



The Kerala Clinical Establishments (Registration and Regulation) Act, 2018

Act No. 02 of 2018

Keywords:

Armed Forces, Emergency Medical Condition

Amendment appended: 35 of 2021

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GOVERNMENT OF KERALA

Law (Legislation-H) Department

NOTIFICATION

No. 11935/Leg. H1/2017/Law.

22nd February, 2018

*Dated, Thiruvananthapuram, 10th Kumbham, 1193
3rd Phalgun, 1939.*

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) Act, 2018 (2 of 2018).

By order of the Governor,

B. G. HARINDRANATH,
Law Secretary.

[Translation in English of “2018-ലെ കേരള ക്ലിനിക്കൽ സ്ഥാപനങ്ങൾ (രജിസ്ട്രേഷനും നിയന്ത്രണവും) ആക്റ്റ്” published under the authority of the Governor.]

ACT 2 OF 2018

THE KERALA CLINICAL ESTABLISHMENTS (REGISTRATION AND REGULATION) ACT, 2018

AN

ACT

to provide for the registration and regulation of clinical establishments rendering services in recognised systems of medicine in the State and for matters connected therewith or incidental thereto.

Preamble.—WHEREAS, it is expedient to provide for the registration and regulation of clinical establishments with a view to prescribe standards of facilities and services which may be provided by them for the improvement of public health;

BE it enacted in the Sixty-ninth Year of the Republic of India as follows:—

CHAPTER I

PRELIMINARY

1. *Short title and commencement.*—(1) This Act may be called the Kerala Clinical Establishments (Registration and Regulation) Act, 2018.

(2) It 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.*—In this Act, unless the context otherwise requires,—

(a) “Appellate Authority” means the Appellate Authority constituted under sub-section (1) of section 34;

(b) “Authority” means a District Registering Authority constituted under sub-section (1) of section 14;

(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,—

- a. the Government or a department of the Government;
- b. a trust, whether public or private;
- c. individual proprietorship or partnership firm;

d. a corporation whether or not owned by the Government (including a co-operative society registered under the Kerala Co-operative Societies Act, 1969 (21 of 1969) or a charitable society registered under the Travancore-Cochin Literary, Scientific and Charitable Societies Registration Act, 1955 (12 of 1955) or under the Societies Registration Act, 1860 (Central Act 21 of 1860);

- e. Local Self Government Institutions,

but does not include the clinical establishments which provide only consultation services and the clinical establishments owned, controlled or managed by the Armed Forces.

Explanation:—For the purposes of this clause,—

(i) “Armed Forces” means the forces constituted under the Army Act, 1950 (Central Act 46 of 1950), the Air Force Act, 1950 (Central Act 45 of 1950) and the Navy Act, 1957 (Central Act 62 of 1957);

(ii) “consultation services” means medical examination, prescribed types of diagnosis and accordingly to administer the medicines and also the first aid and observation;

(d) “Council” means the State Council for clinical establishments established under section 3;

(e) “emergency medical condition” means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) of such a nature that the absence of immediate medical attention could reasonably be expected to result in,—

- (i) placing the life of the individual or, with respect to a pregnant woman, the health of the woman or unborn child, in serious jeopardy; or
- (ii) serious impairment to bodily functions; or
- (iii) serious dysfunction of any organ or part of a body;

(f) “Government” means the Government of Kerala;

(g) “Local Self Government Institution” means a Panchayat at any level constituted under section 4 of the Kerala Panchayat Raj Act, 1994 (13 of 1994) or a Municipality constituted under section 4 of the Kerala Municipality Act, 1994 (20 of 1994);

(h) “notification” means a notification published in the Official Gazette;

(i) “prescribed” means prescribed by rules made under this Act;

(j) “recognised system of medicine” means Modern Medicine (including dentistry), Naturopathy, Ayurveda, Homoeopathy, Sidha and Unani systems of medicine or any other system of medicine recognised by the Government;

(k) “register” means the State register maintained and published by the Authority under sub-section (1) of section 12 of the Act containing details of the registered clinical establishments;

(l) “registration” means the registration under section 16 and the expression registration or registered shall be construed accordingly;

(m) “standards” means the standards that may be prescribed by the Government under section 13 for the registration of clinical establishments;

(n) “to stabilize” with its grammatical variations and cognate expressions means, with respect to an emergency medical condition specified in clause (e), to provide such medical treatment of the condition as may be necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a clinical establishment.

CHAPTER II

THE STATE COUNCIL FOR CLINICAL ESTABLISHMENTS

3. *Establishment of State Council.*—(1) With effect from such date as the Government may, by notification, appoint in this behalf, there shall be established for the purposes of this Act, a Council to be called the State Council for Clinical Establishments.

(2) The Council shall consist of the following members, namely:—

- (a) Secretary, Health and Family Welfare Department, *ex-officio*, who shall be 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, Indian Systems of Medicine, *ex-officio*;
- (f) Director, Homoeopathy 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;

(iii) the Council of Homoeopathy;

constituted under the provisions of the Travancore-Cochin Medical Practitioners Act, 1953 (IX of 1953);

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

(i) the Kerala Dental Council constituted under section 21 of the Dentists Act, 1948 (Central Act 16 of 1948);

(ii) the Kerala Nursing Council constituted under section 3 of the Nurses and Midwives Act, 1953 (10 of 1953);

(j) Government nominees,—

(i) one representative from welfare organisations of the patients in the State;

(ii) an Officer not below the rank of Additional Law 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 of the Kerala Unit;

(v) one representative of Ayurveda Medical Association of India of the Kerala Unit;

(vi) one representative of Indian Dental Association of the Kerala Unit;

(vii) one representative of the Association of Homoeopathy Doctors in Kerala;

(viii) one representative of Medical Laboratory Owner's Association in Kerala;

(ix) one representative of the Association of Physiotherapists of Kerala;

(k) Secretary of the Council.

4. *Functions of the Council.*—(1) The Council shall carry out the following functions, namely:—

(a) determine, within a period of two years from the commencement of this Act, the first set of standards for ensuring proper healthcare by the clinical establishments;

(b) classify and categorise the clinical establishments and to recommend the Government to prescribe the standards for each category;

(c) compile and publish State Register of Clinical Establishments in such manner as may be prescribed;

(d) appoint panel of assessors for inspection and assessment of the clinical establishments in such manner as may be prescribed;

(e) conduct periodic inspection of clinical establishments for ensuring the standards to be maintained in such manner as may be prescribed;

(f) recommend to the Government any modification required in the rules in accordance with the changes in technology or social conditions;

(g) notify data and information which are to be mandatorily provided by clinical establishments including their periodicity; analyse the data and make results available in the public domain in such manner as may be prescribed;

(h) send periodic returns for updating the National Register as required by the Central Government or the National Council constituted under the Clinical Establishments (Registration and Regulation) Act, 2010 (Central Act 23 of 2010);

(i) direct the cancellation of registration of such clinical establishments where there is imminent danger to public health and the health and safety of patients and staff; and

(j) perform such other functions as may be assigned to it by the Government from time to time.

(2) The Council shall recommend to the Government to prescribe the registration and other fees, as it deems fit from time to time.

(3) Any dispute as to whether an establishment is a clinical establishment or not shall be referred to the State Council and the State Council, after giving the interested parties a reasonable opportunity to adduce evidence and of being heard, decide such disputes.

5. *Secretary and other employees of the Council.*—(1) The Government shall appoint an officer not below the rank of Deputy Director of Health Department to be the Secretary of the Council.

(2) The Council may, with the permission of the Government, employ such employees as are necessary for its proper functioning.

6. *Power to seek advice or assistance.*—(1) The Council may associate itself with any person or body and obtain technical assistance or advice as it may deem necessary for carrying out the provisions of this Act.

(2) The Council may appoint such sub-committees as it deems fit, with members or persons who are not members of the Council, for such period, not exceeding two years, for the consideration of any particular matter under this Act or such other matter as may be prescribed.

7. *The Council to follow consultative process.*—The Council shall follow a consultative and transparent process, including public hearing in such places as may be determined by the Council, with adequate notice for making suggestions for altering the mandatory standards and classification of clinical establishments and any other matter under the provisions of this Act and the rules.

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.

9. *Powers and functions of the Executive Committee.*—The Executive Committee shall exercise such powers and perform such functions as may be prescribed.

10. *Vacancy etc. not to invalidate the proceedings of the Council.*—No act or proceedings of the Council shall be invalid on the ground merely of the existence of any vacancy or defect in the constitution of the Council.

11. *Procedure and conduct of business.*—The quorum and the procedure for the conduct of business to be transacted in the meetings of the Council shall be such as may be prescribed.

CHAPTER III

REGISTER OF CLINICAL ESTABLISHMENTS

12. *Register of Clinical Establishments.*—(1) The Council shall compile, maintain and publish a register to be known as the State Register of Clinical Establishments in such form containing such particulars as may be prescribed.

(2) The Secretary of the Council shall be responsible for compiling and updating the State Register of Clinical Establishments.

CHAPTER IV

REGISTRATION AND STANDARDS FOR CLINICAL ESTABLISHMENTS

13. *Categories and standards.*—(1) Different standards shall be prescribed by the Government for clinical establishments of different categories and registration shall be granted to the establishments that have standards in each category.

(2) The Council shall determine, within a period of two years from the date of commencement of this Act, the first set of standards for ensuring proper healthcare in clinical establishments.

14. *Authority for registration.*—(1) The Government shall, by notification, constitute an Authority for each District for registration of clinical establishments with the following members, namely:—

(a) District Collector, *ex-officio*—Chairperson;

(b) District Medical Officer (Health), *ex-officio*—
Vice-Chairperson;

(c) an officer not below the rank of Assistant Director of Health and Family Welfare Department nominated by the Government who shall be the Convenor of the Authority;

(d) a Medical Officer of the Indian Systems of Medicine nominated by the Government;

(e) a Medical Officer of Homoeopathic System of Medicine nominated by the Government;

(f) one member whose tenure shall be three years to be nominated by the District Collector from a professional association in the health sector.

(2) Notwithstanding anything contained in sub-section (1), for the purposes of provisional registration of clinical establishments under sub-section (1) of section 17, the Vice-Chairperson of the Authority shall exercise the powers of the Authority in such manner as may be prescribed.

(3) The Authority shall perform the following functions, namely:—

(a) grant, renew, suspend or cancel registration of a clinical establishment;

(b) ensure compliance of the provisions of the Act and the rules made thereunder;

(c) cancel the registration of such clinical establishment where there is imminent danger to public health and the health and safety of patients and staff;

(d) prepare and submit reports periodically of such nature as directed by the Council;

(e) perform such other functions as may be prescribed.

15. *Conditions for registration.*—Every Clinical Establishment shall fulfil the following conditions for the purpose of registration, namely:—

(a) shall have the standards according to the category of clinical establishment;

(b) the medical and paramedical staff shall have the minimum qualifications fixed by the authorities concerned and advertised by the Council;

(c) undertake to mandatorily comply with the orders issued by the Council from time to time, in such form as may be prescribed;

(d) undertake to furnish such information to the State Government as notified;

(e) maintain standards of safety, infection control and method of treatments maintaining standards, as may be notified.

(f) such other conditions as may be prescribed.

16. *Registration of clinical establishments.*—(1) All clinical establishments in Kerala shall be registered with the Authority concerned under the provisions of this Act and the rules made thereunder.

(2) No person shall run a clinical establishment unless it has been duly registered in accordance with the provisions of this Act and the rules made thereunder.

(3) All clinical establishments functioning at the commencement of this Act shall be granted provisional registration by the Authority concerned.

(4) All clinical establishments having provisional registration shall acquire the standards for permanent registration in the category within such period as may be prescribed.

(5) All clinical establishments which come into existence after the commencement of this Act shall apply for permanent registration with the Authority within such period as may be prescribed.

(6) Where a clinical establishment is offering services in different medical category, such clinical establishment shall apply for separate provisional or permanent registration for each category under this Act:

Provided that a laboratory or a diagnostic centre which is a part of a clinical establishment need not be registered separately.

17. *Application for provisional registration.*—(1) Every clinical establishment functioning on the date of commencement of this Act shall apply for provisional registration in such form along with such fee, as may be prescribed.

(2) All clinical establishments, whether registered or not under any existing law requiring registration of such establishments, shall apply for registration as referred to in sub-section (1).

(3) The Authority shall, within forty five days of the date of receipt of the application, grant to the applicant a certificate of provisional registration in such form and containing such particulars as may be prescribed and if the registration is not granted or declined within this period it shall be deemed to have been granted.

(4) If it is found that provisional registration granted under sub-section (3) was given not in accordance with law, disciplinary proceedings may be initiated against the officer responsible for granting or not declining the registration within the said period.

18. *Validity of provisional registration.*—Provisional registration shall be valid for a period of two years from the date of issuance of the certificate of registration.

19. *Application for permanent registration of a clinical establishment.*—(1) Application for permanent registration of a clinical establishment shall be made to the Authority in such form and in such manner with such fees as may be prescribed, accompanied by such evidence to the effect that the clinical establishment has complied with the standards prescribed for the category.

(2) Every clinical establishment having provisional registration shall apply for permanent registration sixty days prior to the date of expiry of the provisional registration.

(3) The Authority shall, ensure that the details of clinical establishments that have applied for registration are caused to be published, in the manner as may be prescribed, within a period of seven days from the date of receipt of application.

(4) The Authority shall, before granting permanent registration, inspect or cause to be inspected the clinical establishment.

(5) Permanent registration shall be granted by the Authority only when a clinical establishment has fulfilled the prescribed standards.

(6) The Authority shall, within sixty days of the date of receipt of the application, grant to the applicant a certificate of permanent registration in such form and containing such particulars as may be prescribed and if the registration is not declined or granted within this period it shall be deemed to have been granted.

(7) Where the Authority is of the opinion that the clinical establishment has not acquired the standard notified and has submitted incomplete information or if relevant documents are not provided, it shall inform the applicant of its intention to disallow permanent registration with reasons for the same.

(8) The applicant shall, within thirty days from the date of communication received under sub-section (7) respond to the Authority and produce evidence to the effect that the standards have been acquired and informations and documents have been submitted and the Authority may, on examination of the evidence and after a re-examination of the evidence by the assessors, if required, either grant or decline the application for registration.

(9) Where the Authority decides to decline the application for permanent registration, the reason for the same shall be communicated to the applicant within thirty days of the date of such decision.

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

(11) The Authority shall ensure that the registered clinical establishments maintain the prescribed standards as long as the registration remains valid and the Authority shall call for periodic reports, inspect or cause to be inspected every registered clinical establishment at least once in two years to ensure compliance with the standards prescribed and the results of the inspection shall be made available to the public in such manner as may be prescribed.

(12) The Council shall notify a panel of independent assessors to inspect and examine whether the registered clinical establishment adhere to the prescribed standards.

(13) Clinical establishments having received accreditation or certification from the National Accreditation Board for Hospitals or National Accreditation Board for Laboratories or any other body approved for this purpose by Government shall be granted permanent registration without inspection as provided in sub-section (4) and such establishments need not be subjected to inspection by the assessors of the Council till such time the accreditation or certification, as the case may be, remains valid:

Provided that where the accreditation or certification be cancelled or has expired, the Authority shall cause the clinical establishments to be inspected within a period of thirty days from the date of such cancellation or expiry.

(14) Where the clinical establishment has not acquired the standards prescribed, the Authority shall proceed to cancel its provisional or permanent registration in such manner as may be prescribed.

20. *Validity of permanent registration.*—Permanent registration shall be valid for a period of three years following which it may be renewed prior to expiry on payment of such fees as may be prescribed.

21. *Renewal of permanent registration.*—Application for renewal of permanent registration shall be made sixty days prior to the expiry of the validity of the certificate of permanent registration and in case the application for renewal is made after the expiry of such date, the Authority may allow such application on payment of such enhanced fees as may be prescribed.

22. *Acknowledgment of application.*—The Authority shall acknowledge the receipt of the application for provisional registration or permanent registration, as the case may be, in such form as may be prescribed.

23. *Certificate of registration.*—(1) The Authority shall issue the certificate of provisional or permanent registration, as the case may be, in such form and containing such particulars as may be prescribed.

(2) The provisional or permanent registration certificate shall be displayed in a conspicuous place in the clinical establishment.

24. *Certificate of registration to be non-transferable.*—(1) The certificate of registration both provisional and permanent shall be non-transferable.

(2) In the event of change in the name of the establishment, ownership, category, management, location or on the cessation of functioning, such clinical establishment shall return the certificate within thirty days to the Authority.

(3) Where the registration certificate of a clinical establishment is returned under sub-section (2), fresh application shall be submitted to carry on such clinical establishment:

Provided that in the case of change of ownership, new application for registration shall be submitted within thirty days from the date of change of such ownership and if new registration is not received the functioning of such clinical establishment shall be restrained.

(4) If new services are provided in addition to the services being provided by a clinical establishment, it shall be communicated to the authority concerned and within thirty days from the date of commencement of such services, required standards shall be acquired for such new services and it shall be convinced to the authority.

25. *Cancellation of registration.*—(1) If, at any time, after any clinical establishment has been registered, the Authority or the Council is satisfied that,—

(a) the conditions of the registration are not complied with; or

(b) the clinical establishment has knowingly or negligently carried out an act that is harmful to the health of the person seeking care from the clinical establishment,

it may issue notice to the clinical establishment to show cause why its registration should not be cancelled for the reasons to be mentioned in the notice.

(2) Where the Authority or Council is satisfied, after giving a reasonable opportunity to the clinical establishment to be heard, that there has been a breach of any of the provisions of this Act or the rules made thereunder, it may, without prejudice to any other action that may be taken against such clinical establishment, by order cancel its registration.

- (3) Every order made under sub-section (2) shall take effect,—
- (i) where no appeal has been preferred against such order immediately on the expiry of the period prescribed for such appeal; and
 - (ii) where such appeal has been preferred and it has been dismissed, from the date of the order of such dismissal:

Provided that the Authority, after cancellation of registration, for reasons to be recorded in writing, shall restrain immediately the clinical establishment from functioning, if there is imminent danger to the health and safety of patients.

CHAPTER V PENALTIES

26. *Penalty for contravention of the provisions of the Act.*—(1) The Council under this section, and the Authority under other sections of this Act, as the case may be, shall have power to adjudicate upon, enquire and impose penalty regarding contravention of the provisions of this Act and shall exercise such powers and follow such procedures as may be prescribed.

(2) Whoever contravenes any of the provisions of this Act shall, if penalty is not provided elsewhere, be liable for the first contravention to a monetary penalty which may extend to ten thousand rupees, for the second contravention a monetary penalty which may extend to fifty thousand rupees and for any subsequent contravention to a monetary penalty which may extend upto five lakh rupees:

Provided if the Council determines, after notice to the establishment and conducting enquiry that the offence is of such serious nature as to attract the provisions of this section, in addition to the penalty, the Council may order the closure of the establishment.

27. *Penalty for non-registration.*—(1) Whoever carries on a clinical establishment without registration shall, for the first contravention, be liable to a monetary penalty which may extend to fifty thousand rupees, for the second contravention to a monetary penalty which may extend to two lakh rupees and for any subsequent contravention to a monetary

penalty which may extend to five lakh rupees and in case of continuing contravention a monetary penalty of ten thousand rupees for every additional day the clinical establishment functions without registration subject to a maximum of five lakh rupees.

(2) For the purpose of adjudging an offence or contravention under sub-section (1), and for imposing any monetary penalty, the Authority shall conduct an inquiry in the prescribed manner after giving the person concerned a reasonable opportunity of being heard.

(3) While holding an inquiry, the Authority shall have power to summon and enforce the attendance of any person acquainted with the facts and the circumstances of the case to give evidence or to produce any document which in the opinion of the Authority, may be useful for or relevant to the subject matter of the inquiry and if, on such inquiry, it is satisfied that the person has failed to comply with the provisions specified in sub-section (1) it may by order impose the monetary penalty specified in those sub-sections to be deposited within thirty days of the order in the account referred to in section 32.

(4) While determining the quantum of monetary penalty, the Authority shall take into account the category, the size and the type of the clinical establishment and also the local conditions of the area in which the clinical establishment is situated.

(5) Any person aggrieved by the decision of the Authority may prefer an appeal to the Appellate Authority within a period of forty-five days from the date of the said decision.

(6) Every appeal under sub-section (5) shall be made in such form and be accompanied by such fees as may be prescribed.

28. *Disobedience of order, obstruction and refusal of information.*—(1) Whoever wilfully disobeys any direction lawfully given by the Authority, the Council or any person empowered under this Act to give such direction, or obstructs any person or the Authority or the Council in the discharge of any function which such person or the Authority or the Council is required or empowered under this Act to discharge, shall be liable to a monetary penalty which may extend to one lakh rupees.

(2) Whoever being required by or under this Act to supply any information wilfully withholds such information or gives information which he knows to be false or which he does not believe to be true, shall be liable to a monetary penalty which may extend to one lakh rupees.

(3) For the purpose of adjudging under sub-sections (1) and (2), and for the purpose of imposing any monetary penalty, the Authority shall conduct an inquiry in the prescribed manner after giving any person concerned a reasonable opportunity of being heard.

(4) While conducting an inquiry, the Authority shall have power to summon and enforce the attendance of any person acquainted with the facts and the circumstances of the case to give evidence or to produce any document which in the opinion of the Authority, may be useful for or relevant to the subject matter in the inquiry and if, on such inquiry, it is satisfied that the person has failed to comply with the provisions specified in sub-sections (1) and (2), it may by order impose the monetary penalty specified in those sub-sections to be deposited within thirty days of the order in the account referred to in section 32.

(5) While determining the quantum of monetary penalty, the Authority shall take into account the category, the size and the type of the clinical establishment and also the local conditions of the area in which the clinical establishment is situated.

(6) The recovery of fine shall be as laid down under section 421 to 424 of the Code of Criminal Procedure, 1973 (Central Act 2 of 1974).

(7) Any person aggrieved by the decision of the Authority may prefer an appeal to the Appellate Authority within a period of forty-five days from the date of the said decision.

(8) Every appeal under sub-section (7) shall be made in such form and be accompanied by such fees as may be prescribed.

29. *Penalty for minor deficiencies.*—Whoever contravenes any provision of this Act or any rule made thereunder 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 to ten thousand rupees.

30. *Contravention by companies.*—(1) Where a contravention under this Act has been committed by a company, every person who at the time of such contravention, was in charge of, and was responsible to the company for the conduct of the business of the company, as well as the company, shall be deemed to be guilty of the contravention and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this sub-section shall render any such person liable to any punishment, if he proves that the contravention was without his knowledge, or that he had exercised all due diligence to prevent such contravention.

(2) Notwithstanding anything contained in sub-section (1), where a contravention of any of the provisions of this Act or of any rule made thereunder has been committed by a company and it is proved that the contravention has been committed with the consent or connivance of, or is attributable to, any neglect on the part of any director, manager, secretary or other officer of the company such director, manager, secretary or other officer shall be deemed to be guilty of that contravention and shall be liable to monetary penalty.

Explanation:—For the purposes of this section,—

(a) “company” means any body corporate and includes firm, a co-operative society or other association of individuals; and

(b) “director”, in relation to a firm, means a partner in the firm.

31. *Offences by Government Departments.*—Where an offence under this Act has been committed by any clinical establishment under the control of the Government, the officer responsible for that clinical establishment shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this section shall render such officer liable to any punishment if he proves that the offence was committed without his knowledge or that he has exercised all due diligence to prevent the commission of such offence.

CHAPTER VI

FINANCE AND ACCOUNTS

32. *Fees, fines and penalties to be credited to separate account.*—The amount collected by way of fees, fines and penalties by the Council and the Authority shall be credited to such separate account as the Government may, by order, specify in this behalf and shall be utilized for the activities connected with the implementation of the provisions of this Act.

33. *Eligibility for allowances.*—The non-official members of the Council and Authority, members of the grievance redressal committee, assessors and members of the sub-committee shall be eligible for such allowances as may be prescribed.

CHAPTER VII

APPEALS, REVISION AND GRIEVANCE REDRESSAL

34. *Appeals.*—(1) The Government shall, by notification, constitute an Appellate Authority to receive and adjudicate the appeals against the decision of the Authority with the following members, namely:—

(a) Secretary, Health and Family Welfare Department, (*ex-officio*)—Chairperson;

(b) Additional Law Secretary, Law Department, (*ex-officio*)—Member;

(c) Director of Medical Education, (*ex-officio*)—Member.

(2) Any person, aggrieved by an order of the Authority refusing to grant or renew a certificate of registration or cancelling or revising a certificate of registration or under sub-section (1) of section 27 and sub-section (1) of section 28 and section 29 may prefer an appeal to the Appellate Authority in the manner as may be prescribed within forty five days of such a decision.

(3) Every appeal under sub-section (2) shall be made in such form and be accompanied by such fees as may be prescribed.

(4) Every appeal under sub-section (2) shall be disposed of by the Appellate Authority, after giving the appellant a reasonable opportunity of being heard, within sixty days from the date of filing the appeal.

35. *Revision*.—Any person aggrieved by the order of the Appellate Authority may prefer revision before the High Court within sixty days from the date of order of the Appellate Authority.

36. *Grievance redressal*.—(1) The Council shall set up a grievance redressal mechanism in such manner as may be prescribed, to receive complaints from the public regarding the violation of the provisions of this Act or the rules made thereunder, by any clinical establishment and shall give direction to the authority to take appropriate action on the complaints so received.

(2) Notwithstanding anything contained in this Act, the Council shall have the power to give direction to the Authority to review any decision and proceeding or order passed, including the imposition of penalty, by the Authority under this Act either *suo motu* or on any complaint and to summon any person concerned or document, in this behalf.

CHAPTER VIII

INSPECTION OF CLINICAL ESTABLISHMENTS

37. *Inspection*.—(1) The Council or the Authority or the Appellate Authority or any officer authorised by them, shall have the right to cause an inspection of, or inquiry in respect of any clinical establishment, its building, laboratories, diagnostic facilities, equipments and also the works conducted or done by the clinical establishment, to be made by such person or persons as they may direct and to cause an inquiry to be made in respect of any standards or conditions of the registration, after issuing notice to the clinical establishment and giving a right to be represented thereat.

(2) Any officer or assessor carrying out an inspection of any clinical establishment shall file a report, with his findings within 48 hours of the conclusion of inspection, with the Authority authorised for inspection. In case additional information have been sought for he shall file a preliminary report within 48 hours and file the final report within 48 hours after such information has been furnished to him.

(3) The Council shall notify the persons qualified to conduct assessment of the clinical establishments.

(4) The Council or the Authority, as the case may be, shall communicate to the clinical establishment the views of the Council or the Authority with reference to the results of such inspection or inquiry and may, after ascertaining the opinion of the clinical establishment thereon, direct that clinical establishment as to the action to be taken.

(5) The clinical establishment shall report to the Council or the Authority, as the case may be, the action which is proposed to be taken or has been taken upon the results of such inspection or inquiry and such report shall be furnished within such time, as the Council or the Authority may direct.

(6) Where the clinical establishment does not take action to the satisfaction of the Council or the Authority, as the case may be, the Council or the Authority may, after considering any explanation furnished or representation made by the clinical establishment, within a reasonable time, issue such directions as the Council or the Authority deems fit, and the clinical establishment shall comply with such directions.

(7) No such inspection shall be conducted within three months from the date of the first inspection unless it is to verify the claim of clinical establishment that a defect pointed out in the report under sub-section (5) has been rectified and not more than two inspections shall be conducted without the instruction of the Council or Appellate Authority within one year after the defect is rectified.

38. *Power to enter and search.*—The Council or the Authority or any officer authorised by them may, if there is any reason to suspect that anyone is carrying on a clinical establishment without registration, enter and search at any reasonable time, in such manner as may be prescribed, and the clinical establishment shall offer reasonable facilities for inspection or inquiry and be entitled to be represented thereat.

CHAPTER IX

MISCELLANEOUS

39. *Display of the certificate of registration and other information by the clinical establishment.*—(1) Every clinical establishment shall display, in a conspicuous place in the clinical establishment its certificate of registration, provisional or permanent.

(2) Every clinical establishment shall display, in a conspicuous place in the clinical establishment in Malayalam as well as in English the fee rate and package rate charged for each type of service provided and facilities available, for the information of the patients.

(3) All clinical establishments in the State shall display package rates for specific procedures.

(4) No clinical establishment shall charge fees or package rates more than what is displayed.

40. *Maintenance of medical records.*—Every clinical establishment shall maintain medical records of patients, in accordance with the laws for the time being in force, regarding the diagnosis, result of investigations, treatment given, condition at the time of discharge and advice given to the patients and a copy thereof shall be made available to the patient or to relatives free of cost.

41. *Display of Information by the Authority.*—(1) The Authority shall, within a period of thirty days from the grant of provisional or permanent registration, cause to be published in such manner as may be prescribed, the particulars of the clinical establishment.

(2) The Authority shall cause to be published in the website of Kerala Clinical Establishment Council the names of clinical establishment whose provisional or permanent registration has expired, cancelled or ceased to function.

42. *Protection of action taken in good faith.*—(1) No suit, prosecution or other legal proceedings shall lie against any member or employee or any other officer authorised by the Authority or the Council in respect of anything, which is done in good faith or intended to be done in pursuance of the provisions of this Act or the rules made thereunder.

(2) No suit or other legal proceedings shall lie against the Authority or the Council in respect of any loss or damage caused or likely to be caused by anything which is done in good faith or intended to be done in pursuance of the provisions of this Act or the rules made thereunder.

43. *Recovery of penalties.*—Penalties imposed under this Act and remaining unpaid shall be recovered as if it were an arrear of public revenue due on land.

44. *Power to give directions.*—Without prejudice to the foregoing provisions of this Act, the Government shall have the power to give directions for the implementation of the provisions of the Act and to call for returns, statistics and other information that has relevance on public health and health surveillance.

45. *Employees of the Authority and Council to be public servants.*—Every employee of the Council and the Authority while acting or purporting to act under the provisions of the Act or any rules made thereunder shall be deemed to be public servants within the meaning of section 21 of the Indian Penal Code, 1860 (Central Act 45 of 1860).

46. *Bar of jurisdiction of civil courts.*—No civil court shall have Jurisdiction to settle, decide or deal with any question or to determine any matter or to interfere with any order which is by or under this Act required to be settled, decided or dealt with or to be determined or to be issued by the Authority or the Council or any officer authorised by them.

47. *Treatment of victims in emergencies.*—(1) The clinical establishment shall provide, such medical examination and treatment as may be required and can be provided with the staff and facilities available in the establishment, to save the life of the patient and make the safe transport of the patient to any other hospital.

(2) The Council shall notify the life saving services to be provided by each category of clinical establishments.

48. *Term of office, casual vacancies, resignation etc., of members of the Council and Authority.*—(1) The term of office of non-official members of the Council and the Authority shall be three years from the date of notification of their nomination and shall not hold office for more than two terms.

(2) A casual vacancy of a non-official member shall be filled by new nomination by the Chairperson and the member so appointed shall hold office for the remaining period of the term of the person in whose place he is nominated.

(3) Any member of the Council or Authority may, at any time, by writing under his hand addressed to the Chairperson of the Council or Authority as the case may be, resign his office and he shall be deemed to have resigned his office legally from the date mentioned in the resignation letter, or if date is not mentioned, from the date of acceptance of resignation.

49. *Disqualification for membership.*—A person shall be disqualified for being appointed as a member of the Council or Authority if he,—

(a) is declared to be an undischarged insolvent; 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 Central Government or a Corporation owned or controlled by the Government or Central Government; or

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

50. *Annual Report.*—(1) The Council shall prepare for every year a report of its activities under this Act during that year and submit the report to the Government in such form and at such time as may be prescribed.

(2) The Government shall, as soon as possible, after the receipt of the report under sub-section (1), cause the same to be laid before the Legislative Assembly.

51. *Power to remove difficulties.*—(1) If any difficulty arises in giving effect to the provisions of this Act, the Government may, by order published in the official gazette, make provisions which appear to them to be necessary and not inconsistent with the provisions of this Act for the purpose of removing the difficulty:

Provided that no such order shall be made after the expiry of a period of two years from the date of commencement of this Act.

(2) Every order issued under this section shall, as soon as may be after it is made, be laid before the Legislative Assembly.

52. *Power to make rules.*—(1) The Government may, by notification, make rules for carrying out all or any of the provisions of this Act.

(2) In particular, and without prejudice to the generality of the foregoing powers, such rules may provide for all or any of the following matters, namely:—

(a) the types of diagnosis under clause (c) of section 2;

(b) the manner of appointment of panel of assessors for inspection and assessment under clause (d) of sub-section (1) of section 4;

(c) the manner of conducting periodic inspection under clause (e) of sub-section (1) of section 4;

(d) the term of sub-committee appointed under sub-section (2) of section 6;

(e) the powers and functions of the Executive Committee and the manner in which the Executive Committee shall conduct their functions under section 9;

(f) the quorum for a meeting and procedure for conduct of business in the meetings of the Council under section 11;

(g) the form and particulars of the State Register of Clinical Establishments under sub-section (1) of section 12;

(h) the manner in which the Vice-Chairperson exercises the powers of the Authority under sub-section (2) of section 14;

(i) any other functions to be performed by the Authority under clause (e) of sub-section (3) of section 14;

(j) the form of undertaking under clause (c) of section 15;

(k) any other conditions for registration of clinical establishment under clause (f) of section 15;

(l) the period within which the clinical establishments having provisional registration shall acquire the standards for permanent registration under sub-section (4) of section 16;

(m) the period within which the clinical establishments which come into existence after the commencement of this Act shall apply for permanent registration under sub-section (5) of section 16;

(n) the form of application and fee for provisional registration under sub-section (1) of section 17;

(o) the form, manner, and the fee for applying for permanent registration under sub-section (1) of section 19;

(p) the manner of publication of the details of clinical establishment under sub-section (3) of section 19;

(q) the form and details for granting permanent registration under sub-section (6) of section 19;

(r) the manner in which the results of the inspection of clinical establishments are to be made available to the public under sub-section (11) of section 19;

(s) the manner of cancellation of provisional or permanent registration of clinical establishments under sub-section (14) of section 19;

(t) fee for the renewal of permanent registration under section 20;

(u) enhanced fees for the renewal of permanent registration after the expiry of specified date under section 21;

(v) the form of acknowledgement of the receipt of the application for provisional or permanent registration under section 22;

(w) the form and the particulars of certificate of provisional and permanent registration under sub-section (1) of section 23;

(x) the manner in which inquiry is to be held by the Authority under sub-section (2) of section 27 and sub-section (3) of section 28;

(y) manner in which appeal is to be filed under sub-section (2) of section 34;

(z) the form and fee for filing appeal under sub-section (6) of section 27 and sub-section (8) of section 28;

(za) the allowances payable to the members and non-official members of the Council and Authority, members of the grievance redressal committee, assessors and members of the sub-committee under section 33;

(zb) the manner in which the grievance redressal mechanism is to be setup under section 36;

(zc) the manner in which search is to be made in a clinical establishment under section 38;

(zd) the manner of publication of the particulars of clinical establishment by the Authority under sub-section (1) of section 41;

(ze) the manner of report under section 50;

(zf) any other matter which is required to be or may be prescribed under this Act.

(3) Every rule made under this Act shall be laid as soon as may be after it is made, before the Legislative Assembly, while it is in session, for a total period of fourteen days, which may be comprised in one session or in two successive sessions and if, before the expiry of the session in which it is so laid or the session immediately following, the legislative assembly makes any modification in the rule or decides that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.

[Translation in English of “2021-ലെ കേരള ക്ലിനിക്കൽ സ്ഥാപനങ്ങൾ (രജിസ്ട്രേഷനും നിയന്ത്രണവും) ഭേദഗതി ആക്റ്റ്” published under the authority of the Governor.]

ACT 35 OF 2021

THE KERALA CLINICAL ESTABLISHMENTS (REGISTRATION AND REGULATION) AMENDMENT ACT, 2021

An Act to amend the Kerala Clinical Establishments (Registration and Regulation) Act, 2018.

Preamble.—WHEREAS, it is expedient to amend the Kerala Clinical Establishments (Registration and Regulation) Act, 2018 (Act 2 of 2018) for the purposes hereinafter appearing;

BE it enacted in the Seventy-second Year of the Republic of India as follows:—

1. *Short title and commencement.*—(1) This Act may be called the Kerala Clinical Establishments (Registration and Regulation) Amendment Act, 2021.

(2) It shall be deemed to have come into force on the 9th day of November, 2020.

2. *Amendment of section 18.*—In section 18 of the Kerala Clinical Establishments (Registration and Regulation) Act, 2018 (Act 2 of 2018) (hereinafter referred to as the principal Act), for the word “two” the word “four” shall be substituted.

3. *Repeal and saving.*—(1) The Kerala Clinical Establishments (Registration and Regulation) Amendment Ordinance, 2021 (114 of 2021) is hereby repealed.

(2) Notwithstanding such repeal anything done or deemed to have been done or any action taken or deemed to have been taken under the principal Act as amended by the said Ordinance, shall be deemed to have been done or taken under the principal Act as amended by this Act.

