**Title of the Article : A Critical Review of The Karnataka Private Medical Establishments (Amendment) Act, 2017**

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**TYPE OF MANUSCRIPT – Review Article**

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Conflicts of Interest - None

Total number of pages – 11+02

Abstract word count - 153

Word counts for the manuscript - 3521

Total number of tables – 02

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**Title: A Critical Review of The Karnataka Private Medical Establishments (Amendment) Act, 2017**

**Abstract**

Healthcare delivery in India happens predominantly through the private health care system. The private health care system has grown exponentially over the years due to many reasons. The end users prefer less to be treated in a public health system since the private health care system provides the flexibility and ease of access which the patient’s value. There is also a lack of regulations in place to ensure minimum and quality standards of care in the private health care system, such that the private systems have flourished over the years without a check. An array of regulations has been adopted by various states to ensure quality care to its residents and to prevent unscrupulous, unethical practices. Karnataka Private Medical Establishment act is one such regulation that has come up recently to ensure that the health mission of the state is addressed. The article looks to critically analyse the Karnataka Private Medical Establishment Act.

**Key Words –**

KPME Act – 2017;

Karnataka;

Private Health Care;

Public Health Care;

Health Law

**A Critical Review of The Karnataka Private Medical Establishments (Amendment) Act, 2017**

**Introduction**

In India, Right to Health is an important right under the ambit of Article 21 of the Indian Constitution and the state has a responsibility to provide and protect the health of its citizens. The state also has a responsibility to raise the level of nutrition, the standard of living and to improve public health under Article 47(1). Health professionals and Health Establishments are regulated by the Medical Council of India (MCI)(2), State Medical Council, Clinical Establishment Act(3), Medical Termination of Pregnancy Act (MTP Act)(4), Pre Conception and Pre-Natal Diagnostic Techniques Regulation and Prevention of Misuse Act (PC-PNDT Act)(5) , Surrogacy Act(6), HIV Act(7), Transplantation of Human Organs Act (THOA)(8), and Consumer Protection Acts(9). In addition to the above, Psychiatrists come under the purview of Mental Healthcare Act, 2017 (MHCA 2017)(10), Rights of Persons with Disability Act (RPWD Act)(11) and Narcotics Drugs and Psychotropic Substances Act (NDPS Act)(12). Due to the scarcity of resource like unqualified Health Care Providers (doctor; nurse; paramedical professionals) in India, there is an inability to meet the health care demands of the population. The 2005-06 National Family Health Survey (NFHS) III states that the private medical sector remains the primary source of health care for the majority of households in urban (70 per cent) as well as rural areas (63 per cent). Private doctors and private clinics are the main sources of care, catering to 46 per cent of the urban and 36 per cent of the rural households (13). The National Family Health Survey (NFHS) IV of 2014 -15 showed private sector continued to be the predominant service provider catering to 51% while the public sector caters to 45% of the health care needs. The private health sector continues to remain the primary source of health care in urban (56%) and rural areas (49%) (14). The use of the public sector for health care increased from 34 percent in 2005-06 to 45 percent in 2015-16. Even though we are in a stage of transition from the over-reliance on the private health care system, more than 50% of the health care delivery is still largely through the private health care system. The Survey on Morbidity and Health Care: National Sample Survey Office (NSSO) 60th Round, Schedule 25, January 2004 - June 2005 (15) shows the private sector today provides nearly 80% of outpatient care and about 60% of inpatient care. The NSSO estimates as much as 40% of the private care is likely to be by informal unqualified providers and out-of-pocket payments still account for a very large share of 59–71% of total health spending. Overall, the private sector has grown unprecedently. The private sector in India is also largely unregulated and urban-centric and not meeting health gaps in a rural area.

The private health care system in India has grown vastly over the years and is well established and flourishing (1).There are many instances where such private establishment run with poor infrastructure and inadequate human resources, often with under qualified or un-qualified personnel being employed for various reasons. Moreover, there are only a few regulatory agencies in place to check the costs in such setups (16). There is a need to establish certain checks through legislation, and hence the Clinical Establishments (Registration and Regulation) Act, 2010 was enacted by the Central Government under Article 252 of the constitution. Health is a subject of the state, the states are also given independence to accept the Clinical Establishment Act with or without modifications. The Act has taken effect in four States namely; Arunachal Pradesh, Himachal Pradesh, Mizoram, Sikkim, and all Union Territories except the National Capital Territory (NCT) of Delhi since 1st March 2012 vide Gazette notification dated 28th February 2012. The States of Uttar Pradesh, Uttarakhand, Rajasthan, Bihar, Jharkhand and Assam have adopted the Act under clause (1) of article 252 of the Constitution (17).Other states have a choice of implementing this legislation or enacting their own legislation on the subject. States like Karnataka, Kerala, West Bengal and Orissa implemented their own act to regulate private health care establishments in their respective states. The purpose of the Clinical Establishments (Registration and Regulation) Act, 2010, is to provide registration and regulation of clinical establishments and to prescribe minimum standards for the facilities and services, which may be provided by them. The act will be applicable to all clinical establishments (hospitals, maternity homes, nursing homes, dispensaries, clinics, sanatoriums or institutions) by whatever name called, that offer services for diagnosis, care or treatment of patients in any recognised system of medicine (Allopathy, Homeopathy, Ayurveda, Unani or Siddha), public or private, except the establishments run by the armed forces.

**Health Care in Karnataka**

The state of Karnataka is one of the pioneers in the country in providing comprehensive public health services to its people. Karnataka state established primary health unit to provide a curative, preventive, promotive and rehabilitation health to the people of the state under Karnataka State Integrated Health Policy(18); even before the concept of primary health centre was implemented by the government of India. In order to improve the health sector along with the private sector, the government of Karnataka has implemented Karnataka Private Medical Establishments (KPME) Act, 2007. The later government of Karnataka amended in 2010 and did not ratify with the Clinical Establishments Act (CEA) 2010.

Karnataka Private Medical Establishments (KPME) (amendment) Act, 2017 was amended on 27/03/2018 and draft rules were published 09/02/2018 to align and harmonize with the Clinical Establishments Act 2010 and to fulfil the health mission of the state, which is to ‘provide quality health care with equity’ in Karnataka state. The act looks to address issues like

1. High cost of Healthcare in private sector, this raises the issue of affordability and also equity
2. To ensure health care services of acceptable quality and that which prevent negligence and
3. c) To have complete information about private health sectors.

This will, in turn, help future health policy formulation for Karnataka (19). This article aims to critically review the KPME Act, bearing in mind the impact it has on service users and regulatory bodies. We will look at the arguments in favour of and against the Act.

**Salient features** of **Karnataka Private Medical Establishments (Amendment) Act, 2017**

The act provides guidelines for the registration and regulation of clinical establishments and prescribes minimum standards of facilities and services provided by them. This act will be applicable to clinical establishments where investigation, diagnosis and preventive/curative/rehabilitative medical treatment facilities are provided to the public. This includes voluntary or private establishments and is described as “Private Medical Establishments” (PME) as per the act and includes hospitals or dispensary with and without beds, nursing homes, clinical laboratory, diagnostics centre, maternity home, blood bank, radiological centre, scanning centre, physiotherapy centre, clinic, polyclinic, dental clinic or dental polyclinic. The act excludes medical establishment run or maintained or sponsored by the State or Central government.

For the purpose of determination of standards and the amount of registration fees, the PME’s are categorized based on the system of medicine practised as establishments practising an allopathic system of medicine, establishments practising Indian system of medicine, establishments practising a homoeopathic system of medicine; and diagnostic centres and therapy establishments not attached to hospitals.

Registration is mandatory for all clinical establishments and no person shall run a clinical establishment unless it is registered. The establishment has to fulfil the following conditions for being registered as a PME. The establishments are required to maintain minimum standards of facilities in terms of services and staff, as prescribed. PME is also required to maintain records and submit reports and returns as prescribed. Furthermore, the PMEs are required to provide medical examination and treatment as may be required to stabilise an emergency medical condition of any individual brought to such an establishment. The PME are mandated to charge fees within the range determined and issued by the state government for each type of procedures and services. The charges each type of service/facility provide should be displayed in local and English language conspicuously The PME will also have to ensure compliance to the standard treatment guidelines as may be determined and issued by the state government. They are also to ensure the accessibility of doctors by telephone, fax and e-mail to each patient/their attendants. The PME will also have to comply with the CME-compliance mechanism as per the Karnataka Medical Council Act as amended from time to time. They will also have to comply with other directives issued by the Government or the District Registering Authority.

Procedure for Registration: The registration is to be done by the Registration and Grievance Redressal Authority (RGRA) at each district level on application to the said authority with payment of the prescribed amount. The application is to be done online on the IT portal of Health and Family Welfare Department. The registration in Form A is to be done with Aadhaar based electronic signing. The establishments existing before the commencement of the Act will have to apply within three months from the date of the Act coming into effect. RGRA in regard with the provisions of the act 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 90 days from the date of receipts of the complete application. In case of any delay beyond ninety days, the registration shall be deemed to have been granted. Every registration granted shall be valid for a period of five years and may be renewed once in five years on an application made in such form and in such manner, on payment of such fees, as may be prescribed.

The RGRA 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. In case the PME fails to comply with any of the directions given by the RGRA under said act, 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 and opportunity of being heard.

The act also prescribes punishments for not complying with the clauses its clauses. Running a clinical establishment without registration is punishable with imprisonment for a term which may extend to three years and with a fine of one lakh rupees (Sec-19). In case of violation of provisions of the Act, such as Registration conditions, Section 12 (Maintenance of medical records) or sec 13 (Obtaining information), the first time violations have a penalty of Rupees 25000 and Rupees 50000 for the second or subsequent violations. Other violations of the provision of the act or rules other than above mentioned will involve punishment of 1 Lakh rupees. In case of lodging frivolous and vexatious complaints, the RGRA can prescribe a penalty of up to Rupees 1000.

“Patients Charter and Private Medical Establishments Charter (PMEs)” means the rights and responsibilities of the patients and the PMEs as specified in the schedule S of the Act. The same shall be displayed in such place easily accessible to the public at PMEs. There are certain obligations cast on the PMEs. In case of emergencies, the PME must provide necessary first aid, lifesaving or stabilizing emergency measures in all medico-legal or potentially medico-legal cases without insisting for any advance payment. PME must hand over the body immediately without insisting on prior payments of dues.

**KPME Act, 2017 sections in line with addressing the health mission - ‘Provide Quality Health Care with Equity in Karnataka**

The description of PME includes not only Allopathic establishments but also another stream of health care delivering systems like Ayurveda, Unani, and Homeopathic. This establishes a single window for their registration and monitoring in health care in the private sector. Compared to previous Act of 2007, it also includes single/multiple consultation clinics, blood banks, counselling centres etc. thereby establishing a uniform platform in monitoring and curtailing the quackery deep-rooted in the health care system of our country. The Act also mandates PME’s to provide life-saving measures without taking advance payment and extends it to medico-legal cases or potential legal case. This enables victims of accidents to receive services in life threating situations without any hindrance. This also indirectly encourages shifting of patients in such circumstances to the hospital for treatment by the first contact person.

Prescribing the minimum standards for private establishments in terms of infrastructure, human resource and display of the mode of the practices in such setup can improve the patient care and reduce the liabilities on the establishments. The RGRA constituted under the said act consists of one government administrative officer along with two government medical professionals (one from the allopathic system and other Ayush system). It also included two others, one from the Indian Medical Association and another from another medical association. This would ensure adequate representation for the private medical establishments. The Act also curtails the frivolous and vexatious complaints by capping fine (up to Rs.10, 000) for such false claims.

**Table 01: Summarising key favourable points in line with addressing the health mission of Karnataka - ‘Provide Quality Health Care with Equity in Karnataka’**

**KPME Act 2017, a section not in line with addressing the health mission - ‘Provide Quality Health Care with Equity in Karnataka**

The act does not include government setups and military establishments, despite recommendations to include such establishments also under the preview of the act by the Vikramjit Sen committee appointed by the government. Why should the public system not comply with the minimum standards? Are the authorities worried that the public health system will fail to meet the minimum standards as prescribed by the Act? Instead of putting a cap on the private sector, the Government could have taken adequate measures to improve the public health sector so that it could deliver services to the population. The roles and the function of RGRA have been defined in Section 8 of the amended Act. The function of RGRA is to conduct an enquiry on the complaint regarding the Non-compliance of Patients Charter or PME Charter. This means that both the patients and the PMEs can lodge a complaint. However, if the complaint to RGRA pertains to negligence, non-adherence to standard protocols of treatments, procedures and prescription audits, it shall be referred to Karnataka Medical Council (KMC) for submitting a report after enquiry. The scope of this Authority is restricted only to enquire about non-adherence of charters, proper conduct of business by hospitals in line with the Acts and Rules, enquiries into excessive charges and also to levy penalties in proved cases.

**Table 02: Summarising key section of KPME Act 2017 not in line with addressing the health mission - ‘Provide Quality Health Care with Equity in Karnataka**

**KPMEA, 2017 Sections which could increase the health gap due to Defensive Practice by Private Sectors**

The act mandates the right to receive treatment in case of emergency, without being asked for Advance Payments by patients. This is because the emergency treatment to safeguard the life of the person is a far more important issue than making payments. However, the law does not address the issue of inability to pay or the provisions to be implemented in such case after seeking emergency care. The state is looking to be absolved of its responsibility to address issues of financial constraints resulting in non-payment and only serves as a pivotal bridge to smoothen treatment process by linking the treatment seeker to the hospital.

**KPME Act in comparison to the Clinical Establishment Act 2010**

Government of India (GOI), enacted the Clinical Establishment Act which brings both the public and private establishments under its ambit to improve health care systems. The GOI recommends that each state adopt the Clinical Establishment Act of 2010 or enact a law that is similar in nature. KPME Act is enacted by the Government of Karnataka in line with the Clinical Establishment Act, 2010 in the following aspects: minimum standard of facilities and service; excluding defence hospital; state and national register of clinical establishment; annual reporting data; district authority; penalty; standard treatment guidelines; digital data recording and display of charges but differs from it in certain aspects. The KPME Act has excluded both public hospitals and defence establishments and has made these establishments non- accountable in its functioning. KPME Act has a broad-based, comprehensive representation in the RGRA for private establishments. Clinical Establishment Act does not talk about a grievance redressal mechanism with representation for all stakeholders in health care delivery. KPME Act also regulates vexatious complaints by charging a penalty for the same, whereas the Clinical Establishment Act is silent in regards to vexatious complaints. The penalty although minimal is an effective way to curb vexatious complaints.

KPME act made private medical establishments’ responsible for collection, compilation and sharing of all the data pertaining to National Programmes especially RCH Programmes Communicable and Non Communicable Diseases to better the Government data base. It is advisable for the Government to make a digital solution and interfaces for data sharing with private health system through public – private partnership.

KPME act mandated private medical establishments’ to display a Citizen’s Charter explaining the patient’s rights and responsibilities. The doctor’s responsibilities should be exhibited in the lobby or in a prominent place in the hospital in languages like english, kannada & national language.

KPME Act has a provision for mandatory requirement for registering the private medical establishment and has to give an undertaking to provide details of the staff and facilities available and medical examination and treatment as may be required to stabilize the emergency medical conditions of any individual brought to any such establishment

**The way forward of KPME Act 2017**

The private medical establishment act of 2017 which governs the private health sector will bring about a uniform platform for the registration and monitoring of the establishment. This would pave the way to curtail quackery, which is deep rooted in our country. However, the act puts a cap on the income generated through private practice. This could result in private establishments going on the back foot since the minimum charge criteria could lead to:

1. Migration of the specialists
2. The closing of the small clinics (State government policies will continue to levy income tax and taxes on water and electricity, without any benefits for these establishments).

This can be an aggressive step and will also hamper medical tourism involving international patients. This is paradoxical since, on one hand, this welcomes international patients without any support from the government, but on the other hand, will also bring down the medical tourism since the number of establishments providing care could decrease.

Medical professional revolves around the ethical guidelines of the Hippocratic Oath of 376Bc. Once the law comes into the interface of medicine, ethical empathetic clinical practice will suffer due to over-reliance on documentation.

The lack of extensive and adequately funded public health services push a large number of people to incur heavy out of pocket expenditures on services purchased from the private sector. Out of pocket (OOP) expenditures arise even in public sector hospitals, since the lack of medicines would force patients to buy them from outside pharmacies. This results in a financial burden on families in case of severe illness (20). OOP can be reduced only by increasing public expenditure on health and by setting up widespread public health service providers (21). There is also a need to focus on the health care education models and private practice and bring about changes which include:

1. Providing subsidies in medical education and removing the capital or donation for health education in the private sectors so that future doctors are not burdened by loan/debts when they enter into the practice.
2. Making provisions for providing various benefits to start a private practice like an income tax rebate, subsides in land values for starting clinics and for residential homes. This will make a huge difference in terms of the cost while providing service to the people.

**Conclusion:**

Regulating the private practice is a step forward but this should not be at the expense of functioning existing systems. This should also not create roadblocks for people who are inclined to take up a private practice and provide a quality of care to patient who can afford the service. Many states have come up with their own regulatory legislation for the Clinical Establishments in the private sector. This makes it difficult for practitioners from one state to move to an area of need in another state, considering the need to change the mode of practice. Adapting and changing their ways of practice every time will prove to be detrimental to the practice of medicine in the country. There is a need to have a central uniform regulatory guideline for states across India and also invest on public health and enable public health sector to provide quality care at far with international standard to have a healthy competitive manner with the private health sector.

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| Relevant Sections | Point in favour of addressing the health mission ‘Provide Quality Health Care with Equity in Karnataka |
| Definition of PME | Includes Allopathy, Ayurveda, Unani, Homeopathy Establishments, blood banks, counselling centres, |
| Uniform platform to monitor all establishments |
| Helps curtail quackery |
| Emergency Treatment provisions | Provide lifesaving treatment without taking advance payment |
| Enables victims of accidents to get treatment and also |
| Encourages shifting of accident victims by first contact person |
| Prescribing Minimum Standards in infrastructure and human resources | Improves patient care. |
| Reduces liability on the establishments |
| Constitution and role of RGRA | Adequate representation to the doctors and private establishments |

**Table – 01 summarising key favourable points to address the health mission ‘Provide Quality Health Care with Equity in Karnataka**

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| Definition of PME  **Table 02: Summarising key section of KPMEA 2017 not in line with addressing the health mison - ‘Provide Quality Health Care with Equity in Karnataka** | Does not include Public Health Establishments |
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| Minimum charge criteria | Leads to the migration of the specialists, closing of small clinics. A decline in the quality of care. |
| Emergency Treatment provisions | Leads to the financial strain of providing care without taking advance payments in the long run. |
| Constitution and role of RGRA | Reduced to a body that conducts enquiries into non-adherence of charters, proper conduct of business by the establishments, regulate charges and levy penalties.  Leads to over-reliance on the state medical council leading to delays in adjudicating complaints. |
| Patient Charter | Generic prescriptions can lead to a distribution of brand which is sub-par. |
| Clinical protocol recommendations by the Expert Committee | Restriction on the freedom to treat patients since treatment has to be in accordance with the protocols prescribed by the Expert committee even if the currently practised protocol is of a higher standard than the recommended one. |
| Private Medical Establishment Charter | Scheduling of appointments in the Indian context will be difficult considering the volume of patients and low doctor-patient ratio in our country.  Over-reliance on documentation |
| Clinical Laboratories | Restriction of laboratories within 200 metres without any reference points for the measurement.  No clarity on the legality of laboratories close to hospital but functions as a part of existing clinics or nursing homes. |