

Regulation and the Medical Profession

Clinical Establishments Act, 2010

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The Clinical Establishments (Registration and Regulation) Act, 2010 which is in force in a few states is being sought to be placed before the state legislature in Maharashtra amidst vehement protest from the medical fraternity. This legislation, which the Indian Medical Association claims will lead to doctors being harassed, was born of a long patients' rights movement against abysmal infrastructure conditions and poorly qualified staff in small clinics, hospitals, and diagnostic and pathology laboratories.

The Indian Medical Association (IMA) has been running a sustained campaign against the Clinical Establishments (Registration and Regulation) Act, 2010, for some time now. In June 2012, it called a one-day national strike to protest the Act. Under the Act, no hospital, nursing home, clinic, diagnostic centre or any other establishment offering diagnosis or treatment in any recognised system of medicine may function without registration. It applies to establishments of all types of ownership except those belonging to the armed forces. Registration, which must be renewed every five years, is received on meeting certain minimum standards for infrastructure, equipment and human power. These standards, which differ according to the category of establishment, are laid down by a national council with representation from medical councils, associations and government departments (GOI 2010a). All establishments are required to maintain computerised records, conduct audits of their work, and display their rates for various services. The permissible range of rates is determined by the government and depends on the category of establishment (GOI 2010b). Failure to comply with these standards can result in cancellation of registration and a fine of up to Rs 5 lakh (GOI 2010a).

The Act was passed by the Lok Sabha in August 2010, and is now law in Arunachal Pradesh, Himachal Pradesh, Mizoram, Sikkim and the union territories. It is being introduced for adoption in various state assemblies even as the IMA fights it tooth and nail. The most recent controversy concerns the plans to place it before the state legislature in Maharashtra.

Context of the Law

The national legislation has emerged from a patients' rights movement dating back to the 1980s. Health activists across the country responded to growing reports of unethical practices within a highly privatised healthcare system, and the complete failure of self-regulation, through the medical councils, to act against doctors. They turned to the Consumer Protection Act (CPA) for relief against medical negligence and malpractice, arguing that medical treatment was essentially a consumer service. The IMA went to court to oppose this move. In 1995, the movement received a boost when the Supreme Court, in a landmark judgment, said that the CPA applied to the medical profession too (*IMA vs V P Shantha and others 1995*).

The medical profession's stand has been that doctors always act with their patients' welfare in mind above all else, including their own interests. It holds that medical care is not a commercial transaction between consumer and provider, and to view it as such is contrary to the fiduciary nature of the doctor-patient relationship. However, this fiduciary nature is in question today, as doctors practise medicine within a mammoth healthcare industry, and their own interests often conflict with that of their

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patients. For example, when medical students are prepared to “invest” Rs 1 crore for a postgraduate seat, their need to recoup their investment will surely compete with the duty to do the best for their patient.

Horrific Conditions

The patients’ rights movement also drew on a campaign regarding standards in private medical establishments. In 1989, Eruch Tavaría died following a mismatched blood transfusion in a Mumbai hospital, where the person on duty at the time was a homeopath. His daughter, Yasmin Tavaría, along with the health group Medico Friend Circle, approached the Bombay High Court (HC) seeking details on the implementation of the Bombay Nursing Homes Registration Act (BNHRA), 1949, that governs private nursing homes in Maharashtra. They learned that many of these institutions were operating without registration, inspections were rare if ever, and violations of the law were never punished. Forty years after the law was passed, the state had not even formulated rules for its implementation (Iyer 1990).

The Bombay HC ordered the Bombay Municipal Corporation to form a committee to revise the BNHRA, and set up a structure to implement the law. One of the committee members Sunil Nandraj (1992) studied 24 hospitals and nursing homes in the city. The findings, while shocking, only confirmed what everyone already knew. The majority of medical establishments visited were housed in dilapidated buildings – sometimes just tin roof sheds – cramped and overcrowded, with dirty toilets and no running water. Operation theatres had leaking ceilings and peeling paint and lacked essential equipment. The resident doctors were often from other systems of medicine and worked with the support of visiting consultants. Most of the nurses were unqualified. Many of these establishments were not even registered under the BNHRA. A study in Satara district of 53 practitioners and 49 nursing homes/hospitals resulted in similar findings (Nandraj and Duggal 1997). While all this was an open secret, the studies provided further evidence needed for the HC to act.

The BNHRA was amended in 2005. Following this, rules for implementation of the amended Act were drafted after extensive consultation between health rights organisations and doctors’ organisations in the state. These rules include minimum standards for infrastructure, equipment and staffing, procedures for monitoring and for action against infringements of the law, as well as a patient’s rights charter (included on the insistence of the Jan Aarogya Abhiyan, the Maharashtra chapter of the People’s Health Movement – India, which played a critical role in the consultative process). However, there has been no progress since then (Phadke 2010). Still, the sustained advocacy efforts have clearly had a critical role in getting the national legislation in place.

Medical Profession’s Response

Sanjay Nagral, a surgeon and member of the editorial board of the *Indian Journal of Medical Ethics* points out

There is a long history of blanket opposition from the organised medical profession in India, especially the IMA, to any serious attempt at regulation of the practice of medicine. The recent strike action, although hardly effective, was perhaps a more dramatic form of this phenomenon (Nagral 2012).

The vast majority of medical professionals, as well as clinical establishments, are in the private sector which accounts for the bulk of healthcare expenditure in India, hence Nagral’s (ibid) comment: “In a sense... the IMA has morphed into a body representing the trade and commerce of medicine rather than the practice of medicine as a whole.”

Instead of regulation, the IMA would like a purely voluntary process of accreditation, or at least exemption to doctor-run institutions from the law. It argues that accreditation gives medical establishments financial incentives to improve standards, as it opens up a larger market. This may be true of larger hospitals that are looking to capture a part of the medical tourism market. But this would be of little benefit to people using small hospitals as these do not serve medical tourists. Accreditation will have little impact on the thousands of small hospitals, nursing homes, clinics, diagnostic labs and related establishments,

mostly owned and run by medical professionals, which represent the bulk of healthcare in the country. The Maharashtra health minister is quoted as saying: “There is no data of how many hospitals, clinics, pathological laboratories and other diagnostics centres operate in the state (Shivadekar 2012).”

Today, patients approach medical services with trepidation, fearing poor quality treatment. And those who run these services do not seem to feel they are accountable to the public. The medical councils are composed of representatives from the profession, who are loath to take action against fellow-professionals. The courts take decades and in any case the consumer courts are understaffed and overworked, with a resulting massive backlog. The public’s increasing frustration with exorbitantly priced, substandard treatment in hospitals that lack qualified staff and necessary facilities, and the absence of prompt and effective redress of grievances, is expressed in attacks on hospitals and doctors.

The IMA’s arguments (IMA 2010) against the Clinical Establishments Act (CEA) are of three types.

First, doctors will be subject to harassment by an “inspector raj”, adding to existing laws governing healthcare and medical practice. Second, the changes required by the law will force small establishments to close down and healthcare will become unaffordable. Third, inspections will make patients doubt the competence and trustworthiness of their doctors, threatening the doctor-patient relationship, just as the CPA did.

However, there is no law that currently provides for physical standards in clinical establishments, and the basic standards will not be a financial burden on such establishments (Phadke 2010). The profession’s knee-jerk response amounts to a threat to patients.

Need for Regulation

Health activists have pointed out a number of gaps in the law. For example, the human power requirements cannot be met at present. Second, certain provisions, such as the requirement to provide emergency care, are vague. Third, there is no provision for handling the

additional workload of regulating private clinical establishments. Fourth, minimum standards should not be limited to structural standards like physical space, equipment and staff; they should include some process standards, including observance of human rights of patients. Perhaps most importantly, the national council is restricted to government agencies and medical associations without the involvement of civil society organisations and health movements which were responsible for the law in the first place (Ekbal 2012; Phadke 2010).

However, patients' distrust of medical professionals has reached such heights that a law such as the CEA is critical. Our focus must be on addressing the gaps in the law, and ensuring its proper implementation.

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