

# Regulation of Doctors and Private Hospitals in India

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The issue of regulation of doctors and private hospitals is one that is increasingly becoming important for the citizen. The attempts by professional medical associations to scuttle the Clinical Establishments (Registration and Regulation) Act of 2010 is the context for this essay on the issues that afflict the provision of private healthcare. After a critical discussion of all the major issues, the essay outlines what needs to be done to prevent and address the malpractices and abuses that are widely prevalent in the country.

In recent years, the issue of regulation of doctors and hospitals in India has been discussed in the media off and on because of the enactment of or amendments to various healthcare acts or because of some malpractices arising from the doctor-pharma nexus. For example, recently there has been a lot of discussion in the print media on the proposed amendments to the Pre-Conception and Pre-Natal Diagnostic Techniques (PCPNDT) Act which was enacted in 1994 to regulate the use of prenatal diagnostic techniques in order to curb prenatal sex selection of the foetus through sonography or other technology; this notorious practice being widely prevalent in India.

The Indian Radiological Association and the Indian Medical Association (IMA, the lobby of private doctors) have been demanding certain amendments to this act and an expert committee has been formed to consider various suggestions towards this end. On the other hand, women's organisations and organisations like the Jan Swasthya Abhiyan (JSA) (the coalition for the People's Health Movement in India) have been demanding proper, stricter implementation of the PCPNDT in a manner to do justice to the objectives of the act. Second, the Clinical Establishments (Registration and Regulation) Act (CEA), 2010 which was adopted by Parliament in 2011 and seeks to regulate all kinds of clinical establishments, is also a matter of debate. Civil society organisations have welcomed this act (despite their criticism about its lacunae like absence of special body for its implementation, and the absence of mention of patients' human rights), but are worried because so far it is applicable only in a handful of states (Arunachal Pradesh, Himachal Pradesh, Mizoram, Sikkim). On the other hand, the IMA has been against this act and under the guise of demanding certain amendments to make it more doctor-friendly, it has been trying to scuttle it, make it ineffective. The Medical Council of India (MCI), which is supposed to ensure ethics in the medical profession, has been in the news off and on due to allegations that it is not being friendly to patients and is not giving justice to complaints by patients against doctors. The MCI has been in the news also because of the legal wrangle due to alleged corruption by its president Ketan Desai. There are also many news reports about public health facilities being affected by a shortage of staff and supplies, and about doctors absconding from duty and being insensitive to patients.

All these problems in healthcare have also been examined from the human rights perspective, and the National Human Rights Commission in collaboration with JSA is organising a series of public hearings on human rights violations in public and private healthcare. Some of the cases presented during first of

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these hearings in Mumbai on 6–7 January 2016 have been reported in the press. Despite such media coverage of issues related to regulation of doctors and hospitals in India, there has not been any systematic overview of this subject. This paper attempts to do such an overview in the context of the overall neo-liberal policy framework adopted in India after 1990.

### Broader Background for Regulation of Healthcare

In India, regulation of the medical profession and of hospitals has become more important after the adoption of the neo-liberal policy framework from the 1990s onwards due to three interdependent factors which have influenced health and healthcare. First, especially during the last 25 years, unregulated marketisation under the garb of “economic growth” has been at the expense of the health of nature and of the people. This is because India has, especially after 1990, adopted a “pathogenic model” of development. By this I mean, as more development occurs, more premature deaths and new illnesses occur due to the very nature of development, though older diseases tend to disappear or are reduced considerably. The specificity of the Indian situation lies in the fact that it has not been able to overcome many of the “older” diseases like malnourishment and its sequelae. It has not been able to overcome some of the deadly infectious diseases like tuberculosis among the poorer sections of the population and yet at the same time economic development has led to an epidemic of newer diseases, the so-called “diseases of industrialisation” like diabetes, cardiovascular diseases, accidents, addictions, etc.

This epidemic has not been restricted to only the well-to-do, but has affected the poor people also. The poor thus suffer from a “double burden of diseases.” We need a regulated healthcare system which provides healthcare to all and takes care of this double burden of diseases as well as has a strategy to prevent the double burden of diseases. Second, newer technologies and sub-specialties have emerged which have made healthcare more complex and hence needing more than ever, appropriate regulation to prevent misuse. There has also been the increasing sway of the ideology that health can be purchased and under this illusion, well-to-do, upper-class people are seeking more and more of high tech care. They are willing to pay more but want high standard care. This expectation of high quality care cannot be met without regulation of medical care. Third, with the rise and domination of the corporate sector in healthcare, regulation of the medical profession and of hospitals has become far more important to protect the interests of the patients who become much more vulnerable vis-à-vis the medico-industrial complex. Added to this is the state’s support to health insurance instead of expansion of public health services. This choice strengthens marketisation and commodification of healthcare and contributes to the supply-induced demand character of the health economy in India, which facilitates malpractices and irrational and unethical provider behaviour. This calls for better regulation of doctors and hospitals.

These challenges also have sociopolitical dimensions. Due to the outcry in the popular press about the profiteering of the medico-industrial complex, there has been some popular

pressure to regulate private healthcare. Critics of unregulated private healthcare in India have pointed out that it has been widely recognised that the dictum—the market will regulate itself—does not hold true in healthcare because of information and power asymmetries; that healthcare is a classic example of market failure. A recent paper in *Lancet* notes:

Kickbacks from referrals to other doctors or from pharmaceutical and device companies are common, and crass profiteering tempts many private practitioners and hospitals to inflict unnecessary procedures such as CT scans, stent insertions, and caesarean sections. Such practices have flourished because of a weak regulatory climate with no standards or mechanisms to monitor quality or ethics, steadily eroding trust in both the public and private health-care systems (Patel et al 2015).

It is patients who have to bear the burden of this lack of regulation and the poorer sections can not afford to. It is now widely known that 40% of the hospitalised patients have to either borrow money or sell assets to pay for medical expenses and annually about 60 million Indians are pushed below the poverty line due to medical expenses (Martens et al 2014).

Given all this, there has been some popular pressure to improve matters on this front. In its election politics, the Congress Party had taken cognisance of this pressure and this is one of the reasons why the United Progressive Alliance (UPA) government enacted the CEA 2010. Second, in international fora, Indian ministers have been embarrassed by India’s dismal human development index and one of the ways to mend this dismal picture is to extend healthcare coverage through government funds. To achieve this, one important avenue that the government has chosen is to float various state-funded health insurance schemes like the Rashtriya Swasthya Bima Yojana (RSBY) by the national government and a number of other state schemes like the Rajiv Arogyasri, Vajpayee Arogyasri, and Rajiv Gandhi Jeevandayee Arogya Yojana. Governments are spending hundreds of crores of rupees annually to pay for purchasing private healthcare for the poor people through these schemes. The quality and price of this care has to be regulated when such large sums of public money are spent on purchasing private healthcare services. The experience of developed countries shows that effective regulation of private healthcare by the government can occur only when the government buys these services for the people and bargains well for it. Private players see this purchase as an assured market and are ready to accept standardisation of healthcare as a precondition for this purchase.

Thus, the overall regulation of healthcare, of hospitals is not only needed by the people but it has also become a policy need if the increasingly large amount of money the government is now spending to purchase private healthcare is not wasted in purchasing irrational, excessive and overpriced healthcare.

### Regulation of Medical Ethics

It is widely recognised that patients are inherently vulnerable vis-à-vis doctors and other healthcare providers and hence there has to be a special mechanism to protect patients from injustice. From the ancient times there have been special regulatory codes in different societies for healers to protect the interests of the patients. In the Western tradition there is the

Hippocratic Oath, which explicitly expects the healer to give priority to the interests of the patients over interests of the healer. In modern times medical councils lay down a code of conduct for doctors vis-à-vis the patients, fellow doctors and society at large. These councils are supposed to ensure that the doctors follow a code of ethics. In India the respective medical councils for allopathic, ayurvedic, homeopathic and unani systems of medicines are legally empowered bodies meant to ensure that all members of these councils follow the code of conduct laid down by these medical councils.

Medical councils in India have so far failed in ensuring that those doctors who do not observe an ethical code of conduct are punished and disciplined. The ayurvedic and homeopathic councils are least active. But the MCI, the council of allopathic doctors, has also been dormant on this front. On paper, all councils are very strong because nobody can practise unless one gets registered under the council and if the council deregisters a doctor it means a death sentence as a professional. But such deregistration has hardly ever happened during the last 50 years. Even as regards the MCI and the state medical councils in the respective states, if any complaint is made by any patient against a doctor for violating the code of ethics, there is very little chance that the patient will get any timely justice. This is because the MCI has no structure, staff, or budget to investigate these allegations. The council meets quite infrequently because member-doctors can not give more time as the council's work is voluntary and spare time work for them. Because of the very nature of the organisation, only doctors can become members of the MCI. But it is possible for the medical councils to form a Grievance Redressal Committee to hear patient's complaints about violation of medical of ethics and to have some well-known social workers as members or advisers of this committee. Unless such a mechanism is put in place, citizens cannot be expected to have faith in these councils. The actual track record of these councils is also quite depressing for the patients. First, it is a very slow process and in a majority of the instances a case is deliberated and decided after a delay of months and even years. For example, in Maharashtra, through a Right to Information query, it was recently revealed that between January 2014 and September 2015, the Maharashtra Medical Council received 193 complaints against doctors, out of which not a single one was decided till October 2015! Between 2011 and 2013, out of 285 complaints received, only 114 were decided. There is no data available about what proportion of these cases resulted in some action being taken against the doctor. Anecdotal evidence shows that during the process of hearing, patients face an unfriendly environment and witness a pro-doctor bias. The other major limitation of the medical councils is that its mandate is limited only to its members. Hence it has no mandate over corporate and trust hospitals since their owners and managers are non-medicos. All these deficiencies of the MCI and the state councils certainly need to be overcome.

### Private Medical Colleges and Medical Ethics

Orienting and training medical students in medical ethics is obviously quite important. But this has not been part of the

medical curriculum in India. However, students do pick up attitudes from teachers as they observe teachers' behaviour with patients. This behaviour varies greatly as the teachers themselves have no training in medical ethics. The second factor that has adversely impacted medical ethics is the objective obstacle that is created to practising ethically because of the privatisation of medical education. At the time of independence, India had 28 allopathic medical colleges, out of which less than 4% were private. By 1986, their numbers rose to 123 and out of these 17% were private. Thereafter with the advent of the neo-liberal economic policy, the number of private medical colleges increased rapidly. By 2012, there were 161 and 194 public and private medical colleges respectively. Out of these 194 private medical colleges, 160 were established after 1990.<sup>1</sup> Since unregulated medical practice has been a lucrative profession, the newly rich, and the new generation of middle class want to get into the medical profession in larger numbers. Private medical college offered them a chance. This class is ready to pay high fees of private medical colleges to get into the lucrative medical profession. These high fees were initially justified on the grounds of lack of government subsidy/support. However, later the legal and illegal fees (capitation fees) kept on increasing as in the era of neo-liberal policies, profiteering in education gradually became an accepted norm. As reported by *Business Standard*, at the beginning of 2015, the asking capitation fee rate for an MBBS undergraduate seat in a private medical college is Rs 25–50 lakh. With tuition fee at Rs 9–11 lakh a year at private medical colleges, the four-year MBBS programme will cost a student up to Rs 44 lakh. Fees at government colleges are as low as Rs 11,500 a year, or Rs 44,000 for the four-year programme (Pathak 2014). The logical consequence of this phenomenon has been an increase in the trend of substandard private medical colleges getting approval from the MCI by paying bribes to council officials. The majority of these private medical colleges are controlled by politicians who see these colleges as an additional source of easy money. The majority are also of questionable quality since many of them have been approved through corrupt means. This phenomenon of sanctioning substandard medical colleges by MCI officials by accepting bribes was widely known (Srinivasan 2010). It became national news when the Delhi High Court ordered the removal of Ketan Desai as the president of the MCI and directed the Central Bureau of Investigation (CBI) to initiate prosecution against him for his involvement in corrupt practices. Joint commissioner, income tax, Ahmedabad, whose team conducted a raid on the residence of Desai in 2000, had reportedly found with him Rs 5 crore as undisclosed income and gifts of Rs 65 lakh. A division bench of the court comprising Justice Arun Kumar and Justice R C Chopra found Desai guilty of misusing his official position and observed that the apex body for doctors was a “den of corruption” (Pharmabiz 2001). But later Desai got reinstated. In April 2010 he was again caught red-handed, was arrested while taking a bribe of Rs 2 crore and a raid on his premises found 3.5 kg of gold and 60 kg of silver (Nanjappa 2010)! Later the CBI withdrew this case against Desai on the grounds of a “lack of evidence”!

When parents of a medical student spend millions of rupees on medical education, it follows that such a graduate will exploit the patients to recover this “investment” and earn a good “return.” It is thus very difficult for any regulatory mechanism to ensure medical ethics in face of the economic compulsion created by such costly medical education. This is the price Indians have been made to pay for introduction of neo-liberal policies.

Corruption and substandard private medical colleges is only one aspect of the failed regulation of the medical profession in India. The other aspect is that the MCI has hardly taken any proactive interest to improve the quality of medical education, or to make it more relevant to changing times or to improve substantially the pedagogy, the curriculum. The demand to include in medical curriculum topics like the political economy of healthcare, of pharma industry, politics of healthcare, ethics of medical practice, of research, of public health, gender and health, etc, has been ignored. The teaching especially of subjects like anatomy continues in its outdated form of dissection of the entire body without any understanding of its applied significance. Medical education continues to produce substandard doctors (Davey et al 2014). It is only during internship after graduation and in postgraduate residency that doctors acquire some clinical proficiency. This incompetence tends to lead to prescription of unnecessary investigations and medicines because an incompetent, less confident doctor relies more on laboratory tests and medications. Regulation of the medical profession becomes more difficult in such circumstances. For example, Standard Treatment Guidelines for all important ailments are an important tool for regulation of the medical profession but it has become difficult to implement it in face of the substandard medical education.

### Regulating the Influence of Pharma

Regulating the quality of medical education is only one of the functions of the medical councils. The other key function of the councils is to ensure high ethical standards in the medical profession. However it is widely known that these councils have not curbed the irrational, unethical, and exploitative practices which are quite prevalent in the private sector. The homeopathic council does not even mention this as one its objectives.

For many years, pharma or pharmaceutical companies have been the most important corrupting influences of the medical profession. Enticing and luring doctors into prescribing unnecessary, irrational medicines has been widely prevalent in India in the last 50 years. Pharma companies have provided material incentives to doctors ranging from “small” gifts and not so small gifts, to dinner parties, to pleasure trips inclusive of trips to foreign countries. Situation deteriorated further when doctors started buying shares of pharma companies, started investing in pharma retail stores and when hospitals invested in the pharma stores which were started in their own premises. The retail pharmacies are allowed a sales margin of 16%. However, in the case of medicines bought by chemists, doctors and hospitals for selling to their patients, pharma companies keep a margin of 100% or even 500% to 1000% between the purchase-price for doctors and the maximum retail price to be charged

to patients (Singal et al 2011)! All these things show that such doctors, hospitals have developed a financial interest in pharma business and hence also in their unethical marketing practices. Some hospitals have gone one step further. They have made it more or less compulsory for the admitted patients to buy medicines from their own pharma stores, though this compulsion is illegal. The brands prescribed by the doctors in such hospitals are generally available only in these retail stores and their prices are higher than the prices of brands of the same medicines marketed by other reputed companies. In Pune, one patient’s family doggedly fought against this practice in the consumer court and the Pune District Consumer Redressal Forum in its judgment on 30 October 2012 ruled that this compulsion is unfair trade practice.<sup>2</sup> But this practice has hardly stopped. There has to be some regulatory mechanism which would prevent such practices by hospitals and doctors at the behest of pharma business.

One important mechanism which pharma companies use to influence doctors, hospitals and which needs to be regulated is their influence on Continuing Medical Education (CME) for doctors. Good quality, appropriate, mandatory CME has been an important demand of rational doctors to improve the quality of medical care in India. It is only since 2011, that is, almost 50 years since its inception, that the MCI has made it compulsory for all its members (all allopathic doctors) to earn 30 credits of CME within a span of five years.<sup>3</sup> This is a welcome move. However, the role of pharma companies has been an important obstacle in developing a tradition of really useful CME programmes for giving better service to the patients. This is because till 2009 there were no restrictions in India on the role of pharma companies in CME programmes. Pharma companies used to sponsor the CME sessions. Since the expenses for bringing speakers in these CME programmes were borne by pharma companies, they heavily influenced the choice of these speakers. The CME programme was generally accompanied by a sumptuous lunch or dinner sponsored by some pharma company or the other. It is no surprise that such CME programmes resulted in increased sales of the medicines of these companies irrespective of the merit of these medicines. All this is now been prohibited by the MCI. Due to the amendment introduced in December 2009 to the MCI’s (Professional Conduct, Etiquette and Ethics) Regulations, 2002, now there is specific Section 6.8 titled “Code of conduct for doctors and professional association of doctors in their relationship with pharmaceutical and allied health sector industry” which puts a clear embargo on:

(i) “any gift from any pharmaceutical or allied healthcare industry and their sales people or representatives;  
(ii) any travel facility inside the country or outside, including rail, air, ship, cruise tickets, paid vacations, etc, from any pharmaceutical or allied healthcare industry or their representatives for self and family members for vacation or for attending conferences, seminars, workshops, CME programme, etc, as a delegate;  
(iii) any hospitality like hotel accommodation for self and family members under any pretext; any cash or monetary grants from any pharmaceutical and allied healthcare industry for individual purpose in individual capacity under any pretext.”<sup>4</sup>

The vested interests are trying to find a way out of these restrictions. MCI does not have any mandate over non-medical owners, managers of hospitals. Hospitals owned, and managed by such managers can organise CME programmes sponsored by pharma companies. Second, an official of IMA has said that IMA has now obtained permission from MCI to accept sponsorship for annual CME conferences, though routine CME programmes can not be sponsored!

There are now other vested interests in CME programmes. Medical equipment industry, diagnostic centres and even some specialists look upon these programmes as an opportunity to get publicity and thereby new business for themselves. Many of the CME sessions approved by the state medical councils are not designed by medical educationists. It is left entirely to the medical experts who are interested in conducting CME sessions to decide the content of their respective sessions. Many of these experts are interested primarily in sharing the success stories of the newer modalities they have been using. In doing so these experts do not give any orientation about the limitations of these newer modalities and about what extra cost they entail to the patients, leave aside any discussion about the comparative cost-efficacy of these newer modalities. The result of such CME sessions is not an increase in the capacity of the practitioners to diagnose and treat patients in a better way, but the result is that doctors attending the CME sessions tend to refer more patients to these experts. Some experts advocate investigations and procedures without scientific justifications. They are directly or indirectly sponsored by the concerned industry.

Many a time the content of the CME session is not relevant, useful even if the topic is relevant. This is because almost everything is left to the speaker. There is no quality control as regards relevance, scientific validity, practical usefulness and method of presentation in a CME session. In most lectures, even the printout of the PowerPoint presentation is not made available to participants. Given all this background, it is no wonder that in many places, the participation and attendance of the doctors in such CME sessions is perfunctory, merely for the sake of collecting attendance certificates. Unless the CME sessions are made more relevant and unless it is mandatory to follow Standard Treatment Guidelines, doctors are less likely to take CME programmes seriously.

One clear way to regulate the CME programmes in order to make them relevant to the needs of doctors and to keep them away from vested interests is to make standardised CME programmes available online so that practitioners can participate in CME sessions at their convenience by logging on to the particular website at any time convenient for them. Such online courses have a small test at the end of the CME session, which the doctor has to administer successfully to earn a credit point. There can be some mandatory CME programmes about national health programmes. But at the same time there can also be scores of online CME sessions devoted annually to scores of topics. These will have to be developed annually by professional organisations and accredited by a regulatory agency approved by the MCI. Doctors can choose the ones which they

feel are relevant for their practice and earn a requisite number of credits to get renewal of registration from the state medical council. Developing and administering such online CME programmes would be far, far cheaper and far more cost-effective than the current method of conducting CME programmes. Doctors can send by email their queries to a panel of experts and there can be discussions over e-groups. Online CME courses would have a special value for rural practitioners because it is very difficult for them to go to the CME programmes held in cities. Despite these clear advantages no such online CME courses are available in India.

The pharma business must contribute to the fund earmarked for CME of doctors. But this contribution should be an untied one and pharma business should have no involvement in deciding the content and mechanism of the CME programmes. Medical councils for ayurveda, homeopathy, and unani have not yet been instituted such compulsory CME for non-allopathic graduates. They can also develop and manage online CME programmes on the lines outlined above.

The MCI code of ethics, MCI (Professional Conduct, Etiquette and Ethics) Regulations, 2002, has a clause which prohibits advertisements by doctors. But this code of ethics, does not apply to hospitals. Many hospitals misuse this lacuna and we see so many ads by hospitals, which violate with impunity the MCI code of ethics. This code of ethics must be made applicable to all clinical establishments—hospitals, and diagnostic centres, etc. All clinical establishments must mandatorily have a medical superintendent, a medical graduate and on behalf of the clinical establishment s/he must be responsible for following the code of ethics prescribed by the MCI.

### Regulation of Private Hospitals

Hospitals in India are not a homogeneous entity and hence regulation of hospitals is quite a challenging task. A very brief look at their origins and development would give an idea about their evolution into a heterogeneous entity.

At independence, most of the hospitals in India were in cities and an overwhelming majority of them were either state-owned or charitable. Despite the Bhoré Committee's recommendations on the eve of independence, that the government should provide comprehensive healthcare to all citizens, the government did not expand public health facilities sufficiently. Hence a majority of the graduates coming out of government medical colleges entered private practice. On the other hand, the development of the economy after independence created an urban middle class which could afford to go to these private practitioners whereas the rest of the population, urban and rural, went to the rudimentary, sparse public health facilities or relied on self-care and traditional healers. Gradually these independent private practitioners started their own small maternity homes, small hospitals and this tradition of individually-owned small hospitals of doctor-entrepreneurs continues till today. The majority of these private hospitals have fewer than 10 beds and an overwhelming majority have less than 30 beds. Till the 1980s a majority of the big hospitals in the private sector were "Trust Hospitals" set up by philanthropic trusts, registered

under the charity commissioner. These were mostly genuine non-profit philanthropic entities. There were virtually no corporate hospitals.

Though a majority of doctors graduating from government medical colleges went into private practice, and hence private practitioners constituted a majority of doctors in India, till the late 1980s less than half of the hospital beds were in private hospitals. This is because most of the private hospitals were very small ones whereas the public hospitals (teaching hospitals, railway hospitals, Employee's State Insurance Corporation hospitals, district hospitals, rural hospitals, etc) were many times bigger.

During the last 25 years this above picture has been overshadowed by the development of larger, commercial private hospitals, especially multi-specialty hospitals. This is because, first, newer specialties have developed which many middle class and upper middle class people can pay for. In such a situation it is far easier for both doctors and patients to have many specialty services under the one roof of a multi-specialty hospital. Second, many doctors can now mobilise either individually or in partnership, adequate funds and expert human power to start multi-specialty hospitals.

Since the 1990s, the Trust Hospitals have also changed. Many of them, which at one time tried to charge the patients as little as possible, have become money-oriented, especially those who which developed tertiary level facilities. The Trust Hospitals which have been started after the 1990s are more often than not commercial in their functioning though they are formally registered as non-profit, charitable institutions (Kurian 2013: Chapter 6). Lastly after 1990, corporate hospitals have sprung up. These are large multi-specialty hospitals to begin with mostly in the bigger cities but now spreading to smaller towns also, catering to the upper-middle and upper-class people. For ordinary people, the rates of these "for profit" hospitals are way beyond affordability. But these hospitals are quite aggressive and brazen in their marketing and have developed a method of spreading their tentacles around this section of the population also through so called "free diagnostic camps," "screening tests," etc.

As we will see shortly, regulation of these different types of hospitals which have differentiated trajectories is quite challenging. The Indian government has failed to measure up to this challenge. Regulation of minimum standards and of charges of hospitals should be done by a special regulatory agency of the state. According to the Constitution, health is a state subject. However, in India except a handful of states (Maharashtra, West Bengal, Andhra Pradesh, Tamil Nadu, Delhi) even after close to 70 years after independence, there is no law to regulate minimum standards in hospitals and hospital charges. Second, whatever regulation that was enacted in some states was handled by the same public health department which was entrusted with this regulatory work in addition to its ongoing duties of providing health services and performing public health functions. They were not provided with additional competent staff to perform this additional role. There was pressure from different quarters, including from the People's Health Movement to end this sorry state of affairs.

Hence finally the CEA, 2010, was enacted in 2011 by the central government and the rules under this law were passed in Parliament in 2013. We examine below this development and the response to it from the IMA, which is the largest and oldest association of allopathic doctors in India.

### **Clinical Establishment Act, 2010**

The CEA, 2010 is a welcome step because of some of its new, positive features.

All clinical establishments and not just hospitals are covered in this act. Second, along with private clinical establishments, all public health facilities, except those in the armed forces services, have been covered by this act. All doctors will have to adopt Standard Treatment Guidelines, and will have to maintain some minimum standards. These two provisions would prevent sub-standard facilities and prevent irrational, exploitative treatment.

As per rules enacted in 2013 under this act, charges by hospitals, clinics will have to be within a range decided by the government. This range is to be decided after following a consultative process with stakeholders, including representatives from doctors. This provision will curb exorbitant charging resorted to by some doctors. Clinics and hospitals will have to display charges for some of the typical items like consulting charges, room charges, etc. This will help the family of the patient to decide in advance whether they can afford to pay these charges. This would help them to choose hospitals they can afford.

The state and national councils to be set up under this act would be constituted by not only government officials but there would be some space for representatives of doctors and consumers, albeit inadequate.

However, the CEA suffers from some major deficiencies and problems. The important ones are:

- (i) There is no separate, autonomous structure (and budget) for implementation of the act. CEA, 2010 delegates the huge task of regulating the clinical establishments to the already overburdened existing structure consisting of the directorate of health service at the state level. At the district level it is entrusted with the district registering authority, which is to be led by the district collector and district health officer (DHO), who are already overburdened. The DHO already finds it difficult to oversee his/her own staff. Now added to this would be monitoring of implementation of the CEA by doctors in private health services who are today more than five–six times as many as the number of doctors in government service. Given these facts, it is more likely that the CEA would remain largely on paper.
- (ii) As a general principle, the regulatory authority has to be different from the executive authority. But in the CEA, the executive officer in charge at district level, that is, the DHO is now ex officio in charge of the regulatory function also. This implies a conflict of interest. We cannot expect the DHO to take action in case of deficient compliance of CEA in rural hospitals, of whom s/he is the executive officer.
- (iii) It is good that in the multi-stakeholder national and state councils which are meant to guide and steer the implementation of the CEA, some representation of doctors and of civil society organisations has been included. However, at the district level

there is no such multi-stakeholder body. This absence gives scope for misuse of powers by officials, leading to corruption. Moreover, there is no space at all for civil society representatives at the district level.

(iv) Under the act there is a provision of appointment of a police official in the district authority. This unnecessary provision of a police officer gives rise to strong apprehensions among doctors, especially in view of the image and track record of the police department.

(v) In the CEA there is no mention of the crucial issues of “Patient’s Human Rights.” There is no grievance redressal mechanism for patients in case any patient experiences a violation of human rights in a private hospital (for example, if a hospital does not admit on some flimsy grounds a HIV positive patient, or if a hospital refuses to give x-ray or sonography plates to the patients, etc).

(vi) The CEA mandates that all clinical establishments must “stabilise the emergency medical condition of any individual who comes or is brought to clinical establishment.” This is quite a problematic provision despite the caveat in this rule—“within the staff and facilities available.” For example, a patient with a heart attack (acute myocardial infarction) can be stabilised only in a specialised set-up whereas as per this provisions all clinical establishments will have to undertake this responsibility or prove that “within the staff and facilities available” in that clinical establishment, this emergency cannot be handled. Instead of such a sweeping clause, it is only necessary to specify the kind of emergency first aid that every clinic/nursing home must provide. Second, it may also be noted that the definition of clinical establishment in CEA includes pathological laboratories, radiological clinics, etc. It is not correct to expect emergency care of reasonable quality from these para-clinical practitioners.

Another issue is, who will pay for those patients who have no relatives or are poor and hence cannot pay later the charges for the emergency care? Why can not government reimburse these charges at defined rates? The JSA has demanded improvements in the CEA to overcome these lacunae. Out of these suggested improvements, the only one that has been accepted at some level is the inclusion of mandatory observance of patient’s rights in the mandatory minimum standards listed under the CEA rules. Now in the draft of the minimum standards prepared under CEA, this point has been included. In Section 3.1 titled signage, the following provision has been included—“The Hospital shall display appropriate signage which shall be in at least two languages” and in the list of things to be displayed, has been included—“Patients’ rights and responsibilities.”<sup>25</sup> JSA had suggested that a “Standard Charter of Patient’s Rights” be specifically mentioned in the process standards and that there should be a patient-friendly grievance redressal system. But there has been no response to this suggestion.

Since health is a state subject, states have the power to enact a state CEA. The state CEA can be somewhat different from CEA 2010. It cannot of course be contradictory to the central government’s CEA and the state CEA will have to be finally approved by the President of India. Jan Arogya Abhiyan (JAA),

the Maharashtra unit of JSA, made a demand to the Maharashtra government to enact a Maharashtra CEA, which would build upon the above-mentioned positive features of CEA, 2010 but which would avoid its deficiencies. After a lot of advocacy and lobbying by JAA, the then health minister of Maharashtra conceded this demand in principle and appointed an expert committee in December 2013 to prepare a draft bill of Maharashtra CEA. It contained representatives of various statutory bodies, officials from the health department, representatives of doctors’ organisations, including the IMA, a couple of renowned doctors and a representative of JAA. During its tenure of six months, this expert committee met six times, held public consultations in four cities and in June 2014 submitted the Draft Maharashtra CEA Bill. However it was not tabled in the assembly and it is now an open question about position the government that is now in office will take on this Draft Maharashtra CEA Bill.

Though the Draft Maharashtra CEA Bill prepared by the expert committee is an advance over the the central government’s CEA, 2010, it still suffers from certain key deficiencies. It is a compromise document. Hence the JAA has prepared the Draft Maharashtra State Clinical Establishment Act 2015 which attempts to overcome these significant lacunae. In this draft there is a focus on ensuring an accessible mechanism for addressing complaints of patients in a rights-based framework, as well as providing space for doctors who may need to raise issues related to implementation of the act. If such an improved act is adopted by the Government of Maharashtra, it would tremendously benefit ordinary patients and should also be acceptable to doctors who want to do rational and ethical practice in a socially responsible manner. This draft consists mostly of verbatim reproduction of the central CEA so that the debate about it is restricted to only the new/modified provisions suggested by JAA. It has been prepared by making certain additions, deletions, modifications wherever necessary in the CEA. The new structural, institutional provisions in this Draft Maharashtra State Clinical Establishment Act 2015 are:

(i) The executive part of the regulatory structure is not headed by the director of health services but is headed by the director of clinical establishment authority, an autonomous new authority to be created under the secretary (health) to the state government. The director, clinical establishments would be the member-secretary of the state council for clinical establishments which would be, like in the central act, the multi-stakeholder body to guide and steer the overall implementation of the act in the state.

(ii) There is a multi-stakeholder (with representation of various stakeholders) local appellate body at district level, and at the municipal corporation level to deal with appeals against the decision of the local registering authority and to deal with complaints by patients of violations of the Act. It would be chaired by a retired district judge or an equivalent judicial person. A class-1 medical officer at district level or municipal corporation level would be specially designated to carry out the work of this local appellate body as the member-secretary.

This draft bill has been prepared in December 2015 and may be presented in the Maharashtra legislature as a private bill in the budget session of the Maharashtra Legislature in 2016.

### Indian Medical Association's Negative Response

The response of the IMA to these developments has been quite negative, and short-sighted. The IMA gave a strike call in June 2012 to oppose the CEA (Seshagiri 2012). What is more problematic, the IMA indulged in false propaganda against the CEA. Its representatives imputed provisions to the CEA, 2010 and criticised these provisions when in fact these provisions were not there in CEA (Phadke 2010). For example, in their justification for the strike call on 26 June 2012, the IMA representative claimed "CEA would shut down the practice of small and general practitioners as they cannot afford to meet the norms of waiting area, space and conditions of operations, and staff and infrastructural requirements" (Shrivastav 2012). The fact is that the CEA does not lay down any infrastructural requirements. This is to be done by a committee which had not even been appointed till then and in which anyway IMA representatives would be included as IMA has been recognised to be an important stakeholder representative. The JAA pointed out the misconceptions, falsehood on which the IMA's opposition was based. But this opposition on irrational grounds continued. Thus, for example, in an email sent on 15 January 2014 by Jayesh Lele, State Secretary, the Maharashtra State IMA, and Dilip Sarada, the President of Maharashtra State IMA and who was a member of the expert committee set up by the Maharashtra government, claimed the following:

Though the Act is meant for the regulation of clinical establishments in the private sector, it is anomalous that there is no provision for the representation of the private sector at all, in the National Council as envisaged in Sec 3 of the Act.

This is factually wrong and a misleading statement. In the National Council established under the CEA, one representative of private doctors has been included. In fact, out of so many types of organisations mentioned in this section in CEA, only IMA's name has been specifically mentioned, whereas other organisations have been mentioned only in generic terms.

Of all the issues, the one issue on which the IMA has most forcefully opposed regulation is regulation of charges levied by hospitals. Given the inherent vulnerability of patients vis-à-vis hospitals, there has to be some mechanism to regulate hospital charges. The CEA as such does not contain a provision for rate regulation. But when the act was tabled in Parliament, during the debate, some Members of Parliament insisted on rate regulation. Hence in the rules of the CEA published in May 2012, the following provision has been included under para 9(ii) of the rules:

The clinical establishment shall charge rates for each type of procedure and services within the range of rates determined by and issued by the Central government from time to time, in consultation with the State Governments.

A subcommittee has been set up to formulate the template for rate regulation, to make a list of different interventions and list of charges which can be levied by the hospitals for these

interventions. IMA representatives have been included in this subcommittee. On 3 December 2014, during the first meeting of this subcommittee, instead of giving suggestions for making this template for rate-regulation, the IMA representative continued with their stand of opposing rate-regulation as such! The result is that in the absence of inputs from IMA representatives, who so far have generally been representatives of smaller hospitals, the decisions of this subcommittee is likely to be influenced by the representatives of the corporate hospitals.

In Maharashtra also, during the deliberations of the expert committee appointed to prepare the Draft Maharashtra CEA Bill, the IMA representatives fiercely opposed inclusion of rate regulation in the draft bill. The representative of JAA proposed the following clause for rate regulation—

For patients in general wards and semi-private rooms, Hospitals and Nursing Homes shall charge, within the range of rates for fees and services as may be prescribed by the state council.

The range of any professional fee may be decided on the basis of qualification, experience of the healthcare provider, the nature of intervention, and level of institution (primary, secondary etc) at which professional service is being provided as well as the geographical location of the clinical establishment.

The rates for services in different geographical locations (like village, town, metro) may be decided the basis of the cost of infrastructure, of equipment, consumables and of skilled human resources.

These rates may be revised as per annual market inflation.

This formulation is quite reasonable. It is to be noted that the provision suggested by the JAA representative excludes outpatient clinics and deluxe rooms, super deluxe rooms from rate-regulation. This formulation was supported by some doctors in the expert committee. But a majority of the vociferous doctor-representatives affiliated to IMA opposed it and this provision was rejected because the committee was dominated by IMA members, and they were adamantly opposed to any rate-regulation whatsoever.

IMA's negative response to CEA is partly based on the bitter experience of the implementation of regulatory laws like the PCPNDT Act and of the law to regulate the disposal of biomedical waste. However, the lesson to be drawn is to make the whole process of formulating and implementing the act a multi-stakeholder, accountable, transparent process. Second, there has to be greater care in drafting various provisions of any new regulatory act and the rules and making amendments. Lastly, gradually we should move towards a comprehensive single act and a single window system for interfacing for patients/citizens and healthcare professionals. Instead of such a positive approach, IMA's response has been negativist and not justified.

### Regulation of Trust Hospitals

Regulation of Trust Hospitals has its additional features. Many of the Trust Hospitals have received some government aid in some form or the other—land on lease at highly subsidised, nominal rates or some tax concession or the other. While accepting this aid, the concerned hospital agrees to treat a certain proportion of patients either free or at highly subsidised rates. But time and again even various official committees have found that these hospitals do not keep these promises



(Kurian 2013: 37–44). Given this tendency, Section 41AA was introduced in Maharashtra, in the Bombay Public Trusts Act in August 1985 in which it was specified that in case of “state aided public trust” the charity commissioner and state government can issue directions to earmark certain beds, etc, for poorer patients to be treated free of charge or at concessional rates. As per this section, 10% of the beds were to be reserved for poor and economically weaker sections (EWS) respectively (a total of 20% of beds) for free treatment and treatment at concessional rates. But this provision remained on paper. Even the Maharashtra Law Commission in its report submitted in 2004, titled “the 13th Report of the Law Commission on the Revision of the Bombay Public Trust Act, 1950” deprecated the attitude of these hospitals and made recommendations for strict implementation (Kurian 2013: 66). But in vain. Finally, deliberating on a public interest litigation about this non-implementation, the Bombay High Court in its ruling in 2006 laid down a detailed scheme, recommended by an expert committee it had set up. As per this scheme, the “state aided charitable hospitals” must reserve 10% of beds each for the poor (annual income less than Rs 25,000) and the EWS (annual income less than Rs 50,000) of the society for free and concessional treatment respectively. However, even this scheme has hardly been implemented. For example, a study in Mumbai found that of the 42 state-aided charitable hospitals in the city with 50 or more beds, during January 2009 to December 2011, only one hospital spent more than 10% bed-days, and only three hospitals spent 5% or more bed-days for poor patients. As regards the EWS patients, only 4.76% of these 42 hospitals were complying with the court directive (Kurian 2013: 75).

As per this scheme, state-aided charitable hospitals must spend keep apart 2% of their gross income from bills in the Indigent Patient Fund (IPF) for indigent and EWS patients. However, data recovered from the Office of the Joint Charity Commissioner in Pune regarding the operations of 30 hospitals (out of a total of 49 registered charitable trust hospitals in Pune) showed that the average IPF balance per hospital at the end of 2012 was Rs 198.8 lakh (Trivedi 2013). Thus whatever small amount of money that has been earmarked for poor patients remains grossly underspent.

The Delhi High Court had given a similar judgment making it mandatory for charitable hospitals to reserve 30% of the beds for poor and indigent patients. However, in Delhi too the implementation has been quite lax. A 2011 study reported that Apollo Hospitals was expected to keep 200 beds reserved for the EWS, but the average number of EWS patients treated annually remains in the range of 15 to 20 patients. At Fortis Hospital only three out of eight free beds were occupied, and in case of Jessa Ram Hospital only four out of 10 free beds were occupied (SAMA 2011).

It is learnt that some “trusts” plan to convert themselves into “non-profit companies” and are ready to pay the government at a market rate for the land they have received on lease. This should not be allowed. The only option open for them should be to return the land back to the government so that some other institution can run a charitable healthcare institution at this

location. It is essential that the people should have access to a charitable healthcare institution at the original prime location.

It is estimated that in Maharashtra alone there are about 50,000 beds in charitable hospitals. Hence 10,000 beds should be available free of charge/at concessional rates. There should be a website which gives the real-time position as regards occupancy of these beds in each hospital so that such patients can be referred where beds are not already occupied. There should be an adequately equipped special cell in each of the charity commissioner’s offices, to monitor the implementation of this scheme. It should also have a mechanism to receive and act upon any grievance that citizens may have about the functioning of this scheme. All this is possible if there is political will. Experience shows such will is not activated without popular pressure.

### Accreditation of Hospitals

Accreditation of healthcare facilities is usually a voluntary programme, in which trained external peer reviewers evaluate the compliance of a healthcare organisation with pre-established performance standards. It has been argued that accreditation is appropriate as a mechanism for assuring the quality of private sector health services in countries like India with low per capita income and where regulatory systems are weak. It has been argued that a multi-stakeholder process of accreditation is more likely to succeed. However it is also clear that the main obstacle to the introduction of accreditation in poorly resourced settings such as India is financial—who will bear the cost of the accreditation process and whether smaller hospitals which may not have resources to chip in financially may be pushed behind in the market competition. In India in the late 1990s there was an attempt in Mumbai to explore the possibility of initiating a voluntary multi-stakeholder accreditation of hospitals. In a survey, conducted in Mumbai in 1997–98, there was a positive response from different stakeholders to the idea of starting multi-stakeholder accreditation process for hospitals (Nandraj et al 2001). Subsequently “Mumbai Forum for Health Care Standards” was set up to start such voluntary accreditation of hospitals. But things did not move much ahead in practice.

Things have moved forward after the setting up of the National Accreditation Board for Hospitals and Healthcare Providers (NABH) in 2006. The NABH is a constituent board of the Quality Council of India, and has designed an exhaustive healthcare standard for hospitals and healthcare providers, consisting of stringent 600-plus objective elements for the hospital to achieve in order to get the NABH accreditation. However, there are different problems with these NABH standards. First, these standards can be achieved only by bigger hospitals; small hospitals cannot adopt these. In India, we need to have minimum standards to ensure good quality care, but which can be achieved by smaller hospitals also. Second, NABH is a voluntary, self-financed process and is no substitute for a legally enabled, mandatory process which is applicable to all hospitals and other clinical establishments in India. Third, there is no patient friendly grievance redressal system and no mandatory observance of a Standard Charter of Patient’s Rights. Anecdotal information

about one of the NABH accredited hospitals in Pune, where the author of this essay is based, shows that this accreditation does not imply a patient-friendly environment in the hospital and freedom from irrational and exploitative practices. This accreditation process in India in the form of NABH is no substitute for the standards to be laid down and implemented under the CEA. That is why when the IMA recently demanded that accredited hospitals should be excluded from the CEA, the JSA promptly opposed this proposal (Nagarajan 2015).

The main problem in entrusting regulatory work to government bodies is the fact that the government bureaucracy continues the colonial tradition of a system which from the point of view of ordinary citizens, is unaccountable, high-handed and insensitive. The answer to this problem is to make the regulatory structure multi-stakeholder, transparent, accountable and not to jettison the very idea of a general, mandatory, legally enabled public body for regulation of health-care system. Accreditation can be part of such a system and not substitute for it. In general, legal, mandatory regulation should have as much of a component of approved self-regulation as possible. But to be sure, the overall framework has to be a mandatory, legally enabled general system of regulation of all clinical establishments.

## Conclusions

To conclude, there are a number of solid reasons for regulating the ethics, standards and charges of doctors and hospitals. Regulation of doctors and hospitals cannot be separated from regulation by the medical councils. The medical councils and their functioning need a huge overhaul, including of the CME

courses conducted by them. The amendment introduced in 2009 by the MCI titled “Code of conduct for doctors and professional association of doctors in their relationship with pharmaceutical and allied health sector industry” has not been implemented. This must be corrected and the loopholes in it must be sealed. The CEA 2010 has been an important step for regulation of hospitals in India. But its deficiencies have to be overcome. Otherwise instead of helping the patients it will remain either on paper or will result in Babu raj and make life difficult for small hospitals, paving the way for complete domination by the larger commercial hospitals. The Maharashtra Clinical Establishment Bill-2014 is a good step forward in the direction of states using their prerogative to enact their own legislation to regulate hospitals. But the provision for rate regulation of hospitals and for a patient-friendly grievance redressal system must be added to the draft bill. The IMA’s negativistic approach to the CEA has to change. Otherwise this act will primarily benefit the larger commercial hospitals at the expense of small hospitals.

The specificities of Trust Hospitals and public hospitals have to be borne in mind to ensure the furtherance of interests of the patients. The legal provision of reserving beds for poor and eWS by Trust Hospitals in Maharashtra and Delhi has been flouted with impunity. This should be stopped. Accountability of the functionaries of public hospitals has to be enhanced through measures like Community Based Monitoring in order to protect the interests of patients.

Overall, regulation of hospitals in the era of neo-liberalism poses a huge challenge but certainly this challenge should be taken head on and popular pressure is essential for this purpose.

## NOTES

- 1 “List of Colleges Teaching MBBS,” Medical Council of India, <http://www.mciindia.org/InformationDesk/ForStudents/ListofCollegesTeachingMBBS.aspx>.
- 2 *Pune District Consumer Redressal Forum. Jitendra Kelkar v Sahyadri Speciality Hospital*. Judgment by Hon Judge—Ms Anjali Deshmukh on 30/10/2012 regarding complaint number 576/2009.
- 3 Medical Council of India, Code of Ethics Regulations, 2002, <http://mciindia.org/RulesandRegulations/CodeofMedicalEthicsRegulations2002.aspx>.
- 4 Medical Council of India (Professional Conduct, Etiquette and Ethics) Regulations, 2002, <http://www.mciindia.org/RulesandRegulations/CodeofMedicalEthicsRegulations2002.aspx>.
- 5 Clinical Establishment Act Standards for Hospital (Level 1), see page 7, <http://clinicaestablishments.nic.in/WriteReadData/292.pdf>.

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