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Medical Ethics & the Clinical Establishments (Registration and Regulation) Act, 2010 of India: A Perspective

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Abstract: **Medical ethics have deep impact on patients, physicians and health care institutions. Despite the prevalence of 'Code of Medical Ethics' as prescribed by the Medical Council of India, several gaps exists in regulating behaviors of doctors in interest of patients. To bring improvement in public health and doctor patient relationship, in 2010, the Clinical Establishments (Registration & Regulation) Act was enacted. This paper is an insight into the provisions of the said legislation as to find out how far it has helped in plugging the existing loopholes in the medical profession in India.**

Keywords: **Clinical, Doctor Patient Relationship, Healthcare, Medical Ethics, Public Health.**

1. INTRODUCTION

Public health is a State subject under the Constitution[i] which makes primarily the State government responsible to adopt measures for regulating health clinics, hospitals in India. Incidentally, all States, since 1950, did not find it necessary to take steps in this direction.[ii] Due to growing reports of unethical practices within highly privatize healthcare system as well as the complete failure of self-regulatory system of medical councils, led to nation wide discontent and unrest amongst people including health workers. The present paper analyses the reasons behind the need for such enactment of the Clinical Establishments Act, 2010 by the Parliament and evaluate its effectiveness.

2. BACKGROUND & NEED FOR THE SAID LAW

The said National legislation has emerged from a patient's rights movement of 1980s. This movement, not only, highlighted the growing incidents of unethical medical practices, but also drew on a campaign regarding deteriorating standards in private medical establishments.[iii] They approached the consumer courts under Consumer Protection Act (CPA) for relief against medical negligence and malpractices on the ground that medical treatment was essentially a consumer service. Their movement, despite the opposition from Indian Medical Association (IMA), received a boost when the Supreme Court, in a landmark judgment of 1995, held that the CPA does apply to the medical profession.[iv] In this backdrop, the Clinical Establishment (Registration & Regulation) Act 2010 (hereinafter referred as the 2010 Act) was enacted with an objective to provide for the registration and regulation of clinical establishments in order to prescribe minimum standards of facilities and services, so that the mandate of article 47 of the Constitution for improvement in public health may be achieved.[v] The Act has been enacted under Article 252 of the Constitution, after resolutions have been passed by legislatures of the States of Arunachal Pradesh, Himachal Pradesh, Mizoram & Sikkim to this effect that they should be governed by law enacted by the Parliament in this regard. Along with these States, this Act also is made applicable to the Union territories, whereas other States have been given choice of implementing this legislation by passing a resolution under article 252(1) of the Constitution.[vi]

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3. SALIENT FEATURES

1. The Act is applicable to all 'clinical establishments' which includes hospital, maternity home, nursing home, dispensary, clinic, sanatorium or institution by whatever name called that offers services, facilities for diagnosis, treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognize system of medicine established and administered or maintained by any person or body of persons, whether incorporated or not. It shall also include a clinical establishment, which is owned or controlled or managed by the Government or department of the Government or by a trust, whether public or private or by a corporation, which includes society, registered under a Central of State Act. Even an establishment owned, controlled or managed by a local authority or a single doctor is also covered in it. But, this Act does not include the clinical establishment run by the Armed Forces.[vii]

2. Registration is mandatory for all clinical establishments and for that, the establishment has to fulfill the following conditions:

i. the minimum standards of facilities & services as may be prescribed;

ii. the minimum requirement of personnel as may be described;

iii. Provisions for maintenance of record and reporting as may be prescribed.

iv. Such other conditions as may be prescribed.[viii]

3. Under section 12(2), every clinical establishment shall give an undertaking to provide within the staff and facilities available, such medical examination & treatment which may be required to stabilize the emergency medical condition of any individual who comes or brought to any such establishment.[ix]

4. Every clinical establishment will charge the rates for each type of procedure or service within the range of rates determined & issued by the Central Government in consultation with the State Government. The rates charged for each type of service/facility shall be displayed in English and local language conspicuously.[x]

5. Every establishment shall ensure compliance of the standard treatment guidelines as may be determined & issued by the Central or the State Governments in this regard. Every establishment shall also maintain and provide digital health records of every patient in the format, as may be prescribed by the Central or State Government.[xi]

6. Procedure for registration of every clinical establishment is also prescribed. An application for this purpose shall be made within one year from the date of commencement of this statute and in case any clinical establishment comes into existence after the commencement of this Act, it shall apply for permanent registration within a period of six months from the date of its establishment. The registration will be done by the District Registering Authority (Distt. Health Officer) and the provisional registration will be issued within 10 days of submission of application as prescribed, without any inquiry or inspection. Every provisional registration will be renewable annually and it will be non transferable.[xii]

7. Every provisional registration will remain valid up to two years from the date of notification of standards in case of establishments that existed before the notification of the standards and up to six months of notification of standards in those cases where establishments came into existence after the notification of standards.[xiii]

8. Certificate of permanent registration will be granted for a period of 5 years on submission of application along with fees and evidence of compliance with prescribed standards. The particulars of the applicant will be published for information of and objections, if any, by the public within 30 days. In case, any objections are received, the same will be communicated to the clinical establishment for a response within 45 days.[xiv]

9. The registering authority can cancel the registration of any clinical establishment in case it is satisfied that there is violation of the condition of the registration or the person interested with the management of such establishment has been convicted of an offence punishable under this statute. This action will be taken after issuing a show cause notice to such establishment so to explain within 3 months time as to why its registration should not be cancelled for the reasons as mentioned in the notice. After giving reasonable opportunity to such establishment, if the authorities are satisfied that there has been a breach of any provisions of the Act or the Rules made thereunder, it may cancel its registration by an order to this effect. After cancellation of registration for reasons to be recorded in writing, the authority can restrain immediately such establishment from carrying on its functions if there is imminent danger to the health and safety of the patients.[xv]

10. Every order of cancellation of registration shall take effect immediately in those cases where no appeal has been preferred against such order within the stipulated time period and where appeal has been preferred but is dismissed; the cancellation order shall take effect from the date of the order of dismissal.[xvi]

11. The registering authority is required to compile, publish and maintain in digital format a register of all clinical establishment, which are registered by it within a period of 2 years from its establishment. The said authority shall apply to the State Council of clinical establishments a digital copy of every entry made in the register. And the State Council, in turn, will provide the details to the Central Council so as to keep the record updated at all times. Similarly, every State Government as well as the Central Government shall maintain digital register of all clinical establishments at State level and National level respectively.[xvii]

12. The Act also provides various penalties for contravention of its provisions. Running of a clinical establishment without registration shall be punishable with a fine up to 50,000/- for the first offence, up to Rs. 2 lacs for the second offence and for any subsequent contravention penalty up to Rs. 5 lacs shall be imposed. Any person, who, knowingly serves in an unregistered clinical establishment shall also be punished with a fine up to Rs. 25,000/- . Any willful disobedience of lawful direction or obstruction to lawful authority or refusal to submit an information which is asked for by such authority or giving false information knowingly, shall also be punishable with a monitory penalty up to Rs. 5 lacs. In case anyone contravenes any provision of this Act or any rule made thereunder which results in minor deficiencies, not posing an imminent danger to the health and safety of any patient and which can be rectified within a reasonable time, nonetheless, shall be punishable with the fine up to Rs. 10,000/. While determining the quantum of monetary penalty, the authority shall take into account the category, size and type of clinical establishment along with local condition of the area where it is situated.[xviii]

13. In case any company (hospital) has committed violation of any, of the provision of this statute or of any rule made thereunder, then every person who was in charge of or was responsible for the conduct of the business of the company at the time of the said violation, shall be held guilty and liable to fine under section 44. The provisions of section 44 and punishments would be equally applicable to Government departments under section 45.[xix]

14. In case, whosoever, is found guilty of the offence, if fails to pay the fine, then the State Council may prepare a certificate duly signed by an officer authorized in this regard, specifying the fine due from such persons and send it to the District Collector where such person reside or carries on his business or owns any property and the said Collector on receipt of such certificate, shall recover from such person the said fine, as if it were an arrear of land revenue.[xx]

15. The implementation of the provisions of the said Act is to be affected through a 3 tier structure namely the National Council, the State Council and the District Registering Authority. The compositions of such authorities along with their functions are provided within the Act.[xxi]

4. CRITICAL APPRAISAL

1. Although, this new Act is a blanket legislation, making it mandatory for all types of clinical establishments, of all recognized systems of medicine,[xxii] public or private, to get registered by District Registering Authority, yet, it exempts the establishments run by the Armed Forces from the said purpose. Reasons for such exemption has not been explained. Moreover, this being the Central legislation, the States, which already have their own law in this regard (9 States as mentioned in the schedule to the Act) and make the registration mandatory only for the hospitals and nursing homes and not for the clinics, dispensaries etc. and apply only to allopathic system of medicine, their law being contradictory to this new central legislation, will defeat its very purpose.

2. Meeting the prescribed standards for different types of establishments under different system of medicine is very difficult to be implemented, having both cost implications and undue harassment by the authorities. This is one of the reasons that this legislation is being resisted by private clinics who apprehends the return of inspector raj. Monitoring the compliance with the standards by hundreds of thousands of establishments also require an army of officials, making its enforcement a mammoth task.

3. Although, maintenance of electronic health records and electronic medical registers of every patient appears to be a good idea, in principle, but it also put additional work load and cost for clinical establishments. Further, a large percentage of the physicians, especially those belonging to Indian systems of medicines, such as Naturopathy, Yoga etc., may not be computer savvy or even if they are, they may not be able to maintain such digital record due to the expenditure being higher than their income.

4. While confirming to the prescribed minimum standard, their may be a lot of difference between the standard of facility and expertise provided by the establishments, catering to the different locations, clients, standards, expectation, the paying capacity of clients. Hence, every clinical establishment should have the freedom to determine the charges for the services provided by it and Government should not try to regulate the charges for services.

5. Development of the minimum standard of and their periodic review by the Government for ensuring proper health care by the clinical establishments, in principle, appeal to be a good idea, but such guidelines can be acceptable only as long as they are limited to broad principles of health care, life threating emergencies or treatment of major public health problems such as T.B., AIDS etc. Otherwise doctors should have adequate freedom to decide as per their learning and experience, which modality of treatment is to be used in the given situation, in broad compliance with their professional protocols.[xxiii]

6. Publishing the particulars of the clinical establishment for public comments/objections, after grant of provisional registration does not appear to be a sound idea, according to medical professionals. Reason being that the public will have no clue about the technical aspects or standards of newly established clinical establishment and there is minimum likelihood of the local community to come forward with any meaningful comments in this regard. Nevertheless, we can not deny the importance of periodic feedback or comments from public about the quality of the service provided by the establishments which are registered permanently because their renewal will become due after 5 long years, which is quite reasonable time to judge the functioning standards of any such establishment.[xxiv]

7. It is also apprehended that, the present Act, and the clinical establishments (Central Government) Rule 2012, as notified, are sponsored by corporate lobbies to promote "corporatization" of the entire healthcare management system in the country. The very impact of this corporate friendly laws will lead to forcible closure of all small and medium clinical establishments that provide reasonable and low cost treatment and surgery to the common man. Requirement of stringent enforcement of safety regulations and quality control is required in large hospitals dealing with large number of patients. But for small scale clinics, it is not financially viable as in such small establishments the doctor himself is the administrator, quality control officer, pharmacists and even some time driver of the ambulance. Therefore, need is to frame separate rules for the small clinical establishment s keeping in mind their services as healthcare providers in the society.

8. The new Act is also confusing as it does not segregate different systems of medicines and is against medical ethics. For example, as per law, Unani, Ayurveda and other doctors practicing in Indian system of medicines cannot use Allopathic drugs. If they use these drugs in emergency, they will be contravening the Supreme Court judgment of *Poonam Verma* v. *Ashwin Patel* [xxv] where the court held that without registration either with Medical Council of India or the State Medical Council as required under Indian Medical Council Act 1956, no one can practice in allopathy.

5. CONCLUSION

Despite the afore-said lacunae, the said Act is a positive piece of social legislation the need for which was being felt since long. Registration without any inquiry or inspection, on the basis of the documents submitted by the establishment, should encourage many private clinics/nursing homes to come forward to get registration under this law. The drawback, as compared to the advantages, is not very gross and can be rectified keeping in mind the interests of small establishments. Once in place, the system of registration will necessarily help not only in improving the standards of healthcare establishments but also will bring about some uniformity in the standards of healthcare throughout the country. Most importantly, it will help in identifying the hundreds of thousands of quacks that are playing havoc with the lives of millions of ignorant Indians. Maintenance of National & State register of clinical establishments would be a great achievement as it would help in the country wide planning and posting of physicians as well as of healthcare establishments. It would act as the first ever-factual census of the number, category, specialty and location of all the physicians and all the clinical establishments of different systems of medicine in the country. Currently, there is no exact authorized data available in this regard.

To conclude the afore-said Act is the most important public health legislation with far reaching effects. It should be welcomed by medical professionals and they should not fear of its being abused by the authorities against them. We are leaving in a globalized competitive world and to promote medical tourism in India also, we need this type of legislation, which can monitor periodically the functioning of clinical establishments with an objective to provide better healthcare facilities to the people. All the lacunae, if addressed and removed, then medical professionals should welcome it, rising above their vested interests, by thinking of larger public interest.

END NOTES

[i] The Constitution of India schedule 7, List II, entry 6 deals with public health, sanitation, hospitals & dispensaries.

[ii] The Bombey Nursing Homes Registration Act, 1949, West Bengal Clinical Establishment Act, 1950, The Punjab State Nurssing Registration Act, 1991, The Madhya Pradesh Upcharya Griha Tatha Rujopchar Sambandhi Sthapnaye Adhiniyam 1973, The Orisa Clinical Establishments (Control & Regulation) Act 1990, The Manipur Nurssing Homes & Clinics Registration Act 1992, The Nagaland Healthcare Establishment Act, 1997 & The Andhra Pradesh Private Medical Care Establishments (Registration & Regulation) Act 2002. All these States statutes regulate the private clinics/hospitals. available at http://www.indiamedicaltimes.com/2013/11/18/qa-clinical (accessed on May 5, 2014).

[iii] In 1989 Mr. Tavaria died due to mismatched blood transfusion in Mumbai hospital, where the person on duty at that time was a homeopath. His daughter, Yasmin Tavaria, along with the health group Medico Friend Circle, approached the Bombay High Court seeking details on the implementation of the Bombay Nursing Homes Registration Act 1949. Surprisingly, they learnt that many of these institutions were operating without registration, inspection were rare and in the absence of rules for the implementation of the provision of the said Act, no punishment had been given in case of violation of the law. On the direction of the Bombay High Court, the committee was set up in1992 and its report was shocking in all respects regarding the functioning of such clinics from crammed, overcrowded and dilapidated building with dirty toilets and no running water. Moreover, not only the nurses were unqualified, resident doctors were also from other systems of medicines and most of these establishments were not even registered under the law. This led to the amendment of BNHRA in 2005. (S.Iver "Who' ll answer for private hospitals?" The Times of India, 23rd July, reprinted in mfc bulletin. Available at http://www.mfcindia.org/mfcpdfs (accessed on April 24, 2014).

[iv] *Indian Medical Association* v. V.P. *Shantha & Others* (1995) 6 SCC 651. The bench comprised of Hon'ble Justice Kuldeep Singh, S.C. Agarwal & B. L. Hansarria JJ. Para 7 at 660.

[v] The Clinical Establishments (Registration & Regulation) Act, 2010 received the assent of the President on 18th Agust 2010 and published in the gazette of India. The said law has been enacted by parliament under Articles 249 & 250 of the Constitution.

[vi] *Id* Ch. 1 s. 1. Different dates can be appointed for different categories of clinical establishments and for different recognized systems of medicine. The Act has 7 chapters, 56 Sections & Schedule1. Section 56 refers to the States which are exempted from the provision of this 2010 Act due to having their own laws in this regard..

[vii] *Id* s. 2(c). Clinical establishment also includes a place which is established either as an independent entity or part of an establishment such as hospitals etc. where diagnosis or treatment of diseases through genetic, pathological, radiological or investigative services with the aid of laboratory or other medical equipment are carried out.

[viii] *Id.* s. 2(j) defines 'registration' which means to registered u/s. 11 & the expression registration or registered shall be construed accordingly. Also see SS. 11 & 12.

[ix] *Id.* s. 2(d) defines 'emergency medical conditions' which means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) of such a nature that the absence of immediate medical attention could reasonably be expected to result in- (i) placing the health of the individual or with respect to pregnant women, the health of the women or her unborn child, in serious jeopardy; or (ii) serious impairment to bodily functions; or (iii) serious dysfunction of any organ or part of a body.

[x] S.K.Joshi, "Clinical Establishment Act, 2010: Salient Features & Critical Analysis" available at http;//www.indiamedicaltimes.com/2013/07/10 (accessed on April 2, 2014).

[xi] *Ibid.* Every establishment shall maintain information and statistics in respect of all other applicable laws and rules thereunder.

[xii] *Supra* note 5 Ch. 4 SS. 14-20. The clinical establishment must display at a conspicuous place in the establishment certificate of registration, visible to everyone visiting there. And incase of loss of certificate due to any reason, the duplicate certificate shall be issued by the authority on the request of the clinical establishment and on the payment of such fees as may be prescribed.

[xiii] *Id.* s. 23. U/s. 22. The application for renewable of registration must be made before the expiry of the provisional registration.

[xiv] *Id.* ss. 24-30.

[xv] *Id.* s. 32. U/s. 33 the registering authority also has the powers of inquiry and inspection or entry and search of any registered clinical establishment, its building, laborites, equipment etc.

[xvi] *Id.* s. 32(3).

[xvii] *Id.* Ch. 5 SS. 37-39.

[xviii] *Id.* Ch. 6 SS. 41-43. U/s. 40 whoever contravenes any provision of this Act for which no penalty is provided elsewhere, shall be punished with a fine up to Rs. 10,000/- for the first offence, up to Rs. 50,000/- for the second offence and up to Rs. 500,000/- (5 Lacs) for subsequent offence. No person can be punished without an inquiry giving him reasonable opportunity of being heard. And any person aggrieved by the decision of the authority can file an appeal to the State Council within a period of 3 months from the date of the said decision, in the manner as prescribed by the Government for filing of appeal in this regard.

[xix] *Id.* s, 45(1) States where an offence under this Act has been committed by ant department of Government within a period of 6 months after the commencement of this Act, the Head of the Department shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly. Proviso to 45(1) exempts such head of the department from punishment if he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent commission of such offence. Under Section 45(2) if it is proved that the offence has been committed with the consent or connivance of or attributable to ant neglect on the part of, any officer, other than the head of the department then such officer shall also be deemed to be guilty of that offence and be punished accordingly.

[xx] *Id.* s. 46.

[xxi] *Id.* Ch. 2 SS. 3-7 (National Council for Clinical Establishments); Ch. 3 SS. 8-13 (Registration & Standards for State Councils & District Registering Authority)

[xxii] *Id.* s 2(h) defines "Recognised System of Medicine" which means Allopathy, Yoga, Natuopathy, Ayurveda, Homeopathy, Siddha & Unani system of medicine or any other system of medicine as may be recognized by the Central Government.

[xxiii] *Id.* s. 5 (c) & (d).

[xxiv] *Id.* s. 30.

[xxv] 1996 SCC (4) 332. This judgment was delivered by Justices Ahmad Saghir S. and Kuldeep Singh. The case pertained to use of allopathic system of medicine by homeopathic doctor resulting in negligence in the treatment of the patient who was to be shifted in a critical condition to Hinduja Hospital where he died at a young age of 35 years leaving behind widow, 2 children and parents. The court allowed the appellant a sum of Rs. 3 Lacs to be paid by the respondent doctor along with the cost. (also see *Mukhtiar Chand & Others* v. *State of Punjab & Others* (1998) 7 SCC 579.