THE KARNATAKA PRIVATE MEDICAL ESTABLISHMENTS ACT, 2007

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STATEMENT OF OBJECTS AND REASONS

Ι

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 Establishments in the State. The Bill among other things provides for,-

- (i) registration of Private Medical Establishments;
- (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 Establishments;
- (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.]

TT

Amending Act 33 of 2010.- It is considered necessary to amend the Karnataka Private Medical Establishments Act, 2007, to provide for,-

- (1) extension of time prescribed for registration of existing Private Medical Establishments; and
- (2) reconstitution of the District Level Registration Authority.

Hence the Bill.

[L.A.Bill No.26 of 2010, File No.Samvyashe 21 Shasana 2010]

[Entry 6 of List II and entry 26 of list III of the Seventh Schedule to the Constitution of India.]

Ш

Amending Act 37 of 2012.- It is considered necessary to amend the Karnataka Private Medical Establishments Act, 2007 to provide for extension of time prescribed for the registration of existing Private Medical Establishments under the said Act by six months from the date of commencement of the Karnataka Private Medical Establishments (Amendment) Act, 2012.

Hence the Bill.

[L.A. Bill No. 7 of 2012, File No.Samvyashae 4 Shasana 2012] [Entry 6 of List II and entry 26 of List III of the Seventh Schedule to the Constitution of India.]

IV

Amending Act 01 of 2018.- Considering the recommendations of the Joint Select Committee of both the Houses and after holding discussions with delegates of Doctors Associations. It is considered necessary to amend the Karnataka Private Medical Establishments Act, 2007 (Karnataka Act 21 of 2007) to,-

- (i) reconstitute the Registration and Grievance Redressal Authority;
- (ii) enhance transparency in display of rates by the private medical establishments;
- (iii) empower the State Government to fix uniform package rates for treatment and procedures under health assurance schemes of the Government;
- (iv) specify the Patient's Charter and Private Medical Establishment's Charter in the schedule to the Private Medical Establishment Act;
- (v) provide for levy of monetary penalty in case of non-compliance to the Patient's Charter or Private Medical Establishment's Charter;
- (vi) remove imprisonment provisions in case of violation of section 12 and 13;
- (vii) provide emergency treatment as per the need without insisting on payment of advance from patient or representative of patient in specified cases;
- (viii) handover body of the deceased patient to his representative without insisting on prior payment of the dues:
- (ix) enhance certain monetary penalties leviable under section 19;
- (x) certain other amendments incidentals or consequential are also made.

Hence the Bill.

[L.A. Bill No.44 of 2017, File No. Samvyashae 33 Shasana 2017] [Entry 6 of the 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) (As amended by Karnataka Act 33 of 2010, 37 of 2012 and 01 of 2018)

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 Fiftyeighth 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;
- ²[(f-1) "Grievance" means any complaint in respect of non-compliance to the Patient's Charter or Private Medical Establishment's Charter;]²
 - (g) "Hygienic" means a condition congenial for good health;
- ³[(h)" Inspection Committee" means the Inspection Committee constituted under section 7;]³
- (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, Sidda, 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, ¹[Integrated medicine,]¹ Naturopathy and Siddha; and includes Acupuncture and Acupressure treatments ²[and any other manner of treatment as may be prescribed;]²
- (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;
- ²[(m1) Patient's Charter and Private Medical Establishment's Charter" means the rights and responsibilities of the patient and the Private Medical Establishments specified in the schedule;
- (m2) "prescribed" means prescribed by rules made by the State Government under this Act;]²

- (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, ²[Dental Clinic or Dental Polyclinic]² 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 ²[as may be notified by the State Government by notification]² 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) ³[Registration and Grievance Redressal Authority]³ means the ³[Registration and Grievance Redressal Authority]³ referred to in section 4.

²[(s)"schedule" means schedule appended to this Act.]²

- 1. Inserted by Act 33 of 2010 w.e.f. 27.07.2010.
- 2. Inserted by Act 01 of 2018 w.e.f
- 3. Substituted by Act 01 of 2018 w.e.f
- **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 $^2[^1[\mbox{within six months from the date of commencement of the Karnataka Private Medical Establishments (Amendment) Act, <math display="inline">2012]^1]^2$ and pending orders thereon may continue to run or maintain till the disposal of the application. $^3[\mbox{and shall comply with the provisions of this Act}]^3$

- **1.** Substituted by Act 33 of 2010 w.e.f. 27.07.2010.
- **2.** Substituted by Act 37 of 2012 w.e.f. 03.09.2012.
- **3.** Inserted by Act 01 of 2018 w.e.f

¹[**4. Registration and Grievance Redressal Authority.**There shall be a Registration and Grievance Redressal Authority in each district consisting of the following members nominated in such manner with such qualification as may be prescribed, namely:-

a)	The Deputy Commissioner of the District	Chairman
(b)	District Health and Family Welfare Officer	Member
		Secretary
(c)	District AYUSH Officer	Member
(d)	One member each from Indian Medical	Members
	Association and one more association	
(e)	One woman representative when the Authority	Member
	is dealing with a grievance redressal.	

1. Substituted by Act 01 of 2018 w.e.f..

- **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 ¹[Registration and Grievance Redressal Authority]¹ 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.
 - 1. Substituted by Act 01 of 2018 w.e.f..
- **6. Pre-requisites for Registration of Private Medical Establishments.-** The ¹[Registration and Grievance Redressal Authority]¹ 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.

²[Provided that no new Private Clinical Laboratory shall be permitted within a radius of 200 meters from the Government Hospital or from the Hospital promoted or managed by a society or trust or autonomous organization owned or controlled by the State Government or Central Government or Local Bodies with effect from the date of commencement of the Karnataka Private Medical Establishments (Amendment) Act, 2017.]²

- 1. Substituted by Act 01 of 2018 w.e.f..
- 2. Inserted by Act 01 of 2018 w.e.f.
- **7. Disposal of applications.-** ¹[(1) On receipt of an application under section 5 the Registration and Grievance Redressal Authority may having regard to the provisions of section 6 and after such enquiry as may be necessary, by an Inspection Committee, either grant registration subject to the conditions as may be prescribed or reject the application within ninety days from the date of receipt of the complete application in all respects:

Provided further that in case of any delay beyond ninety days the registration shall be deemed to have been granted.]¹

- (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.
- ²[(4) For purpose of sub-section (1), the Registration and Grievance Redressal Authority may constitute the Inspection Committee consisting of such members as may be prescribed.
- (5) On receipt of application for renewal of registration, the Registration and Grievance Redressal Authority may having regard to the provisions of section 6 and after such enquiry as may be necessary by the Inspection Committee constituted under subsection (4) either grant renewal subject to the condition as may be prescribed or reject the application within ninety days from the date of receipt of the complete application in all respect; in case of any delay beyond ninety days the renewal shall be deemed to have been granted.
- (6) The Registration and Grievance Redressal Authority shall not reject the application for registration or renewal without giving an opportunity of being heard to the applicant and without recording the reasons for such rejection.
- (7)The Registration and Grievance Redressal Authority, on its own or based on any written complaint, may cause inspection or direct the Inspection Committee constituted under sub-section (4) to inspect, at a reasonable time, any private medical establishment, to

satisfy itself that the conditions of registration are being duly observed and complied with.

- (8) In case the Registration and Grievance Redressal Authority finds that the private medical establishment is not being run in accordance with the conditions of registration, the Authority shall direct the establishment to remedy the same within the reasonable time as may be specified in the order.]²
- 1. Substituted by Act 01 of 2018 w.e.f..
- 2. Inserted by Act 01 of 2018 w.e.f..
- ¹[8. Functions of the Registration and Grievance Redressal Authority.- (1) The Registration and Grievance Redressal Authority on receiving a complaint regarding non-compliance to the Patient's Charter or Private Medical Establishment's Charter shall enquire into the complaint:

Provided that the complaints pertaining to negligence, non-adherence to standard protocols for treatments, procedures and prescription audit shall be referred to the Karnataka Medical Council for enquiry and report within sixty days to the Authority.

- (2) The Registration and Grievance Redressal Authority shall, while investigating or enquiring any matter under this section, have the powers of a civil court trying a suit under the Code of Civil procedure 1908, and in particular in respect of the following matters, namely:-
 - (i) summoning and enforcing the attendance of any person and examining him on oath;
 - (ii) discovery and production of any documents and witness;
 - (iii) receiving any evidence on affidavits;
 - (iv) requisitioning for any public record or copy thereof from any court or office; and
 - (v) any other matter which may be prescribed.
- (3) The Registration and Grievance Redressal Authority shall, to remedy the Grievance, hear the aggrieved person and the other party and shall dispose of the complaint by a summary trial within ninety days from the date of complaint.]¹

1. Substituted by Act 01 of 2018 w.e.f.

- **9. Standards.-** (1) Every Private Medical Establishment shall conform to the standards ¹[of staffing pattern and infrastructure, etc.,] ¹ laid down in this Act or the rules made there under 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.

 $^1[\mbox{Provided}$ that the number of representatives of private medical establishments shall not exceed one-thirds of the total members.] 1

1. Inserted by Act 01 of 2018 w.e.f.

- ¹[9A. Functions of the Experts Committees and other Committees.-(1) The Expert Committee constituted under section 9 shall also discharge the following functions, namely:-
 - (a) study and recommend classification of the Private Medical Establishments on objective basis for the purpose of clause (b);
 - (b) recommend minimum standards of infrastructure, staffing pattern and staff qualification;
 - (c) recommend standard protocols for treatments and procedures, and prescription audit;
 - (d) make recommendations for fixation of uniform package rates for each procedure and treatment covered under any of the health care assurance scheme of the Government for private medical establishments; and
 - (e) any other functions as may be prescribed by the State Government.
- (2) The State Government, on the recommendation of the Expert Committee, and after previous publication, calling for objections from the persons likely to be affected and considering the same shall fix and notify the following, namely:-
 - (a) classification of Private Medical Establishments;
 - (b) minimum standards of infrastructure, staffing pattern and qualification of staff;
 - (c) standard protocols for treatments, procedures and prescription audit; and
 - (d) uniform package rates for each procedure and treatment covered under any of the health care assurance scheme of the Government for private medical establishments.
- (3) **Other ad-hoc Committees.-** (a) The State Government may also constitute such number of ad-hoc committees with such number of members as may be prescribed;
- (b) The ad-hoc committee shall perform such work as may be prescribed and shall submit its report to the State Government for its consideration;
- (4) The Expert Committee constituted under section 9 or the ad-hoc committee constituted in this sub-section shall follow such procedure, as may be, prescribed in discharge of its functions; and
- (5) The non-official Members of the Expert or ad-hoc Committee shall be eligible for Travelling Allowance and Daily

Allowance or any other allowances, as may be, prescribed by the State Government.]1

1. Inserted by Act 01 of 2018 w.e.f.

- ¹[10. Schedule of charges and establishment details to be notified.- (1) Every Private Medical Establishment for the information of patients and general public shall notify and make available the schedule of charges for consultation fee, investigations, medical treatments, procedures, hospital charges and other services, and establishment details, as may be prescribed, in each of the manners specified below:-
 - (i) display schedule of charges and establishment details in the prescribed manner on a public website to be provided by the Government;
 - (ii) display schedule of charges and establishment details in the prescribed manner on its own website, if any;
 - (iii) display consultation fee, rates of major and largely used investigations, procedures, treatments and other services, and hospital charges on the notice board of the establishment at a conspicuous place at the reception; and
 - (iv) schedule of charges in form of booklets or brochures, which is readily available to patients and public at the establishment at all times:

Provided that in the event of any discrepancy in the schedule of charges notified as per the above detailed manners, the least amount shall be considered to be effective.

- (2) For the services provided, the Private Medical Establishment shall collect from the patient or his relative or attendant an amount not more than the charges notified as per subsection (1), after providing an itemized bill.
- (3) For the services provided to a patient belonging to eligible household under the National Food Security Act, 2013 (Central Act 20 of 2013) and referred under any of the health assurance schemes of the Government, no charges shall be collected from the patient.
- (4) For the services provided to a patient not belonging to eligible household under the National Food Security Act, 2013 (Central Act 20 of 2013) but referred under any of the health assurance schemes of the Government, the charges over and above the amount reimbursable from the Government as per the scheme norms shall be collected subject to the rates notified under subsection (1), after providing an itemized bill.
- (5) In case of any investigation or treatment or procedure being necessary over and above the standard protocol prescribed under clause (c) of sub-section (2) of section 9A for any patient covered under sub-section (2) or (3) or (4), the concerned private medical establishment can undertake the same after explaining the need to the patient or his representative and obtaining his consent, and charge additional amount, subject to the rates notified as under sub-section (1) after providing an itemized bill.

(6) Every Private Medical Establishment shall provide proper estimates for treatments and charges to the patient or attendant of the patient during initiation or due course of treatment and final bill shall not exceed the estimates.]1

1. Substituted by Act 01 of 2018 w.e.f

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; ²[in the event of such emergencies, without insisting on advance payment]²
- (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 ¹[Registration and Grievance Redressal Authority]¹ such particulars in respect of such non-communicable diseases as may be notified by the State Government from time to time.
- ²[(v) display the Patient's Charter and Private Medical Establishment's Charter in such place easily visible to the public;
 - (vi) handover in the event of the death of a patient, the body of the deceased immediately, without insisting on prior payment of the dues:

Provided that in case the patient was admitted under any of the health care assurance schemes the private medical establishment shall claim the amount as per the scheme norms from the Government in accordance with clause (d) of sub-section (2) of section 9A.

Provided further that the due amount in accordance with sub-section (2) of section 10 or balance due amount in accordance with sub-section (4) or (5) of section 10 may be recovered from representatives of the deceased in due course as per law.

- (vii) provide the Grievance Redressal Mechanism at Private Medical Establishment Level in such manner as may be prescribed.]²
- 1. Substituted by Act 01 of 2018 w.e.f

2. Inserted by Act 01 of 2018 w.e.f.

- ¹[11A. Patient's Charter and Private Medical Establishment's Charter.- (1) Every patient or authorized family member and Private Medical Establishment shall have the rights and duties specified in the Patient's and Private Medical Establishment's Charter as contained in the Schedule to the Act.
- (2) Every patient or authorized family member and Private Medical Establishment shall have right to make complaint to the Registration and Grievance Redressal Authority in respect of violation of any of the provisions of sub-section (1) or rules made under the Act in such manner as may be prescribed.]¹

1. Inserted by Act 01 of 2018 w.e.f.

- ¹[11B. Power of State Government to amend the schedule.- (1) The State Government may, by notification, add, amend or omit any of the entries in the Schedule.
- (2) Every notification issued by the State Government under this section shall be laid before both houses of the State Legislature.]1

1. Inserted by Act 01 of 2018 w.e.f

- **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.

¹[Provided that no such information shall be disclosed to any other person.]¹

1. Inserted by Act 01 of 2018 w.e.f

- 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. ¹[Penalty or suspension]¹ or cancellation of registration.- ²[(1) In case of any private medical establishment failing to comply with any of the directions given by the Registration and Grievance Redressal Authority under sub-section (8) of section 7, the Authority may impose a penalty not exceeding fifty thousand rupees and extend the time for compliance or proceed to cancel the registration of the establishment, after giving the establishment an opportunity of being heard.
- (2) In case of a complaint from a patient regarding over-charging the Registration and Grievance Redressal Authority after holding enquiry under sub-section (3) of section 8 finds that the Private Medical Establishment has violated the provisions of sub-section (2), (4) or (5) of section 10 the Registration and Grievance Redressal Authority shall impose a penalty equivalent to one and half times of the overcharged amount, after giving the establishment an opportunity of being heard. Out of the penalty amount an amount equal to the over-charged amount shall be paid to the patient and the balance shall be deposited with the Arogya Raksha Samithi of the district for taking up public health activities:

Provided that in case of such over-charging by a particular private establishment the Registration and Grievance Redressal Authority after holding such enquiry under sub-section (3) of section 8 finds that the Private Medical Establishments has violated the provisions of section 10 for the third time within a calendar year, the Registration and Grievance Redressal Authority shall make a written complaint to the concerned Court for taking up cognizance of the offence and subsequent prosecution. On conviction, the concerned private medical establishment shall be liable for a penalty which may be extend to three-times of the amount over charged or rupees one lakh, whichever is higher.

(3) In case of a complaint from a patient regarding any matter in the Patient's Charter or Private Establishments Charter, other than the over-charging the Registration and Grievance Redressal Authority having found that the Private Medical Establishments has violated the provisions of section 11A shall impose a penalty of rupees ten thousand for the first non-compliance and rupees twenty five thousand for the second non-compliance during a calendar year on the concerned private medical establishment, after giving the establishment an opportunity of being heard. Fifty percent of the penalty amount shall be paid to the patient and the balance fifty percent shall be deposited with the Arogya Rakshana Samithi of the district for taking up public health activities:

Provided that in case of such complaint against a particular private establishment for the third time within a calendar year, the Registration and Grievance Redressal Authority shall make a written complaint to the concerned Court for taking up cognizance of the offence and subsequent prosecution. On conviction, the concerned private medical establishment be liable for a penalty which may be extend to fifty thousand rupees.]²

 3 [(5)] 3 The 1 [Registration and Grievance Redressal Authority] 1 , 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[and also ensure that arrangements are made within reasonable time for uninterrupted health care to the inpatients.]²

³[(6)]³ 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[(7)]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.
 - 1. Substituted by Act 01 of 2018 w.e.f.
 - 2. Inserted by Act 01 of 2018 w.e.f
 - 3. renumbered by Act 01 of 2018 w.e.f.
- **16. Appellate Authority.** ¹[There shall be an Appellate Authority over the Registration and Grievance Redressel 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
- ¹[(c) The Director of AYUSH (Ayurveda, Unani, Siddha, Homeopathy, Nature cure and Yoga): Member
- (d) One Clinician with Post Graduation in General Medicine nominated by the State Government: Member
 - (e) Director of Medical Education: Member.]¹

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.

1. Substituted by Act 01 of 2018 w.e.f.

- 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 filling 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 ¹[Registration and Grievance Redressal Authority]¹, 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.

1. Substituted by Act 01 of 2018 w.e.f.

- **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 ¹[one lakh]¹ rupees.
- (2) When a person is convicted under sub-section (1), the ¹[Registration and Grievance Redressal Authority]¹ 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 ²[XXX]² ¹[with a fine which may extend to twenty five thousand rupees]¹ and in the case of a second or subsequent offence ²[XXX]² ¹[with a fine which may extend to fifty thousand rupees]¹
- (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 ¹[one lakh rupees]¹
- ³[(6) Notwithstanding anything contained in this Act, whoever makes any false and frivolous or vexatious complaint under this Act shall be punishable by the Registration and Grievance Redressal Authority with a fine which may extend to ten thousand rupees.]³
 - 1. Substituted by Act 01 of 2018 w.e.f.
 - 2. Omitted by Act 01 of 2018 w.e.f.
 - 3. Inserted by Act 01 of 2018 w.e.f.
- ¹[19A. Cognizance of offence.- No court shall take cognizance of offence under this Act except on a written complaint by the Registration and Grievance Redressal Authority or any officer authorised in this behalf by the Registration and Grievance Redressal Authority:

Provided that nothing in this section shall prevent the aggrieved person to approach the competent court after exhausting the remedies available under this Act and in case the Registration and Grievance Redressal Authority or the authorised officer fails to make written complaint within thirty days from the date of application to make a complaint.]¹

- 1. Inserted by Act 01 of 2018 w.e.f.
- ¹[19B. Jurisdiction of Magistrates.- No magistrate shall try an offence under this Act unless he is a Judicial magistrate of first class.]¹
 - 1. Inserted by Act 01 of 2018 w.e.f.
- **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 subsection 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 ¹[Registration and Grievance Redressal Authority]¹ regarding the result of the inspection, searches and seizure made by him under sub-section (1), and the ¹[Registration and Grievance Redressal Authority]¹ shall take necessary action on the said report under this Act.
 - 1. Substituted by Act 01 of 2018 w.e.f.
- **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 ¹[Registration and Grievance Redressal Authority]¹ 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.
 - 1. Substituted by Act 01 of 2018 w.e.f.
- **23.** Powers of State Government to give directions to the ¹[Registration and Grievance Redressal Authorities]¹.- The State Government may give such directions to the ¹[Registration and Grievance Redressal Authority]¹ 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 ¹[Registration and Grievance Redressal Authority]¹ to comply with such directions.
 - 1. Substituted by Act 01 of 2018 w.e.f.
- **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.

¹[SCHEDULE

(see clause (s) of section 2 and section 11B) PATIENT'S CHARTER AND ESTABLISHMENT CHARTER

I. PATIENT'S CHARTER

A. PATIENT'S RIGHTS:

- (1) Care.- Every Patient shall have,-
 - (i) a right to receive treatment irrespective of the type of primary and associated illnesses, socio-economic status, age, gender, sexual orientation, religion, caste, cultural preferences, linguistic and geographical origins or political affiliations;
 - (ii) right to receive treatment in cases listed at subsection (i) of section 11 without being asked for advance payment;
 - (iii) right to be heard of his medical problem and concerns;
 - (iv) expectation from the doctor to write the prescription legibly and explain him on the details on dosage, dos and don'ts and generic options for the medicines;
 - (v) to be provided with information and access on whom to contact in case of an emergency;
 - (vi) right to be treated as per the standard protocol prescribed under clause (c) of sub-section (2) of section 9A;
 - (vii) right to know the information regarding the schedule of charges in the manner prescribed under sub-section (1) of section 10
 - (viii) right to be charged not more than the rates notified under sub-section (1) of section 10; and
 - (ix) right to receive clinical records in accordance with sub-section (3) of section 12.

- **(2) Confidentiality and Dignity.-** (a) Every Patient shall have,-
 - (i) right to personal dignity and to receive care without any form of stigma and discrimination;
 - (ii) privacy during examination and treatment;
 - (iii)protection from physical abuse and neglect;
 - (iv) provision for spiritual and cultural preferences; and
 - (v) right to confidentiality about their medical condition.
- (b) In the event of death of a patient, his family members shall have the right to receive the dead body immediately without being asked for prior payment of the dues in accordance with clause (vi) of section 11.
- **(3) Information.-** Every Patient or his authorised family member shall have right to,-
 - (i) information to be provided to him which are meant to be and in a language of the patient's preference and in a manner that is effortless to understand,-
 - (ii) receive complete information on the medical problem, prescription, treatment and procedure details:
 - (iii) a documented procedure for his informed consent to enable him to make an informed decision about his care to be practiced with utmost diligence and transparency;
 - (iv) be educated on risks, benefits, expected treatment outcomes and possible complications to enable him to make informed decisions and involve him in the care planning and delivery process;
 - (v) request information on the names, dosages and adverse effects of the medication that they are treated with;
 - (vi) request access and receive a copy of his clinical records;
 - (vii) complete information on the expected cost of treatment presented as an itemised structure of the various expenses and charges;
 - (viii) information on hospital rules and regulations; and
 - (ix) information on organ donation.
 - (4) Preferences.- Every Patient shall have right to,-
 - (i) seek a second opinion on his medical condition; and
 - (ii) get his treatment options, so that he can select what works best for him.
 - (5) Right to redress.- Every Patient shall have right to,-

- (i) justice through an authority dedicated for this purpose by the healthcare provider organization or with Government Grievance Redressal authorities;
- (ii) a fair and prompt hearing of his concern; and
- (iii)appeal to a higher authority in the private medical establishment and insist in writing on the outcome of the complaint.

B. PATIENTS' RESPONSIBILITIES .-

- (1) Honesty in Disclosure.- Every Patient shall be honest with the treating Doctor in disclosing family or medical history.
 - (2) Treatment Compliance.- Every patient shall,-
 - (i) be punctual for appointments;
 - (ii) do the best to comply with the doctor's treatment plan;
 - (iii) have realistic expectations from the doctor and his treatment:
 - (iv)inform and bring to the doctor's notice if it has been difficult to understand any part of the treatment or of the existence of challenges in complying with the treatment; and
 - (v) display intent to participate intelligently in medical care by actively involving in the prescribed do-athome activities.
- **(3) Intent for Health Promotion.-** Every patient shall do everything in capacity to maintain healthy habits and routines that contribute to good health and take responsibility for health.

(4) Transparency and Honesty.- Every patient shall,-

- (i) make a sincere effort to understand therapies which include the medicines prescribed and their associated adverse effects and other compliances for effective treatment outcomes;
- (ii) not ask for surreptitious bills and false certificates, and/or advocate forcefully by unlawful means to provide with one;
- (iii)in the event of not being happy, shall inform and discuss with doctor; and
- (iv) report fraud and wrong-doing.

(5) Conduct.- Every patient shall,-

- (i) respect the doctors and medical staff caring and treating;
- (ii) abide by the Hospital or facility rules;
- (iii)bear the agreed expenses of the treatment that is explained to in advance and pay bills on time in accordance with section 10; and

(iv) not involve in abusing, assaulting or causing harm to the Doctor or staff of Hospital. (any contravention may attract penalty under the Karnataka Prohibition of Violence Against Medicare Service Personnel and Damage to Property in Medicare Service Institutions Act, 2009 (Karnataka Act 01 of 2009))

II. PRIVATE MEDICAL ESTABLISHMENT'S CHARTER:-

- (1) Transparency and Honesty.-Every Private Medical Establishment shall,-
- (i) provide a printed schedule of fee for office visits, procedures, testing and surgery and provide itemized bills; and
- (ii) inform the doctor's qualifications to perform the proposed

diagnostic measures or treatments.

- **(2) Patient Friendly.-**Every Private Medical Establishment shall,-
 - (i) schedule appointments in such a manner that it may allow patient the necessary time to interact and examine him with minimal waiting times and listen to his problems and concerns without interruptions or distractions; and
 - (ii) encourage patient to bring a friend or relative into the examining room with him.
- (3) Effective Communication for Patient Education.-Every Doctor shall,-
 - (i) explain the patient prognosis, further diagnostic activity and treatment in simple terms such that it facilitates easy understanding to him;
 - (ii) prescribe an Information, Therapy and discuss with the patient diagnostic treatment and medication options, to enable him to make well-informed of decisions; and
 - (iii) not proceed until the patient is satisfied and convinced that he understands the benefits and risks of each alternative and he has his agreement on a particular course of action.
- **(4) Implementation of the patient charter.-** Every Private Medical Establishment shall,-
 - (i) publish the patient charter in Kannada and English;

- (ii) display the patient charter prominently and at multiple locations in the healthcare provider setting; and
- (iii) implement the patient charter in its true spirit in everyday medical practice.]1
- 1. Inserted by Act 01 of 2018 w.e.f.

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.

KARNATAKA ACT 37 OF 2012

(First published in the Karnataka Gazette Extraordinary on the Third day of September, 2012)

THE KARNATAKA PRIVATE MEDICAL ESTABLISHMENTS (AMENDMENT) ACT, 2012

(Received the assent of the Governor on the Thirty First day of August, 2012) An Act further to amend the Karnataka Private Medical Establishments Act, 2007.

Whereas it is expedient further to amend the Karnataka Private Medical Establishments Act, 2007 (Karnataka Act 21 of 2007), for the purposes hereinafter appearing;

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

- 1. Short title and commencement.- (1) This Act may be called the Karnataka Private Medical Establishments (Amendment) Act, 2012
 - (2) It shall come into force at once.

Section 3 is Incorporated in the Principal Act.

KARNATAKA ACT NO. 01 OF 2018

(First Published in the Karnataka Gazette Extra-ordinary on the 06th day of January, 2018)

THE KARNATAKA PRIVATE MEDICAL ESTABLISHMENTS (AMENDMENT) ACT, 2017

(Received the assent of Governor on the 04th day of January, 2018)

An Act further to amend the Karnataka Private Medical Establishments Act, 2007.

Whereas it is expedient further to amend the Karnataka Private Medical Establishments Act, 2007 (Karnataka Act 21 of 2007) for the purposes hereinafter appearing;

Be it enacted by the Karnataka State Legislature in the sixty-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 (Amendment) Act, 2017.
- (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 this Act.

Substitution of expressions.- For the expressions "Registration Authority" or "Registration Authorities" wherever they occur in the Principal Act, the expressions "Registration and Grievance Redressal Authority" or "Registration and Grievance Redressal Authorities" shall be substituted respectively.

Sections 2,3,4,6,7,8,9,10,11,12,15,16,19 and insertion of new Sections 9A, 11A, 11B1 19A and 19B are incorporated in the Principal Act.