

Review Article

Clinical Establishments Act to Check Quality of Health-care Delivery System in India

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ABSTRACT

Introduction: Quality of care provided by the health-care delivery system has come into sharp focus in most of the countries including India. As the quality in health-care delivery system is a crucial factor, so, initiatives to address quality healthcare have become an issue. **Methods:** The Clinical Establishment Act was reviewed and analysed. **Discussion:** According to planning commission, human resource and health, India has 250 health workers per lakh population. The target of WHO is 500 per lakh population. There is a huge demand of medical professional against its production. Under these circumstances, however justified, to check the quality health-care services throughout the country is a huge task. Moreover, current pattern of the health-care delivery system does not provide enough incentives for improvement in efficiency. The mechanisms used to produce greater efficiency, accountability, transparency and more responsible administration in hospitals are yet to be deployed in India. **Conclusion:** Under the present circumstances, there is a need to establish regulatory bodies and systems to monitor clinical and non-clinical establishment and the services offered in the public and private facilities.

Keywords: Health-care system, India, Legal obligations, Check quality, Registration of clinics, Uniform standard

INTRODUCTION

Once upon a time, doctors were considered to be above human, next to God. But now, corruption and unethical practices in the medical profession have become the shocking reality and a first-hand account of the present-day society in the current health-care system. It is a crisis so distinguished by its galactic costs and limited quality care that it affects nearly every person in the country.

In India, concerns have been raised frequently by the common public and a large variety of investors, including government, professional associations, private providers, agencies financing healthcare and insurance companies and others, about how to improve the quality of present health-care delivery system. There also have been attempts to launch techniques and process that would guarantee quality services by the health-care providers^[1].

This review paper has tried to lay out the importance of the 'Clinical Establishments Act' to check quality of health-care delivery system in India and to bring general awareness among the medical establishments and so on.

WHY DO WE NEED ETHICS AND LAW?

With the increased commercialisation of health-care services in India, the well-heard proverb 'Health is Wealth' is almost fully changed from the 'Physical Wealth' to 'Material Wealth'. In today's world of modernisation, doctors have turned materialistic; a doctor pays more attention to his fees rather than caring for a patient's life^[2]. In fact, the facility of healthcare is still a distant dream for the common and poor people in India.

The awareness of medical negligence is on the rise in India, and doctor-patient relationship has strained

considerably leading to the increasing number of malpractice suits^[3] which are somewhat related to the infrastructures and quality of the service. As long as doctors maintain the ethics, there will be no problem, but if they violate it, law comes in force and violation of law is costlier as no one is above the law. Therefore, legislation or imposition of legal restrictions, where all the clinical establishments must follow all the legal requirements, is necessary to come up.

To curb the so-called unnecessary operations, consultation abuses, insurance fraud, sexual harassment, high cost of sub-standard services, this act was formulated. These facts not only reveal the rapacity, egotism, malpractice, sex, power and suffering but also include remarkable portraits of hope, happenings and a deep desire for change. Hence, a major reform in the health-care system is suggested that would drastically reduce costs and dramatically combat waste, fraud and practitioner's abuse while improving the quality of primary healthcare. Therefore, the Clinical Establishments Act, 2010 has come up to standardise the facilities all over India.

THE CLINICAL ESTABLISHMENTS ACT, 2010

The Clinical Establishments (Registration and Regulation) Act, 2010 has been enacted by the Government of India to provide for registration and regulation of all clinical establishments in the country with a view to prescribing the minimum standards of facilities and services provided by them^[4].

As per a report submitted by the Government of India, planning commission, namely 'clinical establishments, professional services regulation and accreditation of health-care infrastructure' for the 11th Five-Year Plan^[4], health regulation in India encompasses a variety of factors and issues. These include promulgation of legislation for health facilities and services, disease control and medical care, human power (education, licencing and professional responsibility), ethics and patient's rights, pharmaceuticals and medical devices, radiation protection, poisons and hazardous substances, occupational health and accident prevention, elderly, disabled and rehabilitation family, women and child health, mental health, smoking or tobacco control, social security and health insurance, environmental protection and nutrition. Hence, the report highlighted for the need of a central legislation for registration of clinical

establishments in the country, and uniform standards need to be developed for the entire country.

Objective of the Act^[4]

To mandate registration of all clinical establishments. All diagnostic centres and single-doctor clinics across all recognised systems of medicine both in the public and private sectors. Establishments run by the defence forces are not included.

Responsibilities of Registering Authority

It facilitates policy formulation, resource allocation and determines standards of treatment. The registering authority can impose fines for non-compliance of the provision of the act.

The act defines the 'Standard Treatment Guidelines' for common disease conditions, for which a core committee of experts has been formed. Further, the act makes all clinical establishments both in the public and private to provide medical care and treatment essential to stabilise any individual who comes or is brought to the clinical establishment in an emergency medical condition, particularly women who come for deliveries and accident cases^[4].

IMPLEMENTATION OF THE ACT

The Clinical Establishments (Registration and Regulation) Act, 2010 has been enacted by the Central Government to provide for registration and regulation of all clinical establishments in the country with a view to prescribe the minimum standards of facilities and services provided by them. The act has taken effect in four states of India, namely Arunachal Pradesh, Himachal Pradesh, Mizoram and Sikkim and all Union Territories except the NCT Delhi since 1 March 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.

AN OVERVIEW OF THE ACT

The state has the responsibilities under Article 47 of the Constitution for aiming at improvement in public health. The state has to consider this responsibility as among its primary duties in particular and shall endeavour to bring about prohibition of the consumption of intoxicating drinks

and of drugs which are injurious to health except for medicinal purposes.

Therefore, the Government of India enacted this act with the objective to provide for the registration and regulation of clinical establishments in India and for matters connected therewith or incidental thereto.

The act defines 'Clinical Establishment' and bring under the ambit of clinical establishment all hospitals, maternity home, nursing home, dispensary, clinic and so on or an institution by whatever name called that offers services, facilities requiring diagnosis, treatment or care for illness, injury and many more or a place established as an independent entity part of an establishment in connection with the diagnosis or treatment of certain diseases. It also includes a clinical establishment which is owned, controlled and managed by government or a department of the government, a trust, a corporation registered under a central, provincial or state act, a local authority and a single doctor^[4].

THE NATIONAL COUNCIL

The act lays down establishment for a council body called 'The National Council' for clinical establishment which is responsible primarily for setting up standards for ensuring proper healthcare by the clinical establishment and develop the minimum standards and their periodic review.

CLINICAL ESTABLISHMENTS AND PROCEDURE FOR REGISTRATION

Section 11 of the act mandates that no person shall run a clinical establishment unless it has been duly registered in accordance with the provisions of the act.

In September 2014, the Government of India, the Ministry of Health and Family Welfare^[5] issued the application format for Permanent Registration of Clinical Establishments which requires the applicant to provide information such as, among others, establishment details, types of service, system of medicine and so on.

MINIMUM STANDARDS TO BE FOLLOWED

Further, Section 12 of the act lays down that for the registration and continuation of a Clinical Establishment, such clinical establishment shall fulfil the conditions, namely

- a. the minimum standards of facilities and services
- b. the minimum requirement of personnel
- c. provisions for maintenance of records and reporting
- d. such other conditions as may be prescribed.

The minimum standards for hospitals are implemented on the basis of level of care provided by such hospitals.

Recently, in September 2014, the National Council for Clinical Establishments under the Chairmanship of Director General of Health Services, Government of India in consultation with various stakeholders, has prepared following draft documents with the objective of implementation of the Clinical Establishments Act^[6,7]:

1. Application format for Permanent Registration of Clinical Establishments
2. Minimum standards
3. Formats for collection of information and statistics
4. Template for display of rates
5. Standard treatment guidelines of Ayurveda.

Accordingly, the draft document issued by the government this draft^[6] divided hospitals into four levels, namely:

Hospital Level One

The level-one hospitals are the primary health-care services provided by qualified doctors. It includes services such as general medicine, paediatrics, first aid to emergency patient, out-patient services, obstetrics and gynaecology, non-surgical and minor surgery and have a bed strength of not more than 30 which can be provided through trained and qualified manpower with support or supervision of registered medical practitioners with the required support systems for this level of care.

Hospital Level Two

This level includes services of surgery and anaesthesia in addition to the services provided at level one through registered medical practitioner under supervision and with support of specialists. It will also have other support systems required for these services like pharmacy, laboratory, diagnostic facility and so on.

Hospital Level Three

This level includes all the services provided at level one and two and in addition the following as well such as

multi-specialty clinical care with distinct departments, general dentistry and intensive care unit. Tertiary health-care services can be provided through specialists. It will also have other support systems required for these services like pharmacy, laboratory and imaging facility.

Hospital Level Four

This level will include all the services provided at level three. It will however have the distinction of being teaching or training institution, and it will have multiple super specialties. Tertiary health-care services can be provided through specialists. It shall have other support systems required for these services. It shall also include the requirements of Medical Council of India (MCI) or other registering body.

Template for Display of Rates

The hospitals are required to follow a particular template for display of the various rates related to outpatient departments, investigation, diagnostic, emergencies and so on, which is detailed in the draft documents issued by the Ministry.

CONCLUSION

India has already outshined itself in the global strata of pharmaceutical market. Indian Government has shown enthusiastic approach towards striving at the objective of the Clinical Establishments (Registration and Regulation) Act, 2010 for the improvised health-care delivery system. With the execution of this carefully drafted standards through this act, it is expected that in the coming years, all the clinical establishment in India will be structured and severely compelled and equipped with all the basic minimum standard of health-care delivery system and hence, the scenario of health-care system in India is

expected to grow through an extremely appreciable revolution.

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