

Fourteenth Kerala Legislative Assembly

Bill No. 79

10/8/17

**THE KERALA CLINICAL ESTABLISHMENTS
(REGISTRATION AND REGULATION)
BILL, 2017**

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THE KERALA CLINICAL ESTABLISHMENTS (REGISTRATION AND REGULATION) BILL, 2017

A

BILL

to provide for the registration and regulation of clinical establishments rendering services in recognised systems of medicines 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 minimum standards of facilities and services which may be provided by them for the improvement of public health;

BE it enacted in the Sixty-eighth 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, 2017.

(2) It shall come into force on such date as the Government may, by notification in the Gazette, 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 36;

(b) "Authority" means a District Registering Authority constituted under sub-section (1) of section 17;

(c) "clinical establishment" means,—

(i) a hospital, maternity home, nursing home, dispensary, 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 or pregnancy 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 owned, controlled or managed by the Armed Forces.

Explanation:—For the purposes of this clause " 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);

(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 health of the individual or, with respect to a pregnant woman, the health of the woman or her 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, Naturopathy, Ayurveda, Homoeopathy, Sidha and Unani systems of medicine or any other system of medicine as may be recognised by the Government;

(k) "register" means the register maintained by the Authority and the State Register maintained and published under sub-section (1) of section 15 of the Act, containing details of clinical establishments registered;

(l) "registration" means the registration under section 19 and the expression registration or registered shall be construed accordingly;

(m) "standards" means the standards that may be prescribed by the Government under section 16 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 (d), 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 to the Government, Health and Family Welfare Department, *ex-officio* who shall be the Chairperson;

(b) Director of Health Services, *ex-officio*;

(c) Director of Indian System of Medicine, *ex-officio*;

(d) Director of Homoeopathic Department, *ex-officio*;

(e) Director, Public Health Laboratory, *ex-officio*;

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

(i) the Council of Modern Medicine;

(ii) the Council of Indigenous Medicine; and

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

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

(i) the Kerala Dental Council constituted under section 21 of the Dentists Act, 1948 (Central Act 15 of 1948);

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

(h) one representative of patient welfare organisations in the State nominated by the Government;

(i) an officer not below the rank of Additional Secretary to Government, Law Department to be nominated by the Government;

(j) an Officer not below the rank of Additional Secretary to Government, Finance Department to be nominated by the Government;

(k) one representative of Indian Medical Association, Kerala Unit;

(l) one representative of Ayurveda Medical Association of India; and

(m) 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 standards for ensuring proper healthcare by the clinical establishment;

(b) classify and categorise the clinical establishments and determine the minimum standards for each category and recommend to the Government for approval and notification;

(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 may 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 an 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 Services to be the Secretary of the Council.

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

(3) 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 the provisions of the Act or such other matter as may be prescribed.

6. Power to seek advice or assistance.—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.

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.*—There shall be an Executive Committee consisting of the following members of the Council, namely:—

- (i) Director, Health Services, who shall be the Chairperson;
- (ii) Director, Indian Systems of Medicine;
- (iii) Director, Homeopathic Department;
- (iv) Director, Public Health Laboratory;
- (v) one of the representatives of patient welfare organisations nominated by the Government; and
- (vi) the Secretary of the Council.

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

10. *Disqualification for appointment as member of the Council.*—A person shall be disqualified for being appointed as a member of the Council if he,—

- (a) has been convicted of an offence which involves moral turpitude and sentenced to undergo imprisonment; or
- (b) is an undischarged insolvent; or
- (c) is of unsound mind and stands so declared by a competent court; or
- (d) has been removed or dismissed from the service of the Government or a Corporation owned or controlled by the Government or Central Government; or
- (e) has, in the opinion of the Government, such financial or other interests in the Council as is likely to affect prejudicially the discharge of his functions as a member.

11. *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.

12. *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.

13. *Term of office of members of the Council.*—The non-official members of the Council shall hold office for a period of three years from the date of their nomination:

Provided that a member shall not hold office for more than two terms.

14. *Allowances to the non-official members of the Council.*—The non-official members of the Council shall be entitled to such allowances as may be prescribed.

CHAPTER III

REGISTER OF CLINICAL ESTABLISHMENTS

15. *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

16. *Categories and standards.*—(1) Different standards shall be developed for different categories of clinical establishments and registration shall be granted to the establishments that satisfy the standards notified for 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 health care in clinical establishments.

17. *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, *ex-officio*-Vice-Chairperson;

(c) a Medical Officer of the District Medical Office 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 two 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 20, the Convenor 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) enforce 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 .

(4) A casual vacancy of the non-official member in the Authority shall be filled by the District Collector by making fresh nomination and the member so nominated shall hold office only for the remaining term of the person in whose place he is so nominated.

(5) The Council, with the permission of Government, shall provide the Authority with such employees as are necessary for the proper functioning of the Authority.

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

(a) the minimum standards according to the category of clinical establishment as may be notified by the Government;

(b) the medical and paramedical staff shall have the minimum qualifications as may be prescribed;

(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 standard treatment guidelines as may be notified by the Government;

(f) such other conditions as may be prescribed.

19. *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 minimum 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 more than one 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.

(7) A clinical establishment providing only consultation services by a practitioner from a recognised system of medicine would be required only to register it and clause (a) of section 18 of the Act will not be applicable to such clinics.

Explanation:—For the purposes of this sub-section “practitioner” means a practitioner registered under the Travancore-Cochin Medical Practitioners Act, 1953 (IX of 1953) or under The Kerala Dental Council constituted under section 21 of the Dentists Act, 1948 (Central Act 16 of 1948).

20. *Application for provisional registration.*—(1) Every clinical establishment functioning at the 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 thirty 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.

21. *Validity of provisional registration.*—(1) Provisional registration shall be valid for a period of one year from the date of issuance of the certificate of registration:

Provided that registration may be extended for a further period of one year by the Authority, if the Authority is convinced, for reasons to be recorded in writing, that the failure to acquire permanent registration was due to reasons beyond the control of the clinical establishment:

Provided also that where clinical establishments in respect of which standards have been notified by the Government, provisional registration shall not be granted or renewed beyond the period of two years from the date of notification of the standards in case of clinical establishments which came into existence before the commencement of this Act.

(2) Application for extension of provisional registration shall be made thirty days prior to the expiry of the validity of the certificate of provisional registration and in case the application for extension is made after the expiry of the provisional registration, the Authority shall allow extension of registration on payment of such fees as may be prescribed.

22. *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, within a period of seven days from the date of receipt of application cause to be published in the prescribed manner the details of the clinical establishments that have applied for permanent registration.

(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 minimum 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 achieved the minimum 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 may, within thirty days from the date of such communication, respond to the Authority and produce evidence to the effect that the standards have been met and or submitted the information, documents and the Authority may, on examination of the evidence and after a re-examination of the evidence by the assessors, if required, either allow or reject the application for registration.

(9) Where the Authority decides to reject 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 providing such evidence, as may be required, of having rectified the compliance with prescribed standards after curing the defect.

(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 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 remains valid:

Provided that where the accreditation 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 attained the minimum standards prescribed, the Authority shall proceed to cancel its provisional or permanent registration in such manner as may be prescribed.

23. *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.

24. *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.

25. *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.

26. *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.

27. *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 of ownership, category, management, location or on the cessation of functioning, such clinical establishment shall communicate the same to the Authority.

(3) New owner or any person seeking recommencement of the clinical establishment shall apply afresh for grant of certificate of registration within 30 days of change of ownership.

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

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

(b) the person entrusted with the management of the clinical establishment has been convicted of an offence punishable under this Act; or

(c) the clinical establishment has knowingly carried out an act that is prejudicial to the health of the person seeking care from the clinical establishment,

the Authority 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 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

29. *Penalty for contravention of the provisions of the Act.*—(1) 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 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.

30. *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 hold 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 35.

(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.

31. *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 hold an inquiry in the prescribed manner after giving any person concerned a reasonable opportunity of being heard.

(4) 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 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 35.

(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 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.

32. *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.

33. *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.

34. *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

35. *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.

CHAPTER VII

APPEALS, REVISION AND GRIEVANCE REDRESSAL

36. *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 to the Government, Health and Family Welfare Department, *ex-officio*, who shall be the Chairperson;

(b) Additional Secretary to the Government, Law Department;

(c) The Director, Directorate of Medical Education.

(2) Any person, aggrieved by an order of the Council refusing to grant or renew a certificate of registration or cancelling or revising a certificate of registration and under sub-section (1) of section 29, sub-section (1) of section 30, sub-section (1) of section 31 and section 32 may prefer an appeal to the Appellate Authority 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 an opportunity of being heard, within sixty days from the date of filing the appeal.

37. *Revision*.—Any person aggrieved by the order of the Appellate Authority may prefer revision before the Hon'ble High Court of Kerala.

38. *Grievance redressal*.—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.

CHAPTER VIII

INSPECTION OF CLINICAL ESTABLISHMENTS

39. *Inspection*.—(1) The Council or the 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 and equipment and also of the work 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 that establishment shall be entitled to be represented thereat.

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

(3) The Council shall notify the person qualified to conduct assessment of the hospitals.

(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, within a reasonable time, 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, 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 and not more than two inspections shall be conducted within one year unless it is to verify the claim of clinical establishment that a defect pointed out in the earlier report has been rectified.

40. *Power to enter.*—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

41. *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 rates 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.

42. *Maintenance of medical records.*—Every clinical establishment shall maintain the medical records of patients regarding the diagnosis, result of investigations, treatment given, condition at the time of discharge and advice to the patient and copies thereof shall be made available to the patient or to relatives.

43. *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.

44. *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.

45. *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.

46. *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.

47. *Employees of the Authority and Council to be public servants.*—Every employee of the Council and of 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).

48. *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.

49. *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 establishment.

50. *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.

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

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

(c) the term of sub-committee appointed under sub-section (3) of section 5;

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

(e) the quorum for a meeting and procedure for conduct of business in the meetings of the Council under section 12;

(f) the allowances payable to the non-official members of the Council under section 14;

(g) the form and particulars of the State Register of Clinical Establishments under sub-section (1) of section 15;

(h) the manner in which the Convenor exercises the powers of the Authority under sub-section (2) of section 17;

(i) any other functions to be performed by the Authority under clause (e) of sub-section (3) of section 17;

(j) the minimum qualifications required for the medical and paramedical staff of clinical establishments under clause (b) of section 18;

(k) the form of undertaking under clause (c) of section 18;

(l) any other conditions for registration of clinical establishment under clause (f) of section 18;

(m) the period within which the clinical establishments having provisional registration shall acquire the minimum standards for permanent registration under sub-section (4) of section 19;

(n) 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 19;

(o) the form of application and fee for provisional registration under sub-section (1) of section 20;

(p) the fee for the extension of provisional registration after its expiry under sub-section (2) of section 21;

(q) the form, manner, and the fee for applying for permanent registration under sub-section (1) of section 22;

(r) the manner of publication of the details of clinical establishment under sub-section (3) of section 22;

(s) the form and details for granting permanent registration under sub-section (6) of section 22;

(t) 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 22;

(u) the manner of cancellation of provisional or permanent registration of clinical establishments under sub-section (14) of section 22;

(v) fee for the renewal of permanent registration under section 23;

(w) enhanced fees for the renewal of permanent registration after the expiry of specified date under section 24;

(x) the form of acknowledgement of the receipt of the application for provisional or permanent registration under section 25;

(y) the form and the particulars of certificate of provisional and permanent registration under sub-section (1) of section 26;

(z) the manner in which inquiry is to be held by the Authority under sub-section (2) of section 30 and sub-section (3) of section 31;

(za) manner in which appeal is to be filed under sub-section (5) of section 30 and sub-section (8) of section 31 and sub-section (2) of section 36;

(zb) the form and fee for filing appeal under sub-section (6) of section 30 and sub-section (8) of section 31;

(zc) the manner in which the grievance redressal mechanism is to be set up under section 38;

(zd) the manner in which search is to be made in a clinical establishment under section 40;

(ze) the manner of publication of the particulars of clinical establishment by the Authority under sub-section (1) of section 43;

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

(4) 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.

STATEMENT OF OBJECTS AND REASONS

The Central Government have enacted the Clinical Establishments (Registration and Regulation) Act, 2010 and some of the States have adopted it. The said law was enacted with an aim to bring uniformity in health care system by prescribing minimum standards of facilities and services that may be provided by the clinical establishments in the country.

2. In Kerala more than seventy percent of healthcare is provided by the hospitals, dispensaries and laboratories in the private sector. There is no law in the State to regulate the functioning of these institutions effectively. Government consider that a separate law exclusively applicable to the State is necessary as the situation in Kerala is different from other States. Government after consultation with the experts in the field have decided to bring a Bill suitable to the circumstances of the State. The Government considered the Bill mainly it necessary to prescribe minimum standards of facilities and services provided by the clinical establishments and for their registration and effective regulation, for improving public health. The Bill also envisages a mechanism for issuing license to the clinical establishments. The provisions of the Bill are applicable to the clinical establishments belonging to all recognised systems of medicine except those under the control of Defence Services.

3. The Bill is intended to achieve the above objects.

FINANCIAL MEMORANDUM

This Bill is intended to provide for registration and regulation of clinical establishments. The registration procedure may be carried out under the supervision of the State Council constituted as per clause 3. The State Council shall have a Secretary. Registration procedure as per the proposed law can be implemented online with the creation of minimum posts. Monitoring, inspection and enforcement of the provisions of this law can be implemented using the existing staff of the Health Department. Since revenue is anticipated from the registration process, the preliminary expenditure of fifty lakh rupees is expected for the first two years.

MEMORANDUM REGARDING DELEGATED LEGISLATION

Sub-clause (2) of clause 1 of the Bill empowers the Government to issue notification appointing the date of commencement of this Act.

2. Sub-clause (1) of clause 3 of the Bill empowers the Government to issue notification constituting a Council by name the State Council for clinical establishments.

3. Item (b) of sub-clause (1) of clause 4 of the Bill empowers the Government to make rules prescribing the manner of preparing and publishing the State Register of clinical establishments.

4. Item (d) of sub-clause (1) of clause 4 of the Bill empowers the Government to make rules prescribing the manner of appointing panel of assessors for inspection and assessment of clinical establishments.

5. Item (e) of sub-clause (1) of clause 4 of the Bill empowers the Government to make rules prescribing the manner of conducting periodic inspection for ensuring the standards to be maintained by the clinical establishments.

6. Item (g) of sub-section (1) of clause 4 of the Bill empowers the Government to make rules prescribing the manner in which the data has to be analysed.

7. Clause 9 of the Bill empowers the Government to prescribe the powers and functions of the Executive Committee.

8. Clause 12 of the Bill empowers the Government to prescribe quorum and the procedure for the conduct of business in the meetings of the Council.

9. Clause 14 of the Bill empowers the Government to prescribe the allowances of the non-official members of the Council.

10. Sub-clause (1) of clause 15 of the Bill empowers the Government to prescribe the particulars to be included in the State Register of clinical establishments.

11. Sub-clause (1) of clause 17 of the Bill empowers the Government to issue notification constituting an Authority in each District for the registration of clinical establishments.

12. Sub-clause (2) of clause 17 of the Bill empowers the Government to prescribe the manner of exercising the powers of the authority by the convenor of the authority for the purposes of provisional registration.

13. Item (e) of sub-clause (3) of clause 17 of the Bill empowers the Government to prescribe such other functions to be performed by the Authority.

14. Item (a) of clause 18 empowers the Government to notify the minimum standards required for different category of clinical establishments.

15. Sub-clause (b) of clause 18 of the Bill empowers the Government to prescribe minimum qualifications for the medical and paramedical staff.

16. Sub-clause (c) of clause 18 of the Bill empowers the Government to prescribe the form of undertaking to be given by the clinical establishments that the orders of councils shall be complied.

17. Sub-clause (f) of clause 18 of the Bill empowers the Government to prescribe such other conditions for registration.

18. Sub-clause (4) of clause 19 of the Bill empowers the Government to prescribe the period within which the establishment with provisional registration shall acquire minimum standards for permanent registration.

19. Sub-clause (5) of clause 19 of the Bill empowers the Government to prescribe the period within which application for permanent registration shall be made.

20. Sub-clause (1) of clause 20 of the Bill empowers the Government to prescribe fee and the form to apply for the provisional registration.

21. Sub-clause (2) of clause 21 of the Bill empowers the Government to prescribe fees to be paid for extending the provisional registration after the expiry of the provisional registration.

22. Sub-clause (1) of clause 22 of the Bill empowers the Government to prescribe the manner and the form of application for permanent registration.

23. Sub-clause (3) of clause 22 of the Bill empowers the Government to prescribe the manner of publishing the details of clinical establishment applied for permanent registration.

24. Sub-clause (11) of clause 22 of the Bill empowers the Government to prescribe the manner of making available to the public the results of the inspection conducted by the Authority.

25. Sub-clause (14) of clause 22 of the Bill empowers the Government to prescribe the manner of cancelling the provisional or permanent registration.

26. Clause 23 of the Bill empowers the Government to prescribe the fees to be paid for renewing the permanent registration before its expiry.

27. Clause 24 of the Bill empowers the Government to prescribe the enhanced fees to be paid for permanent registration after its period of expiry.

28. Clause 25 of the Bill empowers the Government to prescribe the form of acknowledgement for the receipt of the application of provisional or permanent registration.

29. Sub-clause (1) of clause 26 of the Bill empowers the Government to prescribe form and the particulars to be included in the provisional or permanent registration certificate.

30. Sub-clause (2) of clause 30 of the Bill seeks to empowers the Government to prescribe the manner of conducting inquiry by the Authority against one who carries on a clinical establishment without registration.

31. Sub-clause (6) of clause 30 of the Bill empowers the Government to prescribe the fees and the form in which appeal is to be preferred to the Appellate Authority.

32. Sub-clause (3) clause 31 of the Bill empowers the Government to prescribe the manner of conducting inquiry by the Authority against one who disobeys orders or obstructs in discharge of function or refuses to give information.

33. Sub-clause (8) of clause 31 of the Bill empowers the Government to prescribe the fees and the form in which appeal is to be preferred to the Appellate Authority.

34. Sub-clause (1) of clause 36 of the Bill empowers the Government to issue notification constituting an appellate authority for receiving and adjudicating appeals against the decision of the authority.

35. Sub-clause (3) of clause 36 of the Bill empower the Government to issue notification prescribing the fees and the form in which appeal is to be preferred to the Appellate Authority.

36. Clause 38 of the Bill empower the Government to prescribe the manner of establishing a grievance redressal mechanism by the Council to receive complaints from the public.

37. Sub-clause (3) clause 39 empowers the council to issue notification of the persons qualified to conduct assessment of the hospitals.

38. Clause 40 of the Bill empowers the Government to prescribe manner for conducting search in any clinical establishment by the Council or the Authority.

39. Sub-clause (1) of clause 43 of the Bill empowers the Government to prescribe the manner in which the Authority shall publish the details in respect of the registered clinical establishment.

40. Sub-clause (1) of clause 50 of the Bill empowers the Government to issue order not inconsistent with the provisions of this Act, to remove any difficulties arising while giving effect to the provisions of this Act.

41. Sub-clause (1) of clause 51 of the Bill empowers the Government by notification to make rules required for the implementation of the provisions of this Act.

42. The matters in respect of which rules or regulations may be made or notifications issued or rules may be made, are matters of procedure and are of routine and administrative in nature. Further, the rules are subject to the scrutiny of the Legislative Assembly. The delegation of legislative power is therefore of a normal character.

K. K. SHYLAJA TEACHER.

NOTES ON CLAUSES

Clause 2—This clause intends to define certain words and phrases used in the Act.

Clause 3—This clause intends to empower the Government to establish a State Council by notification.

Clause 4—This clause intends to prescribe the functions of the Council.

Clause 5—This clause intends to provide for empowering Government to appoint an officer not below the rank of Deputy Director as Secretary of the Council and empowering the Council to employ other employees with the permission of the Government.

Clause 6—This clause intends to provide power to the Council to associate with any person or body and obtain technical assistance or advice for carrying out the provisions of the Act.

Clause 7—This clause intends to provide for following consultative and transparent process by the Council for making suggestion for altering the mandatory statements and clarification by clinical establishment and any other matter.

Clause 8—This clause intends to provide for the constitution of the executive committee of the Council.

Clause 9—This clause intends to provide for the powers and functions of the executive committee.

Clause 10—This clause intends to provide for the disqualification for appointment as member of the Council.

Clause 11—This clause provides that no act or proceedings of the Council shall become invalid merely by reason of the existence of any vacancy or defect in the constitution of the Council.

Clause 12—This clause intends to provide for prescribing the quorum and procedure for the conduct of business to be transacted in the meetings.

Clause 13—This clause intends to provide for term of office of the members of the Council.

Clause 14—This clause intends to provide for prescribing allowances to non-official members of the Council.

Clause 15—This clause provides for compiling, maintaining and publishing a register by the clinical establishments.

Clause 16—This clause provides for prescribing different criterion for different categories of establishments and for giving registration to such establishments.

Clause 17—This clause intends to provide for the constitution of an authority for registering clinical establishments.

Clause 18—This clause intends to provide for the conditions to be fulfilled by every clinical establishment for registration.

Clause 19—This clause intends to provide for the registration of all clinical establishments in Kerala.

Clause 20—This clause intends to provide for the application for the provisional registration of clinical establishments functioning at the beginning of this Act.

Clause 21—This clause intends to provide for the validity of provisional registration.

Clause 22—This clause intends to provide for the manner of submitting application for permanent registration of clinical establishment.

Clause 23—This clause intends to provide for the validity of permanent registration.

Clause 24—This clause intends to provide for the manner of renewal of permanent registration.

Clause 25—This clause intends to provide for acknowledgment of application by the authority.

Clause 26—This clause intends to provide for the issuance of registration certificate.

Clause 27—This clause intends to provide for non transferring of provisional or permanent registration certificate.

Clause 28—This clause intends to provide for the reason for the cancellation of registration of clinical establishments and the reasons for such cancellation at any time by the Council.

Clause 29—This clause intends to provide for penalty for contravention of the provisions of the Act.

Clause 30—This clause intends to provide for penalty for non registration.

Clause 31—This clause intends to provide for imposing penalty for disobedience of order, obstruction and refusal of information.

Clause 32—This clause intends to impose penalty for minor deficiencies.

Clause 33- This clause intends to provide penalty for the contravention by the companies.

Clause 34—This clause intends to provide for the responsibility of the officer where any offence under this Act has been committed by any clinical establishment under the control of the Government.

Clause 35—This clause intends to provide for crediting the amount collected by the Council and Authority by way of fees and fines to special account to be prescribed for it.

Clause 36—This clause intends to empower the Government to constitute an Appellate authority by notification.

Clause 37—This clause intends to provide for the provisions for revision.

Clause 38—This clause intends to direct the Council to set up for grievance redressal mechanism to receive complaints from the public.

Clause 39—This clause intends to provide for the power of Council and Authority to conduct inspection in clinical establishments.

Clause 40—This clause intends to provide that the Council or Authority or any officer have power to enter in all clinical establishments.

Clause 41—This clause provides for displaying the registration certificate and other information by the clinical establishment.

Clause 42—This clause intends to provide for maintaining and making available the medical records of patients regarding the diagnosis, result of investigations, treatment given, condition at the time of discharge and advice to the patient by the clinical establishments.

Clause 43- This clause intends to provide for publishing the details of clinical establishments by the Authority.

Clause 44—This clause intends to provide protection for any action taken in good faith by any member or employee or any other officer authorized by the Authority or the Council.

Clause 45—This clause intends to provide for recovering the penalties imposed under this Act and the remaining unpaid as if it were an arrear of public revenue due on land.

Clause 46—This clause intends to provide for empowering the Government to give directions for the implementation of the provisions of the Act.

Clause 47—This clause intends to provide that each employee of the Council and Authority shall be public servants within the meaning of section 21 of the Indian Penal Code, 1860.

Clause 48—This clause intends to make provision for barring the jurisdiction of the civil court to deal with or interfere with the functions to be done by the Council or Authority or any other officer.

Clause 49—This clause intends to provide that the clinical establishment shall provide facilities and employees for saving the life of patients.

Clause 50—This clause intends to make provisions not inconsistent with the Act, for removal of difficulties arising in the implementation of the provisions of the Act.

Clause 51—This clause intends to provide for making rules for the implementation of the provisions of this Act.
