

Ensure Social Accountability and Regulation of the Private Healthcare Sector!

India has one of the largest private medical sectors in the world – yet this gigantic entity has remained almost completely unaccountable and unregulated until now. We are all aware of the serious problems of frequent financial exploitation of patients, often accompanied by sub-standard and irrational care in private hospitals and nursing homes, which regularly surface in sharing of personal experiences. Costs of private medical services have spiraled, having more than doubled in absolute terms between the mid-1980s and the mid-1990s. It is estimated that Health care expenditures account for more than half of all Indian households falling into poverty, with nearly 4 crore Indian people being pushed into poverty every year due to such costs. While ordinary patients are suffering tremendously due to this situation, it also should be kept in mind that due to growing corporatisation and commercialization of the entire health care sector, it is also becoming extremely difficult for the dwindling numbers of rationally

practicing doctors and genuinely non-profit health facilities to practice ethically.

How can this situation change?

We would argue here that located in the context of a range of broader measures for strengthening public health services and rolling back privatisation, *comprehensive social regulation of the private*

medical sector is an outstanding need today. In

this policy brief we examine the situation of the private medical sector in some detail and suggest

concrete regulatory measures required to effectively address this situation from a pro-people, rights based perspective.



The extent of private healthcare sector in India

Private Healthcare Services are today the dominant component of the Health Care System in India.

The share of private providers in various components of health care in India is as follows-

- Medical graduates: 90%
- Post-graduate doctors: 95%
- Outpatient care: 80%
- Inpatient care: 60%
- Medical colleges: 30%
- Manufacture of medicines: 99%
- Manufacture of medical instruments: 100%

Under the influence of neoliberal policies since 1990s pushing for globalization, privatization and corporatization, there has been an exponential growth of private healthcare sector. For doctors, policy makers as well as for patients, 'Health-care' has become a commodity to be traded. The 'noble profession' which should be devoted to the service of humankind is now being converted into a profit making industry, operating under the strong influence of the pharmaceutical industry and increasingly commercialized medical education.

Key features of the private healthcare sector in India

1) Characteristics of private healthcare sector in India

- a) This sector is totally **unregulated and lacking in mechanisms for standardization and rationalisation**. Private sector has **all encompassing predominance in the health care scenario**; hence today it overshadows and distorts even the public health system.
- b) This development of the private sector has led to setting up some quality health care facilities as well as a few genuinely non-profit hospitals engaged in serving poor, tribal and vulnerable sections, but these form only a minuscule section of a wide spectrum of private providers, **which include a growing corporate sector, large private hospitals, so-called charitable hospitals flouting their social commitments, smaller nursing homes and semi-qualified and unqualified practitioners**, overall characterized by complete lack of regulation.
- c) **Private medical colleges** as well as **corporate hospitals** have increased much more rapidly during the era of globalization, privatization and liberalization.

2) Major problems with the current private healthcare sector

- a) **Substandard infrastructure**- Although some of the private providers in India maintain physical and process standards in their facilities, the quality of care is not uniform; overall, it is often substandard. *Much is lacking especially in providing basic minimum infrastructural facilities to patients in terms of adequate space, privacy, cleanliness and sufficient trained paramedical staff.*
- b) **Massive wastage due to excessive/irrational medications**- Unnecessary use of antibiotics, vitamins, irrational Fixed Dose Combinations (FDCs), and of medicines with no or doubtful value etc. constitute a huge wasteful expense for the patients.
- c) Doing **surgical procedures even when they are not necessary** has been an increasing trend. The classic example is that of unindicated removal of uterus (hysterectomy) which has been reported by studies from different parts of India.
- d) The **fees charged by surgeons are also often unreasonably high**. A caesarean delivery is charged an amount in India which amounts to several times the monthly per capita income.
- e) Excessive **investigations**- With the advent of corporate interests in health care, the tendency of carrying out excessive laboratory investigations has increased. During the last decade, some purely commercial pathological laboratories and diagnostic centres have developed aggressive marketing strategies, and have lured general practitioners into referring patients for unnecessary investigations, in exchange for commissions.
- f) **Violation of medical ethics**- Medical ethics demands that given the inherent vulnerability, helplessness of the patients, it is the doctor's duty to consciously keep patient's interests uppermost. But this ethical principle is being routinely flouted. **Hundreds of thousands of sex-selective abortions** have been performed in India by doctors during last two decades, by especially misusing sonography. **Commercial surrogacy** has become the emerging method of misuse of new reproductive medical technology. Using patients as guinea pigs by **violating medical ethics of clinical trials** has surfaced as a new addition to the list of unethical practices.

- g) **Violation of patient's human rights-** For example, right to emergency care, right to information, right to informed consent, right to second opinion, right to choice of specific treatment, etc are violated quite frequently.
- h) A report commissioned for the Government of India found that ***hospitals subsidized by the state and expected to provide free treatment to poor patients were simply failing to do so.***
- i) There are numerous misuses of privileges, ***medical malpractice and medical negligence*** among licensed private doctors.

Failed regulatory mechanisms and non-functional laws related to the private healthcare sector

1) **Failed self regulation-**

Medical Councils and Medical Associations have completely failed in instituting self-regulation to ensure standards. Despite having one of the largest private health care sectors in the world providing 80 percent of care in India, ***the fact that it should function practically unregulated is a matter of grave concern.***

2) **Failed existing legal mechanisms-**

Over 30 million cases are pending in numerous courts across India. At the current rate, analysts say that it could take anywhere between 350 to 400 years to sort out the entire backlog! Given this general background of our legal system, there is hardly any chance that going to the court to complain against medical negligence will provide justice to patients. Added to this problem is the tendency among doctors not to testify against colleagues. This same tendency also plagues the cases of medical negligence in the consumer protection cells. ***No wonder that general judiciary or consumer courts have played a negligible role to regulate the private medical sector.***

3) **Very lenient, inadequate current laws focused on registration, without teeth for effective regulation of clinical establishments-**

Until today, the only registration act that is in place in states like Maharashtra is the Bombay Nursing Home Registration Act (***BNHRA***) 1949. This act is ***only for registration of a nursing home.*** It does not contain provisions that would enable it to effectively rationalise and standardize the private medical sector. Similarly are various acts in some other states like Karnataka and Andhra Pradesh. The national Clinical Establishment Act 2010 is yet to be adopted in most states of India.

Essential Components for a pro-people framework to regulate the private healthcare sector

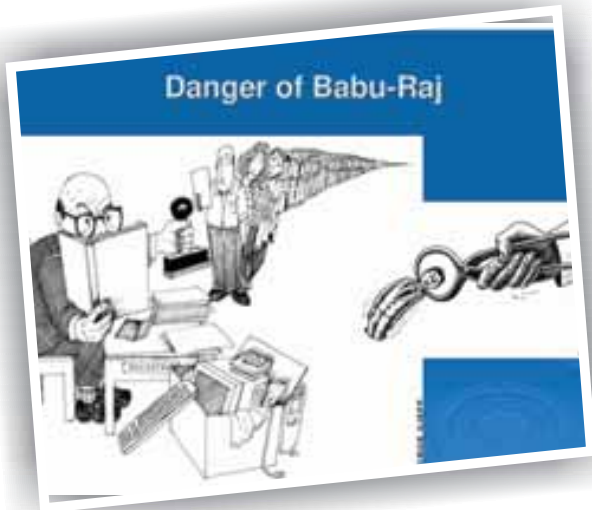
The regulatory framework should -

- 1) Include and protect ***patients' rights***, ensure transparency, informed decisions, and freedom to patients to choose, select and refuse.
- 2) Function to ***assure that every patient receives good quality, rational, evidence based treatment*** at the hands of private healthcare sector with ***reasonable rates.***
- 3) Take care of the ***concerns of ethical private providers***, small nursing homes, and genuinely charitable hospitals, health care facilities working in vulnerable and tribal areas.

- 4) **Not allow corporate hospitals** to enforce their interests through standards and treatment guidelines.
- 5) **Avoid bringing in Babu raj**, prevent **corruption** and make the **executive authority accountable to multi-stakeholder bodies** comprising of citizens, patient' representatives, CSOs and health care professionals.



- 6) Has **an effective and people-friendly redressal mechanism** for complaints of the patients as well as doctors.



The national Clinical establishments act 2010

The 'Clinical Establishments Act 2010' (CEA) passed by the central government is indeed a step forward towards standardization of quality and costs of care.

Certain positive elements in central CEA-

- a) Provision of Standard treatment guidelines.
- b) Move towards standardisation of rates.
- c) Display of rates by establishments.
- d) The act registers nearly all clinical establishments/ branches of medicine and is not just restricted to allopathy.

Serious gaps and problems inherent in the present national act

- i. ***There is no specification of separate, autonomous structure, additional staff (and related dedicated budget) for implementation of clinical establishment act-*** The number of doctors in private health services is today more than five-six times the number of doctors in the government service. ***To effectively regulate this huge private health sector is a stupendous task.*** As per the CEA-2010 this task has been given to the already over-burdened existing structure consisting of Directorate of Health Service at State level whereas at district level it is entrusted with District Registering Authority to be led by overburdened District Collectorate and District Health Officer. In its present form, there is a risk that the Act would remain by and large on paper.
- ii. ***There is no district level multi-stake holder review committee*** with representation of consumers/patients, health sector civil society organisations, as well as doctors- ***All the members of the District Registering Authority are either doctors or bureaucrats. There is no formal space for other stakeholders including representatives of health rights organisations.***
- iii. There is ***no mention or provision for protection of Patient's Human Rights.***
- iv. There is ***no Grievance redressal mechanism*** for patients or mechanism for making complaints by patients.
- v. ***The manner in which CEA covers Public Health Services appears problematic.*** Provisions of closure of establishment or charging of fine in case of non-fulfillment of standards are not appropriate for Public health facilities, which have a broader public mandate and where accountability needs to be enforced in a manner different from private facilities. It also needs to be examined whether making executive officers of the Public Health Services the ex-officio in charge of the regulation of all facilities including public facilities in their area, involves conflict of interest. Making provision of specifically dedicated public officials for regulation, who would be autonomous from existing public health managers, would be desirable.
- vi. ***Inclusion of a police officer in the regulatory structure*** of clinical establishments is unwarranted and doctors' apprehensions about this unwarranted inclusion are justified.
- vii. After the permanent registration has been granted, if any patient or citizen finds that the clinical establishment does not now comply with the minimum standards, ***there is no scope for making a complaint against the clinical establishment.***
- viii. Some of the provisions in the national act/rules are impracticable or not very relevant.
 1. For example the ***requirement to 'stabilize the emergency medical condition of any individual who comes or is brought to clinical establishment' is quite problematic.*** For example a patient with a heart attack (Acute Myocardial Infarction) can be stabilized only in a specialized set up not in any clinical establishment like an ophthalmic hospital!

2. **Specifying infrastructural requirements for single doctor outpatient clinics** is likely to be of minimal practical value.

- ix. **The process for setting standards for Clinical Establishments is highly centralized;** it will take place only at **National level**. Recent developments have fuelled the fears that such centralized decision making in CEA would be used ***much more easily by large commercial hospitals to increase their dominance by pushing in the rules***, such unnecessarily high minimum standards ***which cannot be implemented by smaller hospitals***.

The need for action given the context of Central CEA with serious gaps.

Arunachal Pradesh, Himachal Pradesh, Mizoram, Sikkim, and all Union Territories have adopted central CEA ***in its existing version*** since 1st March, 2012 vide Gazette notification dated 28th February, 2012.

The states of Uttar Pradesh, Rajasthan, Bihar and Jharkhand have adopted the Act under clause (1) of article 252 of the Constitution.

Kerala, Punjab are going ahead with developing their own acts. **Maharashtra** is also now in process of formulating a state clinical establishment act with civil society inputs.

Health services are a state subject in the Indian constitution.

It is not mandatory for any state government to accept the CEA 2010 in its existing form.

State governments have full powers and rights to build upon all the positive features of central CEA 2010, while modifying it to remove the gaps and deficiencies, and to come out with their own improved State CEA.

States should adopt acts which are modified and improved compared to the central CEA!

In parallel, attempts should be made to modify the national regulatory framework in pro-people direction!

For health activists and civil society organizations working in the health sector, there is an urgency to intervene and demand a *modified pro-people State CEA devoid of the deficiencies of Central CEA.*

State governments should not bring in any act unilaterally without consulting Health rights activists, Civil Society Organisations working in the health sector, patients' representatives and consumer activists and doctors' organizations including groups of rational doctors. States must hold multi-stakeholder consultations to discuss various issues involved in their proposed act while developing such legislation.

To effectively serve people's interests any CEA needs

- 1) Modification to provide **separate, autonomous regulatory structure, additional staff at different levels, mechanism for implementation and related dedicated budget**. Without this, there is a risk that the Act would remain by and large on paper.
- 2) A clause providing **space for district level multi stake holder District appellate body** which can also act as a **review forum** about the **decisions taken by the Local Registering Authority**.
- 3) **Inclusion of provisions for display and observance of Patient's human rights and also a Grievance Redressal mechanism for patients at district level**.
- 4) **Mechanism for addressing complaints** by patients or citizens regarding any clinical establishment, and a separate **state level as well as regional level commission** to conduct inquiry into complaints regarding **denial of patients rights**.
- 5) **To remove infrastructural requirements (floor-space requirements) for single doctor outpatient clinics** (these clinics should be required to follow process standards like treatment guidelines)
- 6) **Make Emergency treatment mandatory** for specific kinds of hospitals and nursing homes prescribed in rules like Surgical, Medical, Gynaecology, Orthopedic establishments where emergency treatment is possible, and not at various other clinical establishments like ophthalmic hospitals or only outpatient clinics where such emergency care for all cases cannot be given.
- 7) **To assign the process of setting standards at state level** and not at central level.

Fronts for action ...

a. **Health activists and Civil Society Organizations should elicit and document:**

- i. Cases of denial of patients' rights including gross overcharging; violation of basic rights to information, informed consent, emergency care, non-discrimination etc.; performance of clearly excessive or unindicated procedures.
- ii. Testimonies of prominent practicing doctors who are dissatisfied regarding growing commercialization of the medical sector, irrational procedures treatments, and unnecessary investigations and increasing corporate influence over the medical profession.

b. Such **collected stories, testimonies** should be extensively publicised and circulated in the media **to bring the discourse of regulation of private healthcare sector onto the agenda**.

c. **There is need to build pressure on the state governments which have not yet adopted the existing Central CEA, to develop and enact state CEAs in participatory manner**. Health activists and Civil Society Organizations could conduct **various forms of campaigns including dialogue** with community groups, local IMA representatives and individual sensitive private doctors who may be ready for some form of regulation of private healthcare sector.

It may be noted that in response to advocacy and lobbying by Jan Arogya Abhiyan (JAA) in Maharashtra, the Health ministry has decided to formulate a state specific CEA for Maharashtra. A committee has been appointed for drafting the same, which is in the process of coming out with Maharashtra CEA. JAA has submitted to the state ministry of health a draft Maharashtra Clinical Establishment Act which has been formulated by making appropriate changes in the central CEA to address patients and citizens concerns. This is available on the website – www.privatehospitalswatch.org.

Lack of Political Will



- d. Health rights coalitions like Jan Swasthya Abhiyan, Health activists and civil society organizations **should actively advocate** for **modified state level clinical establishment acts** in their respective states.
- e. Especially keeping in view states which have already adopted the central CEA, attempts should be made to **suggest modifications in the national rules, and to intervene in the process of formulation of standards at national level**, keeping various mentioned considerations in mind. On this front, some positive developments have taken place as of January 2014.

The Health ministry has now invited JSA to be part of three sub-committees of the national council to prepare: (1) draft minimum standards for clinical establishments, (2) range of rates for hospitals and (3) templates for collecting information from hospitals. A JSA representative may also be an invitee for the national council meetings.

There is an urgent need to push the demand that the national standards to be observed by clinical establishments should be not only physical standards but also process standards for provider-patient interaction, particularly observance of patients' rights. In parallel, mechanisms for grievance redressal by patients need to be provided for, preferably in the rules.

We should demand that States should come out with their own comprehensive clinical establishment acts to regulate the private healthcare sector urgently.

Key modifications in the act should be:

- **Focus on patients' rights with effective grievance redressal mechanisms.**
- **Taking into consideration genuine concerns of ethical private doctors, small hospitals, genuinely charitable hospitals working in vulnerable, tribal and difficult areas with limited resources.**
- **Corporate interests and unilateral interests of the Indian Medical Association should not be allowed to dominate the process of developing rules for the clinical establishment act.**
- **Pro-people social accountability mechanisms must be inbuilt in the act: multi stakeholder state and district appellate body for complaints against local registration authority, regional level and state level commissions to look into cases of denial of patients rights.**

Regulation of the private medical sector should be one component of a broader plan of action to transform the Health sector in a pro-people direction. This plan should include major strengthening and expansion of the Public health system, while making it more accountable and responsive to people's needs, and rolling back various forms of privatisation of public health services. Regulation of private health care providers should be part of a broader plan for effective regulation of the pharmaceutical industry and private medical and paramedical education, to ensure that private players must be made to conform to public logic, and should move in the direction of socialised health care.



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