing staff as per the scope of service provided and the medical or nursing care:

Sl No.	Clinical Establishment	Minimum HR required
1.	Nursing Home	<p>i) Qualified doctor (MBBS) shall be available round the clock on site (Qualified doctor is a MBBS approved as per state government rules & regulations as applicable from time to time) .If the Nursing home is more than 20 beds than one additional doctor is necessary and the number will increase as per increase of the beds. If specialty services is given in the establishment than have specialist doctor who will be on call round the clock in case of emergency.</p> <p>ii) Qualified nurses per unit per shift shall be available as per requirement laid down by “The Indian Nursing Council, 1985”.</p> <p>iii) Specialist visiting doctor with details information 24 x 7 must be displayed.</p> <p>iv) Minimum 1 D. Pharma pharmacist and DMLT Lab technician.</p>

		v) 1 GDA for every 6 beds/ shift. vi) 4 Receptionists. vii) 1 Driver. viii) 1 SCA for every 10 bed/shift.
1.	OPD/ Clinic	1 GDA
2.	Polyclinic	2 GDA (1 preferably female) , 1 Receptionist
3.	Laboratory	1 Qualified Lab Tech (Minimum DMI/T Qualified) , 1 Receptionist , 1 GDA
4.	Radiological Center	1 Qualified Technician , 1 Receptionist , 1 GDA
5.	Collection Center	1 Qualified Technician , 1 Receptionist , 1 GDA
6.	Others	As per the qualification (technical)

ANNEXURE - IV

[See Rule 4 (f)]

Format of Inspection & Report by the District Supervising Team:

A. General Information:

1. Name of the Clinical Establishment		
2. Registration Number of the Clinical establishment		
3. Address		
Village/Town/City		Block
District	State	Pincode
Tel. No (with STD Code):		Mobile:
Email ID		Website(If any):
4.Name of Contact Person		

B. Type of establishment: (please tick whichever is applicable)

Sl No.	Establishment	Tick	Sl No.	Establishment	Tick
1.	Clinic (Out patient)		7.	Diagnostic Imaging centres	
2.	Polyclinic		8.	Polyclinic with Diagnostic Center	
3.	Day Care facility		9.	Collection centers	
4.	Hospitals including Nursing Home		10.	AYUSH	
5.	Dental Clinics and Dental Hospital		11.	Physical Therapy Unit	
6.	Medical Diagnostic Laboratories		12.	Other (Specify)	

C. Updated documents as per the Annexure – VI (if any lapses specify) –

D. Status of Standards:

E. Remarks (in details) :

Annexure - V
[See Rule 9]
(Format of Register)

A. General Information:

1. Name of the Clinical Establishment: _____
2. Registration Number of the Clinical establishment: _____
3. Address _____
Village/Town/City _____ Block _____
District _____ State _____ Pincode _____
Tel. No (with STD Code): _____ Mobile: _____
Email ID _____ Website (If any): _____
4. Name of Contact Person _____
Contact Details (Cell/Landline/email) _____
5. Clinical establishment Type:
[] General practice [] Speciality practice [] Super-Speciality practice [] Others

B. Basic Information:

Sl. No	Description	Male	Female
1	Total OPD Patients		
2	Total IPD Patients		
3	Total Deaths		
4	Number of Maternal Deaths		
5	Live Births		
6	No. Of Child full immunized		
7	No. of Neonatal Deaths(within 24 hours of Birth)		
	No. of Deaths of Children(0 to 28 days)		
	No. of Deaths of children(0 to 1 year)		
	No of Deaths of children under 5 years of age		

C. Specialty/ Department wise Reports: Specific Information:

Name of Specialty	Name of Disease/Procedure	No. of Cases
Ophthalmology	Cataract operations done	
	Glaucoma Cases	
	Corneal transplants done	

Mental Health	No. of Psychosis cases under treatment	
Gynae and Obstetrics	No. of institutional deliveries conducted(including Caesarian deliveries)	
	No. of cases received ANC (new cases)	
	No. of Still Births	
	No. of Maternal Deaths	
Neurology	No. of Strokes	
	Epilepsy	
CTVS		
Cardiology		
Gastroenterology	No. of Cirrhosis cases	
Trauma	No. of Major Head Injuries	
	Coma cases	
	No. of Brain Stem Death Certified	
Cancer	Type of Cancers	
Nephrology	Chronic Kidney Diseases(indicate Grade)	
	CRF	
	No. of Patients on Dialysis	
Physiotherapy	No. of Patients	
Physical therapy	No. of Patients	

D. Information to be collected Monthly from Diagnostic Imaging Centres under Clinical Establishments:

No. of tests performed in the following departments.		
Sl. No	Department	Tests Number
1	X- ray	
2	USG	
3	CT Scan	
4	MRI	
5	Mammography	
6	Bone Densitometry	
7	Doppler	
8	ECG	
9	ECHO cardiography	
10	Holter monitoring	
11.	Endoscopy	
12.	Colonoscopy	
13	Others	

E. Information to be collected Monthly from Laboratory under Clinical Establishments:

No. of tests performed in the following departments.		
Sl. No	Category	Tests Number
1	No. of test performed (Biochemistry)	
2	No of test performed (Microbiology)	
3	No of test performed (Pathology)	
4	Other	

Place:

Signature

Date:

Doctor/Supervising Doctor.

ANNEXURE – VI

(A) Check list for new registration/renewal of registration under Tripura Clinical Establishment Act for OPD/CLINIC providing examination, consultation, prescription to outpatients excluding dispensing of medicines:

1. Duly filled –FORM-A/ B application.
2. Treasury challan.
3. Up to date Bio Medical Waste Certificate for proper Disposal.
4. Facility for electricity, water supply, biomedical Wastage disposal.
5. List of Doctors, Staff Nurses & other working staff.
6. Maintenance of various registers online / offline as per the reporting format.

(B) Check list for new registration/renewal of registration under Tripura Clinical Establishment Act for Polyclinic/ Nursing Home/ Private Hospital/ Laboratory/ Radiological clinic/ Pathological collection centre etc.

1. Duly filled – in FORM-A/ B application.
2. Treasury challan.
3. Up to date Trade License.
4. Up to date Drug License.
5. Up to date Sanitary Clearance Certificate.
6. Upto date Pollution Control Board Certificate.
7. No objection from the owner of house.

8. NOC from neighbours.
9. Facility for electricity, water supply, biomedical Wastage disposal.
10. List of Doctors, Staff Nurses & other working staff.
11. Consent from attached Medical Practitioner / Nursing Staffs and other Staffs with qualification certificates.
12. Up to date Bio Medical Waste Certificate for proper disposal.
13. Submission of Names of visiting Medical Practitioners / Surgeons from outside Tripura along with the Certificate of Registration in Tripura Medical Council to the District Registering Authority.
14. Maintenance of various registers like Admission Register / Operation Register / Discharge Register, Death Register, Cash book etc.
15. Clearance Certificate from Director Fire Services, Government of Tripura regarding fitness of the fire fighting arrangement and lift.
16. Clearance Certificate from the appropriate authority regarding soundness of Internal Electrification of the building.
17. Clearance Certificate from the concerned Urban Local Body to the effect that the building has been constructed in pursuance of Tripura Building Rules (Latest) and with due permission.
18. Land and construction permission certificate
19. FSSAI license for operating a kitchen.
20. Vehicle registration for ambulance.
21. Atomic energy regulatory body approval in case of radiology.
22. License for the blood bank.
23. Name with identical proof preferably Aadhar card of the technical and non technical staff who are working in clinical establishment.