

KARNATAKA ACT NO 21 OF 2007

(First Published in the Karnataka Gazette Extra-ordinary on the sixteenth day of August, 2007)

THE KARNATAKA PRIVATE MEDICAL ESTABLISHMENTS ACT, 2007

Arrangements of Sections

Sections:

- 1.Short title and commencement
- 2.Definitions
- 3.Registration of Private Medical Establishments
- 4.Registration Authority
- 5.Application for Registration
- 6.Pre-requisites for Registration of Private Medical Establishments
- 8.Local Inspection Committee.-
- 9.Standards.-
- 10.Schedule of charges to be notified.-
- 11.Obligations of Private Medical Establishments.-
- 12.Maintenance of clinical records.-
- 13.Procedure for obtaining information.-
- 14.Restrictions on furnishing of information.-
15. Suspension or cancellation of registration
16. Appellate Authority
17. Appeal
18. Private Medical Establishments to report the names of government doctors on their establishments
19. Penalties
20. Offences by a Company
21. Power of entry, inspection etc.-
22. Sealing premises of un-registered Private Medical Establishments.-
23. Powers of State Government to give directions to the Registration Authorities
24. Protection of action taken in good faith
25. Removal of difficulties
26. Power to make rules

27. Rules and orders to be placed before the State legislature

28. Repeal and Savings

STATEMENT OF OBJECTS AND REASONS

Amending Act 21 of 2007.- It is considered necessary to bring a comprehensive legislation in place of the Karnataka Private Nursing Home (Regulation) Act, 1976 to have effective control over Private Medical Establishment in the state. The bill among other things provides for,-

- (i) registration of Private Medical Establishment;
- (ii) pre-requisite for registration of Private Medical Establishments;
- (iii) constitution of Local inspection Committee;
- (iv) laying down the standards of Private Medical Establishments;
- (v) requiring to notify the schedule of charges payable for different medical treatment and other services in the form of brochures or booklets;
- (vi) prescribing statutory obligations to be performed by a Private Medical Establishment;
- (vii) maintenance of clinical Records;
- (viii) to make available to the persons or his family member a copy of the gist of observations, treatment, investigation, advice and diagnostic opinion pertaining to the person;
- (ix) suspension or cancellation of registration;
- (x) penalties for violation of the provisions of the Act and cancellation of the registration.

Certain other consequential and incidental provisions are also made.

Hence the Bill.

[L.A. Bill No. 10 of 2007]

[Entry 6 of list II of the Seventh Schedule to the Constitution of India]

KARNATAKA ACT NO 21 OF 2007

(First Published in the Karnataka Gazette Extra-ordinary on the sixteenth day of August, 2007)

THE KARNATAKA PRIVATE MEDICAL ESTABLISHMENTS ACT, 2007

(Received the assent of the Governor on the thirteenth day of August, 2007)

An Act to provide for the Promotion and Monitoring of Private Medical Establishments in the State of Karnataka and matters connected therewith or incidental thereto.

Whereas it is expedient in the public interest to promote quality health care and monitor by law the running of Private Medical Establishments in the State by stipulating minimum standards for quality of service in keeping with the principles of medical ethics;

Be it enacted by the Karnataka State Legislature in the Fifty-eighth year of the Republic of India, as follows:-

1. Short title and commencement.- (1) This Act may be called the Karnataka Private Medical Establishments Act, 2007.

(2) It shall come into force on such date as the State Government may, by notification, appoint and different dates may be appointed for different provisions of the Act.

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

(a) 'Appellate Authority' means the Appellate Authority referred to in section 16;

(b) 'Appointed day' means the date appointed under sub-section (2) of section 1;

(c) 'Clinical Laboratory' means an establishment where,-

(i) biological (pathological), bacteriological, radiological, microscopic, chemical or other tests, examinations or analysis; or

(ii) the preparation of cultures, vaccines, serums or other biological or bacteriological products in connection with the diagnosis or treatment of diseases, are or is usually carried out;

(d) "Clinical record" means any paper, film print out, slide, solution or medium which can be deciphered or used to indicate and diagnose condition of the human body or a part of it or any material taken out of it and the course of treatment administered to, or undergone by, the person;

(e) "Department" means the Department of Health and Family Welfare or the Department of Indian Systems of Medicine and Homeopathy, Government of Karnataka, as the case may be;

(f) "Family member" means husband or wife or any son, daughter or any other legal heir or legal guardian irrespective of their age;

(g) "Hygienic" means a condition congenial for good health;

(h) "Local Inspection Committee" means Local Inspection Committee constituted under section 8;

(i) "Manager" in relation to a Private Medical Establishment means the person, by whatever name or designation called, who is in charge of, or is entrusted with, the management or running of the Private Medical Establishment;

(j) "Maternity Home" means an Establishment where women are usually received or accommodated or both, for the purpose of confinement and antenatal or post-natal care in connection with child-birth and includes an establishment where women are received or accommodated for the purpose of sterilization or medical termination of pregnancy;

(k) 'Medical Practitioner' means a medical practitioner registered under the Homeopathic Practitioners Act, 1961 (Karnataka Act 35 of 1961), Ayurvedic, Naturopathy, Siddha, Unani or Yoga Practitioners Registration and Medical Practitioners Miscellaneous Provisions Act, 1961 (Karnataka Act 9 of 1962), Medical Registration Act, 1961 (Karnataka Act 34 of 1961), Indian Medicine Central Council Act, 1970 (Central Act 48 of 1970), Homeopathy Central Council Act, 1978 (Central Act 59 of 1973) and Medical Council Act, 1956 (Central Act 102 of 1956) to practice the system of medicine which he has studied, qualified and registered and includes a Dentist registered under the Dentists Act, 1948 (Central Act 16 of 1948);

(l) "Medical treatment" means systematic diagnosis and treatment for prevention or cure of any disease, or to improve the condition of health of any person through allopathic or any other recognised systems of medicine such as Ayurveda, Unani, Homeopathy, Yoga, Naturopathy and Siddha; and includes Acupuncture and Acupressure treatments;

(m) "Nursing Home" means an establishment where persons suffering from illness, injury or infirmity (whether of body or mind) are usually received or accommodated or both for the purpose of treatment of diseases or infirmity or for improvement of health or for the purposes of relaxation or for any other purpose whatsoever, whether or not analogous to the purposes mentioned in clause (l) of this section;

(n) "Private Medical Establishment" means a hospital or dispensary with beds or without beds, a Nursing Home, Clinical Laboratory, Diagnostic Centre, Maternity Home, Blood Bank, Radiological Centre, Scanning Centre, Physiotherapy Centre, Clinic, Polyclinic, Consultation Centre and such other establishments by whatever name called

where investigation, diagnosis and preventive or curative or rehabilitative medical treatment facilities are provided to the public and includes Voluntary or Private Establishments but does not include Medical Establishments run or maintained or sponsored by,-

- (i) the State Government or a Local Authority or other Statutory body;
 - (ii) the Public Sector undertakings owned or controlled by the State or Central Government;
 - (iii) autonomous institutions owned or controlled by the State or Central Government;
 - (iv) a Co-operative Society registered under the Karnataka Co-operative Societies Act, 1959 in which more than fifty per cent of shares are held by the State or Central Government or both;
 - (v) a Society registered under the Karnataka Societies Registration Act, 1960 and which is owned or controlled by the State or Central Government;
 - (vi) a trust owned or managed by the State or Central Government or any Local Authority.
- (o) "Physiotherapy establishment" includes an establishment where massaging, hydro-therapy, remedial gymnastics or similar work is usually carried on, for the purpose of treatment of diseases or infirmity or for improvement of health or for the purposes of relaxation or for any other purpose whatsoever, whether or not analogous to the purposes mentioned in clause (l) of this section;
- (p) "Public Authority" means an Authority established by or under any law.
- (q) "Registration" means registration granted under section 7;
- (r) "Registration Authority" means the Registration Authority referred to in section 4.

3. Registration of Private Medical Establishments.- On and after the appointed day, no Private Medical Establishment shall be established, run or maintained in the State except under and in accordance with the terms and conditions of registration granted under this Act:

Provided that a Private Medical Establishment in existence immediately prior to the appointed day shall apply for such registration within ninety days from the appointed day and pending orders thereon may continue to run or maintain till the disposal of the application.

4. Registration Authority.- There shall be a Registration Authority in each district consisting of the following members, namely:-

- (a) The Deputy Commissioner of the district. --- Chairman

- | | | |
|---|------|--------|
| (b) District Health and Family Welfare Officer | --- | Member |
| (c) President/Secretary, Indian Medical Association of the concerned district | ---- | Member |

5. Application for Registration.- (1) Every person desiring to establish, run, maintain or continue to run and maintain a Private Medical Establishment shall make an application to the concerned Registration Authority in such form, in such manner and along with such fees as may be prescribed and different amount of fees may be prescribed, for different class or classes of Private Medical Establishments.

6. Pre-requisites for Registration of Private Medical Establishments.- The Registration Authority shall before granting the registration consider whether the following prerequisites for registration of a Private Medical Establishment are satisfied, namely:-

- (i) that the premises housing the Private Medical Establishment is located in hygienic surroundings and otherwise suitable for the purpose for which it is established or sought to be established;
- (ii) that the Private Medical Establishment is adequately staffed with qualified doctors, qualified and trained para medical personnel;
- (iii) that the Private Medical Establishment has the necessary buildings with adequate space for performing its various functions, equipments and other infrastructure facilities;
- (iv) that the Private Medical Establishment conforms to the standards referred to in section 9;
- (v) such other factors as may be prescribed.

7. Disposal of applications.- (1) On receipt of an application under section 5, the Registration Authority may having regard to the provisions of section 6 and after such enquiry as may be necessary, by Local Inspection Committee, either grant registration subject to such conditions as may be prescribed or reject the application:

Provided that the Registration Authority shall not reject the application without giving an opportunity of being heard to the applicant and without recording the reasons for such rejection.

(2) Every order passed under sub-section (1) shall be communicated to the applicant forthwith.

(3) Every registration granted under sub-section (1) shall be valid for a period of five years and may be renewed once in five years on an application made in such form, in such manner and on payment of such fees, as may be prescribed.

8. Local Inspection Committee.- (1) The Registration Authority of each district may constitute one or more Local Inspection Committee for each district consisting of

such persons as it may specify for the purposes specified in sub-sections (1) of section 7 and sub-section (2) of this section.

(2) The Local Inspection Committee, either with prior intimation or on receiving a complaint, may at reasonable time, inspect, a Private Medical Establishment to satisfy itself that the provisions of this Act and the rules made thereunder and the conditions of registration are being duly observed.

(3) If any defects or deficiencies are noticed during inspection, the Local Inspection Committee shall report to the Registration Authority which may direct the Manager of the Private Medical Establishment to remedy the same within such reasonable time as may be specified in the order. Thereupon the Manager shall comply with every such direction and report the compliance to the Registration Authority within the time so specified.

(4) The Manager of the Private Medical Establishment shall provide all reasonable facilities for such inspection.

9. Standards.- (1) Every Private Medical Establishment shall conform to the standards laid down in this Act or the rules made thereunder or any other law for the time being in force concerning the staff and their qualifications, operation theatre, buildings, space requirements, equipment, facilities to be provided to the patients and their attendants, maintenance and other matters.

(2) Different standards may be set for different class or classes of Private Medical Establishments, in respect of different areas, as determined by the State Government. Expert Committees may be constituted by the State Government for suggesting the standards for different class or classes of Private Medical Establishment for different areas from time to time. The composition, powers and responsibilities, of the Expert Committees and the terms and conditions of service of members of the Expert Committee shall be as may be prescribed.

10. Schedule of charges to be notified.- (1) Every Private Medical Establishment shall for the information of the patients and general public make available the schedule of charges payable for different medical treatment and other services, in the form of brochures or booklets and shall also display such schedule of charges on the notice board of the private Medical Establishment. A copy of such brochure or booklet shall be sent to the Registration Authority.

(2) No Private Medical Establishment shall collect from the patient or his relatives or attendants any amount in excess of the charges printed in the brochure or booklet, and without issuing proper receipt for the amount charged and collected.

11. Obligations of Private Medical Establishments.- Every Private Medical Establishment shall:-

- (i) administer necessary first aid and take other life saving or stabilising emergency measures in all medico-legal or potentially medico-legal cases such as victims of road accidents, accidental or induced burns or poisoning

or criminal assaults and the like which present themselves or are brought before it at the establishment;

- (ii) actively participate in the implementation of all national and State health programmes in such manner as the State Government may specify from time to time; and furnish periodical reports thereon to the concerned authorities;
- (iii) perform statutory duties in respect of communicable diseases to prevent the spread of the disease to other persons and report the same to the concerned public health authorities immediately;
- (iv) furnish to the Registration Authority such particulars in respect of such non-communicable diseases as may be notified by the State Government from time to time.

12. Maintenance of clinical records.- (1) Every Private Medical Establishment shall maintain clinical records of its activities relating to the patients under its care in the prescribed manner.

(2) Every clinical record shall be open to inspection, in due discharge of his duties, by the District Surgeon or any other officer specifically empowered in this behalf by the State Government.

(3) Every person or his family member shall be entitled to obtain a copy of the clinical record pertaining to himself on payment of appropriate charges.

13. Procedure for obtaining information.- (1) Every Private Medical Establishment shall, as soon as possible, after the purpose for which the person had visited or had been admitted is over, make available to the person or his family member a copy of the gist of observation, treatment, test, investigation, advice and diagnostic opinion pertaining to the person.

(2) A public authority, in due discharge of its duties or the person himself or any other person specifically authorised by the person to this effect, or any family member of the person in case there is no authorization because the person concerned is a minor or is deceased or incapacitated (permanently or temporarily) may request for copy of clinical records on payment of necessary charges to the private medical establishment and on such charges being paid, the private medical establishment shall, within a period of seven days, make available such copy.

(3) Every Private Medical Establishment shall display, at a prominent place, the charges for obtaining such information.

14. Restrictions on furnishing of information.- The Manager of the Private Medical Establishment may, for reasons to be recorded in writing, refuse to furnish the information, pertaining to the clinical records if he is satisfied that,-

- (a) the treatment or test or assessment has been conducted on the direction of a public authority and it has the first right to receive the information.

- (b) the report if made available to the person, is likely to cause injury to the person or his family members.

15. Suspension or cancellation of registration.- (1) The Registration Authority, on the basis of a complaint or otherwise if a prima facie case exists about the contravention of any provisions of this Act or the rules made there under or conditions of registration may, by order in writing and for the reason to be recorded in writing suspend or cancel the registration of a Private Medical Establishment:

Provided that no such order shall be made except after giving a reasonable opportunity of being heard, to the Private Medical Establishment.

(2) Every order made under sub-section (1) shall contain a direction that the inpatients of the Private Medical Establishment shall be transferred to such other Private Medical Establishment as may be specified in that order and it shall also contain such provisions as to the care and custody of such inpatients pending such transfer.

(3) Every order made under sub-section (1) shall take effect,-

- (a) where no appeal has been preferred against such order under section 17, immediately on the expiry of the period specified for such appeal; and
- (b) where such appeal has been preferred and the same has been dismissed, from the date of order of such dismissal.

16. Appellate Authority.- There shall be an Appellate Authority consisting of the following members, namely:-

- (a) the Commissioner for Health and Family Welfare, Karnataka-Chairman
- (b) the Director of Health Services, Karnataka - Member
- (c) the Director, Indian System of Medicine and Homeopathy - Member

Note: The Director of Health Services, Karnataka shall be a member in respect of appeals preferred by a Private Medical Establishment treating patients through allopathic system of medicine and the Director Indian System of Medicine and Homeopathy shall be a member in respect of appeals preferred by other Private Medical Establishments treating patients through Ayurveda, Unani, Homeopathy, Yoga, Naturopathy or Siddha system of medicine.

17. Appeal: (1) A Private Medical Establishment whose application for registration is rejected under section 7, or whose registration has been suspended or cancelled under section 15 or is otherwise aggrieved by any original order made under this Act except an order made under section 24 may prefer an appeal to the Appellate Authority in such manner and on payment of such fees as may be prescribed.

(2) Every such appeal shall be preferred within thirty days from the date of receipt of the order appealed against;

(3) The Appellate Authority may, after holding an enquiry pass such order as it deems fit as far as possible within a period of sixty days from the date of filing of the appeal.

18. Private Medical Establishments to report the names of government doctors on their establishments.- Every Private Medical Establishment shall report to the State Government and the Registration Authority, the names of government doctors and para medical staff, whose services are utilized in the Private Medical Establishment for consultations or any other basis whether on payment basis or not.

19. Penalties.- (1) Where any person establishes, runs or maintains a Private Medical Establishment without registration granted under section 7 he shall, on conviction, be punished with imprisonment for a term which may extend to three years and with fine which may extend upto ten thousand rupees.

(2) When a person is convicted under sub-section (1), the Registration Authority shall direct immediate closure of the un-registered Private Medical Establishment, except where a registration is cancelled or suspended and an appeal filed against such cancellation or suspension is pending.

(3) Every order made under sub-section (1) shall contain a direction that the inpatients of such unregistered Private Medical Establishment shall be transferred to such other Private Medical Establishment as may be specified in that order and it shall also contain such other provisions as to the care and custody of such inpatients pending such transfer.

(4) Where any person runs or maintains a Private Medical Establishment in contravention of the conditions of registration or contravenes the provisions of section 12 or 13, or fails to comply with the direction issued under sub-section (2). he shall, on conviction, be punished with imprisonment for a term which may extend to six months and with a fine which may extend to two thousand rupees and in the case of a second or subsequent offence with imprisonment for a term which may extend to one year and with a fine which may extend to five thousand rupees.

(5) Where a person contravenes any other provision of this Act or the rules made thereunder he shall, on conviction, be punishable with a fine which may extend to five thousand rupees.

20. Offences by a Company.- (1) Where an offence against any of the provisions of this Act or any rule made thereunder has been committed by a company, every person who, at the time the offence was committed, was incharge of, and was responsible to, the Company, for the conduct of business of the company, as well as the Company, 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 sub-section shall render any such person liable to any punishment, provided in this Act if he proves that the offence was

committed without his knowledge or that he had exercised all due diligence to prevent the commission of such offence.

(2) Notwithstanding anything contained in sub-section (1) where an offence under this Act has been committed by a company, and it is proved that the offence was committed with the consent or connivance of or is attributable to, any neglect on the part of the director, manager, secretary or other officer of the company, such director, manager, secretary or other officer of the company, shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Explanation:- For the purposes of this section,-

- (a) "a company" means any body corporate and includes a trust firm, a society or other association of individuals; and
- (b) "the director" in relation to:-
 - (i) a firm means a partner in the firm;
 - (ii) a society, a trust or other association of individuals means the person who is entrusted under the rules of the society, trust or other association, with management of the affairs of the society, trust or other association, as the case may be.

21. Power of entry, inspection etc.- (1) Subject to such rules as may be prescribed, the State Government may, specially authorise any officer of the State Government (hereinafter in this section and section 22 referred to as authorised officer) to,-

- (a) enter, at all reasonable times, and with such assistants if any, being persons in the service of the State Government as he thinks fit, any place which is, or which he has reason to believe is being used as a Private Medical Establishment.
- (b) Make such examination of the premises of a Private Medical Establishment and of any register, record, equipment, article or document found therein and seize any document or record as he may deem necessary for the purpose of examination, analysis or investigation and retain them as long as he thinks it necessary to do so for such purpose, provided the authorised officer after seizing documents and records shall intimate the reason for such seizure to the Manager of the Private Medical Establishment as early as is practicable.
- (c) Make such enquiry and take on the spot or otherwise the statement of any person as he deems necessary:
- (d) Exercise such other powers as may be necessary; for carrying out the purposes of this Act.

Provided that no person shall be required under this sub-section to answer any question or give any evidence tending to incriminate himself:

Provided further that, no residential accommodation (not being a Private Medical Establishment-cum-residence) shall be entered into and searched by the authorised officer except on the authority of a search warrant issued by a Magistrate having jurisdiction over the area and all searches and seizures under this section shall so far as may be, made in accordance with the provisions of the Code of Criminal Procedure , 1973 (Central Act 2 of 1974).

(2) The authorised officer shall make a report to the Registration Authority regarding the result of the inspection, searches and seizure made by him under sub-section (1), and the Registration Authority shall take necessary action on the said report under this Act.

22. Sealing premises of un-registered Private Medical Establishments.- (1) Without prejudice to the provisions of section 19, if on a report made by the authorised officer under sub-section (1) of section 21 or otherwise the Registration Authority has reason to believe that any Private Medical Establishment is run or maintained without registration under section 7, it may order immediate closure of such Private Medical Establishment and also seal the premises:

Provided that no order under this sub-section shall be made without giving an opportunity of being heard to the person likely to be affected thereby.

(2) Every order made under sub-section (1) shall contain a direction that the inpatients of such un-registered Private Medical Establishment shall be transferred to such other Private Medical Establishment as may be specified in that order and it shall also contain such provisions as to the care and custody of such inpatients pending such transfer.

23. Powers of State Government to give directions to the Registration Authorities.- The State Government may give such directions to the Registration Authority as are in its opinion necessary or expedient for carrying out the purposes of this Act. The State Government shall record the reasons necessitating issuance of the said directions and it shall be the duty of the Registration Authority to comply with such directions.

24. Protection of action taken in good faith.- No suit, prosecution or other legal proceeding shall lie against the State Government or any officer, authority or person in respect of anything which is in good-faith done or intended to be done in pursuance of the provisions of this Act, or any rule or order made thereunder.

25. Removal of difficulties.- If any difficulty arises in giving effect to the provisions of this Act the State Government may, by order published in the Official Gazette, make such provisions not inconsistent with the provisions of this Act as appear to it to be necessary or expedient for removing the difficulty:

Provided that no such order shall be made after expiry of a period of two years from the appointed day.

26. Power to make rules:- (1) The State Government may, by notification and after previous publication, make rules for carrying out the purposes of this Act.

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

- (a) the manner in which an application for registration shall be made and the fee which shall be accompanied under section 5;
- (b) such other factors for registration under section 6;
- (c) manner and payment of fees to be accompanied for renewal of registration;
- (d) Standards to be maintained by every Private Medical Establishment under section 9;
- (e) manner of maintaining clinical records under section 12;
- (f) the manner in which an appeal may be preferred and fees for such appeal under section 17;
- (g) the manner of taking custody of the premises under section 22;
- (h) all matters expressly required or allowed by this Act to be prescribed or in respect of which this Act makes no provision or makes insufficient provision and a provision is, in the opinion of the State Government, necessary for the proper implementation of the Act.

27. Rules and orders to be placed before the State legislature:- Every order made under section 26 and every rule made under section 27 shall be laid as soon as may be after it is made, before each House of the State Legislature while it is in session for a period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid both Houses agree in making any modification in the rule or order both Houses agree that the rule or order should not be made the rule or order 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 or order.

28. Repeal and Savings:- (1) The Karnataka Private Nursing Homes (Regulation) Act, 1976 (Karnataka Act 75 of 1976) is hereby repealed.

(2) Notwithstanding such repeal,-

- (a) anything done or any action taken under the repealed Act shall be deemed to have been done or taken under the corresponding provisions of this Act;

(b) all applications made under the repealed Act for registration or renewal prior to the commencement of this Act and pending consideration on the date of commencement of this Act shall abate and the fee paid, if any, in respect of such application shall be refunded to the applicant and such applicants may apply afresh for Registration under the provisions of this Act.

The above translation of the ಕರ್ನಾಟಕ ಖಾಸಗಿ ವೈದ್ಯಕೀಯ ಸಂಸ್ಥೆಗಳ ಅಧಿನಿಯಮ, 2007 (2007ರ ಕರ್ನಾಟಕ ಅಧಿನಿಯಮ 21) be published in the official Gazette under clause (3) of Article 348 of the Constitution of India.

RAMESHWAR THAKUR
Governor of Karnataka

By order and in the name of the President of India,

G. K. BOREGOWDA
Secretary to Government,
Department of Parliamentary Affairs and
Legislation.