

Thirteenth Kerala Legislative Assembly
Bill No. 230

**THE KERALA CLINICAL ESTABLISHMENTS
(REGISTRATION AND REGULATION)
BILL, 2013**

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[Translation in English of the “2013-ലെ കേരള ക്ലിനിക്കൽ സ്ഥാപനങ്ങൾ (രജിസ്ട്രേഷനും നിയന്ത്രണവും) ബിൽ” published under the authority of the Governor.]

**THE KERALA CLINICAL ESTABLISHMENTS (REGISTRATION AND
REGULATION) BILL, 2013**

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 improvement in public health;

BE it enacted in the Sixty-fourth 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, 2013.

(2) It shall come into force on such date as the Government may by notification in the Gazette appoint or different dates may be appointed for different recognized system of medicines.

2. *Definitions.*—In this Act, unless the context otherwise requires,—

(a) “authority” means the District Registering Authority constituted under section 18;

(b) “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 (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) whether or not owned by the Government;
- (e) local self government institution,

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);

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

(d) “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;

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

(f) “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);

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

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

(i) “recognised system of medicine” means Modern Medicine, Yoga, Naturopathy, Ayurveda, Homoeopathy, Sidha and Unani system of medicines or any other system of medicine as may be recognised by the Government;

(j) “register” means the register maintained by the Authority and/or the State Register maintained and published under sub-section (1) of section 16 of the Act, containing details of clinical establishments registered;

(k) “registration” means the registration under section 20 and the expression registration or registered shall be construed accordingly;

(l) “standards” means the standards that the Government may prescribe under section 17 for the registration of clinical establishments;

(m) “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, Kerala, *ex-officio* ;
- (d) Director of Homoeopathic Department, Kerala, *ex-officio* ;
- (e) Director, Public Health Laboratory, Thiruvananthapuram, *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 Dentist 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; and
 - (j) a representative of Indian Medical Association, Kerala Unit;
 - (k) a representative of Indian Ayurveda Medical Association; and
 - (l) Secretary of the Council.

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

- (a) classify the clinical establishments into different categories in accordance with the minimum standards for each category as may be prescribed;
- (b) compile and publish State Register of Clinical Establishments;
- (c) appoint panel of Assessors for inspection and assessment of the clinical establishments;
- (d) hear appeals against the orders of the Authority;
- (e) conduct periodic review of clinical establishments for verifying the standards to be maintained;

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

(g) notify data which are to be mandatorily provided by clinical establishments; analyse the data and make the results available to the public;

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

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

(j) establish and maintain a grievance redressal mechanism to receive and investigate complaints received about clinical establishments; and

(k) perform such other functions as may be prescribed by the Government from time to time.

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

(2) The Government shall provide the Council with such other employees as are necessary for the proper functioning of the Council.

6. *Sub-Committees of the Council.*—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.

7. *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.

8. *The Council to follow consultative process.*—The Council shall follow a consultative and transparent process for the classification of clinical establishments and altering the mandatory standards including conducting of public hearing in such places as may be determined by the Council.

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

(i) Director of Health Services, who shall be the Chairperson;

(ii) Director of Indian Systems of Medicine;

- (iii) Director of Homoeopathic Department;
- (iv) Director, Public Health Laboratory, Thiruvananthapuram;
- (v) one of the representatives of patient welfare organisations nominated by the Council; and
- (vi) the Secretary of the Council.

10. *Powers and functions of the Executive Committee.*—The Executive Committee shall exercise such powers and perform such functions as may be delegated to it by the Council.

11. *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, in the opinion of the Government 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
- (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.

12. *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.

13. *Procedure and conduct of business.*—The Council may, subject to the previous approval of the Government, make Regulations fixing the quorum and the procedure for the conduct of business to be transacted in its meetings.

14. *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 their nomination and may be eligible for re-nomination for one more term:

Provided that the member nominated shall be deemed to have vacated his office on his ceasing to be the holder of the office by virtue of which he was nominated.

15. *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

16. *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.

(3) The Authority shall supply to the Council, in digital format a copy of every entry in the Register of Clinical Establishments maintained by the Authority in such manner as may be prescribed.

CHAPTER IV

REGISTRATION OF CLINICAL ESTABLISHMENTS

17. *Categories and standards.*—Different standards may be prescribed for different categories of clinical establishments and registration shall be granted to the establishments that satisfy the standards prescribed for each category, irrespective of the category applied for.

18. *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) Health Officer of the District Medical Office to be nominated by the Government—Convenor;
- (d) a Medical Officer of the Indian Systems of Medicine; to be nominated by Government;
- (e) a Medical Officer of Homoeopathic System of Medicine;
- (f) one member to be nominated by the District Collector from a professional association in the health sector for a period of two years and is eligible for re-nomination for two terms.

(2) 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) investigate complaints of breach of the provisions of the Act or the rules made thereunder and take appropriate action;

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

(e) report to the Council on a quarterly basis the action taken against non-registered clinical establishments;

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

(3) 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.

(4) The Government shall provide the Authority with such employees as are necessary for the proper functioning of the Authority.

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

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

(b) the minimum qualifications for the Medical and Para-Medical Staff as may be prescribed;

(c) standards of safety, infection control and standard treatment guidelines as may be prescribed; and

(d) such other conditions as may be prescribed.

20. *Registration of clinical establishments.*—(1) All clinical establishments in Kerala shall be registered with the Authority 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.

(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.

21. *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) Where a clinical establishment is already registered under any existing law requiring registration of such establishments, it 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.

22. *Validity of provisional registration.*—(1) Every provisional registration shall be valid up to the last day of the twelfth month of the date of issue of the certificate of registration or on obtaining permanent registration whichever is earlier.

(2) Renewal of provisional registration may be granted up to another twelve months 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.

(3) Application for renewal 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 renewal is made after the expiry of the provisional registration, the Authority shall allow renewal of registration on payment of such enhanced fees as may be prescribed.

(4) Every clinical establishment having provisional registration shall apply for permanent registration under section 23 sixty days prior to the date of expiry of the provisional registration.

23. *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 evidence and an affidavit stating that the clinical establishment has met the standards prescribed for the category.

(2) The Authority shall, within a period of seven days, cause to be published in the prescribed manner the details of the clinical establishments that have applied for permanent registration.

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

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

(5) Where the Authority is of the opinion that the clinical establishment has not achieved the minimum standard prescribed, it shall inform the applicant of its intention to disallow or cancel permanent registration with reasons for the same.

(6) The applicant may within thirty days from the date of such communication, appear before the Authority and produce evidence to the effect that the standards have been met and the Authority may, on examination of the evidence and after a re-examination by the Assessors, if needed, take a final decision to allow registration or not.

(7) Where the Authority decides not to grant permanent registration, reason for the same shall be made available to the applicant, in writing, within thirty days of the date of such decision.

(8) Rejection of an application for permanent registration shall not be a bar for applying afresh for permanent registration under this section after providing such evidence, as may be required, of having rectified the deficiencies based on which the earlier application was rejected.

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

(10) The Council shall notify a panel of independent Assessors to inspect and examine the adherence to the prescribed standards by the clinical establishment.

(11) Clinical establishments that have received accreditation from the National Accreditation Board for Hospitals or the National Accreditation Board for Laboratories shall be granted permanent registration without inspection as provided in sub-section (3):

Provided that in the case of clinical establishments, accreditation of which has been cancelled by the Boards, the Authority shall cause such clinical institutions to be inspected within a period of one month from the date of cancellation of accreditation and shall cancel permanent registration of the clinical establishments which has not fulfilled minimum standards as may be prescribed.

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

25. *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.

26. *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.

27. *Certificate of registration.*—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.

28. *Duplicate Certificate of registration.*—In case the certificate of provisional or permanent registration is lost, destroyed, stolen, mutilated or damaged, the Authority may issue a duplicate certificate on the request of the clinical establishment and on payment of such fees as may be prescribed.

29. *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 or change of category or change of management or change of location or on ceasing to function as a clinical establishment, the certificate of registration in respect of such clinical establishment shall be surrendered to the Authority.

(3) The new owner or any person seeking to restart the clinical establishment shall apply afresh for grant of certificate of registration.

30. *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 or acts that are prejudicial to the health of the persons accessing 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 show cause, 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, may restrain immediately the clinical establishment from carrying on, if there is imminent danger to the health and safety of patients.

CHAPTER V

PENALTIES

31. *Penalty for contravention of the provisions of the Act.*—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 up to five lakh rupees.

32. *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) Whoever knowingly serves in a clinical establishment which is not duly registered under this Act, shall be liable to a monetary penalty which may extend to twenty five thousand rupees.

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

(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 of 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 37.

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

(6) Any person aggrieved by the decision of the Authority may prefer an appeal to the Council within a period of three months from the date of the said decision.

(7) The manner of filing the appeal referred to in sub-section (6) shall be such as may be prescribed.

33. *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), the Authority shall hold an inquiry in the prescribed manner after giving any person concerned a reasonable opportunity of being heard for the purpose of imposing any monetary penalty.

(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 37.

(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) Any person aggrieved by the decision of the Authority may prefer an appeal to the Council within a period of three months from the date of the said decision.

(7) The manner of filing the appeal referred to in sub-section (6) shall be such as may be prescribed.

34. *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.

35. *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.

36. *Offences by Government Department.*—Where an offence under this Act has been committed by any clinical establishment under the control of 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

37. *Fees, fines and penalties to be credited to separate account.*—The amounts 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 the Act.

CHAPTER VII

APPEALS, REVISION AND GRIEVANCE REDRESSAL

38. *Appeals.*—(1) 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 may, in such manner as may be prescribed and within forty five days of such refusal or cancellation or revision, prefer an appeal to the Council:

Provided that the Council may entertain an appeal preferred after the expiry of forty five days if it is satisfied that the appellant was prevented by sufficient cause from preferring the appeal in time.

(2) Every appeal under sub-section (1) shall be made in such form and be accompanied by such fee as may be prescribed.

(3) Every appeal under sub-section (1) shall be disposed of by the Council, after giving the appellant an opportunity of being heard, within ninety days from the date of filing the appeal.

39. *Revision.*—The Government may, *suo-motu* or on application made to it, call for the records of any case in which an order has been passed by the Council and if it appears to the Government that the order is improper or illegal, it may, after giving an opportunity of being heard to the concerned, pass such order as it deems fit.

40. *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

41. *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) The Council shall notify the person qualified to conduct assessment of the hospitals;

(3) 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.

(4) 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.

(5) 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.

(6) 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.

42. *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

43. *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 regional language as well as in English the rates charged for each type of service provided and facilities available, for the information of the patients.

44. *Maintenance of medical records.*—Every clinical establishment shall maintain the medical records of patients and the copy thereof shall be furnished to the patients or to their relatives on request.

45. *Display of Information by the Authority.*—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.

46. *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.

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

48. *Power to give directions.*—Without prejudice to the foregoing provisions of this Act, the Government shall have the power to issue directions for the implementation of the provisions of the Act and to call for returns, statistics and other information regarding the functioning of the clinical establishment.

49. *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).

50. *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.

51. *Treatment of victims of emergencies.*—The clinical establishment shall provide, such medical examination and treatment as may be required and shall provide the staff and facilities available in the establishment to save the life of

the patient and make the transport of the patient to any other hospitals safely. The Council shall notify the life saving services to be provided by each category of clinical establishments.

52. *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 such provisions not inconsistent with the provisions of this Act as it may deem necessary or expedient for the removal of such 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.

53. *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 minimum standards for each category of clinical establishment;
- (b) allowances payable to the non-official members of the Council;
- (c) the form and particulars of the State Register of Clinical Establishments;
- (d) the manner in which the register of clinical establishments is to be maintained by the Authority;
- (e) other functions to be performed by the Authority;
- (f) minimum qualifications for the medical and para medical staff of clinical establishments;
- (g) standards of safety, infection control and Standard Treatment Guidelines to be maintained by clinical establishments;
- (h) other conditions for registration of clinical establishments;
- (i) the period within which the clinical establishments having provisional registration shall acquire the minimum standards for permanent registration;
- (j) the period within which the clinical establishments which come into existence after the commencement of the Act shall apply for permanent registration;

- (k) the form of application and fee for provisional registration ;
- (l) the enhanced fee for the renewal of provisional registration after its expiry;
- (m) the form for, and the manner of, and the fee for, applying for permanent registration;
- (n) the manner in which the results of the inspection of clinical establishments are to be made available to the public;
- (o) fee for the renewal of permanent registration;
- (p) enhanced fees for the renewal of permanent registration after the expiry of specified date under section 25;
- (q) the form of acknowledgement of the receipt of the application for provisional or permanent registration;
- (r) the form and the particulars of certificate of provisional and permanent registration;
- (s) fee for duplicate certificate of provisional or permanent registration;
- (t) the manner in which inquiry is to be held by the Authority under this Act;
- (u) the manner in which appeal is to be filed under this Act;
- (v) the fee for filing appeal under this Act;
- (w) the manner in which the grievance redressal mechanism is to be set-up under section 40;
- (x) the manner in which search is to be made in a clinical establishment under section 42;
- (y) the manner in which the particulars of the clinical establishment are to be published by the Authority under section 45.

(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.

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.

In Kerala more than seventy per cent of health care 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 now brought the Bill suitable to the circumstances of the State. The Bill mainly provides for minimum standards of facilities and services provided by the Clinical Establishments and for their registration and regulation, for improvements of 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 belong to all recognised systems of medicine except those under the control of Defence Services.

The Bill is intended to achieve the above object.

FINANCIAL MEMORANDUM

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

MEMORANDUM REGARDING DELEGATED LEGISLATION

Sub-clause (1) of clause 3 of the Bill seeks to empower the Government to constitute, by notification, a Council called the State Council for Clinical Establishments.

2. Item (a) of clause 4 of the Bill seeks to empower the Government to classify the clinical establishments by prescribing minimum standards. Item (k) of the said clause seeks to empower the Government to assign to the Council other functions, not mentioned in the said clause.

3. Clause 13 of the Bill seeks to empower the Council to make regulations with the previous approval of the Government for fixing the quorum of the meeting and the procedure for the conduct of business.

4. Clause 15 of the Bill seeks to empower the Government to prescribe the allowances to non-official members of the Council.

5. Sub-clause (1) of clause 16 of the Bill seeks to empower the Government to prescribe the manner in which the State Register is to be maintained by the Clinical Establishments and the particulars to be included therein. Sub-clause (3) of the said clause seeks to empower the Government to prescribe the manner in which the Council shall give the copy of each entry in the said Register to the Authority.

6. Clause 17 of the Bill seeks to empower the Government to prescribe different standards for different categories of clinical establishments.

7. Sub-clause (1) of clause 18 of the Bill seeks to empower the Government to constitute, by notification, an Authority for registration of Clinical Establishments in each district. Item (f) of sub-clause (2) of the said clause seeks to empower the Government to prescribe, other functions not mentioned in the said clauses and to be performed by the Authority.

8. Item (a) of clause (19) seeks to empower the Government to prescribe the standards according to the category of the clinical establishment. Item (b) of the said clause seeks to empower the Government to prescribe the minimum qualifications, necessary for the medical and para medical staff. Item (c) of the said clause seeks to empower the Government to prescribe the standards of safety, infection control and standard treatment guidelines to be complied by the clinical establishments. Item (d) of the said clause seeks to empower the Government to prescribe other conditions to be complied by the clinical establishments for the purpose of the registration.

9. Sub-clause (4) of clause 20 of the Bill seeks to empower the Government to prescribe the period within which permanent registration shall be acquired by all the Clinical Establishments having provisional registration. Sub-clause (5) of

the said clause seeks to empower the Government to prescribe the period within which all clinical establishments, which come into existence after the commencement of this Act, shall apply to the Authority for permanent registration.

10. Sub-clause (1) of clause 21 of the Bill seeks to empower the Government to prescribe the form and fee for provisional registration for all clinical establishment functioning at the commencement of this Act. Sub-clause (3) of the said clause seeks to empower the Government to prescribe the form for the certificate of provisional registration and the particulars to be included therein.

11. Sub-clause (3) of clause 22 of the Bill seeks to empower the Government to prescribe the enhanced fees to be paid in the Authority for renewal of registration in the case where the application for renewal is made after the expiry of the provisional registration.

12. Sub-clause (1) of clause 23 of the Bill seeks to empower the Government to prescribe the form and the manner and fees for permanent registration of a clinical establishment. Sub-clause (2) of the said clause seeks to empower the Government to prescribe the manner in which the Authority shall publish the particulars of the clinical establishments, applied for permanent registration. Sub-clause (9) of the said clause seeks to empower the Government to prescribe the manner in which the results of the inspection, conducted by the Authority, be made available to the public. Sub-clause (10) of the said clause seeks to empower the Council to notify a panel of independent assessors to ensure that the standards prescribed are being adhered to by the clinical establishments.

13. Clause 24 of the Bill seeks to empower the Government to prescribe the fees for the renewal of registration prior to the expiry of validity of permanent registration.

14. Clause 25 of the Bill seeks to empower the Government to prescribe the enhanced fees to be paid for the renewal of registration, in the case where the renewal application is made after the expiry of the validity of the certificate of permanent registration.

15. Clause 26 of the Bill seeks to empower the Authority to prescribe the form for the acknowledgement of the receipt of the application for provisional registration or permanent registration.

16. Clause 27 of the Bill seeks to empower the Government to prescribe the form of registration certificate for temporary or permanent registration issued by the Authority and the particulars to be included therein.

17. Clause 28 of the Bill seeks to empower the Government to prescribe the fees to be paid to the Authority for the issue of duplicate certificate.

18. Sub-clause (3) of clause 32 of the Bill seeks to empower the Government to prescribe the manner in which the Authority shall conduct the inquiry to impose monetary penalty on a clinical establishment which is not registered. Sub-clause (7) of the said clause seeks to empower the Government to prescribe the manner of filing appeal before the Council against the decision of the Authority that has imposed monetary penalty.

19. Sub-clause (3) of clause 33 of the Bill seeks to empower the Government to prescribe the manner in which the Authority shall conduct inquiry to impose monetary penalty for the purpose of sub-clauses (1) and (2) of the said clause. Sub-clause (7) of the said clause seeks to empower the Government to prescribe the manner of filing appeal as referred to in sub-clause (6).

20. Sub-clause (1) of clause 38 of the Bill seeks to empower the Government to prescribe the manner in which an appeal shall be preferred to the Council by 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. Sub-clause (2) of the said clause seeks to empower the Government to prescribe the form and fee for appeal preferred as per sub-clause (1).

21. Clause 40 of the Bill seeks to empower the Government to prescribe the manner in which the Council shall establish a grievance redressal mechanism to receive complaints from the public.

22. Clause 42 of the Bill seeks to empower the Government to prescribe the manner in which the Council or Authority or any officer authorised by them to conduct an inspection in a clinical establishment without having registration.

23. Clause 45 of the Bill seeks to empower the Government to prescribe the manner in which the Authority shall publish the particulars of the clinical establishment which is registered.

24. Sub-clause (1) of clause 52 of the Bill seeks to empower the Government to issue orders to remove the difficulties.

25. Clause 53 of the Bill seeks to empower the Government, by notification, to make rules for carrying out all or any of the provisions of the Act.

The matters in respect of which notifications or orders may be issued or rules or regulations 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.

V. S. SIVAKUMAR.