

Kerala Clinical Establishments (Registration and Regulation) Act 2018

Purpose

- ❖ To provide for the registration and regulation of all private as well the public clinical establishments in the state from all recognized systems of medicine.
- ❖ Prescribe minimum standards for different category of establishments
- ❖ **Desired Impact:** Improvement in quality of the services provided by the establishments and thus envisage an improved Public health.

Definitions

(c)"clinical establishment" means,-

(i) a hospital, maternity home, nursing home, clinic, sanatorium or an institution, by whatever name called, that offers services, facilities with or without beds requiring treatment, diagnosis, or care for illness, injury, deformity, abnormality, dental care, pregnancy or infertility in any recognised system of medicine established and administered or maintained by any person or body of persons, whether incorporated or not; or

(ii) a place established as an independent entity or part of an establishment referred to in sub-clause (i), in connection with the diagnosis or treatment of diseases where pathological, bacteriological, genetic, radiological, chemical, biological investigation or other diagnostic or investigative services with the aid of laboratory or other medical equipment, are usually carried on, established and administered or maintained by any person or body of persons, whether incorporated or not, and shall include a clinical establishment owned, controlled or managed by,-

Includes

Clinical establishments across all systems of medicine owned, controlled or managed by:

- The Government or a department of the government;
- A trust, private or public;
- Individual proprietorship;
- Partnership firm;
- Corporation registered under a Central, Provincial or State act whether or not owned by the government;
- A local authority

Excludes

- ❖ Clinical establishments owned, controlled or managed by the Armed Forces.
- ❖ Establishments offering only consultation services.
 - “consultation services” means medical examination, prescribed types of diagnosis and accordingly to administer the medicines and also the first aid and observation;

Section 2 (c) (ii)

Salient Features of the Act

- ❖ **Mandatory Registration of All Clinical Establishments under the District Registration Authority** (Section 16 (1))
- ❖ **Web based technology**
 - Application for registration, verification of applications and approval, rejection and cancellation.
 - Assessment, Inspections, Inquiry, Appeals and Grievance Redressal
 - Online Register of Clinical Establishments (Section 12)
- ❖ **Display of information about Clinical Establishments' in public domain**
 - Facilities and services available in the Clinical establishments to be displayed.
- ❖ **Data and information to be provided to the Government.** (Section 15(d))
- ❖ **Charges and fees in each establishment to be displayed.**

Institutional Mechanisms

❖ **State Council:** to classify clinical establishments into different categories and determine minimum standards and review them periodically. (Section 3)

- 22 member multi stakeholder body with Secretary Health as Chairperson
- Executive Committee: 9 member body chaired by Secretary Health

❖ **District Registration Authority**

- Key implementation body
- Consists of Collector as Chairperson, DMO as the Vice chairperson and others
- grant registration, enforce compliance, cancel registration, conduct inspections.

❖ **Appellate Authority**

- 3 members, Secretary Health, Additional Law Secretary and DME
- to hear appeals from the clinical establishments. (Section 34)

❖ **Grievance Redressal: 3 members**

- Mechanism to hear and decide on complaints from the public. (Section 36)

State Council

The Council consists of the following members, namely:-

- a) Secretary to the Government, Health and Family Welfare Department, *ex-officio* – the Chairperson;
- (b) Secretary, Ayush Department, *ex-officio* who shall be the Vice Chairperson;
- (c) Director of Health Services, *ex-officio*;
- (d) Director of Medical Education, *ex-officio*
- (e) Director of Indian System of Medicine, *ex-officio*;
- (f) Director of Homoeopathic Department, *ex-officio*;
- (g) Director, Public Health Laboratory, *ex-officio*;
- (h) one representative each to be nominated by,-
 - (i) the Council of Modern Medicine;
 - (ii) the Council of Indigenous Medicine; and
 - (iii) the Council of Homoeopathy.

(i) one representative each to be nominated by,-

(i) the Kerala Dental Council

(ii) the Kerala Nursing Council

(j) Government Nominees:

i. one representative from patient welfare organisations in the State of Kerala

ii. an officer not below the rank of Additional Secretary to Government, Law Department

iii. an Officer not below the rank of Additional Secretary to Government, Finance Department

iv. one representative of Indian Medical Association, Kerala Unit;

v. one representative of Ayurveda **M**edical Association of India; Kerala Unit;

vi. one representative from the Indian Dental Association, Kerala Unit;

vii. one representative from the Association Homeopathy doctors in Kerala

viii. one representative from the Association for the Medical Laboratory Owners in Kerala

ix. one representative from the association of physiotherapists in Kerala

(k)Secretary of the Council. (An officer not below the rank of Deputy DHS to be appointed by Govt)

Functions

- ❖ Within a period of two years from its establishment, classify the clinical establishments into different categories and develop minimum standards.
- ❖ Compile and publish State Register of Clinical Establishments.
- ❖ Appoint panel of assessors for inspection and assessment of the clinical establishments.
- ❖ Conduct periodic review of clinical establishments for verifying the standards to be maintained.
- ❖ Recommend to the Government any modification required in the rules in accordance with the changes in technology or social conditions;

- ❖ Notify data and information which are to be mandatorily provided by the clinical establishment onto the public domain.
- ❖ Send periodic returns for updating the National Register as required by Govt of India or the National Council constituted under the CEA, 2010
- ❖ Direct to cancel registration of such CE where there is imminent danger to public health and the health and safety of patients and staff;
- ❖ Establish and maintain a grievance redressal mechanism to receive and investigate complaints

Responsibilities

- ❖ The Council shall meet at least once in three months initially for a period of two years thereafter at least once in six months.
- ❖ Compile and update the State Register containing details of the clinical establishments.
- ❖ The register will be an online one with live updation and it will be published in a monthly basis.
- ❖ Publish and update the details on the website for public access.

Executive Committee

8. *Executive Committee.*-The Council shall have an Executive Committee consisting of the following members, namely:-

- (i) Secretary, Health and Family Welfare Department, who shall be the Chairperson;
- (ii) Secretary, Ayush Department, who shall be the Vice- Chairperson;
- (iii) Director of Health Services;
- (iv) Director of Medical Education;
- (v) Director of Indian Systems of Medicine;
- (vi) Director of Homoeopathy Department ;
- (vii) Director of Public Health Laboratory;
- (viii) one representative of the welfare organisation of patients, nominated by the Government; and
- (ix) Secretary of the Council, who shall be the Convenor.

Executive Committee

- ❖ Executive Committee would be responsible for managing the day to day affairs of the Council.
- ❖ The Executive Committee would meet at least once every month
- ❖ The Executive committee would also:
 - Facilitate the development of the minimum standards, forms, templates , guidelines;
 - Provide guidance and assistance to the Authority, Appellate Authority, Grievance Redressal Committee in the implementation of the provisions of the Act and rules.
 - Order inspections in consultation with the Authority in case of public health emergency and recommend, steps for closure and cancellation of the registration.
 - Manage the website of the Council

District Registration Authority

Registration Authority for each District consists of following members:

- (a) District Collector, *ex-officio*- Chairperson;
- (b) District Medical Officer, *ex-officio*-Vice-Chairperson;
- (c) A medical officer of the District Medical Office nominated by the Government- Convenor;
- (d) A medical officer of the Indian System of Medicine nominated by Government
- (e) A medical officer of the Homeopathic system of Medicine nominated by Government
- (f) One member to be nominated by the District Collector from a professional association in the health sector for a period of two years.

Functions

- ❖ Grant, renew, suspend or cancel registration of a clinical establishment;
- ❖ Enforce compliance of the provisions of the Act and the rules made thereunder;
- ❖ Cancel registration of such establishments where there is imminent danger to public health and the health and safety of patients and staff;
- ❖ Prepare and submit reports periodically of such nature as directed by the Council;
- ❖ Report to the Council on a quarterly basis the action taken against non-registered clinical establishments;

Responsibilities

- ❖ The Authority shall meet at least once in two months.
- ❖ The Vice-Chairperson may on behalf of the Authority:
 - Accept the applications submitted by the clinical establishments.
 - Verify the application and if found to be satisfactory issue a certificate for provisional registration within 45 days of application.
- ❖ In order to update and maintain the State Register, the District Registration Authorities of all the districts shall submit a quarterly report which includes
 - Details of the newly registered clinical establishments
 - Clinical establishments which have lost the registration due to various reasons
 - Clinical establishments currently registered.

Conditions for Registration

- ❖ Achieve and adhere to **minimum standards** according to the category of the clinical establishment
- ❖ **Have minimum qualifications** for the Medical and Para- Medical Staff
- ❖ Mandatorily **comply with the orders issued by the Council** from time to time
- ❖ **Furnish such information** to the state government as notified.
- ❖ **Maintain standards of safety, infection control and standard treatment guidelines**

Provisional Registration

- ❖ Existing clinical establishments- from all recognised systems of medicine
- ❖ Provisional registration valid for 2 years
- ❖ District Registration Authority shall, verify online and grant provisional registration within forty five days of the date of receipt of the application
- ❖ There **will not be** any assessment before granting provisional registration
- ❖ Registration Authority and State Council shall have power to cancel the registration of the clinical establishments which fails to comply with the conditions prescribed in the Act and its Rules.

Registration of Government Clinical Establishments

- ❖ All government clinical establishments i.e. health center's, hospitals, dental, laboratories and diagnostic center's should be registered.
- ❖ Details of human resources and diagnostic equipment's need to be filled and submitted along with the online registration form.
- ❖ Registration fee, renewal fee and assessment **fees are exempted.**
- ❖ Onus of responsibility on person in charge of the establishment in case of non registration on time and may invoke penalty and disciplinary proceedings.

Responsibilities of the District Registration Authority

- Verification and approval of the applications submitted.
- Renewal (permanent), suspension and cancellation of registration.
- Incomplete or wrong applications can be returned or rejected.
- Process to be completed before 45 days for provisional registration and within 60 days for permanent registration.
- If approval is not done by the DRA, automatic approval will be done by the online system.
- If such automatically issued certificates are later found to be inappropriate then the issuing authority will be held accountable as per the provisions of this Act.

The Authority must be familiar with

- I. [Form 2](#) - Application form for the hospitals with or without laboratory services
- II. [Form 2A](#) - Application form for the Laboratory & Diagnostic Imaging Centre (stand alone establishments)
- III. [Form 3](#) - Acknowledgement
- IV. [Form 4](#) - Provisional certificate provided to the establishment

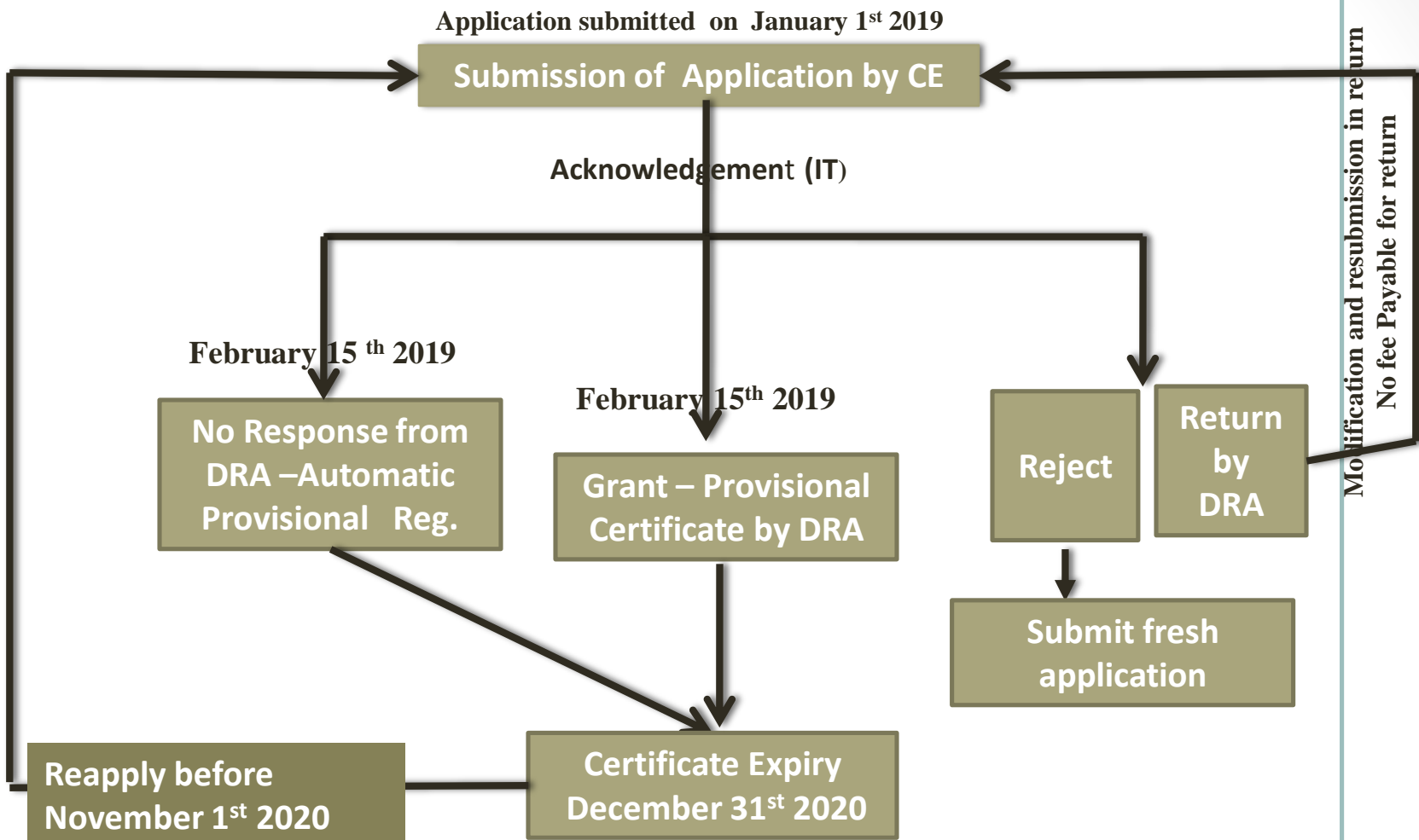
Application for provisional registration

- ❖ An establishment offering services in more than one category needs to apply for a separate provisional registration for each category of establishment.
- ❖ Laboratories/ diagnostic imaging center's and dental clinics which are part of a hospital need not register separately.
- ❖ Separate registration is required if services are provided by different systems of medicine.
- ❖ The applicant applies for the provision registration in an application Form 2 and or 2A, with supporting documents, certificates, self declaration accompanied by fees online.
- ❖ An automated acknowledgement, Form 3 is sent to the registered Email ID of the applicant.

Provisional Registration Process

- ❖ The Authority verifies the documents submitted within specified time period and grant provisional registration or reject the application and inform the applicant.
- ❖ The DRA can return an application for clarification within 15 days and such applications can be resubmitted without additional fee.
- ❖ The Application shall be considered rejected if the defects are not rectified within fifteen days of such notice.
- ❖ Rejection of application will not be a hindrance to the applicant applying afresh, after rectifying the deficiencies.
- ❖ If such automatically issued certificates are later found to be inappropriate then the issuing authority will be held accountable as per the provisions of this Act.

Process of provisional registration: Illustration



Appeals

- ❖ Any clinical establishment aggrieved by the order of the Authority or the Council may file an appeal to the Appellate Authority within **forty-five** days from the date of receipt of the order along with fee.
- ❖ The appeals will be acknowledged electronically on submission with a number, which could be used to track the status of the appeal online.
- ❖ The Appellate Authority may confirm the legality or the propriety of the order passed by the DRA and dispose of the appeal appropriately within **60 days**.
- ❖ Any appeal against orders of Appellate Authority would be to High Court within **60 days** of any such order.

Grievance Redressal Mechanism

- ❖ The Council with the permission of the Government shall constitute a grievance redressal committee.
- ❖ Committee would consist of
 - Retired Government Additional Secretary
 - A retired medical officer
 - An NGO
- ❖ Receives and takes necessary action against complaints received from the public.
- ❖ The public can submit grievances/ complaints as per the rules and also to get information regarding the status of the complaints and action taken through the online provision.
- ❖ The committee shall examine the grievances and dispose them within **three months** and inform the decision to the complainant.
- ❖ The orders of the grievance redressal mechanism would be binding on the State Council, DRA or the Clinical Establishment as the case may be

Permanent Registration

- ❖ Permanent registration would be undertaken after categorization, classification and development of minimum standards within two years of notification of the Act
- ❖ Application for permanent registration to be made to the Authority with prescribed fees and evidence that the clinical establishment has complied with the standards prescribed for the category. (Section 19)
- ❖ Certificate granted after assessment within **60 days of submission** of application
- ❖ Panel of independent assessors to assess the standards maintained by the clinical establishment. (Section 4 (d)19(12))
- ❖ Permanent registration is valid for three years. (Section 20)
- ❖ Application for renewal should be submitted 60 days prior to expiry of registration.

Assessment, Inspections, Inquiry and Penalties

- ❖ **Assessment:** Assessment team to verify that standards are achieved for the category of registration before granting the permanent registration certificate.
- ❖ **Inspections:** To check compliance to standards **or** on receiving a valid complaint.
 - Trained inspection team with persons from same speciality/branch of medicine
 - At least once in 2 years but not more than twice a year.
 - No inspection for establishments with NABH or other govt. approved accreditation/ certification within the validity period.
- ❖ **Penalties:**
 - Quantum of monetary penalty as per the category, the size, type of the clinical establishment and the local conditions of the area in which the clinical establishment is situated. (Section 27 (4))
 - Closure of establishments in emergencies may be authorized by State Council
- ❖ **Inquiries:** For adjudging the penalties the Authority shall hold an inquiry on ensuring the person concerned a reasonable opportunity of being heard.

Penalties

- ***Penalty for contravention of the provisions of the Act.-***

Whoever contravenes any of the provisions of this Act shall be liable:

The first contravention to a monetary penalty upto **Rs. 10,000/-**

The second contravention a monetary penalty upto **Rs. 50,000/-**

Subsequent contravention to a monetary penalty upto **Rs. 5,00,000/-**

Provided if the Council determines, after notice to the establishment that the offence is of such serious nature, in addition to the penalty, the Council may order the closure of establishment.

- ***Penalty for non-registration.-***

Whoever carries on a clinical establishment without registration shall :

The first contravention, be liable to a monetary penalty upto **Rs. 50,000/-**

The second contravention to a monetary penalty upto **Rs. 2,00,000/-**

Subsequent contravention to a monetary penalty upto **Rs. 5,00,000/-**

In case of continuing contravention a monetary penalty of **Rs. 10,000/-** for every additional day the clinical establishment functions without registration subject to a **maximum of Rs. 5,00,000/-**

Penalties contd....

❖ **Disobedience of order, obstruction and refusal of information.** *Section 28*

- Whoever wilfully disobeying any direction lawfully given by the Authority, the Council or any person empowered under this Act, or obstructs any person or the Authority or the Council in the discharge of any function be liable to a monetary penalty upto **Rs.1,00,000/-**
- Whoever wilfully withholds information or gives false or untrue information shall be liable to a monetary penalty **Rs. 1,00,000/-**.

❖ **Penalty for minor deficiencies:** *Section 29*

- Whoever contravenes any provision of this Act or its rules resulting in deficiencies that do not pose any imminent danger to the health and safety of any patient and can be rectified within a reasonable time, shall be liable to a monetary penalty which may extend **Rs. 10,000/-**.

Present Status

- ❖ Draft Rules have been passed by the Subject Committee and will be notified soon.
- ❖ The State Council and the District Registration Authorities for all 14 districts have been constituted and will be notified soon
- ❖ The National Informatics Centre, GoK, has developed the Web portal for various aspects of the implementation of the Act and Rules
- ❖ Orientation and Trainings on the registration process as well as the verification and approval from the administrators side will be conducted.
- ❖ The Committees for categorizing and classifying various Clinical Establishments and developing standards for each category are being constituted.

Need & Benefits and outcomes

- ❖ Defining and ensuring uniformity of minimum standards will lead to improved quality and consistency of health care and patient safety
- ❖ Entire process of registration and the data of clinical establishments in the public domain
- ❖ Details of charges, facilities available would be prominently displayed at a conspicuous place at each establishment
- ❖ Generation of reliable and comprehensive digital database would aid in policy formulation, resource allocation, engagement and public health interventions including Improving disease surveillance and response to epidemics, disasters and public health emergencies

Annexures:

Form 1	Register of Clinical Establishments
Form 2	Application Form for Provisional Registration of Clinical Establishments
Form 2 A	Application Form for Provisional Registration of Clinical Establishments
Form 3	Provisional Application - Acknowledgement
Form 4	Provisional Registration - Certificate
Form 5	Application Form for Permanent Registration of Clinical Establishments - Hospitals
Form 5 A:	Application Form for Permanent Registration of Clinical Establishments - Laboratory
Form 6:	Permanent Application - Acknowledgement
Form 7:	Permanent Registration Certificate
Form 8:	Application for Appeal to Appellate Authority
Form 9:	Appeal - Acknowledgement
Form 10:	Grievance Redressal
Form 11:	Inspection Report
Schedule 1	Fees for Registration, Renewal, Late Application, Appeals

**Kerala Clinical Establishments (Registration and Regulation) Act
2018**

Register of Clinical Establishments

Details of Clinical Establishments

1. By District
2. By Ownership
3. By System of Medicine
4. By Services offered
5. Application received
6. Applications approved
7. Application Pending
8. Application Rejected
9. Application Cancelled
10. Details of change of ownership, change of category, ceasing
11. Names of Clinical establishments where penalty charged
12. Details of Appeals
13. Details of Inspections

Detail of registered Clinical Establishments in the State

1. Name of the Clinical Establishment
2. Address
3. Year of Establishment
4. Name of the owner
5. Name and details of the person in charge
6. Ownership
7. System of Medicine
8. Services offered
9. Infrastructure Details
10. Human Resources Details
11. Date of issue of certificate and validity

Kerala Clinical Establishments (Registration and Regulation) Act 2018

Application Form for Provisional Registration of Clinical Establishments

Hospital (includes Maternity homes, dental establishments, health centres, day care centres, Single, multi specialty, teaching from all recognised systems of medicine) with or without attached Laboratory & / Diagnostic Imaging Centre

1. Name of the Establishment: _____

2. Address: _____

Village/Town: _____ Taluk: _____

District: _____ State: _____ Pin code _____

Tel No (with STD code): _____ Mobile: _____

Email ID: _____ Website (if any): _____

3. Location: Panchayat Municipality Corporation

4. Year of starting the establishment: (If beyond 2015, kindly mention the Month)

5. Name of the owner: _____

Address: _____

Village/Town: _____ Taluka: _____

District: _____ State: _____ Pin code _____

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

6. Name, Designation and Qualification of person in-charge

First _____ Middle: _____ Last _____

Designation: _____

Diploma/Certificate/Degree: _____

E-mail ID: _____ Tel No (with STD code): _____ Mobile: _____

7. Ownership (for private sector kindly upload copy of registration certificate of establishment)

- a) Public Sector: Central government State government
 Local government Public Sector Undertaking

 Railways Police

 Other ministries and departments

 Employee State Insurance Corporation

 Autonomous organization under Government

 Any other (please specify): _____

- b) Private Sector Individual Proprietorship Partnership
 Registered Company Co-operative Society
 Trust / Charitable Any other (please specify): _____

Systems of Medicine offered: Homeopathy Unani Modern Medicine Ayurveda Siddha

9. Type of Establishment: Maternity Home Health Centre Day Care Centre
 Single Specialty Hospital Multi Specialty Hospital
 Teaching Hospital Dental Laboratory
 Diagnostic Imaging Centre Any other (please specify): _____

10. Services Offered; (please tick whichever is applicable)

I) Outpatient Inpatient Any other (please specify): _____

II) a) Hospital (includes Maternity Homes, Health Centres, Day Care Centres, Single, multispecialty, Teaching)

b) Hospital with attached Laboratory & Diagnostic Imaging Centre

III) (a) Modern Medicine:

Specialty:

General Medicine Paediatrics Psychiatry
 Tuberculosis & Respiratory Medicine Rheumatology
 Physical Medicine and Rehabilitation
 Dermatology, Venereology, Leprosy General

Surgery

Orthopaedics Ophthalmology
 Obstetrics & Gynaecology
 Otorhinolaryngology (ENT)

Medical Super Specialty: Cardiology Neonatology Nephrology Neurology

Nuclear Medicine Medical
 Endocrinology Medical & Surgical

Gastroenterology

Clinical Haematology including Stem Cell therapy
 Any other (Please specify);

Oncology

Surgical Super Specialty:

Cardiothoracic & Vascular Surgery Urology
 Paediatric Surgery Neuro-Surgery
 Plastic & Reconstructive Surgery
 Surgical Gastroenterology Endocrine Surgery
 Gynaecological Oncology Any other (please specify)

(b) Ayurveda:

Visha Chikitsa Shalya Chikitsa
 Kshara Bootra Chikitsa Marma Chikitsa
 Kaya Chikitsa Panchakarma

Chikitsa

Rasayana and Vajeeakarana Chikitsa

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☐
☐
☐

- Manasikaroga ☐ Chikitsa ☐
 ☐ Nethra-siroroga ☐ Chikitsa ☐ ☐ Bala ☐ Chikitsa ☐
 ☐ Prasoothi & Streeroga ☐ Chikitsa ☐ ☐ Swasthavritha ☐
 ☐ Any other please specify _____ ☐
 ☐

(c) Unani: ☐

☐
☐
☐

- ☐ Matab ☐ ☐ Jarahat ☐
 ☐ Ilaj-bit-Tadbeer ☐ ☐ Hifzan-e-Sehat ☐
 ☐ Any other please specify _____ ☐

(d) Siddha: ☐

☐
☐

- ☐ Maruthuvam ☐ ☐ Sirappu ☐ Maruthuvam ☐
 ☐ Varmam ☐ Thokknam ☐ ☐ Any other please specify ☐

(e) Homeopathy: ☐

☐
☐

- ☐ General Homeopathy ☐ ☐ Any other please specify ☐

IV) Laboratories and Diagnostics: ☐

☐
☐

- ☐ Clinical Pathology ☐ Basic Hematology
 ☐ Basic Biochemistry
 ☐ Basic Microbiology
 ☐ Basic Radiography- X ray
 ☐ ECG
 ☐ Specialized Hematology ☐ Histopathology ☐ Cytopathology,
 ☐ Specialized Biochemistry
 ☐ Specialized Microbiology and Serology ☐
 ☐ Specialized X - ray Techniques and Ultrasound
 ☐ Advanced Hematology ☐ Advanced Cytopathology
 ☐ Advanced Biochemistry
 ☐ Advanced Microbiology and Molecular Biology
 ☐ Interventional Radiology ☐
 ☐ MRI ☐ CT ☐ PET ☐ Mammography
 ☐ EEG ☐ EMG ☐ ECHO ☐ TMT
 ☐ Any other please specify: _____ ☐

☐

11. Infrastructure ☐

- a) Area of the establishment (in Sq. Ft): _____ ☐
 b) Total no. of Out Patient Clinics: _____ ☐
 c) Total number of beds: _____ ☐
 d) Specialty-wise distribution of beds (including ICU), please specify: ☐
 ☐

Sl. No ☐	Specialty ☐	Number of Beds ☐
☐	☐	☐
☐	☐	☐
☐	☐	☐
☐	☐	☐

☐
☐

12. Human Resources ☐

- a) Total number of staff: _____ ☐
 b) Please furnish the details of staff: (as per format in excel sheet provided and upload) ☐

Name of the Clinical Establishment
Staff Details

As on _____
Filled by _____
Designation _____

Sl. No.	Name	Qualification	Registration No.	Council Registered (Doctors, Nurses, Dentists, Pharmacists)	Nature of Service (permanent/Temporary/Visiting)
	Doctors				
	Nursing Staff				
	Para-medical Staff (specify)				
	Dentists				
	Pharmacists				
	Administrative Staff (specify)				
	Support staff (specify)				
	Others (specify)				

13) Details of Medical & Diagnostic Equipment

Name of the Clinical Establishment
Medical & Diagnostic Equipment

As on _____
Filled by _____
Designation _____

Sl. No.	Equipment	Name of Company	Specifications	Quantity / No.	Functioning status	Year of Manufacture	Year of Expiry

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 Kerala Clinical Establishment (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 requirements for the facilities and services provided and other conditions as stipulated under the aforesaid Act and Rule there-under.

Name of the person filling in the application form: _____

Designation: _____

Date: _____

Kerala Clinical Establishments (Registration and Regulation) Act 2018

Application Form for Provisional Registration of Clinical Establishments

Laboratory & Diagnostic Imaging Centre (stand alone establishments)

1. Name of the Establishment: _____

2. Address: _____

Village/Town: _____ Taluk: _____

District: _____ State: _____ Pin code _____

Tel No (with STD code): _____ Mobile: _____

Email ID: _____ Website (if any): _____

3. Location: Panchayat Municipality Corporation

4. Year of starting the establishment: (If beyond 2015, kindly mention the Month)

5. Name of the owner: _____

Address: _____

Village/Town: _____ Taluka: _____

District: _____ State: _____ Pin code _____

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

6. Name, Designation and Qualification of person in-charge

First _____ Middle: _____ Last _____

Designation: _____

Diploma / Certificate / Degree (please specify): _____

E-mail ID: _____ Tel No (with STD code): _____ Mobile: _____

If technician (kindly provide details below and attach copy of relevant documents)

Diploma/Certificate/Degree: (specify details and attach document)

Institution/University and place:

Year of passing: _____

Name of the Council (if any, kindly specify) ; _____

Registration Number: _____

7. Ownership (kindly upload relevant documents)

- a) Public Sector: Central government State government
 Local government Public Sector Undertaking
 Railways Police

Other Ministries and Departments

Employee State Insurance Corporation

Autonomous Organization Under Government

Any other (please specify): _____

b) Private Sector Individual Proprietorship Partnership

Registered Company Co-operative Society

Trust/Charitable Any other (please specify): _____

8. Laboratories and Diagnostics:

Clinical Pathology Basic Hematology

Basic Biochemistry

Basic Microbiology

Basic Radiography- X ray

ECG

Specialized Hematology Histopathology Cytopathology,

Specialized Biochemistry

Specialized Microbiology and Serology

Specialized X - ray Techniques and Ultrasound

Advanced Hematology Advanced Cytopathology

Advanced Biochemistry

Advanced Microbiology and Molecular Biology

Interventional Radiology

MRI

CT

PET

Mammography

EEG

EMG

ECHO

TMT

Any other please specify: _____

9. Infrastructure

a) Area of the Establishment (in Sq. Ft): _____

c) Total Number of Beds: _____

10. Human Resources

a) Total Number of Staff: _____

b) Please furnish the details of staff: (as per format provided)

Name of the Clinical Establishment

Staff Details

As on _____

Filled by _____

Designation _____

Sl.No		Name	Qualification	Registration No	Council Registered Certified (Doctors, Nurses, Technical staff)	Nature of Service (permanent/Temporary/Visiting)
	Doctors					
	Nursing Staff					
	Technical Staff (specify)					

☐	Para-medical Staff (specify) ☐	☐	☐	☐	☐	☐
☐	Administrative Staff (specify) ☐	☐	☐	☐	☐	☐
☐	Support Staff (specify) ☐	☐	☐	☐	☐	☐
☐	Others' (specify) ☐	☐	☐	☐	☐	☐

☐
d) Details of Medical & Diagnostic Equipment
Name of the Clinical Establishment
Medical & Diagnostic Equipment

As on ___ ☐
Filled by ___ ☐
Designation ___ ☐

Sl. No. ☐	Equipment ☐	Name of Company ☐	Specifications ☐	Quantity/ No. ☐	Functioning status ☐	Year of Manufacture ☐	Year of Expiry ☐
☐	☐	☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐	☐	☐

☐
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 Kerala Clinical Establishment (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 requirements for the facilities and services provided and other conditions as stipulated under the aforesaid Act and Rule there-under.

☐
Name of the person filling in the application form: _____ ☐

Designation: ☐

Date: ___ ☐

☐

☐

☐

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**Kerala Clinical Establishments (Registration and Regulation) Act
2018**

?

Provisional Application

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Acknowledgement

?

?

The application for provisional registration of the Clinical Establishment has been received by the District Registration Authority on _____ (date)

?

The temporary application number is: (Computer Generated)

?

?

This acknowledgement does not confer any rights on the applicant for grant of registration.

?

?

?

?

Place & Date: (Computer Generated)

?

This is a computer-generated acknowledgment



Kerala Clinical Establishments (Registration and Regulation) Act 2018

Provisional Registration Certificate

Provisional Registration No: (Computer Generated)
Date of issue: (Computer Generated)
Valid upto: (Computer Generated)

Name of the Clinical Establishment: _____
Address: _____
Owner of the Clinical Establishment: _____
Person in Charge: _____
System of Medicine: _____
Type of Establishment: _____

Is hereby provisionally registered under the provisions of Kerala Clinical Establishments (Registration and Regulation) Act, 2018 and the Rules made there under.

This authorization is subject to the conditions as specified under the Kerala Clinical Establishments (Registration and Regulation) Act 2018 and the Rules made there under.

Designation of the Issuing Authority (Computer Generated)
Place & Date: (Computer Generated)

District Registration Authority

Address: _____

In case of any grievance, kindly refer to <https://www.clinicalestablishments.kerala.gov.in> for details and procedure. Thank you for the needful.

?

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Kerala Clinical Establishments (Registration and Regulation) Act 2018

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Application For Appeal to the Appellate Authority

?

I, from would like to appeal to the Appellate Authority.

?

I would like to furnish that

?

I kindly request the appellate authority to consider my appeal. I could provide any clarification, document and any other evidence that may be required. I would be willing to appear before the appellate authority for a personal hearing, if necessary. I am making the necessary payment

?

Thanking you,

?

?

?

Date:

Signature:

Name:

Kerala Clinical Establishments (Registration and Regulation) Act 2018 Schedule of Fees

Application Fees (in Rs.)

Type of Clinical Establishment	Panchayat		Municipality/Corporation	
	Provisional (For 2 yrs.)	Permanent (For 3 yrs.)	Provisional (For 2 yrs.)	Permanent (For 3 yrs.)
In Patient Care				
Less than 20 beds	1000	2000	2000	4000
21 - 50 beds	1500	3000	3000	6000
51-100 beds	3000	6000	6000	12000
101-200 beds	9000	18000	18000	36000
201 - 500 beds	12000	24000	24000	48000
Above 500 beds	15000	30000	30000	60000
Day care centres conducting procedures	5000	10000	10000	20000
Dental				
1-3 chairs	1000	2000	2000	4000
4-6 chairs	2500	5000	5000	10000
7-12 chairs	5000	10000	10000	20000
Dental College, Hospital	12000	24000	24000	48000

Laboratories & Diagnostics Centre				
Level 1 1. Clinical Pathology/ Basic Hematology 2. Basic Biochemistry 3. Basic Microbiology 4. Basic Radiography- X- Ray 5. ECG	2000	4000	4000	8000
Level 2: With or without Level 1 facilities and 1. Specialized Hematology / Histopathology/Cytopathology 2. Specialized Biochemistry 3. Specialized Microbiology and Serology 4. Specialized X- ray Techniques and Ultrasound	4000	8000	8000	16000
Level 3: With or without Level 2 facilities and 1. Advanced Hematology/Advanced Cytopathology 2. Advanced Biochemistry 3. Advanced Microbiology and Molecular Biology 4. Interventional Radiology 5. MRI/CT/PET/Mammography 6. EEG/EMG/ECHO/TMT	8000	16000	16000	32000

Renewal: the amount shall be same as the permanent application amount

Late Application: The amount shall be addition of 25% of the application amount

Appeal Fee: the amount shall be Rs. 1000

Grievance redressal complaints: The amount shall be Rs. 250

Thank You

For more information

www.clinicalestablishments.kerala.gov.in