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കേരള ഗസറ്റ് KERALA GAZETTE

അസാധാരണം
EXTRAORDINARY

ആധികാരികമായി പ്രസിദ്ധപ്പെടുത്തുന്നത്
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GOVERNMENT OF KERALA

HEALTH AND FAMILY WELFARE (FW) DEPARTMENT.

NOTIFICATION

G.O (P) No.13/2021/H&FWD .

Thiruvananthapuram .
2021 February 10

In pursuance of clause (3) of Article 348 of the Constitution of India the Governor of Kerala is pleased to authorise the publication in the Gazette of the following translation in English language of the Kerala Clinical Establishments (Registration and Regulation) Rules, 2018 .

(By order of the Governor)
RAJAN NAMDEV KHOBRADE
Principal Secretary to Government.



To:

The Director of Medical Education, Thiruvananthapuram

The Director of Health Services, Thiruvananthapuram

The Secretary, Kerala State Council for Clinical Establishments,

2nd Floor Hostel Block, Kerala State Institute of Health and Family Welfare,
Thycaud, Thiruvananthapuram

The State Mission Director, National Health Mission, Thiruvananthapuram

The Executive Director, State Health and Systems Resource Centre, Thycaud, Thiruvananthapuram

All District Medical Officers (through Secretary KSCCEs)

All District Collectors (through Secretary KSCCEs)

The Principal Accountant General (Audit/A&E), Kerala, Thiruvananthapuram

The I&PRD(Web and New Media)

The Law Department (vide u.o no 1494/leg H1/2019/Law dated 12.03.2020)

The Finance Department

The Stock File/Office Copy

Forwarded /By order

Section Officer

Copy to : The PS to Hon'ble Minister (Health)

The PS to Principal Secretary (Health)

**Kerala Clinical Establishments
(Registration and Regulation) Rules, 2018**

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GOVERNMENT OF KERALA
Health and Family Welfare (FW) Department
NOTIFICATION

G.O.(P)No.159/2018/H&FWD. Dated, Thiruvananthapuram, 26th December, 2018
11th Vrischikam, 1194.

S.R.O.No.929/2018.- In exercise of the powers conferred under section 52 of the Kerala Clinical Establishments (Registration and Regulation) Act, 2018 (Act 2 of 2018) the Government of Kerala hereby make the following rules, namely:-

RULES
CHAPTER 1
Preliminary

1. *Short title and commencement.*- (1) These rules may be called the Kerala Clinical Establishments (Registration and Regulation) Rules, 2018.

(2) These rules shall come into force on such date as the Government may, by notification appoint and different dates may be appointed for different recognized system of medicines.

2. *Definitions.*- (1) In these rules, unless the context otherwise requires,-

- (a) "Act" means the Kerala Clinical Establishments (Registration and Regulation) Act, 2018 (Act 2 of 2018);
(b) "Grievance Redressal Committee" means the grievance redressal mechanism constituted by the



Council as per section 36 of the Act;

(c) "Form" means the form appended to these rules;

(d) "Schedule" means the schedule appended to these rules;

(e) "Sub-committee" means the sub-committee constituted by the Council as per sub-section (2) of section 6 of the Act.

(2) The words and expressions used but not defined in these rules, but defined in the Act shall have the meaning respectively assigned to them in the Act.

CHAPTER 2

The Council

3. *Headquarters of the Council, Secretary, other employees etc.*- (1) The Headquarters of the Council shall be at Thiruvananthapuram.

(2) For assisting the Council, a Secretary may be appointed by the Government and necessary other employees may be appointed by the Council with the permission of the Government.

(3) The employees shall perform the functions and duties entrusted by the Secretary.

(4) The Secretary shall be responsible for the day to day administration of the Council.

(5) In addition to the functions specified in the sub rules (3) and (4), the Secretary shall also perform, the following functions and duties, namely:-

(i) to conduct cases on behalf of the Council in which Council is a party;

(ii) to sign all the deeds, documents and contracts for and on behalf of the Council, as per the directions of the Council;

(iii) to sign and seal all documents and proceedings which require approval of the Council, subject to the approval of the Council;

(iv) to attend the meetings of the Council and record decisions;

(v) to implement all the decisions and policies taken by the Council; and

(vi) to perform such other functions as entrusted by the Council.

(6) The Secretary shall be vested with the responsibility to take lawful actions as may be necessary for the fulfillment of any or all the objectives of the Council.

(7) During his absence, with the prior permission of the Executive Committee under section 8, the Secretary shall have power to delegate his duties and functions to an officer of the Council.

(8) The Secretary shall verify all the bills relating to the functioning of the Council and countersign them before presenting for payment, maintain proper accounts and account registers for the funds received and spent by the Council, make arrangements to cause the annual accounts of the Council be audited by the auditors approved by the Council and place the audit report before the Council.

4. *Register of clinical establishments.*- (1) The Secretary shall prepare the State Register of clinical establishments in Form 1, containing details of the clinical establishments registered under the Act till the end of a month and maintain it on behalf of the Council and officially publish through website before 10th of the succeeding month.

(2) For timely updation of the State Register of clinical establishments, all the Authorities shall



submit a quarterly report regarding the details of newly registered clinical establishments in that district, of the clinical establishments which lost registration due to various reasons and of the clinical establishments currently having valid registration, as fixed by the Council, to the Secretary of the Council.

(3) The register shall be live and the public may verify through website.

5. *Meetings of the Council.*- (1) The Council shall meet at least once in three months during the first two years and thereafter at least once in six months. The Secretary shall convene the meeting of the Council as per the direction of the Chairperson or in his absence, the Vice Chairperson.

(2) Meetings of the Council shall be presided over by the Chairperson and in the absence of Chairperson, the Vice Chairperson and in the absence of both, one of the official members of the Council shall be elected from the members present, to preside over the meeting.

(3) No decisions of the Council shall be invalid for the reason that the Chairperson or Vice Chairperson was not present in the meeting.

(4) Notice and agenda of every meeting other than a special meeting shall be given to all members of the Council by the Secretary, not less than seven days before the date of meeting.

(5) If any member wishes to include any matter relating to the provisions of the Act or the rules made thereunder in the agenda of the meeting, that member shall give notice to the Secretary informing the matter, not less than ten days prior the date of meeting.

6. *Quorum of the meetings.*- (1) The quorum for the meeting of the Council shall be one third of the total members of which half the members, including the Chairperson or the Vice Chair person, shall be ex-officio members.

(2) All the decisions of the meeting shall be based on majority opinion and in the case of difference of opinion among the members on any matter, the opinion of the majority shall prevail and in such matters voting may be done by raising hands unless the meeting specifically decides to take a secret balloting. In the case of equal votes, the presiding member shall have the right to exercise a casting vote.

(3) If the Council so decides and if so required, it may invite persons who are not members to participate the meeting of the Council. But such invitees shall not have right to vote in the meeting.

(4) Draft minutes of all the meetings shall be submitted to the Chairperson by the Secretary within seven days after the meeting and after getting approval, it shall be sent to the members of the Council within seven days. If no dispute regarding its correctness is received within ten days of such despatch, the same may be finally approved and if any disputes are raised approval shall be obtained by presenting it in the next meeting.

7. *Emergency meeting or Special Meeting.*- For considering matters of emergency or important or special subjects, the Chairperson or the Vice-Chairperson or the Secretary, on his own motion or on the written request of not less than one third of the members or on the direction of the Government, may convene, emergency meeting or special meeting. In the intimation of such meeting the purpose of the meeting shall be specified and at least three days prior notice shall be given to the members. In such meetings, the matters specified in the notice alone shall be discussed.

8. *Sub-committees.*- The Council may, for the purpose of implementing the provisions of the Act and the rules made under the Act or for the purpose of performing the functions or for the purpose of fixing the standards of clinical establishments or for other purposes as deems fit, appoint sub-committees.



CHAPTER 3
Executive committee

9. *Powers and functions.*- (1) The general administration of the Council shall, subject to its decision, vests with the Executive Committee. The Executive Committee shall have the following powers and functions namely:-

- (i) to assist the Council for preparing outlines for fixing the standards of clinical establishments and implementing the guidelines;
- (ii) to take decisions required for the efficient implementation of financial and administrative matters of the Council;
- (iii) to supervise the functioning of the office of the Council and to render assistance and guidance to the Secretary for the effective execution of its functions and responsibilities;
- (iv) to render guidance and assistance to the Authority, Appellate Authority, Grievance Redressal Committee for the implementation of the provisions of the Act and the rules made thereunder;
- (v) to control the financial matters of the Council and submit half yearly financial report to the Council;
- (vi) if attention of the Council is required on any matter, examine it, prepare a report regarding the same and submit the said report to the Council;
- (vii) to examine and recommend follow up actions on the representations received by the Council;
- (viii) to approve with the permission of the Government, the remuneration to be given, terms and conditions of service, tenure and other aspects of the employees deputed for the functioning of the Council and of the persons who render technical assistance or advice to the Council;
- (ix) to order inspection in emergency medical conditions, in consultation with the Authority and , if necessary, give directions to the Authority for stopping the functioning temporarily and for taking other appropriate action;
- (x) to undertake investigations or studies and record them;
- (xi) to manage the website of the Council; and
- (xii) to perform such other functions as may be assigned by the Council from time to time.

(2) For the administration, the Executive Committee may delegate any of its powers to the Convenor, subject to such conditions imposed by it, and he shall be responsible for executing the same accordingly.

(3) The Council shall, in the very next meeting, examine the decisions and actions taken by the Executive Committee and take appropriate decision.

10. *Functions of the Convenor.*- (1) It shall be function of the convenor to implement the day to day activities of the Executive Committee and to convene meetings as per the directions of the Chairperson.

(2) The convenor shall submit the decisions taken by the Executive Committee and the report on action taken thereon, in the next meeting of the Council and if the Council proposes any suggestion or modification on the same, he shall examine and take further action.

11. *Meetings.*- (1) The Executive Committee shall meet at least once in a month and in any case the interval between two meetings shall not exceed forty five days.

(2) Meeting of the Executive Committee shall be presided over by the Chairperson and in his absence the Vice-Chairperson and in the absence of both, one of the ex-officio members present shall be elected as presiding officer.

(3) Notice and agenda of every meeting other than special meeting shall be given by the Convenor to all the members not less than three days before the date of meeting.

(4) The quorum of the meeting shall be one third of the total membership.

(5) All the decisions of the meeting shall be based on majority opinion and in case, in any matter



there is equal opinion among the members, the presiding officer shall have right to exercise a casting vote.

(6) Minutes of the meeting shall be made available to the members within five days after the meeting.

(7) For considering matters of emergency, the convenor may convene emergency meetings as per the direction of the Chairperson or the Vice Chairperson and the notice and agenda of the said meeting shall be given to the members prior to one working day of the meeting and the minutes of such meeting shall be made available to the members within one working day.

CHAPTER 4

Authority and Provisional Registration of Clinical Establishments

12. *Meetings of the Authority.*- (1) The Authority shall meet at least once in two months.

(2) The Chairperson or in his absence the Vice-Chairperson shall preside over the meeting of the Authority.

(3) The quorum of the meeting shall be one half of the total membership.

(4) All the decisions of the meeting shall be based on majority opinion and in case, in any matter there is equal opinion among the members, the presiding officer shall have right to exercise a casting vote.

(5) The minutes of the meeting shall be made available to the members within five days after the meeting.

(6) For considering matters of emergency the Convenor may convene emergency meetings as per the direction of the Chairperson or the Vice Chairperson and the notice and agenda of the said meeting shall be given to the members prior to one working day of the meeting and the minutes of such meeting shall be made available to the members within one working day.

13. *Application for Provisional Registration.*- (1) The Clinical Establishments shall apply to the Authority online for provisional registration in Form 2 or 2A, as the case may be, along with all required documents, certificates, fee prescribed in the Schedule and declaration.

(2) As soon as an application under sub-rule (1) is received, an acknowledgment in Form 3 shall be given to the applicant.

(3) On the application submitted under sub-rule (1), the Authority shall within the fixed time, after verifying the documents produced, either issue a provisional certificate in Form 4 to the establishment or issue notice to rectify defect or intimate that the application is rejected.

(4) Where a clinical establishment is offering services in different medical category, separate applications for provisional registration shall be given for each category.

(5) All the clinical establishments whether registered under any existing law or not, shall apply for registration as per these rules and obtain registration.

(6) All clinical establishments functioning in the State at the commencement of the Act shall apply for provisional registration in the Form 2 or 2A, as the case may be, along with the fixed fees.

(7) If the application is incomplete or requires clarification or requires information or documents or certificates, the Authority may require the applicant/establishment to rectify such defects within fifteen days.

(8) If the applicant does not rectify the defects within the fifteen days the application shall be rejected and the information of rejection shall be given to the applicant in writing. Rejection of application shall not be a bar for applying afresh, after rectifying the defects.

(9) The Authority shall publish the details of clinical establishments applying for registration as per sub-rule (1), in the website of the Council within seven days of receipt of application,

14. *Powers of the Vice Chairperson with regard to Provisional Registration.*- (1) As per the provisions of the Act and the rules made thereunder, the Vice Chairperson, shall receive the



applications for provisional registration submitted by the clinical establishments, on behalf of the Authority, issue acknowledgment for it in Form 3 and after examining the application and related documents, if found that the clinical establishment is eligible for provisional registration, issue certificate of provisional registration in Form 4 or otherwise, issue a notice of rejection of the application to the applicant/establishment in writing.

(2) The procedure specified in the sub rule (1) shall be completed by the Vice Chairperson within fortyfive days of receipt of the application.

(3) The cases of issue of certificate of provisional registration and of rejection as per sub rule (1) shall be submitted in the next meeting of the Authority by the Vice-Chairperson for consideration and approval.

(4) If the Authority proposes any change in the disposal by the Vice-Chairperson on the provisional registration of any clinical establishment which had submitted application, the same shall be implemented within seven days.

CHAPTER 5

Permanent Registration of Clinical Establishments

15. *Application for permanent registration.*- (1) A clinical establishment shall submit an application for permanent restration in Form 5 or Form 5A, as the case may be, before the Authority along with required documents and fee specified in the schedule. The Authority shall issue an acknowledgment in Form 6, for the same.

(2) In the case of a clinical establishment offering services in different medical categories such clinical establishment shall submit separate applications for permanent registration for each category.

(3) The details of the clinical establishments those submitted application as per sub-rule (1) or sub-rule (2) shall be published in the website of the Council by the Authority within seven days of receipt of application.

(4) The establishment applying for registration shall enclose evidence to the effect that it has been complying with the standards prescribed for the category by the Council or the Government, as the case may be.

(5) The establishments functioning with valid provisional registration certificate shall apply for permanent registration sixty days prior to the date of expiry of the said certificate, as provided in sub-rule (1).

(6) As soon as an application as per this rule is received, the Authority shall immediately inspect or cause to be inspected the clinical establishment and shall prepare or make available its report.

(7) On inspection, if the Authority is convinced that the establishment is maintaining the prescribed standards , it shall grant a registration certificate in Form 7, as per the provisions of the Act and these rules, within the specified time.

(8) Those clinical establishments which existed at the commencement of the Act and these rules but not provisionally registered at the time of submitting application for permanent registration shall convince the Authority the reasons for non-registration. After examining the said reasons, if it is found acceptable, the Authority may consider the application, on realising double the amount fixed as fee for the provisional registration for that category along with fee for permanent registration of that category.

(9) If the Authority is of the opinion that the clinical establishment applying for permanent registration has not attained the prescribed standards or has submitted incomplete information or has not given relevant documents, it shall inform the clinical establishment/applicant its intention to disallow registration with reasons for the same.



(10) The clinical establishment/applicant shall, within thirty days from the date of receipt of the intimation under sub-rule (9), give reply to the Authority and produce evidence to the effect that the standards have been attained and the informations and documents have been submitted and the Authority shall, on examination of the evidence and after a re-examination of the evidence through the assessors, if required, either grant or reject the application for permanent registration.

(11) If the Authority decides to reject the application for permanent registration, that decision and the reasons for the same shall be intimated to the applicant within thirty days from the date of such decision.

(12) Rejection of an application for permanent registration shall not be a bar for applying afresh after rectifying the defects and producing evidence to show that prescribed standards are being maintained.

(13) In the cases where applying afresh after rectifying the defects, the Authority may take steps for inspection, assessment etc. and if in the inspection and assessment it is found that the clinical establishment is maintaining the prescribed standards, permanent registration certificate shall be issued.

(14) The Authority shall complete the procedure for the issue of permanent registration within sixty days from the date of receipt of the application.

(15) The Authority shall, within thirty days from the date of issuance of the provisional registration certificate as per rule 13 or permanent registration certificate as per this rule, as the case may be, publish the name of such clinical establishment, the provisional/permanent registration number, address, ownership, name of person in charge, medical category offered, category of establishment, type, facilities, details of services offered, declaration that standards have been attained (applicable for permanent registration), details of staff etc. through the website of the Council.

16. *Renewal of Permanent registration.*- (1) A clinical establishment shall apply for renewal of permanent registration through online in form 5 or 5A, as the case may be, along with required documents, evidence showing that the establishment has been maintaining the prescribed standards and prescribed fees to the Authority within sixty days prior to the expiry of the validity of the certificate of permanent registration.

(2) While applying for renewal of permanent registration, if there is any change in the details and information given at the time of applying for permanent registration, the clinical establishment shall convince the Authority along with evidence and the Authority shall examine or cause to be examined the same and take appropriate decision.

(3) When the clinical establishments, which could not apply for renewal within the time fixed as per sub-rule (1), are applying with enhanced fee specified in the schedule, the Authority may examine it and take appropriate decision. The realisation of such enhanced fee shall not exempt the clinical establishment/ individual from subjecting to the actions under section 27 of the Act.

Chapter 6 Conditions for Registration

17. *Conditions for Registration.*- The clinical establishments shall comply with all the orders and instructions with regard to safety, infection control and method of treatment maintaining standards, notified or issued by Government or Council, from time to time.



18. *Furnishing of Information and Statistics.*- The Council shall, prescribe the data and information to be furnished by the clinical establishments and inform the clinical establishments through the website or by any other mode of communication including its periodicity. The said data and information shall be examined and the same shall be made available to the public through the public domain in the website of the council. The manner for the same may be decided by the council.

19. *Display of Certificates and fee rates.*- (1) Each clinical establishment shall display the fee rate charged for each type of service provided and facilities available from that establishment, in a conspicuous place in the clinical establishment in Malayalam and in English, in printed or digital form, for the information of the patients and the relative of the patients. Depending on the magnitude of the information to be displayed, it shall be published in detail in such a manner as to be made available to the patients and relatives, in the official website of the establishment or in any other appropriate manner and the address and methodology to access such website shall also be displayed in writing in Malayalam and in English in the same place where it is to be so displayed, so as to enable layman to understand.

(2) If data is displayed in digital form, the clinical establishments shall provide adequate facilities, within their premises, for patients and relatives of the patients to verify the digital data.

(3) The package rates for treatment procedure shall be made available at the reception in printed or digital form and copy be provided on demand to the patient or relative of patient for reference. Copies may be made available on demand by realising the actual cost incurred.

(4) The clinical establishments shall provide detailed bill specifying the treatment, investigation, consultation charges and other charges to the patient.

20. *Ensuring of standards.*- For ensuring whether the registered clinical establishments are maintaining prescribed standards and whether they are functioning in accordance with the instructions and provisions for registration, the District Authorities concerned shall make available to the public the result of the inspection conducted as per sub-section (11) of section 19 through the website of the Council.

CHAPTER 7

Appointment of Assessors for Inspection and Assessment

21. *Manner of preparation of the panel of Assessors.*- (1) The Council shall appoint panel of assessors for inspection and assessment of standards of a clinical establishment.

(2) The panel appointed as per sub-rule (1) has to examine whether a clinical establishment which has applied for permanent registration or for its renewal has the prescribed standards and whether it is able to maintain the said standards.

(3) The term of a member included in the panel shall be three years. Thereafter the Council, may after evaluating the performance of that member, take appropriate decision as to whether his term be extended or not.

(4) A member who is included in the panel shall not be eligible to be deputed for assessment of clinical establishment in which he or his family members has any direct or indirect connection. If so deputed, he shall abstain from the same on informing the Authority and on receiving such information the Authority shall make necessary alternate arrangements, without any delay.

(5) The Council may oust a member from the panel, before the completion of tenure, for the reason



of professional misconduct, favouritism, giving false information, actions done not in good faith and not submitting report in time.

22. *Qualifications of Assessors.*- (1) Experienced in health care sector and those who are self motivated to contribute to improve the healthcare quality and those having qualifications as specified in these rules shall be included in the panel of assessors.

(2) Persons working in Government sector, academic sector or research institutions are eligible to apply to be selected to the panel.

(3) Apart from the qualifications stated in sub-rules (1) and (2) above, they shall have the following qualifications, as the case may be, to be included in the panel of assessors, namely:-

(i) *Clinicians*

(a) shall have ten years experience in any of the categories of MBBS (Bachelor of Medicine and Bachelor of Surgery) or BDS (Bachelor of Dental Surgery) in modern medicine, Ayurveda, Yoga, Naturopathy, Unani, Siddha and Homeopathy coming under AYUSH, of which for a minimum of five years shall be worked in any clinical establishment, or

(b) five years experience after obtaining recognised post-graduate degree in system of medicines like MBBS or BDS.

(ii) *Administrators.*- Post-graduate degree in healthcare management or health care administration with ten years of experience or five years experience in the post of Manager in the Administrative wing in health care establishments or diagnostic centre or laboratory after attaining the Post-graduation.

(iii) *Nurses.*-

Diploma in General Nursing and Midwifery and registered with the Kerala Nursing and Midwives Council with twenty years experience in hospitals of which ten years experience shall be in health centres or diagnostic centre or laboratory.

or

Post Basic Nursing Degree or B.Sc. (Bachelor of Science) in Nursing or Post-Graduation in Nursing and registered with Kerala Nurses and Midwives Council with twelve years of experience in health care sector of which six years experience shall be in health centre or diagnostic centre or laboratory.

(iv) *Lab Technician/Medical Equipment Technician.*-

Degree in B.Sc. Medical Laboratory Technology with twelve years of experience in this sector of which a minimum of six years experience shall be in hospital laboratory or diagnostic centre or laboratory.

or

Inspectors of Atomic Energy Regulatory Board (AERB)

or

degree or post-graduate degree in Bio-medical Engineering or ten years of experience in the concerned field of which a minimum of five years experience shall be in a hospital labs or diagnostic centre or laboratory.

or

Standard assessing expert recognized by NABL/NABH

(v) *Pharmacists*

Diploma in Pharmacology and registration with Kerala State Pharmacy Council with twenty years of experience.

or

B.Pharm (Bachelor of Pharmacy) or M.Pharm (Master of Pharmacy) or Pharm.D (Doctor of Pharmacy) and registration with Kerala State Pharmacy Council and qualification equivalent to



become a Drug Inspector, with twelve years of experience in the concerned field, of which minimum of six years experience shall be in hospital pharmacy

or

Drug controller or Inspector in the Drugs Control Department, Government of Kerala.

23. *Selection of assessors.*- (1) For getting empanelled as assessor, those having prescribed qualifications shall submit online application to the Council along with necessary documents containing details of qualification.

(2) The said selection process shall be conducted from time to time as fixed by the Council. The Council shall publish the details of the selected persons in the official website.

(3) A sub-committee functioning under the Council shall scrutinise the applications to determine whether the qualifications of the applicants meet the eligibility criteria and shall prepare a short-list of candidates and if required conduct interview directly or through telephone/video.

(4) After conducting such interview, the sub-committee shall prepare a panel of eligible persons to become assessors and submit it to the Council and the council shall consider it and take appropriate decision as per the provisions of the Act.

(5) The Council may also search eligible persons from National Accreditation Board for Hospitals (NABH), National Accreditation Board for Testing and Calibration Laboratories (NABL) or any other accredited institutions approved by the Government to be empanelled as assessors.

(6) If the Council deems it necessary to revise the eligibility criteria of assessors, it shall submit recommendation to the Government for it.

(7) Council shall impart necessary training to the empanelled assessors from time to time, for performing their duties.

24. *Manner of assessing standards.*- (1) The Authority concerned shall have power to determine the number and category of assessors from the panel of assessors, taking into account the category and requirement of the clinical establishment which is to be assessed. The panel of team of assessors shall be prepared on the basis of the area of treatment of the clinical establishment to be assessed. The assessing experts of one medical category shall not be deployed for the process of assessment of an establishment which falls under another medical category.

(2) The Council shall lay down guidelines, from time to time, for the constitution of team of assessors, assessment indicators, standard check lists, method of determining assessment, model of assessment and its reporting, and the Authority shall after taking into consideration the peculiarities of the clinical establishment of which the standard is to be assessed and adhering to the guidelines laid down by the Council, issue orders deploying assessment team specifying the constitution of team of assessors of each clinical establishments, assessment indicators, standard check lists, method of conducting assessment, its model and reports.

(3) The assessors shall visit clinical establishments directly and conduct inspection and assess standards. The Authority shall issue orders selecting one of the members of the team, deputed for assessment of a clinical establishment, as the team leader and he shall divide the work and distribute among the members of his team, fix the days of work, conduct assessment in such manner and submit report in such model and within such period, as ordered by the Authority.

(4) In the process of assessment of standard the assessors shall inspect the clinical establishment directly and ensure that standards as fixed in accordance with the provisions of the Act and the rules are maintained.

(5) The assessment team shall intimate the clinical establishment to be assessed, in writing or by electronic media or through any other mode, about the inspection, forty eight hours prior to the proposed date to conduct the assessment process.



(6) The assessors shall inspect and assess all physical facilities, equipments and furniture in use and all records related to the establishment, educational qualifications of the employees and its proof, informations recorded in the application submitted for registration and the state of affairs for maintaining the registration.

(7) The assessment team deputed by the Authority may inspect clinical establishment at any reasonable time, in the manner specified below, namely:-

- (i) to inspect the clinical establishment or part of it or its premises;
- (ii) to inspect any instruments, equipments, products, or things used or found in the clinical establishment and if necessary take samples and conduct test;
- (iii) to observe and examine the activities and other treatment practices carrying out in the clinical establishment without disturbing patients' privacy and disrupting treatment;
- (iv) to require the owner of the clinical establishment or operators of the establishment or any employee of the establishment to produce required documents or records;
- (v) to examine any records or documents, if thinks necessary and to collect copies or extracts thereof;
- (vi) to require the owner or any employee of the establishment to ensure the authenticity of such copies and make such copies available to the assessment team free of cost;
- (vii) to ask relevant questions and seek quick answers, or otherwise require and take statement of any person if necessary;
- (viii) to understand the actual situation of any matter enquire the owner of the establishment or any employee or patient of the establishment on relevant matters; and
- (ix) to ask relevant questions and elicit the best answers as per his knowledge and belief.

(8) While conducting inspection in the clinical establishment the team members shall take utmost care in the following matters, namely:-

- (i) not to disturb or interrupt with the services providing to the patients; and
- (ii) shall be cautious in keeping accuracy in inspection and maintaining discipline in behaviour and work.

(9) All persons connected with the running of the establishment shall be bound to supply clearly the full information regarding the functioning of the establishment to the assessment team. Any person or persons who obstructs the activities of the team or impedes the execution of duties of the team while conducting the process of assessment of clinical establishment shall be subjected to actions under section 28(1) of the Act and other laws in force.

(10) Any person who is bound as per the Act or these rules or any orders or directions may be issued under it, does not give or refuses without reasonable cause, any information required by the assessment team or does not produce without delay any of the records, registers, reports, instruments, medical or medico-legal records, mandatory or confidential medical records etc. without delay or gives any information misleading the assessment team shall be subjected to actions as per section 28(2) of the Act.

(11) Team members shall keep the facts and matters relating to the functioning of the clinical establishment as confidential. So also shall manage the informations regarding patients as confidential.

(12) The Council may with the permission of the Government, impose fixed fees on the clinical establishments undergoing assessment, taking into account its size and characteristics.

25. Standard Assessment Report.- (1) The assessment report shall be submitted with specific recommendations of the team to the Authority within such time and in such format as the Authority decides, after examining the evidence regarding the standards of clinical establishments and the informations provided by the establishment.

(2) It shall be the responsibility of the team leader to prepare the final report on standard assessment and make recommendations. If any member of the team has any dissenting opinion on the final report so prepared, it shall be tendered to the team leader as a note and the team leader shall include



the same along with his comments in the report.

(3) If the findings of the assessment team are not in conformity with the documents and informations given in the application submitted for registration of clinical establishment and with the provisions of the Act and the rules made thereunder, the team leader shall submit that information together with proposal for further action and recommendations to the Authority for necessary further action.

(4) The Authority may, after bringing the notice of the head of the clinical establishment or the applicant into the relevant portions of the report regarding the defects in the standards of clinical establishments, allow maximum thirty days for rectifying the defects and deficiencies and the Authority shall send a copy of the reply given by the head of the clinical establishment clarifying that the defect has been rectified, to the team leader of the standard assesment team, which shall be re-examined by the assessment team and, if needed, it shall again inspect the clinical establishment and convince themselves whether the defects and deficiencies are rectified and shall submit one more report and upon such report the Authority shall take further actions as per rule.

CHAPTER 8

Inspection of Clinical Establishments

26. *Manner of Inspection.*- (1) If there is any reason to suspect that a clinical establishment is functioning without registration, the Council or the Authority or any other officer authorized by them may conduct an inspection after due notice to the establishment and giving a right to represent.

(2) In the inspection so conducted following procedures shall be complied with:

(a) Inspection orders shall be issued in writing by the Secretary on behalf of the Council or by the Vice Chairperson on behalf of the Authority.

(b) For purpose of inquiry photographs, videos, audio-recording, testimonials, records etc. may be collected as evidence during inspection.

(c) The officer /team conducting inspection may interact with connected or responsible persons of the establishment.

(3) No person of the establishment shall cause any kind of obstruction during inspection.

(4) The officer conducting inspection may enter the clinical establishment with supporting staff at any reasonable time and conduct inspection in the following manner, namely:-

(i) to inspect the premises or physical circumstances of the clinical establishment;

(ii) to inspect equipments, instruments, products or things in use or found in the clinical establishment and if necessary, take samples;

(iii) to observe and examine activities and other treatment procedures carrying out out in the clinical establishment without disturbing patients' privacy and without obstructing treatment;

(iv) to require the owner or manager of the clinical establishment or any employee of the establishment to take necessary steps to produce required documents or records;

(v) to examine any records, documents and collect its copies or extracts;

(vi) to require the owner or manager of the clinical establishment or any employee of the establishment to ensure the authenticity of such copies and to make such copies available to the assessment team free of cost;

(vii) to ask relevant questions and seek answers or otherwise take statement of any person, if necessary; and

(viii) to understand the factual situations, ask the owner of the establishment or any employee of the establishment or any patient, relevant matters.

(5) While conducting such inspection, the inspecting officer.-

(a) shall be careful in not disturbing or interrupting the services being provided to the patients;

(b) shall keep accuracy in inspection and maintain discipline in behaviour and work.



- (6) All persons connected with the running of the establishment shall be bound to give full and correct information to the inspecting officers.
- (7) Any person who obstructs, in any manner the discharge of duties of the inspecting officer shall be subjected to actions under section 28(1) of the Act and other connected laws.
- (8) If any person does not give or refuses without reasonable cause, information required by the inspecting officer or does not produce without delay any records, registers, reports, instruments, medical or medico-legal records, mandatory or confidential medical records etc. or gives any information misleading the inspection team, shall be subjected to actions as per section 28(2) of the Act.
- (9) Nothing in these rules shall prevent any inspecting officer from inspecting a confidential record maintained in respect of any patient who is taking/has taken treatment from a clinical establishment, but the officer deputed for inspection shall ensure that it is not disclosed in public.
- (10) Those who are deputed for inspecting clinical establishment shall submit their results of inspection within forty-eight hours of completing the inspection in Form Number 11, to the authority which entrusted them.
- (11) If reliable information is received that there is chance of imminent danger to public health, and health and safety of patients and staff, the Council or the Authority or any officer authorized by them may conduct inspection emergently without notice.
- (12) Report on such inspection shall be submitted within 24 hours to the authority which entrusted the inspection.

CHAPTER 9

Inquiry

27. Inquiry of the Council.- While conducting inquiry as per section 26, on the contraventions of the provisions of the Act, the Council shall exercise the following powers and comply the following the procedures, namely:-

- (i) Council shall issue notice, on the alleged contravention of law and the penalty that may be imposed, to the accused or the clinical establishment, to show cause why penalty shall not be imposed, with explanation and evidence, if any, within fifteen days;
- (ii) in case no explanation is received within fifteen days from the accused or the clinical establishment within fifteen days and if the Council thinks it necessary to conduct further inquiry in any other manner, by conducting the same or otherwise and after examining and evaluating the evidence and documents before the Council, impose fine as specified in the Act;
- (iii) if the accused furnish explanation with documentary or other evidence, Council shall issue a written notice to the accused for inquiry and the accused/clinical establishment may either directly or through responsible persons or through Advocate or through authorised agent submit his/establishment's arguments and evidence before the Council. The Council shall have power to cause records and evidences to be produced and to summon persons connected with this for adducing evidence for the purpose of enquiry;
- (iv) after giving the accused/ clinical establishment a reasonable opportunity of being heard, if the Council convinces that the accused/ clinical establishment has contravened the provisions of the Act



as alleged, it may impose the penalty as specified in the Act, in accordance with the gravity of the contravention. While imposing such penalty, if the accused is a clinical establishment, facts such as its size, category, type and the location where the establishment is functioning shall be taken into account.

28. *Inquiry of the Authority.*- (1) While conducting inquiry against establishments which are not registered, the Authority shall exercise the following powers and comply the following procedures, namely:-

(i) if a clinical establishment is functioning without registration, the Authority shall issue notice to the responsible persons of the clinical establishment, on the contravention alleged against the said establishment and the penalty that may be imposed thereon to show cause why penalty shall not be imposed and requiring to submit written explanation along with substantiating evidence, if any, within fifteen days;

(ii) in the case where no such written explanation is received within fifteen days from the accused and if the Authority deems that enquiry is to be conducted in any other manner, it may, after conducting such enquiry or otherwise and examining and evaluating the evidences and records before the Authority, impose penalty as specified in the Act;

(iii) in the case where the accused establishment submits an explanation, the Authority shall consider the same and if inquiry is needed upon it, fix the place and date for the same and issue notice in writing to the officials of the accused establishment for the enquiry;

(iv) during enquiry the accused establishment may submit their arguments and evidences before the Authority through responsible persons or through Advocate or through authorised agent. While conducting an enquiry, the Authority shall have power to summon any person having direct knowledge about the facts and circumstances of the case, for adducing evidence which may be useful or relevant to the subject matter of the inquiry or for producing any document and for ensuring his attendance, if the Authority deems it necessary;

(v) after giving the accused establishment a reasonable opportunity of being heard and if Authority is convinced that the said clinical establishment has functioned without registration, it may impose penalty as specified in sub-section (1) of section 27 of the Act. While determining the penalty, the provisions under

sub-section (4) of section 27 also shall be taken into account; and

(vi) the order imposing penalty shall be sent to the accused/accused establishment within fifteen days from date of order.

CHAPTER 10

Appeals

29. *Appeals.*- (1) Any person and clinical establishment aggrieved by the order or decision of the Authority may file an appeal to the Appellate Authority through online in Form 8 within forty five days from the date of such order or decision along with the prescribed fee:

Provided that if the Appellate Authority is satisfied that there are sufficient reasons due to which the appellant could not submit the appeal within the fixed time limit, it may accept the appeals submitted beyond forty five days.

(2) For the appeals submitted, a receipt shall be obtained electronically in Form 9 along with a number. Using this number status of the appeal can be verified through online.

(3) An appeal application shall contain facts, circumstances and reasons which lead to the appeal and the relief sought.

(4) Appeal application shall be submitted along with the following documents:



- (a) The order/decision against which the appeal is filed;
- (b) The documents relied upon as evidence.
- (5) Along with the appeal, appeal fees shall be remitted online, in the account specified in section 32 of the Act and evidence of payment shall also be submitted.
- (6) After receiving the appeal, the Appellate Authority may, if it deems necessary, call for report from the Authority concerned and on considering the same and on examining the documents produced and giving the appellant a reasonable opportunity of being heard, the Appellate Authority shall pass an order disposing of the appeal and a copy of the same shall be given to the appellant and the Authority.

CHAPTER 11

Grievance Redressal Mechanism

30. *Formation of the Grievance Redressal Committee.*- (1) The Council shall, with the permission of the Government, constitute a Grievance Redressal Committee for receiving complaints from public and for taking action thereon.

- (2) The Grievance Redressal Committee shall have the following members, namely:-
 - (i) An officer retired from service by holding the post not below the rank of an Additional Secretary under the Government and has degree in Law, who shall be the Chairperson of the committee;
 - (ii) A retired doctor from Government service after a minimum of twenty years of service; and
 - (iii) A person who has expertised service of minimum fifteen years, in either one or more sectors of Medical science, paramedical, emergency services, public health, law, finance, healthcare research, other medical branches, geriatric care, mental health, rights of differently abled and public health management.
- (3) The Council shall select the members to the Grievance Redressal Committee by inviting application through advertisement through its official website and other means, as it thinks proper and by conducting interview by a sub-committee consisting of the Chairperson of the Council and two official members proposed by the Council for it.
- (4) The tenure of a member of the Grievance Redressal Committee shall be three years from the date of appointment. A member shall not hold the said post for more than two terms.
- (5) A member who desires to resign from the Grievance Redressal Committee shall send his resignation letter to the Chairperson of the Council in writing and the resignation shall come into effect from the date mentioned by the member in the resignation letter or in case no date is mentioned, from the date of receipt of resignation letter by the Chairperson.
- (6) The Council shall, with the permission of the Government fix the other terms and conditions of the service of the members including Chairperson .
- (7) The Grievance Redressal Committee shall, after conducting such inquiry as it thinks proper, on the petitions it consider, give directions to the Authority concerned to take such remedial measures based on its finding.

31. *Disqualification for membership.*- A person shall be disqualified for becoming a member of the Grievance Redressal Committee if he,-

- (a) is declared to be an undischarged insolvent by a Court of competent jurisdiction; or
- (b) becomes unsound mind and stands so declared by a court of competent jurisdiction; or
- (c) has been convicted for an offence which, in the opinion of the Government involves moral turpitude or financial irregularities; or
- (d) has been removed or dismissed from the service of the Government or the Central Government or from the service of a Corporation, owned or controlled by the Government or the Central Government; or



(e) in the opinion of the Government or the Council, has financial or such other interests in the Council or Authority which is likely to affect adversely the discharge of his functions as a member.

32. *Vacancy.*- A casual vacancy in a Grievance Redressal Committee shall be filled by the Council through selection as provided in sub-rule (3) of rule 30.

33. *Functions.*- (1) The Grievance Redressal Committee shall perform the following functions, namely,-

(i) receive complaints from the public regarding violations of provisions of the Act or the rules made thereunder by any clinical establishments;

(ii) to register the complaint without delay, examine the details and issue acknowledgement receipt in Form 10 denoting the number and details which can be used as reference for tracking the progress of the said complaint;

(iii) to examine the complaints received by the Grievance redressal committee and if, in its opinion, there is no substance in the complaint or do not fall under the purview of the Act or the rules made thereunder, record the same and dispose of the complaint immediately and inform the complainant that the complaint is disposed of.

(iv) to conduct necessary inquiry, by providing the alleged clinical establishment and the complainant a reasonable opportunity of being heard on the complaint and suggest remedial measures to the Authority and inform the complainant of the same in writing.

(2) The Council or the Authority, as the case may be, shall ensure that steps have been taken by the establishment to rectify the defects within the time limit fixed by the Grievance Redressal Committee. The Authority or the Council, as the case may be, shall, give an action taken report to the Grievance Redressal Committee within thirty days on the report submitted by the establishment after rectifying the defect.

34. *Disposal of the complaint.*- The Grievance Redressal Committee shall dispose of the complaints in a speedy manner and inform the decision to the complainant within three months from the date of receipt of the complaint. An online solution shall be arranged by the Council in its website for the public to submit complaints as per these rules and also to get information regarding status of the complaints and action taken on it.

CHAPTER 12

Miscellaneous

35. *Special provisions regarding the clinical establishments under the control of Government.*- (1) In respect of the clinical establishments under the control of Government, it shall be the duty of the person-in-charge of the clinical establishment concerned, to take actions and accomplish the responsibilities under the Act or the rules made thereunder.

(2) The fee required for registration of a clinical establishment or the fee fixed by the Council or Authority for assessing the standard or for inspection, as per the provisions of the Act or rules, shall not be applicable to the clinical establishments under the control of Government and need not be remitted:

Provided that the clinical establishments under the ownership of Government, which are not provisionally registered at the time of applying for permanent registration are liable to remit double the amount as stated in sub-rule (8) of rule 15 and in the event of such remittance, disciplinary action may be taken against the officer who is responsible for not registering provisionally.

36. *Accounts.*- (1) The Secretary shall carry out the administration of the Council in accordance with the directions and decisions of the Council and maintain the accounts.

(2) The fees, fines and penalties realized by the Council and the Authority under the provisions of the



Act and the rules made thereunder shall be credited to the special account opened for it with the permission of the Government and shall be utilized for the implementation of the provisions of the Act and these rules.

37. *Audit.*- (1) All the accounts of the Council including administrative expenditure shall be audited by a Chartered Accountant decided by the Council before 31st of October every year. The audit report along with the audited statement, after getting the approval of the Council, shall be submitted to the Government with suggestions or explanation, if any, of the Council before 31st of December.

(2) The expenses relating to the auditing shall be payable from the account of the Council by including the same in the administrative expenditure.

38. *Annual Report.*- The Secretary shall prepare a detailed report of the activities of the Council in a financial year and submit it for the approval of the Council and after getting it approved by the Council, it shall be submitted to the Government before 30th of November. In addition to the regular activities of the Council, the annual report shall contain matters regarding registration of clinical establishments, actions taken against clinical establishments, amount of fine and penalties recovered from them for contravening the provisions of the Act and such other matters as the Council deems proper. Immediately after the receipt of annual report, the Government shall, as soon as possible, lay the same before the Legislative Assembly.

39. *Allowances.*- (1) The official members of the Authority and the Council shall be eligible for travelling allowances and daily allowances as per the Government rules from the same fund from which their salary is drawn.

(2) The non-official members of the Authority and the Council, Assessors and members of Sub-committees shall be eligible for travelling allowances as applicable, to the Class 1 officers of the Government, from time to time, as per Kerala Service Rules and daily allowances at the rate as may be fixed by the Government from time to time for participating in the meetings.

(3) Besides, the assessors who carry out the work of assessment of standard shall be eligible for remuneration as fixed by the Council from time to time.

Form 1

[See Rule 4(1)]

State Council for Clinical Establishments Register of Clinical Establishments

Sl. No.	Name of Clinical Establishment, Address, Phone No, E mail, District	Owner / Name of person in charge Address, Phone No., Email	System of Medicine (If Hospital)/ Lab Diagnostic Centre and Others (Specify)	Standard (Category)	Registration No. Date, Period	Remarks
<hr/>						



Form 2
[See Rule 13(1)]

Application Form for Provisional Registration of Clinical Establishments
(applicable for hospitals only)

1. Name of the Clinical

Establishment: _____

2.

Address: _____

Village/Town: _____ Taluk _____

District: _____ State _____ Pin
code _____

Telephone No (STD code) _____ Mobile _____

E-mail Address: _____ Website (if
any) _____

3. Location: Panchayat Municipality Corporation

4. Year of starting the establishment: _____

5. Name of the owner:

Address _____

Village/Town _____ Taluk _____

District _____ State _____ Pincode _____

Telephone No (STD code) _____ Mobile _____ E-mail _____

Address _____

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

Name _____

Designation _____

Qualification _____

E-mail Address _____ Telephone No (STD code): _____

Mobile: _____

7. Ownership (Kindly upload registration certificate/license of establishment)

(a) Public Sector: (select applicable from software)

(b) Private Sector: (select applicable from software)

8. System of Medicine : (select applicable from software)

9. Type of Establishment: (select applicable from software)

10. Services offered:

(i) (Select applicable from software)



- (ii) (a) Modern Medicine (including Dentistry):
 (i) Speciality: (Select applicable from software)
 (ii) Medical Super Speciality: (Select applicable from software)
 (iii) Surgical Super Speciality: (Select applicable from software)
 (b) Ayurveda: (Select applicable from software)
 (c) Unani: (Select applicable from software)
 (d) Siddha: (Select applicable from software)
 (e) Homoeopathy: (Select applicable from software)
 (f) Naturopathy: (Select applicable from software)

- (iii) Laboratory and Diagnostics: (Select applicable from software)
 (iv) Diagnostic Imaging Centre: (Select applicable from software)

11. Infrastructure:

- (a) Area of the establishment (sq. ft) _____
 (b) Total no. of Out Patient Clinics _____
 (c) Total number of beds _____
 (d) Speciality-wise distribution of beds (including ICU), please specify:

Sl.No	Speciality	Number of Beds

e) Details of Medical/Diagnostic equipments

Sl. No	Equipment	Name of Company	Item wise details	Quantity/No.	Functioning status	Remarks

12. Human Resources

- a) Total number of Staff: _____
 b) Details of staff: (upload the details in scanned format in the website)
 (upload in the excel sheet format given)

Sl.No.	Name	Qualification	Registration No.	Council which Registered/Certified (Doctor, Nurse, Technical Staff)	Nature of Service (permanent/Temporary/Visiting)
	Doctor				



	Nursing Staff					
	Technical Staff (specify)					
	Para-medical Staff (specify)					
	Administrative Staff (specify)					
	Supporting staff (specify)					
	Others (specify)					

Submitted by: Name of the person /Name of the Clinical Establishment
Designation:

Date:

DECLARATION

1

I/We.....hereby declare that the details stated above for the purpose of obtaining registration under Clinical Establishment (Registration and Regulation) Act, 2018 and the rules made thereunder, for the establishment under my/our (Company/Partnership) ownership are true and correct to the best of my knowledge and belief and in case any change occurs, I/We shall immediately inform the same to the District Authority and also undertake that I/we are ready to undergo legal actions as per law, in case it is found that registration is obtained by furnishing false informations.

Signature:
Name:

Date:

Place:

2

I/We.....hereby undertake that if the institution by name under the ownership of obtains registration as per Clinical Establishment (Registration and Regulation) Act, 2018, all the provisions of the Clinical Establishment (Registration and Regulation) Act, 2018 and the rules made thereunder and all orders issued by the State Council for the Clinical Establishment and the District Registration Authority, from time to time, shall be complied with, as long as the said registration is valid.

Signature:
Name:



- 1.
- 2.
- 3.

Date: _____

Form 2A

[See rule 13(1)]

Application Form for Provisional Registration of Clinical Establishments

(Applicable to other Clinical establishments except Hospitals)

1. Name of the Clinical Establishment: _____

2.

Address: _____

Village/Town: _____ Taluk

District: _____ State _____

Pincode _____

Telephone No. (STD code): _____ Mobile _____

Email Address: _____ Website (if any): _____

3. Location: Panchayat Municipality Corporation

4. Year of starting the establishment: _____

5. Name of the owner: _____

Address: _____

Village/Town: _____ Taluk

District: _____ State _____

Pincode _____

Telephone No. (STD code): _____ Mobile _____ Email _____

Address _____

6. If Technician kindly provide details below and attach documents of proof

Name: _____

Institution/University/place: _____

Year of passing: _____

Name of the Council (if any, applicable) : _____

Registration Number: _____

Designation: _____

Qualification: _____

E-mail Address: _____



Telephone No. (STD code): _____ Mobile _____

7. Ownership (Kindly upload registration certificate/license of establishment)

(a) Public Sector: (Select applicable from software)

(b) Private Sector: (Select applicable from software)

8. Laboratories and Diagnostic centres: (Select applicable from software)

9. Infrastructure

(a) Area of the establishment (sq. ft): _____

(b) Number of beds: _____

10. Human Resources

(a) Number of Staff: _____

(b) details of staff: (upload the details in scanned format in the website)

(upload in the excel sheet format given)

Sl.No.	Name	Qualification	Registration No.	Council which Registered/Certified (Doctor, Nurse, Technical Staff)	Nature of Service (permanent/Temporary/Visiting)
	Doctor				
	Nursing Staff				
	Technical Staff (specify)				
	Para-medical Staff (specify)				
	Administrative Staff (specify)				
	Supporting staff (specify)				
	Others. (specify)				

(c) Details of Medical & Diagnostic equipments

Sl. No.	Equipment	Name of Company	Item wise details	Quantity/ No.	Functioning status	Remarks

Submitted by: Name of the person /Name of the Clinical Establishment:

Designation:

Date:



DECLARATION

1

I/We.....hereby declare that the details stated above for the purpose of obtaining registration under Clinical Establishment (Registration and Regulation) Act, 2018 and the rules made thereunder, for the establishment under my/our (Company/Partnership) ownership are true and correct to the best of my knowledge and belief and in case any change occurs, I/We shall immediately inform the same to the District Authority and also undertake that I/we are ready to undergo legal actions as per law, in case it is found that registration is obtained by furnishing false informations.

Signature:

Name:

Date:

Place:

2

I/We.....hereby undertake that if the institution by name under the ownership of obtains registration as per Clinical Establishment (Registration and Regulation) Act, 2018, all the provisions of the Clinical Establishment (Registration and Regulation) Act, 2018 and the rules made thereunder and all orders issued by the State Council for the Clinical Establishment and the District Registration Authority, from time to time shall be complied with, as long as the said registration is valid.

Signature:

Name:

1.

2.

3.

Date:

Form 3

[See rule 13(2)]

State Council for Clinical Establishments**District Registration Authority**

-----District

Acknowledgment receipt of Application for Provisional Registration

The application for provisional registration of the Clinical Establishment submitted by the person/establishment below mentioned has been received by the District Registration Authority on _____ (date).

Name and Address of establishment/ person	Date of Application	Receipt Number (Computer Generated)

This acknowledgment receipt does not confer any right on the applicant for grant of registration.

Place & Date: (Computer Generated)

Form 4

[See rule 13(3)]

State Council for Clinical Establishments

District Registration Authority

-----District

Provisional registration No: (Computer Generated)

Date of issue: (Computer Generated)

Valid up to: (Computer Generated)

Provisional Registration Certificate

Certified that the establishment mentioned below is provisionally registered under the provisions of the Kerala Clinical Establishments (Registration and Regulation) Act, 2018 and the rules made thereunder as a clinical establishment.

Name of the Clinical Establishment: _____

Address: _____

Name and address of owner of the Clinical Establishment:

Name and address of the Person in Charge:

Systems of Medicine: _____

Category of Establishment: _____

This certificate is subject to the conditions specified in the Kerala Clinical Establishments (Registration and Regulation) Act, 2018 and the rules made there under.

Designation/Authority Issuing Registration/(Computer Generated)

Place & Date: (Computer Generated)



In case of any grievance, kindly visit to <https://www.clinicalestablishments.kerala.gov.in>

Form 5
[See rule 15(1)]
**Application Form for Permanent Registration/Renewal of Registration
of Clinical Establishments**
(Applicable only to Hospitals)

1. Name of the Clinical

Establishment: _____

(Temporary Registration Number: _____)

[Registration Number (in case of renewal): _____]

2. Address:

Village/Town: _____

Taluk: _____

District: _____ State: _____

Pincode _____

Telephone No. (STD code): _____ Mobile: _____

Email Address: _____ Website (if any): _____

3. Location: Panchayat Municipality Corporation

4. Year of starting the establishment: _____

5. Name of the owner:

Address: _____

Village/Town: _____

Taluk: _____

District: _____ State: _____ Pin

code _____

Telephone No. (STD code): _____ Mobile: _____ E-mail

Address: _____

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

Name: _____

Designation: _____

Qualification: _____

E-mail Address: _____ Telephone No (STD code): _____ Mobile: _____

7. Ownership (kindly upload registration certificate/license of establishment)

(a) Public Sector: (Select applicable from software)

(b) Private Sector: (Select applicable from software)

8. System of Medicine : (Select applicable from software)

9. Type of Establishment: (Select applicable from software)



10. Services offered: (√ mark the suitable)

- (i) (Select applicable from software)
(ii) (a) Modern Medicine: (Select applicable from software)
(i) Medical Super Speciality: (Select applicable from software)
(ii) Surgical Super Speciality: (Select applicable from software)
(b) Ayurveda: (Select applicable from software)
(c) Unani: (Select applicable from software)
(d) Siddha: (Select applicable from software)
(e) Homoeopathy: (Select applicable from software)
(f) Naturopathy: (Select applicable from software)
(iii) Laboratory and Diagnostics: (Select applicable from software)

11. Infrastructure

- (a) Area of the establishment (sq.ft): _____
(b) Total no. of Out Patient Clinics: _____
(c) Total number of beds: _____
(d) Speciality-wise distribution of beds (including ICU), please specify:

Sl.No.	Speciality	Number of Beds

(e) Details of Medical / Diagnostic equipments

Sl. No	Equipment	Name of Company	Item wise details	Quantity/ No.	Functioning status	Remarks

12. Human Resources

- a) Total number of Staff: _____
b) Details of staff: (upload the details in scanned format in the site)

(upload in the excel sheet format given)

Sl.No.	Name	Qualification	Registration No.	Council which Registered/Certified (Doctor, Nurse, Technical Staff)	Nature of Service (permanent/Temporary/Visiting)
	Doctor				
	Nursing Staff				
	Technical Staff (specify)				
	Para-medical Staff				



	(specify)				
	Administrative Staff (Specify)				
	Supporting staff (specify)				
	Others (specify)				

Submitted by: Name/Name of the Clinical Establishment

1. Designation:

Date:

DECLARATION

1

I/We.....hereby declare that the details stated above for the purpose of obtaining registration under Clinical Establishment (Registration and Regulation) Act, 2018 and the rules made thereunder, for the establishment under my/our (Company/Partnership) ownership are true and correct to the best of my knowledge and belief and in case any change occurs, I/We shall immediately inform the same to the District Authority and also undertake that I/we are ready to undergo legal actions as per law, in case it is found that registration is obtained by furnishing false informations.

Signature:
Name:

Date:

Place:

2

I/We.....hereby undertake that if the institution by name under the ownership of obtains registration as per Clinical Establishment (Registration and Regulation) Act, 2018, all the provisions of the Clinical Establishment (Registration and Regulation) Act, 2018 and the rules made thereunder and all orders issued by the State Council for the Clinical Establishment and the District Registration Authority, from time to time shall be complied with, as long as the said registration is valid.

Signature:
Name:

1.

2.



3.

Date:

Form 5A
[See rule 15(1)]

Application Form for Permanent Registration/Renewal of Clinical Establishments

(Applicable to other Clinical Establishments except Hospitals)

1. Name of the Establishment:

_____)
(Temporary Registration Number: _____)
[Registration Number (in the case of renewal): _____]

2. Address:

_____ Taluk: _____
Village/Town: _____

_____ Pin
District: _____ State: _____ code _____

Telephone No. (STD code): _____ Mobile: _____

Email Address: _____ Website (if any): _____

3. Location: Panchayat Municipality Corporation

4. Year of starting the establishment: _____

5. Name of the owner:

_____ Address: _____

_____ Village/Town: _____

_____ Taluk: _____

_____ Pin code _____
District: _____ State: _____

Telephone No (STD code): _____ Mobile: _____

Email Address: _____

6. If technician, kindly provide following details and attach copy of documents of proof

Name : _____

Institution/University/place: _____

Year of passing: _____

Name of the Council (if any applicable): _____

Registration Number: _____

Designation: _____

Qualification: _____

E-mail Address: _____ Telephone No. (STD code): _____ Mobile: _____

7. Ownership (kindly upload registration certificate/license of establishment)

(a) Public Sector: (Select applicable from software)

(b) Private Sector: (Select applicable from software)

8. Laboratories and Diagnostics: (Select applicable from software)



9. Infrastructure

a) Area of the establishment (sq. ft): _____

c. Number of beds: _____

10. Details of Medical & Diagnostic equipments

Sl. No	Equipment	Name of Company	Item wise details	Quantity/No.	Functioning status	Remarks

11. Human Resources

a) Total number of Staff: _____

b) Details of staff: (upload the details in scanned format in the site)

(upload in the excel sheet format given)

Sl.No.	Name	Qualification	Registration No.	Council in which Registered/Certified (Doctor, Nurse, Technical Staff)	Nature of Service (permanent/Temporary/Visiting)
	Doctor				
	Nursing Staff				
	Technical Staff (specify)				
	Para-medical Staff (specify)				
	Administrative Staff (Specify)				
	Support staff (specify)				
	Others (specify)				

Submitted by: Name/Name of the clinical establishment
Designation:

Date:



DECLARATION

1

I/We.....hereby declare that the details stated above for the purpose of obtaining registration under Clinical Establishment (Registration and Regulation) Act, 2018 and the rules made thereunder, for the establishment under my/our (Company/Partnership) ownership are true and correct to the best of my knowledge and belief and in case any change occurs, I/We shall immediately inform the same to the District Authority and also undertake that I/we are ready to undergo legal actions as per law, in case it is found that registration is obtained by furnishing false informations.

Signature:
Name:

Date:
Place:

2

I/We.....hereby undertake that if the institution by name under the ownership of obtains registration as per Clinical Establishment (Registration and Regulation) Act, 2018, all the provisions of the Clinical Establishment (Registration and Regulation) Act, 2018 and the rules made thereunder and all orders issued by the State Council for the Clinical Establishment and the District Registration Authority, from time to time shall be complied with, as long as the said registration is valid.

Signature:
Name:

- 1.
- 2.
- 3.

Date:

Form 6
[Rule 15(1)]

State Council for Clinical Establishments

District Registration Authority

-----District

Acknowledgment receipt of Application for Permanent Registration

The application for permanent registration of the Clinical Establishment submitted by the following



person/establishment has been received by the District Registration Authority on
_____ (date)

Name and address of the establishment/ person	Application date	Receipt Number (Computer Generated)

This acknowledgment receipt does not confer any right on the applicant for grant of registration.

Place & Date: *(Computer Generated)*

Form 7
[See rule 15(7)]

State Council for Clinical Establishments
District Registration Authority
-----**District**

Permanent Registration No: *(Computer Generated)*

Date of issue : *(Computer Generated)*

Valid up to : *(Computer Generated)*

Permanent Registration Certificate

Certified that the establishment mentioned below is granted Permanent Registration under the provisions of the Kerala Clinical Establishments (Registration and Regulation) Act, 2018 and the rules made thereunder as a clinical establishment.

Name of the Clinical Establishment: _____

Address: _____

Name and address of the Owner of the Clinical Establishment: _____

Name and address of the Person in Charge: _____

Owner of the Clinical
Establishment: _____

System of Medicine: _____

Category of Establishment: _____

This Certificate is subject to the conditions specified in the Kerala Clinical Establishments (Registration and Regulation) Act, 2018 and the rules made thereunder.

Designation/Authority issuing registration *(Computer Generated)*



Place & Date: *(Computer Generated)*

In case of any grievance, visit <https://www.clinicalestablishments.kerala.gov>.

Form 8

[See rule 29(1)]

**Appeal filed before the Appellate Authority as per the Kerala Clinical Establishments
(Registration and Regulation) Act, 2018**

Appeal No.

Appellant:

Respondent:

Appeal filed against the decision No..... dated of the District
Authority, as per sub-section (2) of section 34 of the Kerala Clinical Establishments
(Registration and Regulation) Act, 2018.

Statement of facts (Add)

Decision of District Authority (Add)

The above said decision of the District Authority is not valid and unsustainable because of the
following reasons.

Reasons (add)

Relief sought (add)

Appeal fees of ₹ 1000/- is hereby remitted.

Appellant/
for the Appellant

Place:

Date:

Documents produced:

Form 9

[See rule 29(2)]

**Appellate Authority as per the Kerala Clinical Establishments (Registration and Regulation)
Act, 2018**

Acknowledgment Receipt

Appeal filed by(Clinical establishment/person) before this Appellate



Authority has been received on _____ (date)

Receipt Number is: *(Computer Generated)*

Place & Date: *(Computer Generated)*

This is a computer generated acknowledgement

Appellate Authority

This acknowledgement receipt does not confer any right to allow appeal of the applicant.

Form 10

[See rule 33(1) (ii)]

Acknowledgment receipt

**Issued by the Grievance Redressal Committee as per the Kerala Clinical Establishments
(Registration and Regulation) Act, 2018**

The complaint filed by (name and address of the complaint) before this
Grievance Redressal Committee has been received on _____ (date).

The Receipt number : *(Computer Generated)*

Place & Date: *(Computer Generated)*

This is a computer generated acknowledgement

Grievance Redressal Committee

This acknowledgment receipt does not confer any right to allow the complaint of the complainant.



Form 11
[See rule 26(10)]
The Kerala Clinical Establishments (Registration and Regulation) Act, 2018
Format for submitting assessment/Inspection Report

Number of visits made with dates: _____

Names and other details of assessors/members of the inspection team: _____

Name of the clinical establishment visited: _____

Details for contact of clinical establishment visited _____

Procedure followed in inspection (kindly describe whom was met with, what records were examined, etc.) _____

Salient observations /findings: _____

Conclusions:

Specific recommendations:

1. To the Clinical Establishment

2. To the District Registering Authority

* If there is no consensus among the members of the Inspection team, please specify.

(Signature of assessors)

Place:

Date:

SCHEDULE

A. Registration Fees (in rupees)

<i>Type of Clinical Establishment Description</i>	Panchayath		Municipality/Corporation	
	Provisional (for 2 years)	Permanent (for 3 years)	Provisional (for 2 years)	Permanent (for 3 years)
In patient treatment				
Upto 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	55000
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 and Diagnostics Centres				
Level 1: 1. Clinical Pathology/ Basic Haematology 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 1. Specialized Haematology/ 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 1. Advanced Haematology/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



B. Fees for renewal of registration : The same rate as for permanent registration

C. Fees for late application : An addition of 25% of registration fee shall be paid.

D. Appeal Fee : ₹.1000 (Rupees one thousand only)

By order of the Governor,

RAJEEV SADANANDAN
Additional Chief Secretary

Explanatory Note

(This does not form part of the notification, but is intended to indicate its general purport.)

Sub-sections (1) and (2) of section 52 of the Kerala Clinical Establishments

(Registration and Regulation) Act, 2018 (Act No.2 of 2018) empowers the Government to make rules for the implementation of the provisions of the said Act. Government have decided to make rules for the above said purpose.

This notification is intended to achieve the above object.

