

# ANALYSING REGULATION OF PRIVATE HEALTHCARE IN INDIA

With focus on Clinical Establishments Acts  
Current status, challenges and  
recommendations



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# ABBREVIATIONS

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MOHFW	Ministry of Health and Family Welfare
GOI	Government of India
CEA	Clinical Establishments Act
GDP	Gross Domestic Product
OOP	Out of pocket
SAARC	South Asian Association for Regional Cooperation
NCR	National Capital Region
UT	Union territory
AYUSH	Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy
IPD	In Patient Department
OPD	Out Patient Department
NHRC	National Human Rights Commission



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## **SECTION I STATUS OF REGULATION OF PRIVATE HEALTHCARE, FOCUSSED ON CLINICAL ESTABLISHMENT ACTS**

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# BRIEF OVERVIEW OF THE PRIVATE HEALTHCARE SECTOR IN INDIA

India's healthcare system is dominated by a fragmented and highly diverse private healthcare sector ranging from large multi-specialty and corporate hospitals, diagnostic centres, not-for-profit hospitals, charitable trust hospitals and nursing homes, to individual practitioner led clinics (qualified and unqualified), chemist shops and traditional healers. Healthcare has traditionally been a low political priority in India, with governments investing a little over 1% of the Gross Domestic Product (GDP) on public health since 2009, far below the average for lower-middle income countries (2.4%) and for upper-middle income countries (3.8%).<sup>1</sup> Public spending (i.e. expenditures incurred by health departments of Central and State Governments) on health have stagnated at around 0.9% of the GDP since the 1980s.<sup>2</sup> Decades of under investment in public health facilities and underfunding of National Health Programmes have led to an under-resourced and overstretched public health system, which is struggling to cope with demand for quality healthcare. The gap in provision is filled by India's burgeoning private healthcare sector, which has grown steadily in size and strength from the 1990s, aided by the liberalization-privatization process.

Currently, the public sector in India has 25,778 hospitals and 7,13,986 beds, while the private sector has an estimated 43,487 hospitals with 1,185,242 beds.<sup>3</sup> The 75<sup>th</sup> round on Health conducted by the National Sample Survey Office<sup>4</sup> during 2017-18 showed that **among ailments, which were treated, 69.9% were treated by the private sector.** The same report stated that regarding those **patients that required hospitalization,**

**54.3% in rural settings and 64.7% in urban settings were treated by private hospitals.** India also has a large informal healthcare sector in rural areas, with informal providers being defined as producers of goods and services that are not State authorised or registered, who are nonetheless estimated to have a market share from 48 to 80%.<sup>5</sup>

Lack of access to quality care in public health facilities forces people to turn to the private health sector and the resultant out of pocket (OOP) expenditure on health has resulted in impoverishment for vast numbers of people. A paper<sup>6</sup> quantifying the financial burden of households between 1986-2004 pointed out that the number of hospitalisation episodes in which an ailing **population had to pay out of pocket, has risen dramatically from about 41% to close to 72%.** This increased OOP resulted in "people falling below state-specific official poverty lines, and the percentage of households falling below the poverty line has increased from 4.19% in 1993-1994 to 4.48% in 2011-2012. This translates to 55 million persons in 2011-2012."

***India thus has one of the most highly privatised and commercialised healthcare sectors in the world, along with an underfunded public health system. This combination reinforces the social and economic inequities, and often has ruinous consequences for majority of its people, especially women, marginalised and vulnerable sections of society.***

Moreover, the gender divide affects women's access to crucial healthcare services, right from childhood.<sup>7</sup> The high costs of healthcare in the private health sector, and

1 Global Health Observatory Data, WHO - <https://apps.who.int/gho/data/view.main.GHEDGGHEDGDPSHA2011WBv?lang=en>

2 Ministry of health and family welfare, government of India (2005) Report of the National Commission on Macroeconomics and Health. MoHFW, HOI, New Delhi. P. 7. <http://www.who.int/macrohealth/action/Report%20of%20the%20National%20Commission.pdf>

3 [https://cddep.org/wp-content/uploads/2020/04/State-wise-estimates-of-current-beds-and-ventilators\\_24Apr2020.pdf](https://cddep.org/wp-content/uploads/2020/04/State-wise-estimates-of-current-beds-and-ventilators_24Apr2020.pdf)

4 [http://www.mospi.gov.in/sites/default/files/NSS75250H/KI\\_Health\\_75th\\_Final.pdf](http://www.mospi.gov.in/sites/default/files/NSS75250H/KI_Health_75th_Final.pdf)

5 Iles RA (2018) Informal healthcare sector and marginalized groups: Repeat visits in rural North India. PLoS ONE 13(7): e0199380. <https://doi.org/10.1371/journal.pone.0199380>

6 Selvaraj S, Farooqui HH, Karan A; Quantifying the **financial** burden of households' out-of-pocket payments on medicines in India: a repeated cross-sectional analysis of National Sample Survey data, 1994-2014 *BMJ Open* 2018;**8**:e018020. doi: 10.1136/bmjopen-2017-018020

7 <https://www.bmj.com/company/newsroom/extensive-gender-discrimination-in-healthcare-access-for-women-in-india/>

the low priority placed on women's health in traditional Indian society (women and girls themselves do not seek or delay seeking healthcare, till the situation becomes very pressing), leading to detrimental consequences on women's health. Additionally, women also form a major part of the informal economy, which represents 88 % of total employment in India<sup>8</sup>. Despite this, their access to healthcare services is often compromised due to their inability to pay out of pocket for healthcare. **Marginalised communities** such as the rural and urban poor, Dalits, Adivasis, specific religious and ethnic minority groups are particularly vulnerable and get least access to preventive and curative health services, and **face a higher healthcare expenditure burden**.<sup>9</sup>

## GROWING CORPORATISATION OF HEALTHCARE IN SOUTH ASIA WITH INDIA AS EPICENTRE

India's private healthcare sector is not only one of the largest in the world, but is also significantly more developed as compared to other South Asian countries. From medical education to hospitals and allied healthcare branches like diagnostics, the private healthcare sector in India is established, diversified and hence more influential in policy-making<sup>10</sup>. Starting from the late nineties, private provisioning of healthcare (particularly secondary and tertiary health services) has been promoted in an organized manner as a lucrative business opportunity<sup>11</sup> and a highly profitable economic investment option with handsome returns. The healthcare sector in India has therefore become an attractive area for private capital investment by global investment firms, private equity funds, and high net worth individuals, including global financial institutions such as the International Finance Corporation (IFC). Several Indian multinational healthcare companies

have a growing presence in neighbouring South Asian countries, Gulf and African countries. Several have also been listed on stock exchanges to access more capital to finance their expansions<sup>12</sup>.

This influx of capital has resulted in a burgeoning corporate healthcare sector pan India, particularly in the past decade now, displacing the earlier model of employment of healthcare professionals in small and medium-sized hospitals and individual run clinics<sup>13</sup>. It is noteworthy that **India ranks fifth on the Medical Tourism Index, due to its affordable medical expertise and attracts many people seeking healthcare from neighbouring SAARC countries, Africa and the Middle East**. On the other hand, it ranks a dismal **145<sup>th</sup> among 195 countries on the global Healthcare Access and Quality Index (HAQ)**.<sup>14</sup>

## IMPERATIVE FOR REGULATION OF PRIVATE HEALTHCARE SECTOR IN INDIA

India's current substantial reliance on the private healthcare sector is a reason for grave concern, owing to its lack of comprehensive regulation and standardisation. Due to extremely weak and ineffective mechanisms for accountability and regulation, the private healthcare sector's quest for profit maximization often results in frequent unwarranted treatments, exorbitant healthcare bills and a commercialised approach towards patients<sup>15</sup>. An impersonal and profit-driven corporate management style in multi-specialty hospitals, with doctors being set performance targets and incentivised for achieving numbers has had far reaching consequences on the practice of medicine – from hyperinflation in costs of healthcare, increasing instances of malpractice and corruption to a growing trust deficit between doctors and

8 Bhan, Gautam et al. "Informal work and maternal and child health: a blind spot in public health and research." *Bulletin of the World Health Organization* vol. 98,3 (2020): 219-221. doi:10.2471/BLT.19.231258

9 Baru, R., Acharya, A., Acharya, S., Kumar, A., & Nagaraj, K. (2010). Inequities in Access to Health Services in India: Caste, Class and Region. *Economic and Political Weekly*, 45(38), 49-58. Retrieved September 5, 2020, from <http://www.jstor.org/stable/25742094>

10 Abhijit More, SATHI (2018): Troubling realities of private hospitals in Key South Asian countries: Need for regulatory checks and balances to safeguard patient's interests; COPASAH Policy Brief

11 The term "healthcare industry" is used as an umbrella term while referring to hospitals, diagnostic centers, drugs and pharmaceutical-medical equipment and devices and the insurance industries. The hospital sector is reported to be the major segment, and hence the term healthcare industry is often used while talking about corporate and other big private hospitals.

12 Cleaton-Jones I.P. (2015) Private Hospitals in Latin America: An Investor's Perspective. *World Hospitals and Health Services*. 2015;51(2):7-9.

13 Marathe S, Hunter BM, Chakravarthi I, et al The impacts of corporatisation of healthcare on medical practice and professionals in Maharashtra, India *BMJ Global Health* 2020; 5: e002026.

14 [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(18\)30994-2/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)30994-2/fulltext)

15 Gadre A, Shukla A. *Dissenting Diagnosis* 2016, Penguin India



patients<sup>16</sup> and incidents of violence against hospitals and healthcare workers.

The Government of India has been receiving many complaints<sup>17</sup> regarding malpractices in clinical establishments, particularly large multi-specialty hospitals and corporate establishments such as billing of arbitrary and exorbitant charges; total lack of transparency in diagnosis, treatment and billing; gross deficiencies in services provided to the patients; absence of adherence to standard treatment protocols leading to unnecessary investigations, procedures, surgeries and medications. Patients admitted in hospitals are often forced to avail of in-house diagnostics services and to purchase medicines, consumables and implants from select vendors.

An analysis of bills from four reputed private hospitals in the Delhi and NCR region by the National Pharmaceutical Pricing Authority (NPPA), Govt. of India revealed that they make **profit margins from 100 % to 1,737% on drugs, consumables and diagnostics and these three components account for about 46% of a patient's bill**<sup>18</sup>. These malpractices and profit driven functioning are leading to increased out of pocket expenditure on healthcare and impoverishment of vast and vulnerable population in India.

Reports of uncontrolled exploitation of vulnerable patients seeking healthcare in private hospitals has led to **growing unrest** amongst people. Increasingly frustrated with the lack of options for redressal and an unresponsive judiciary, people have begun to voice their discontent and suspicion through attacking medical institutions and frontline healthcare personnel. Rising instances of verbal and physical violence over billing, detainment of patients or dead bodies of patients by private hospitals for non-payment of bills, are being reported all across the country. This entire

situation underscores the urgent need for regulation of the private medical sector in India, to safeguard the interests of patients and the legitimate interests of private healthcare providers. There is a growing demand within civil society and ordinary citizens for effective regulation and transparency in charges levied by private clinical establishments.

It should be emphasised that **women are affected disproportionately due to the lack of regulation of private healthcare**, including lack of standard treatment protocols in the healthcare sector. In 2019, there were reports<sup>19</sup> of large scale **unwarranted hysterectomies** (surgical removal of the uterus) in women working as sugarcane cutters in Beed, Maharashtra. This once again underscored the prevalence of this sake of profit maximisation practice across India for **sake of profit** over the past decade. Across states like Andhra Pradesh, Karnataka, Rajasthan, Chhattisgarh and Bihar, women especially from rural areas and poor households have been subjected to unnecessary hysterectomies in the private sector, often to avail insurance benefits under state-sponsored insurance schemes.<sup>20</sup> Along with hysterectomies, the rising numbers of **caesarean section births** in India, largely performed without any medical indications, is also a matter of grave concern as these procedures pose risks and have long term consequences for maternal and child health. Research has shown **that caesarean section births are nearly three times more in the private sector as compared to the public sector**<sup>21</sup> in India. With **17% of all institutional deliveries being conducted through caesarean section** in 2015-16, India has already **crossed the World Health Organizations threshold of 15%**.<sup>22</sup>

Regulation of the healthcare sector assumes even more relevance in the light of increasing coverage of publicly funded, privately provided **healthcare**

16 Marathe S, Hunter BM, Chakravarthi I, *et al* The impacts of corporatisation of healthcare on medical practice and professionals in Maharashtra, India *BMJ Global Health* 2020;**5**:e002026.

17 Union Health Secretary, Govt of India's letter to Chief Secretaries of all states regarding adoption of the Charter of Patients' rights, dated 2nd June 2019 - <http://clinicalestablishments.gov.in/WriteReadData/9901.pdf>

18 <https://timesofindia.indiatimes.com/india/private-hospitals-making-over-1700-profit-on-drugs-consumables-and-diagnostics-study/articleshow/62997879.cms>

19 Hysterectomies in Beed district raise questions for India - The Lancet, July 20, 2019 [https://doi.org/10.1016/S0140-6736\(19\)31669-1](https://doi.org/10.1016/S0140-6736(19)31669-1)

20 <https://www.thehindu.com/news/national/spree-of-hysterectomies-to-make-a-fast-buck/article5007641.ece>

21 Singh, Priyanka *et al*. "High prevalence of cesarean section births in private sector health facilities- analysis of district level household survey-4 (DLHS-4) of India." *BMC public health* vol. 18,1 613. 10 May. 2018, doi:10.1186/s12889-018-5533-3

22 Guilamoto CZ, Dumont A. Trends, Regional Variations, and Socioeconomic Disparities in Cesarean Births in India, 2010-2016. *JAMA Netw Open*. 2019;2(3):e190526. doi:10.1001/jamanetworkopen.2019.0526



**insurance schemes** like the Pradhan Mantri Jan Arogya Yojana (PMJAY), where public money is transferred to private hospitals on a large scale in an environment of regulatory uncertainty. Emergence of such public private partnerships (PPP) for delivery of healthcare services highlights the need for standardisation of rates of private providers on public platforms, underlining the urgent need for comprehensive regulatory reforms.

Regulation of private healthcare providers has **other benefits**<sup>23</sup> namely:

- Ensure a certain standard of quality and cost of healthcare, which will check medical malpractice, negligence and financial exploitation of people.
- Creation of a comprehensive registry of clinical establishments across the country and systematic collection of data and information which will aid in healthcare policy formulation.

- Better maintenance of records, better surveillance, better response and management of outbreaks and public health emergencies.
- Standard Treatment Guidelines (STGs) will help healthcare providers and patients to make informed choices about their medical treatment with better clarity.

While regulation of private healthcare has a number of dimensions, *in this paper we will focus on the regulation of rates and quality of services by healthcare institutions* – aspects which are of core and direct importance to patients and their caregivers, who access services in the private sector. *Hence, our emphasis in this paper will be on describing and analysing Clinical Establishment Acts and similar laws at Central and State levels.*

<sup>23</sup> Operational Guidelines for Clinical Establishment Act; [www.clinicalestablishments.gov.in](http://www.clinicalestablishments.gov.in)

# CLINICAL ESTABLISHMENT (REGISTRATION AND REGULATION) ACT 2010: BACKGROUND AND LEGAL PROVISIONS IN BRIEF

Healthcare is a state subject in India, and the Parliament of India generally lacks power to legislate on items from the State List. However, two or more States may ask the parliament to legislate for them on an issue that is otherwise reserved for the state. Other states may then also choose to adopt the resulting legislation. In 2010, in pursuance of clause (1) of Article 252 of the Constitution, resolutions were passed by all the Houses of the Legislatures of the States of Arunachal Pradesh, Himachal Pradesh, Mizoram and Sikkim to the effect that clinical establishments should be regulated in those states by Parliament, by a law with the view to prescribe minimum standards for facilities and services in clinical establishments in those states, and a proper legislation could therefore be passed by the Parliament. There was an elaborate discussion in Parliament on the need to bring in such legislation. In view of consent given by more than two states, Parliament, in exercise of powers under Article 252(1) of the Constitution, enacted the "Clinical Establishments (Registration and Regulation) Act, 2010" in December 2010. The Act has taken effect in these four states and all Union Territories except Delhi since 1st March, 2012 vide Gazette notification dated 28th Feb, 2012.

## LEGAL PROVISIONS IN BRIEF:

### PREAMBLE

The Preamble to the Act mentions the reasons why Parliament thought of enacting the said legislation:

**"WHEREAS, IT IS CONSIDERED EXPEDIENT TO PROVIDE FOR THE REGISTRATION AND REGULATION OF CLINICAL ESTABLISHMENTS WITH A VIEW TO PRESCRIBE MINIMUM STANDARDS OF FACILITIES AND SERVICES WHICH MAY BE PROVIDED SO THAT MANDATE OF ARTICLE 47 FOR IMPROVEMENT IN THE PUBLIC HEALTH IS MET."**

Clearly, the purpose of the enactment is to register and regulate clinical establishments based on minimum standards in order to improve the quality of health care in the country.

### SCOPE AND APPLICABILITY OF CEA

The Clinical Establishments (Registration and Regulation) Act, 2010 (henceforth referred to in this document as CEA 2010) is applicable to all systems of medicine recognized by the Government of India which includes modern medicine, commonly referred to as Allopathy and Homoeopathy, Ayurveda, Siddha and Unani, Naturopathy, Yoga and Sowa-Rigpa. The term 'clinical establishments' is wide enough to cover hospitals, maternity homes, nursing homes, clinics, dispensaries, pathology/ microbiology/ genetic laboratories, radio-diagnostic imaging centres, physiotherapy centres, day care centres etc which are owned, controlled or managed by the Government or a department of the Government, local self-government body, a charitable trust (whether public or private), a corporation (including a society - whether public or private) registered under a Central or State Act, single doctor clinics by private practitioners etc. Thus, it includes all kinds of clinical establishments owned or controlled by the government or any arm of the government or private entity.

Clinical Establishments not covered under the CEA 2010 are:

- Clinical establishments owned, controlled or managed by the Armed Forces
- Clinical Establishments in the States / UTs mentioned in the schedule of the Act; unless they repeal their existing Acts and adopt the central Clinical Establishments Act
- Clinical Establishments of categories exempted by the state government



## PROVISIONAL REGISTRATION, STANDARDS NOTIFICATION AND PERMANENT REGISTRATION

Section 11 of CEA provides that no person shall run a clinical establishment unless it is duly registered with the **District Registering Authority** and fulfils the stipulated conditions. On application to the District Registering Authority, all clinical establishments will automatically be issued provisional registration (to be renewed every year) within a stipulated period. Permanent registration of such establishments is only to be considered after notification of Minimum Standards. Clinical establishments will be required to meet **minimum standards** before grant of Permanent Registration<sup>24</sup>. Once the minimum standards for clinical establishments are notified by the Ministry of Health and Family Welfare (MoHFW), Government of India, then those clinical establishments which are provisionally registered, will be issued permanent registration (to be renewed every five years), after submitting declaration and evidence that they have fulfilled conditions of registration and compliance with relevant notified standards for that particular category of clinical establishments (Section 25).

Therefore, *the assessment of compliance of clinical establishments with standard treatment guidelines, minimum standards for facilities, patient safety and hygiene can only be carried out during the process of granting permanent registration and through monitoring thereafter*, making these steps a very crucial mechanism of the regulatory process.

## CONDITIONS OF REGISTRATION

The conditions of registration form an important part of this legislation. Section 12 of the CEA 2010 stipulates that every clinical establishment needs to fulfil the following **conditions of registration**, namely compliance with:

- Prescribed minimum standards of facilities and services
- Prescribed minimum requirement of personnel
- Provision and maintenance of records and reports
- Any other condition of registration to be prescribed

Beside these conditions, a critical provision states that clinical establishments should **stabilize patients with emergency medical conditions** within available resources and expertise. Failure to comply with these

conditions of registration may lead to cancellation of registration. If there is any **imminent danger to the health and safety of patients** in the clinical establishment, then the authority may immediately restrain the clinical establishment. There is also a provision for levying of **monetary penalties** ranging from Rs 10,000 to 5 lakhs, depending on nature of offence.

## IMPLEMENTATION MECHANISM FOR CEA 2010

The Act has envisioned the following three implementing agencies, which will oversee and manage the implementation of this Act:

### NATIONAL COUNCIL FOR CLINICAL ESTABLISHMENTS

The National Council is a multi-stakeholder apex body at national level with the Director General of Health Services of India as a Chairperson. The Council is entrusted with responsibilities, among other things, of compiling and publishing a National Register, classifying the clinical establishments into different categories, developing the minimum standards through a consultative process with due regard to local conditions and their periodic review and to determine the first set of standards within a period of two years of its establishment.

### STATE COUNCIL FOR CLINICAL ESTABLISHMENTS

The State Council is a multi-stakeholder apex body at the state level with the Health Secretary as a chairperson. It is entrusted with the responsibility of compiling and updating the State Registers, sending monthly returns for updating the National Register, hearing of appeals against the orders of the District Registering Authority and publication of an annual report on the implementation of standards.

### DISTRICT REGISTERING AUTHORITY

The District Registering Authority is a 5-member body headed by the District Collector, while the District Health Officer acts as a Convener and shall exercise the powers of the District Registering Authority. The District Registering Authority is entrusted with the responsibility and power to grant, renew, suspend or cancel registration of clinical establishments within the district. It can investigate complaints and inspect clinical establishments if needed. It is the duty of District Registering Authority to enforce compliance of the CEA 2010 and to submit its report to State Council.

## A STEP AHEAD - CEA RULES 2012

The **CEA Rules were notified in 2012** and specified some of the most important conditions for registration of clinical establishments in Section 9 of the Rules as follows:

- Prominent display of details of rates charged and facilities available at a conspicuous place in the clinical establishment in local and English languages
- Charge the rates for procedures and services within the range of rates determined by the Central Government in consultation with the State Governments

- Compliance with prescribed Standard Treatment Guidelines
- Maintain and provide Electronic Medical Records
- Maintain information and statistics in accordance with rules

While provisions in CEA 2010 focus on registration, **key regulatory provisions like transparency in rates, standardisation of rates and standard treatment guidelines are included in the rules.**



# STATUS OF IMPLEMENTATION OF CEA 2010 AT NATIONAL LEVEL

## GAZETTE NOTIFICATION OF THE CEA 2010, NATIONAL COUNCIL AND RULES

- The Clinical Establishments (Registration and Regulation) Act, 2010 came into force in the states of Arunachal Pradesh, Himachal Pradesh, Mizoram and Sikkim along with all Union Territories except Delhi vide Gazette notifications dated 28<sup>th</sup> February 2012.
- The National Council for Clinical Establishments under this Act was notified on 19<sup>th</sup> March, 2012.
- Clinical Establishments (Central Government) and Rules, 2012 under this Act were notified on 23<sup>rd</sup> May, 2012. The Rules provide for constitution of District Registering Authority, powers of District Health Officer/Chief Medical Officer. Section 9 of rules is important as it relates to conditions for registration and continuation of clinical establishments.

## ADOPTION OF CEA 2010 BY STATE AND UTS

As discussed previously, health is a state subject in the Indian Constitution. However, as far as CEA 2010 is concerned, there are two options for state governments:

- To adopt CEA-2010 under clause (1) of article 252 of the Constitution
- To enact their own state level legislation on similar lines

According to Operational Guidelines for Clinical Establishments Act, prepared by Ministry of Health and Family Welfare, Government of India, 11 States and 6 Union Territories have adopted the Clinical Establishment Act, 2010 by 2020.

### States which have adopted CEA 2010

Arunachal Pradesh, Himachal Pradesh, Sikkim, Mizoram, Bihar, Jharkhand, Rajasthan, Uttar Pradesh, Uttarakhand, Assam, Haryana

### UTs which have adopted CEA 2010

Andaman & Nicobar Islands, Daman & Diu, Dadra & Nagar Haveli, Puducherry, Chandigarh, Lakshadweep

*Annexure 1* shows the timeline of state and UT level notifications related to CEA 2010, and displays the major variation and delay concerning adoption of the CEA 2010 by the states and notification of the State rules, Council and District Registering Authority (DRA). In the case of Uttar Pradesh, this delay is as much as 6 years, while notification of State Councils and DRA is still pending in Haryana, Bihar and Uttar Pradesh.

## NATIONAL COUNCIL FOR CLINICAL ESTABLISHMENTS

The National Council is the apex governing body for the implementation of CEA 2010. It is a 20-member council formed as per the gazette notification dated 19<sup>th</sup> March 2012. A secretariat for the National Council has been set up for coordinating its tasks.





**MEETINGS OF NATIONAL COUNCIL:**

1 <sup>st</sup> meeting 01.06.2012	2 <sup>nd</sup> meeting 31.10.2012	3 <sup>rd</sup> meeting 24.06.2013	4 <sup>th</sup> meeting 13.01.2014	5 <sup>th</sup> meeting 18.07.2014	6 <sup>th</sup> meeting 08.12.2014
7 <sup>th</sup> meeting 18.09.2015	8 <sup>th</sup> meeting 21.03.2016	9 <sup>th</sup> meeting 19.12.2016	10 <sup>th</sup> meeting 08.09.2017	11 <sup>th</sup> meeting 13.07.2018	<b>No meeting held after 13.07. 2018 till 15.12.2020</b>

Source: www.clinicalestablishments.gov.in; accessed on 31st August 2020

The National Council was formed in 2012 after the notification, and as per the details specified in the table above, a total of **11 meetings have taken place till date**, scheduled rather erratically. Three meetings were held in the year 2014, two meetings each in years 2012 and 2016 and only one meeting in the years 2015, 2017, 2018. There were zero meetings in the year 2019 and 2020. *The National Council has not held any meeting for the past two years from 13<sup>th</sup> July 2018 till 15<sup>th</sup> December 2020.*

### **NATIONAL REGISTER OF CLINICAL ESTABLISHMENTS, PROVISIONAL AND PERMANENT REGISTRATIONS**

A dedicated website (www.clinicalestablishments.gov.in) has been made operational. Provisions for online registration of clinical facilities as well as operational guidelines for implementation of the Clinical Establishments Act are available on this website.

Annexure 2 shows that as of 31<sup>st</sup> August 2020, **the National Register for Clinical Establishments has 27,030 clinical establishments** provisionally registered from 5 UTs and 8 states namely: Andaman—Nicobar Islands, Chandigarh, Dadra & Nagar Haveli, Daman & Diu, Puducherry, Arunachal Pradesh, Assam, Haryana, Himachal Pradesh, Jharkhand, Mizoram, Rajasthan and Uttarakhand. *There is zero provisional registration from Uttar Pradesh, Bihar, Sikkim and Union Territory of Lakshadweep in the national register.*

*It must be noted that the critical process of permanent registration of clinical establishments has not commenced in any state even after a decade of the*

*enactment of the Act, defeating its entire purpose.* Private hospitals continue to run as usual, thwarting attempts at effective regulation. *The reason behind this interminable delay may be attributed to the failure of notification of minimum standards, a process that was supposed to be completed within two years of formation of the National Council in 2012.*

### **MINIMUM STANDARDS FOR FACILITIES AND SERVICES**

As per CEA 2010, the National Council was supposed to release the first set of minimum standards within two years of its constitution. The National Council was notified vide Gazette notifications dated 19th March, 2012.

However, **it took almost six years for the council to formulate draft minimum standards for Medical Diagnostic Laboratories**, following which the MOHFW, GOI notified minimum standards for Medical Diagnostic Laboratories in the Gazette of India on 18<sup>th</sup> May, 2018, which were again modified subsequently in a notification dated 14<sup>th</sup> February 2020.

On 17<sup>th</sup> July 2019, the MOHFW, GOI finalised the draft notification for minimum standards for different categories of Allopathy and AYUSH establishments, and shared them on their website for public feedback. Minimum standards were drafted for 35 specific categories of Specialty or Super specialty clinical establishments/ departments along with 8 categories of General Minimum Standards for clinical establishments which includes clinic and polyclinic, hospitals (level 1,2,3), health check-up centre, dental lab, physiotherapy, dietetics, integrated counselling centre

and minimum standards for clinical establishments providing Ayurveda, Homeopathy, Unani, Siddha, Yoga, Sowa-Rigpa, Naturopathy.

*However, these standards still have not been notified till date, with the consequence that the entire process for permanent registration of clinical establishments has been held in abeyance for nearly a decade.* In the absence of notified minimum standards for clinical establishments, the real process of regulation of clinical establishments with implementation of minimum standards, standard treatment guidelines, transparency in charges, standardisation of rates etc. has only remained on paper till date.

**put up on the website.** However, **these STGs are yet to be notified** and are therefore not in force as of 31<sup>st</sup> December 2020. No STGs have been drafted for Homeopathy, Yoga, Naturopathy, Sowa-Rigpa, Unani and Siddha<sup>25</sup>.

### **RATE TRANSPARENCY AND STANDARDISATION:**

Rate transparency and standardization is the most critical and politically contentious aspect of the regulation of clinical establishments. Transparency in rates charged by clinical establishments is the most necessary reform needed in the opaquely functioning private healthcare sector in India and one that is most frequently demanded by citizens. However, the **National Council has not undertaken any specific steps to**

**THE ABOVE SUMMARY DESCRIPTION OF PROGRESS ON CEA 2010 SHOWS THAT ALL FIVE CRUCIAL ASPECTS OF REGULATION OF CLINICAL ESTABLISHMENTS LIKE PERMANENT REGISTRATION, NOTIFICATION OF MINIMUM STANDARDS, NOTIFICATION OF STANDARD TREATMENT GUIDELINES, TRANSPARENCY IN CHARGES, AND STANDARDIZATION OF RATES ARE YET TO BE IMPLEMENTED. THE NATIONAL COUNCIL HAS BEEN EXTRAORDINARILY SLOW AND INEFFECTIVE IN LEADING AND FACILITATING THIS PROCESS. AS FAR AS RATE STANDARDIZATION IS CONCERNED, THE NATIONAL COUNCIL SEEMS TO HAVE SHRUGGED OFF ITS RESPONSIBILITY, AND NOW EXPECTS STATE GOVERNMENTS TO COMPLETE THIS COMPLEX YET IMPORTANT TASK.**

### **STANDARD TREATMENT GUIDELINES**

Standard Treatment Guidelines (STGs) are very crucial for maintaining the quality of healthcare and ensuring patient safety. STGs which are systematically developed by expert committees with due regard to local conditions would definitely help doctors and patients in informed decision-making. They are also necessary to eliminate or check ongoing medical malpractice in the form of unnecessary medications, tests, surgeries/ procedures leading to exploitation of patients.

So far, **Standard Treatment Guidelines (STGs) for 227 medical conditions in Allopathy and 18 medical conditions in Ayurveda have been formulated and**

**ensure transparency in rates.** Further, it has **dissolved its sub-committee on rate standardization and shifted the responsibility for rate standardization to the concerned 11 states and 6 UTs** who have adopted CEA 2010.

After due discussions in the 11<sup>th</sup> meeting of the National Council dated 30<sup>th</sup> July 2018<sup>26</sup>, it was decided that the states/UTs would develop standard costs of procedures and services referring to a list of more than 3500 procedures / services and standard template of costing as approved and shared by the National Council. States and UTs would define such costs for common procedures as applicable to their

<sup>25</sup> [www.clinicalestablishments.gov.in](http://www.clinicalestablishments.gov.in); Minutes of 11th meeting of National Council dated 30.07.2018

<sup>26</sup> [www.clinicalestablishments.gov.in](http://www.clinicalestablishments.gov.in); Minutes of 11th meeting of National Council dated 30.07.2018

states taking into other local factors into account and submit the first list of costs of procedures within 2 months. However, only Chandigarh and Dadra and Nagar Haveli; Andaman and Nicobar Island, Daman and Diu responded by 18<sup>th</sup> February 2019.<sup>27</sup> Chandigarh has proposed to implement Ayushman Bharat PMJAY package rates for procedures and CGHS rates for consultation. The administration of Union Territory of Dadra and Nagar Haveli is in process to finalise rates of Medical Procedures and Services.

### CHARTER OF PATIENT'S RIGHTS AND RESPONSIBILITIES:

The National Human Rights Commission (NHRC) shared a draft of a Charter of Patients' Rights<sup>28</sup> with the Ministry of Health and Family Welfare (MoHFW), Government of India on 30.08.2018 for implementation in all States and UTs in all clinical establishments, whether public or private.

This Charter draws inspiration from international obligations, domestic legislations and the Constitution of India. It was created as a guide for the Central and State Governments to formulate standard, concrete mechanisms that would protect the following patients' rights:

This charter was discussed in the 11<sup>th</sup> meeting of National Council for Clinical Establishments, which then recommended Do's and Don'ts for patients and clinical establishments. Subsequently, the Union Health Secretary wrote in a letter dated 2<sup>nd</sup> June 2019<sup>29</sup>, to Chief Secretaries of all states and UTs, urging them to adopt the attached Charter of Patients' rights, which was a considerably abridged and diluted version of the NHRC charter, with just 12 rights.

It is worthwhile to note that the MOHFW released a draft notification for **minimum standards<sup>30</sup> for different categories of Allopathy and AYUSH establishments, which do include a charter for patients' rights and**

## NHRC PATIENTS' RIGHTS CHARTER

1. Right to information
2. Right to records and reports
3. Right to Emergency Medical Care
4. Right to informed consent
5. Right to confidentiality, human dignity and privacy
6. Right to second opinion
7. Right to transparency in care, and care according to prescribed rates where relevant
8. Right to non-discrimination
9. Right to safety and quality care according to standards
10. Right to choose alternative treatment options if available
11. Right to choose source for obtaining medicines or tests
12. Right to proper referral and transfer, which is free from perverse commercial influences
13. Right to protection for patients involved in clinical trials
14. Right to protection of participants involved in biomedical and health research
15. Right to take discharge of patient, or receive body of deceased from hospital
16. Right to Patient Education
17. Right to be heard and seek redressal

27 [www.clinicalestablishments.gov.in](http://www.clinicalestablishments.gov.in); Submission of reply and Order of CIC in respect of Second Appeal of Sh. S.K. Verma; dated 18th Feb 2019

28 <http://clinicalestablishments.gov.in/WriteReadData/8431.pdf>

29 <http://clinicalestablishments.gov.in/WriteReadData/9901.pdf>

30 [https://main.mohfw.gov.in/sites/default/files/clinicalestablishment\\_updated.pdf](https://main.mohfw.gov.in/sites/default/files/clinicalestablishment_updated.pdf)



**responsibilities, as an annexure in some categories.** However, this **charter** is an even briefer version of the 12 patients' rights mentioned in the Union Health Secretary's letter.

There is an obligation on the Union and State Governments to take positive steps to make these rights functional and enforceable by law. This is especially true with respect to the right of patients to a

speedy and effective grievance redressal mechanism, in case of a violation of their rights as enshrined in the patient's rights charter. **Establishment of such an expeditious grievance redressal mechanism for patients is necessary** for any meaningful realization of the Patient's rights charter, and the realization of the positive obligation of the State to protect people's Right to Health.

## BRIEF OVERVIEW OF STATUS OF IMPLEMENTATION IN STATES AND UTs WHICH HAVE ADOPTED CEA 2010

The CEA 2010 is adopted by 11 states namely- Arunachal Pradesh, Assam, Himachal Pradesh, Bihar, Jharkhand, Sikkim, Uttar Pradesh, Uttarakhand, Rajasthan, Mizoram, Haryana and six Union Territories namely- Andaman & Nicobar Islands, Daman & Diu, Dadra & Nagar Haveli, Puducherry, Chandigarh and Lakshadweep. In these 11 States and 6 UTs, the status of notification of State Rules, State Council and District Registering Authorities is as follows :<sup>31</sup>

- Notification of State/UT Rules- done by all 11 states and 6 UTs
- Notification of State / UT Council- done by 10 states (exception- Uttar Pradesh) and 5 UTs (exception- Chandigarh)
- Notification of District Registration Authorities- done by 10 states (exception- Uttar Pradesh) and 6 UTs. In Bihar, the State rules, State Council and District Registering Authorities have been notified but stayed by the High Court.

### REVIEW OF IMPLEMENTATION OF CEA IN SELECTED STATES:

**JHARKHAND:** Among states which have adopted the Act, Jharkhand is at the forefront of the process of provisional registration of establishments for CEA 2010. It adopted the CEA 2010 in February 2012, notified District Registering Authorities in November 2012, notified State Council in February 2013 and notified State rules in May 2013. Till 31<sup>st</sup> August 2020, the highest numbers of provisional registration of the clinical establishments in the country were done by Jharkhand. So far, 7636 clinical establishments have been provisionally registered.

**BIHAR:** Bihar state adopted the CEA 2010 in August 2011, notified State rules in November 2013 and notified District Registering Authorities and State Council in May 2015. However, the High Court stayed the implementation of the Act in response to a PIL filed by Bihar Health Services Association (BHSA) in 2016. The provisional registration of clinical establishments has, therefore, not yet started in Bihar.

**UTTAR PRADESH:** UP adopted the CEA in February 2011 and notified State Rules in July 2016. But it has not yet notified the State Council and District Registering Authorities, making it the only state amongst the eleven to not have even initiated the most basic process of provisional registration of clinical establishments.



<sup>31</sup> [www.clinicalestablishments.gov.in](http://www.clinicalestablishments.gov.in); Submission of reply and Order of CIC in respect of Second Appeal of Sh. S.K. Verma; dated 18th Feb 2019

## TRAJECTORY OF CENTRAL CEA OVER LAST DECADE– A BRIEF ANALYSIS

Prevailing socio-political conditions, economy and state-market relationships have defined the contours of regulatory processes over the last seven decades of independent India. However, we observe a remarkable variance in the state-market relationship in the country between second half of the 20<sup>th</sup> century as compared with the 21<sup>st</sup> century. The pendulum in India has fully swung from the ‘Welfare State’ in the era of mixed economy with the State at ‘commanding heights of economy’ after Indian Independence, to ‘Free Market’ economy in the era of ‘Neoliberalism’ with the State being limited to a ‘Stewardship’ role. This transition has shaped and dictated our national health policy, regulatory frameworks and other processes in the healthcare sector.

The CEA 2010 was a considerable and long overdue improvement over the nursing home centric, outdated regulatory legislation, which existed in India from the 1970s, and was confined to registration and licensure. The idea of inclusion of a variety of stakeholders like medical professionals, civil society, patients in regulatory processes are largely absent in old legislations. Scope of the CEA 2010 encompasses almost the entire spectrum of different types of clinical establishments that have sprung all over India in the last three decades after liberalisation of the economy. Most importantly, the CEA 2010 moves beyond the registration and licensure process and intends to regulate different aspects of healthcare like quality, transparency, rationality, affordability, patient safety, hygiene, digitisation of medical records etc. Section 9 in the rules framed in the year 2012 under this legislation is an extremely important step towards this direction.

However, in the neoliberal era, any state intervention in the economy is viewed very suspiciously by business interests, and the idea of regulation of the private sector is often perceived through the prism of old memories of the so called ‘inspector raj’ and bureaucratic red tape.

***The CEA 2010 attempts to circumvent ‘inspector raj’ (unjustifiably restrictive and arbitrary regulation) in two***

***ways-*** firstly by ensuring participation of the medical community in the ongoing decision-making related to regulatory processes, especially the technical aspects and secondly, by not providing discretionary powers to the registering authority while implementing the Act. CEA 2010 provides for the creation of a multi-stakeholder regulatory authority at the national and state levels in the form of National Clinical Establishment Council and State Clinical Establishments Councils. Standards to be followed by the clinical establishments are to be defined in a consultative manner by these multi-stakeholder councils with the help of expert committees of medical personnel. There is no provision in the CEA 2010 for mandatory inspection by District Registering Authority (DRA) before registration. If there is a complaint regarding facilities and services in the clinical establishment, the subsequent inspection by the DRA is subject to a specified process and adequate checks and balances are built into the law to avoid potential misuse of power by DRA. State Council has overriding appellate jurisdiction over the decisions of the District Registering Authority. Thus, the legal architecture of the CEA 2010 tries to overcome some dangers of bureaucratic overreach, by giving up mandatory inspection while retaining other regulatory functions.

However, this Act does have its deficiencies, which will be covered in the next section. The **membership of multi-stakeholder national and state councils is heavily skewed in favour of the medical community** while not offering commensurate representation of patients’ rights groups, consumer groups and civil society. There is a tokenistic representation of consumer groups, which lack the numerical strength within the National Council or State Council to protect or press for the legitimate interests of patients.

***Despite more participative decision-making as envisioned in the CEA 2010, the Act was vehemently opposed by Indian Medical Association*** and some other medical associations who tried to create roadblocks in its implementation even after the



enactment of the legislation. In June 2019, the Health Secretary of MOHFW, Government of India sent a letter to Chief Secretaries of all states, in which it was even conceded that lobbies of clinical establishments, medical associations are stiffly opposing and influencing state governments to not adopt the CEA 2010<sup>32</sup>. Partly for that reason and partly due to the centralised processes of National Council with no powers for state governments to amend the CEA Act/ Rules, there was very little interest shown by many state governments to adopt this act.

It is important to note that enactment of CEA 2010 was not preceded by any large-scale movements or social mobilisation leading to a broad social demand for regulation of private healthcare sector. Interestingly, this coincided with a period of enactment of other entitlement-based legislations in social welfare spheres like education, rural employment, food security, forest rights etc. in Indian Parliament. However, the initiative shown by the Government of India in the initial phase for implementation of CEA 2010 was not reciprocated by many state governments.

Broadly, *the trajectory of implementation of CEA 2010 in the past decade can be grouped into two periods—firstly from 2011 to 2014, and secondly from 2015 till 2020*. The initial momentum for implementation of CEA 2010 observed during the first phase of 2011 to 2014 considerably slowed down or even stalled during the second phase starting from 2015 onwards till date.

The CEA 2010 came into force vide Gazette notifications dated 28<sup>th</sup> February 2012. In the next month itself, the National Council for Clinical Establishments was notified on 19<sup>th</sup> March, 2012. Within the next two months, Ministry of Health and Family Welfare, Government of India notified the Clinical Establishments (Central Government) and Rules, 2012. ***Out of the 11 states and 6 UTs who have adopted the CEA 2010 till this date, all of them, with the exception of Assam and Haryana, adopted the Act in 2011 and 2012.*** Notification of state rules, state council and district registering authority was almost completed in eight states and six UTs between 2012 to 2014, with the exception of Assam, Haryana and Uttar Pradesh.

After the notification of the National Council, a total of 11 meetings have taken place, out of which six meetings took place in the first three years i.e. from 2012 to 2014. Whereas in the past six years i.e. from 2015 to June 2020, only five meetings of the National Council took place. There was no meeting of the National Council for almost two years from 13<sup>th</sup> July 2018 till end 2020. Only provisional registration was initiated and carried out in this period.

***As per CEA 2010, the minimum standards for clinical establishments were supposed to be notified within two years of establishment of National Council i.e. by March 2014.*** Clearly, that did not materialise, and the process dragged on for six years. It was finally on 17<sup>th</sup> July 2019 that the Ministry of Health and Family Welfare, Government of India published the draft notification for minimum standards for different categories of Allopathy and AYUSH clinical establishments on its website for public feedback. ***More than a year has gone by since the publishing of the draft notification, but standards have not yet been notified.*** The only exception are the minimum standards for Medical Diagnostic Laboratories, which were notified on 18<sup>th</sup> May 2018 and subsequently modified by notification dated 14<sup>th</sup> February 2020. The ongoing litigations in various High Courts and the Supreme Court about authenticity of pathology laboratory reports have influenced the speeding up of the process for notification of standards for laboratories.

As mentioned earlier in this paper, ***the process of permanent registration, monitoring of adherence to standard treatment guidelines, transparency and standardisation of rates cannot be implemented in the absence of notified minimum standards for clinical establishments. This crucial roadblock has completely stalled the entire implementation of the CEA 2010.*** Ironically, this is coincidental with the roll out of the Pradhan Mantri Jan Arogya Yojana (PMJAY) as a part of the Ayushman Bharat programme which is the 'world's largest health insurance scheme' as per claims of Government of India. This scheme covers 10 crore poor families which are assured to receive cashless tertiary healthcare covering expenses up to Rs 5,00,000 per family per year. The PMJAY is a Public-

32 Letter by Health secretary to Chief Secretaries of all states, N. Z28015/ 09/2018- MH-II/MS dated 2nd June 2019



Private Partnership scheme where large amounts of public funds are handed over to empanelled private hospitals at predefined package rates for specified 1350 procedures. However, implementation of the PMJAY without any substantial regulations in place to monitor empanelled hospitals is fraught with risk and potential for malpractice, as was observed in the case of mass hysterectomies conducted on impoverished women in Rajasthan, Chhattisgarh, Bihar and Karnataka under the Rashtriya Swasthya Bima Yojana (RSBY) and other state insurance schemes between 2010 and 2015.<sup>33</sup> It should be emphasised that **large scale public financing and public outsourcing of care to private hospitals** through major national schemes like RSBY and PMJAY, **without ensuring essential regulation of quality, rationality and standards of care as a broader measure, appears to be an inherently flawed approach.** This approach assumes that public good would be served, by handing over public funds to private actors

who have mostly been aggressively pursuing profit making (in contrast to public interest) until now. It is expected that sections of private providers will start behaving rationally, ethically and will start providing standard quality of care just by joining publicly funded programmes, without the need to ensure acceptance of essential public standards and regulation as a norm by the entire sector.

India has lost a decade due to its inability to effectively implement much needed regulatory frameworks for the private healthcare sector. Without any substantial implementation of regulatory functions, there are disastrous consequences for millions of people - especially the most marginalised and vulnerable - who have suffered greatly and continue to do so due to the unchecked exorbitant charging, malpractices and irrational care in many private hospitals.

<sup>33</sup> <https://www.thehindu.com/news/national/spree-of-hysterectomies-to-make-a-fast-buck/article5007641.ece>

# BRIEF REVIEW OF SELECTED STATE LEVEL LEGISLATIONS TO REGULATE CLINICAL ESTABLISHMENTS

A letter written by the Union Health Secretary Ms. Preeti Sudan to Chief Secretaries of all states on 2<sup>nd</sup> June 2019 frankly admits that the MoHFW is trying to convince state governments to adopt CEA 2010 or enact similar legislations to regulate private clinical establishments. This letter states that, ... *“it is felt that there has been reluctance and resistance on part of these remaining states in adoption of this legislation for various reasons including reluctance and stiff resistance by lobbies of clinical establishments to coming under regulatory framework of this act.”*

However, some State governments have enacted their own regulatory legislations for clinical establishments much before CEA 2010. These legislations are listed in the schedule to CEA 2010 and are exempted from CEA 2010 as follows:

- The **Andhra Pradesh** Private Medical Care Establishments (Registration and Regulation) Act, 2002
- The **Bombay** Nursing Homes Registration Act, 1949 (applicable to **Maharashtra and Gujarat**)
- The **Delhi** Nursing Homes Registration Act, 1953
- The **Madhya Pradesh** Upcharyagriha Tatha Rujopchar Sambandhi Sthapanaye (Registrikaran Tatha Anugyapan) Adhinyam/ Nursing Homes and Clinical Establishment Act (Registration and Licensing), 1973
- The **Manipur** Nursing Homes and Clinics Registration Act, 1992
- The **Nagaland** Health Care Establishments Act, 1997
- The **Orissa** Clinical Establishments (Control and Regulation) Act, 1990
- The **Punjab** State Nursing Home Registration Act, 1991

- The **West Bengal** Clinical Establishments Act, 1950

Some of these are very old, outdated legislations, which have lost their relevance in today's era. Most of these legislations only have provisions for registration, without effective provisions for regulating quality and rates of care, increasing transparency, standardization, grievance redressal etc. A majority included only registration of nursing homes and hospitals, and have not considered other private healthcare providers like laboratories, diagnostic, imaging, physiotherapy and day care centers etc. These regulatory mechanisms were marred by inordinate delay in framing rules and inadequate implementation. In the past decade, some of these legislations have been amended, such as in West Bengal. Meanwhile, other states like Chhattisgarh and Odisha proceeded with their own legislations to regulate the private healthcare sector.

## STATUS OF PRIVATE HEALTHCARE REGULATION IN CHHATTISGARH

The **Chhattisgarh Nursing Home Act was passed in 2010 and rules were framed in 2013**. As per the fusion chart available on the portal<sup>34</sup> a total of 11,502 applications were received for registration of clinical establishments, out of which only 6500 (56.50%) have been processed and verified, with licenses issued to only 3292 (28.62%) applicants. The process of implementation of the act is taking a long time, as is evident by a **whopping backlog of 43.50 % of pending applications for registrations of nursing homes**.

A study by the Public Health Resource Network (PHRN)<sup>35</sup> explored the perspective of each stakeholder about implementation of this act in Chhattisgarh. Private healthcare providers perceived delays in the

<sup>34</sup> <http://cghealth.nic.in/health/nursinghomeact/Default.aspx#>; accessed on 9th June 2020

<sup>35</sup> Unraveling The Clinical Establishment Act In Chhattisgarh: A Campaign and A Study; Sulakshana Nandi, Deepika Joshi, Rajesh Dubey. PHRN – Public Health Resource Network, Raipur (Chhattisgarh), India; 10.1136/bmjgh-2016-EPHPabstracts.54



registration process as harassment by authorities and would like it to be quick, smooth, transparent, corruption free and without hurdles if all requirements were complied with. The district health administration felt that the Chhattisgarh Nursing Home Act created a lot of extra work for them, without the appointment of any dedicated staff.

Thus, the study shows an urgent need for dedicated staff deployment and provision of adequate budget. Chhattisgarh being a tribal state with many remote locations, the district health administration found that compliance with infrastructure and human resource standards was challenging to implement. Hence, flexibility in standards, depending on the district location is the norm. Moreover, the study reported that specialist doctors lend their name to 15–20 Clinical Establishments (CEs), especially in underserved districts. The non-profit charitable private hospitals faced problems with licensing their nurse-run outreach clinics in remote tribal areas.

The study highlights the lack of proper consultative process with relevant stakeholders while formulating standards and the need to modify infrastructure and human resource standards in a consultative manner with all relevant stakeholder participation while considering the situation on ground. Chhattisgarh was the first state to formally include patient's rights in regulatory provisions, but there is a major lack of awareness and transparency about Patients' Rights amongst people and the medical community. Engagement of civil society and community participation is a must in monitoring the implementation of the act. However, Chhattisgarh Nursing Home Act doesn't provide such institutionalised space to civil society members in its current form to monitor its implementation.

## STATUS OF PRIVATE HEALTHCARE REGULATION IN ODISHA

The Director of Medical Education and Training (DMET), Odisha Government is the Supervisory Registration Authority for clinical establishments in Odisha. The DMET website shows data on registration and renewals of CE till 1<sup>st</sup> March 2016<sup>36</sup>, with no further updates. A PIL filed by Arun Kumar Sahoo of Orissa Consumers Association (filing number 1050/2015)<sup>37</sup> submitted that the Orissa Clinical Establishment Act has been poorly implemented. The court had already directed the state government in November 2007 to form a task force for effective implementation of the Orissa Clinical Establishment (Control & Regulation). In a hearing on 19<sup>th</sup> August 2019, the Orissa High Court came down heavily upon the state government<sup>38</sup> after detecting that its order issued in response to a PIL 11 years ago for strict implementation of the Orissa Clinical Establishment Act had not been complied with and asked the state government to file a status report of the district wise implementation of Orissa Clinical Establishment Act. Consequently, the Odisha Health and Family Welfare Minister Nabkishore Das addressed a press conference on 9<sup>th</sup> September 2019 and announced the launch of an '**Online Clinical Establishment Management System**' (CEMSO) for registration and renewals of clinical establishments in the state<sup>39</sup>. He also informed the press that 1800 clinical establishments were registered in Odisha so far. On 30<sup>th</sup> September 2019, Odisha Government was able to give details of implementation of the Act in only nine out of 30 districts. In a subsequent hearing, the Government furnished reports from the remaining 21 districts, but affidavits about status of implementation of fire safety under Orissa Clinical Establishment Act were awaited in February 2020<sup>40</sup>.

36 [http://dmetodisha.gov.in/clinical\\_establishment.html](http://dmetodisha.gov.in/clinical_establishment.html); accessed on 9th June 2020

37 <https://timesofindia.indiatimes.com/city/cuttack/orissa-hc-asks-government-to-act-against-illegal-clinics/articleshow/70748716.cms>

38 <https://timesofindia.indiatimes.com/city/bhubaneswar/hc-sets-today-deadline-for-state-to-give-report-on-clinical-act/articleshow/71381638.cms>

39 <https://www.newindianexpress.com/states/odisha/2019/sep/09/system-to-register-clinics-online-launched-by-odisha-government-2031066.html>

40 <https://www.newindianexpress.com/states/odisha/2020/jan/29/orissa-hc-directs-state-government-to-file-report-on-fire-safety-in-clinical-establishments-2096031.html>

## RATE REGULATION IN SELECTED STATE LEGISLATIONS

One of the important differences between Clinical Establishment Act and Rules (Central Government) and the versions of various similar state legislations is the missing provision of regulation of hospital charges. Rule 9 of Clinical Establishment (Central Government) Rules, 2012 prescribes an establishment to “charge the rates for each type of procedures and services within the range of rates determined and issued by the Central Government from time to time, in consultation with the State Governments”.

Except for the West Bengal Clinical Establishments (Registration, Regulation and Transparency) of Act 2017, ***all other existing state level legislations contain no provisions to regulate health care charges.*** Similarly, neither the state level legislations nor the rules prescribe compliance with Standard Treatment Guidelines, except for Karnataka Private Medical Establishment (Amendment) Act 2017. We will briefly review regulatory legislations in Karnataka and West Bengal, which did attempt to introduce rate regulation in the private health sector in some form and met with mixed success.

**KARNATAKA: Amendments** to the **Karnataka Private Medical Establishments (KPME) Act in year 2017**, which were modelled on the lines of West Bengal Clinical Establishment Act led to a bitter battle between medical practitioners and the government<sup>41</sup>. Stiff resistance by the organized private healthcare sector lobby forced the Karnataka Government to make four critical changes in the bill, namely.

- Dropping imprisonment clauses except for running a private medical establishment without registration.
- Registration and Grievance Redressal Authority would not handle complaints related to medical negligence or non-adherence to standard treatment protocols or violation of prescription audits. These complaints would be handled by the Karnataka Medical Council, which would submit its report to the Registration and Grievance Redressal Committee.

- Doctors can be represented by their lawyers in front of the Registration and Grievance Redressal Authority.
- The state government would fix uniform costs for only those procedures that are funded by government healthcare insurance schemes.
- Larger provision of rate standardization was dropped.

The Bill was passed in the Karnataka Legislature in November 2017, received the Governor’s assent in January 2018 and a gazette notification was issued in March 2018. Some key provisions of the Karnataka Private Medical Establishments Act have, however, still not been implemented<sup>42</sup>. The heavily debated provision of fixation of cost of procedures that patients undergo under government-funded insurance schemes was done in early 2019<sup>43</sup>. However, civil society groups heavily criticised the poor implementation of the amended KPME Act.

**WEST BENGAL:** Following amendments in 2017, the **West Bengal Clinical Establishments (Registration, Regulation and Transparency) Act 2017** has the following key provisions for rate regulation, grievance redressal, patient’s rights and institution of an autonomous regulatory commission:

- Provision to set up the West Bengal Clinical Establishment Regulatory Commission, a 13-member commission chaired by Retired High Court judges, which has regulatory and supervisory functions, including a provision for grievance redressal in matters related to patient care service, deviations from declared fees and charges, refusal to supply copy of medical records and allied matters, alleged irrational and unethical trade practice etc. except medical negligence; it also has powers to adjudicate and order compensation.
- Provisions for rate standardization and rate transparency.
- Provision to prevent delay in releasing the dead body of patients or service recipients to their

41 [www.deccanherald.com/state/speaker-miffed-kpme-act-yet-704810.html](http://www.deccanherald.com/state/speaker-miffed-kpme-act-yet-704810.html)

42 [www.deccanherald.com/state/speaker-miffed-kpme-act-yet-704810.html](http://www.deccanherald.com/state/speaker-miffed-kpme-act-yet-704810.html)

43 <https://www.thehindu.com/news/national/karnataka/kpme-state-government-finally-sets-up-expert-committee-for-price-fixation/article26178708.ece>



representatives due to billing or other issues, including inability to pay the treatment cost.

- Provision of Internal Grievance Cell in each clinical establishment.
- Provision which makes it mandatory for those clinical establishments which have received land from the Government to provide free treatment to 20% of OPD patients and 10% of IPD patients.
- Similarly, provision for mandatory Corporate Social Responsibility for Corporate Hospitals to provide free treatment to 20% OPD, 10% IPD patients as defined.

The implementation of this Act in West Bengal has been quite controversial, and met with major resistance from the private healthcare sector and criticism from political leaders. The IMA along with other professional associations called for strikes, protesting against provisions related to penalties and imprisonment for doctors.<sup>44</sup> It is yet to be

seen whether the stated provisions are effectively converted into people-centred entitlements, or they pave the way for exercise of concentrated power by the state apparatus.

Beside the above-mentioned states, there are other States<sup>45</sup> which are enacting their own Acts to regulate private clinical establishments, but were not mentioned in the Schedule to CEA 2010. **Kerala, J&K, Goa, Tamil Nadu, Assam, Meghalaya, Tripura, Gujarat, Punjab and Meghalaya** are at some stage in the process of **enacting legislation on the lines of the central Act** i.e. CEA 2010 with some modifications. Maharashtra, Goa and Delhi are in the process of repealing their existing legislations and enacting laws on the lines of CEA 2010 with some modifications.<sup>46</sup> However, many of these state level processes have been majorly delayed and prolonged, with resistance from private healthcare lobby being an important factor.

44 <https://indianexpress.com/article/india/clinical-establishment-act-2017-doctors-observe-national-black-day-4631126/>

45 [www.clinicalestablishments.gov.in](http://www.clinicalestablishments.gov.in); Minutes of 7th meeting of National Council dated 18.09.2015

46 [www.clinicalestablishments.gov.in](http://www.clinicalestablishments.gov.in); Minutes of 7th meeting of National Council dated 18.09.2015



## COMPARISON OF REGULATORY LEGISLATIONS IN SELECTED STATES AND CENTRAL CEA

The following chart presents a brief comparative analysis of provisions in State level regulatory legislations in Chhattisgarh, Odisha and Karnataka vis-à-vis provisions in CEA 2010. The state of Karnataka has been specifically included here as a

basis for comparison, as it has recently introduced important amendments in its regulatory act, with explicit provisions related to Patients' Rights and rate transparency.

	CEA 2010	Chhattisgarh	Odisha	Karnataka
<b>Name of the Act</b>	Clinical Establishment (Registration and Regulation) Act 2010; Rules made in 2012;	Chhattisgarh State Upcharyagriha-Tatha Rogopchar Sambandhi Sthapanaye Anugyapan-Adhinyam 2010; Rules in August 2013	Orissa Clinical Establishment (Control and Regulation) Act 1990; Amendment in Act in 2016; Rules in 2018	Karnataka Private Medical Establishments Act, 2007; Rules in 2009; Amendment in Act in 2017; Amended in Rules in 2018
<b>Mandatory registration of Private CEs</b>	Yes	Yes	Yes	Yes
<b>Applicable to public hospitals</b>	Yes	Yes, but deemed to be registered	No	No
<b>Healing systems covered</b>	Allopathy, Ayurveda, Homeopathy, Unani, Siddha, Naturopathy and Yoga	Allopathy, Ayurveda, Homeopathy, Unani, Siddha, Naturopathy and Yoga	Allopathy, Ayurveda, Homeopathy, Unani, Siddha, Naturopathy and Yoga	Allopathy, Ayurveda, Homeopathy, Unani, Siddha, Naturopathy, Yoga, Acupuncture, and Acupressure
<b>Any specific exemptions from the Act</b>	Clinical Establishments owned and controlled by Armed Forces	No	<ul style="list-style-type: none"> <li>Public Hospitals, clinics</li> <li>Psychiatric Hospital or Nursing Home licensed under Mental Health Act 1987</li> <li>OPD clinics run by qualified medical practitioner without admission facility</li> </ul>	Not applicable to Public Hospitals, Clinics
<b>Minimum standards for facility, services</b>	Yes	Yes	Yes	Yes

	CEA 2010	Chhattisgarh	Odisha	Karnataka
<b>Standard Treatment Guidelines</b>	Yes	No	No	Yes
<b>Display of key indicative rates</b>	Yes	No	No	Yes; both notification and display of rates
<b>Standardisation of Rates</b>	Yes	No	No	Provision for uniform package rates in private medical establishments for healthcare insurance schemes by government. Overcharging than self-notified/ self-declared rates in case of private patients or government declared rates for publicly funded health insurance scheme then clinical establishment will be fined penalty.
<b>Provision for life-saving first aid in case of emergency medical conditions</b>	Yes; stabilization of emergency patients within available resources and staff	Yes	Yes; stabilization of emergency patients within available resources and staff	In medico-legal cases only e.g. road accidents, burns or poisoning or criminal assaults
<b>Patient's Rights Charter and access to medical records</b>	No	Yes, mentioned in the rules	No	Yes, mentioned in the Act
<b>Grievance redressal mechanism for patients</b>	No specific mechanism	Yes; person aggrieved by wilful negligence towards treatment/ admission may complain to a committee chaired by Dy. Collector as chairperson and specialist doctors of concerned discipline to examine the complaints; committee submits report to DHS after hearing both parties; DHS take appropriate action—maximum imprisonment for 6 months to 3 years, fine till 50,000 rupees.	No specific mechanism but patient can complain to supervisory authority and he may issue instructions to CE upon inquiry	Yes; non-compliance with Patient's Charter or Private Medical Establishment's Charter can be raised with Registration and Grievance Redressal Authority; Complaints related to medical negligence, violation of standard treatment protocols and prescription audit to be referred to Karnataka Medical Council to submit report within 60 days to Registration and Grievance Redressal Authority for action

	CEA 2010	Chhattisgarh	Odisha	Karnataka
<b>Dedicated agency, manpower for implementation</b>	No	No	No	No
<b>Multi-stake holder state council</b>	Yes; Health Secretary as a chairperson and Director of Health Services as a secretary and other members	No	No	No
<b>Registering Authority</b>	District Registering Authority- <ul style="list-style-type: none"> <li>• Chairperson- District Collector</li> <li>• District Health Officer as a Convener</li> <li>• Police representative</li> <li>• Local self-government representative 5) Representative from professional medical association</li> </ul>	District Collector as a supervisory authority Registration and Licensing Authority at district level – 1) Chief Medical and Health officer as a chairperson 2) Dy. collector 3) Civil surgeon, 4) CEO of Zilla Parishad 5) CMO- Urban Local Body of district town 6) District Ayurveda Officer 7) Chhattisgarh Environment Conservation Board member	Director of Medical Education and Training as Supervisory Authority	Registration and Grievance Redressal Authority at District level- <ul style="list-style-type: none"> <li>• The Deputy Commissioner of the district. - Chairperson</li> <li>• District Health and Family Welfare Officer—Member Secretary</li> <li>• District AYUSH Officer- Member (4) One member from IMA(5) One member from another medical association (6) One women member when Authority dealing with grievance redressal</li> </ul>
<b>Multi-stake holder appellate body at state level</b>	Yes; State Council acts as an appellate body for appeals against decisions District registering Authority	No multi-stakeholder body; one can appeal to State Government (Director of Health Services, Director of Medical Education, Director of AYUSH) against decisions of Supervisory Authority	No multi-stakeholder body; one can appeal to Prescribed Authority i.e. Health Secretary against decisions of Supervisory authority	No multi-stakeholder body; Completely executive body- <ul style="list-style-type: none"> <li>• Commissioner for Health and Family Welfare, Karnataka-Chairman</li> <li>• Director of Health Services, Karnataka - Member</li> <li>• Director of AYUSH – Member</li> <li>• Director of Medical Education- Member</li> <li>• One clinician with post-graduation in general medicine recommended by government</li> </ul>
<b>Consultative process to draft standards</b>	Yes, but at the central level	No	No	Yes, at state level
<b>Participation of civil society</b>	Yes, in state council; but not at district level	No	No	No

	CEA 2010	Chhattisgarh	Odisha	Karnataka
<b>Maximum punishment</b>	From Rupees 25,000 to 5,00,000 or cancellation of registration; no imprisonment	Imprisonment upto 3 years or fine upto 50,000 Rupees or both or cancellation of registration	Upto 5 Lakh rupees or Imprisonment upto 3 years or both or cancellation of registration	Maximum fine upto 50,000 rupees or cancellation of registration Overcharging than self-notified/declared rates or charging money from the beneficiaries of government funded health assurance scheme for treatment under these schemes then clinical establishment will be fined penalty equivalent to one and half times (150%) of the overcharged amount. Overcharged amount (100%) to be returned to patient and remaining penalty (50%) to be deposited in Arogya Raksha Samiti funds

The above chart shows that the Karnataka State Government moved beyond the legal framework provided by CEA 2010. It took progressive steps to clearly include Standard Treatment Protocols, Patient's Rights Charter, Grievance Redressal Mechanism for patients, standardisation of package rates of treatments/procedures covered under publicly funded healthcare insurance schemes, detailed description of transparency in rates etc. in the text of the KPME amended Act. This is a significant step forward as compared to the CEA 2010, which includes these

crucial provisions in the rules framed in 2012, but not in the text of the Act itself. But the provision for rate standardisation in the general private medical sector was vehemently opposed by private medical associations and was subsequently withdrawn. However, the Karnataka State Government did manage to include provisions for notification of rates by private establishments, and penalty for overcharging above self-declared / notified charges.



## OTHER REGULATORY LEGISLATIONS COVERING PRIVATE HEALTHCARE



Besides the CEA 2010 and similar state level regulatory acts, doctors and clinical establishments are covered by a variety of laws and acts which govern various aspects of hospital management such as commissioning of a hospital, regulation of its business aspects, the sales and storage of drugs and safe medications, the qualifications, practice and conduct of healthcare professionals, environmental protection and safety, employment of human power, safety of patients, public and staff within the hospital premises, medico-legal aspects, professional training and research and biomedical research. Apart from national legislations, state governments have also adopted a number of laws and regulations. The Medical Council of India, State Medical Councils, Central Council for Indian Medicine, Central Council for Homeopathy and other

national and state level bodies govern the education, certification and conduct of medical professionals, although they do not have direct jurisdiction over hospitals and healthcare establishments.

However, these laws are often implemented in fragmented manner through multiple agencies, and the execution varies from state to state. Description of these diverse legislations is beyond the scope of this paper, however, some selected legislations which deal directly with quality of patient care or provisions concerning clinical care are outlined in Annexure-3, while a comprehensive review of such legislations can be referred to, for further details.<sup>47</sup> The National Patient Safety Framework (2018-2025) also offers a comprehensive review of the existing situation of patient safety in India along with a roadmap ahead.<sup>48</sup>

47 Singh MM, Garg US, Arora P, Laws applicable to medical practice and Hospitals in India. *Int J Res Foundation Hosp Healthc Adm*2013;1(1):19-24

48 [https://main.mohfw.gov.in/sites/default/files/national%20patient%20safety%20implimentation\\_for%20web.pdf](https://main.mohfw.gov.in/sites/default/files/national%20patient%20safety%20implimentation_for%20web.pdf)



## SECTION II

# ANALYSIS OF REGULATORY DYNAMICS AND ROADBLOCKS TO IMPLEMENTATION

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As we have seen in Section –I, the Clinical Establishment (Registration & Regulation) Act (CEA 2010) was introduced by the Union government in August 2010, with the intention to introduce a uniform system of registration and regulation of all clinical establishments in the country, and to prescribe a minimum standard of facilities and services provided by them. The Rules for CEA 2010 were notified in March 2012, and the Central CEA has subsequently been adopted by 11 States and six Union territories. Some other states have chosen to draft their own regulatory acts, or to amend older acts to regulate private hospitals and nursing homes. ***Nevertheless, whichever is the form of legislation – Central or State, old or new, regulation of clinical care by private healthcare providers has been largely unsatisfactory from the viewpoint of patients and the general public.*** Organised resistance by the private medical lobby has been a central factor responsible for retarding and preventing this implementation of regulation until now, hence we need to understand the basis for this resistance.

# OBJECTIONS FROM THE PRIVATE SECTOR AND CONCERNS FROM PEOPLE'S PERSPECTIVE REGARDING CENTRAL CEA 2010

## MULTIPLE REGULATORY ACTS ALREADY EXISTING; CEA 2010 PERCEIVED AS STATE ATTEMPT TO CONTROL THE PRIVATE HEALTH SECTOR

The Indian Medical Association (IMA) which represents practitioners of Allopathy (western medicine based on biomedical science), claimed that private doctors and clinical establishments already have to comply with multiple existing regulations and licensing for various services (Annexure 3). The IMA argues that the CEA would **add yet another layer of regulation, which would increase the number of bureaucratic procedures to be followed by private hospitals and has demanded exception for individual practitioner-led clinics and small and medium sized hospitals below a certain size.**

However, it may be noted that until now, most regulation of the private healthcare sector has been focussed on the structural aspects (fire safety, solid waste disposal) or aspects like regulation of individual doctors, that have been entrusted to bodies like Medical Councils which have been prone to regulatory capture<sup>49</sup>, due to overwhelming influence of the Indian Medical Association and representation of private health care providers in related bodies. The Pre- Conception & Pre-Natal Diagnostics Act (PCPNDT) is a partial exception to this observation. However, it is limited to one specific clinical practice (pre-natal sex determination) and its implementation has been uneven across states. Given this context, *core aspects of regulation of private healthcare services such as rates, quality, rationality of care, and patients' rights – which impinge upon the main operations and profitability of private providers – have remained persistently unaddressed in the Indian context.*

## OBJECTIONS TO CERTAIN PROVISIONS IN THE CEA 2010 AND IN THE RULES 2012

Central and state chapters of the IMA have strenuously objected over the years to certain provisions in the Central CEA, arguing that they have been drafted with inadequate consideration to existing heterogeneity in the private healthcare sector, while pointing out certain practical implications and challenges in implementation. **Provisions to which objection has been taken include:**

- Mandatory provision of emergency treatment to patients till their condition stabilises (Section 12/2). (The IMA observes that it is **not practically and financially possible for every clinical establishment to have the necessary equipment and expertise to treat medical emergencies**).
- Provision to engage specified **minimum number of qualified doctors, nurses, paramedical staff, and other categories of employees** in all establishments. (IMA points out that this stipulation is difficult to fulfill for many clinics and hospitals in **remote and rural areas**, given the crippling shortage of qualified and experienced healthcare workers in the country).
- Inclusion of **Police officer in District registering authority** (IMA feels that Police officials would not be appropriate for taking decision about registration of hospitals, and this provision may lead to harassment or corruption).
- Perception that the **minimum standards** related to infrastructural requirements may **favour larger hospitals in metro cities** (including corporate hospitals) which have more resources fuelled by high fees and investments, while it may be **difficult for smaller providers** to fulfill such standards.

49 <https://www.newsclick.in/reforming-regulator-parliamentary-committee-report-medical-council-india>



Central and state chapters of the IMA have repeatedly called for agitations to protest against the passing of the CEA 2010 and similar state legislations over the past decade. The IMA had submitted a list of six suggested amendments to the CEA 2010 to the MOHFW and called for a nationwide ‘Satyagraha’ on 16<sup>th</sup> November, 2015. Amongst its demands were **exemption from licensing under CEA for hospitals accredited with the NABH** (National Accreditation Board for Hospitals & Healthcare Providers), **rights of private hospitals to fix charges for their patients, scaling down of penalties, and that costs involved in emergency case management** should be borne by the government.<sup>50</sup> The ‘Satyagraha’ was called off only after then Health Minister constituted an inter-ministerial committee to look into these demands with representation of the IMA.

However, Jan Swasthya Abhiyan (JSA) had criticised this stance of the IMA, pointing out in a letter to the then health minister<sup>51</sup> that **accreditation was a completely voluntary process** and in no way should be considered as a substitute for licensing under CEA<sup>52</sup>. The JSA letter also pointed out that exemption of certain hospitals from licensing under CEA would defeat the purpose of standardizing the private healthcare sector.

### KEY LIMITATIONS IN THE FRAMEWORK OF THE CEA 2010 FROM PEOPLE’S PERSPECTIVE

- The text of the CEA 2010 or Rules 2012 **does not mention the words ‘patient’ or ‘patients’ rights’** even once. Key provisions like regulation of rates by clinical establishments are missing in the main act.
- The CEA **does not articulate any specific structures and mechanisms**, such as additional budget and

staff at central and state level for implementation of the CEA. The Act is **meant to be implemented through the District Health Officer’s office**, which is already overwhelmed with the responsibility of running the Public Health System in that district, and would find it very challenging to take on such additional major duties without dedicated staff.

- The process of **standards formulation is highly centralised at national level**, which may not augur well for consideration of local conditions across a geographically and socially diverse country like India. States which have adopted this act will have no power to amend the act or rules, giving them very little flexibility to customize the Act, depending on their priorities.
- The Act focuses on registration and physical infrastructure (structural standards) of clinical establishments, but **does not address process standards related to healthcare settings**, which are very important from the patients’ perspective. Process measures help to inform people about medical care they may expect to receive for a given condition or disease based on standard recommendations and can contribute toward improving health outcomes.<sup>53</sup>
- Government bureaucrats and representatives from medical associations make up the bulk of members of implementing and monitoring agencies constituted by the Act. These key bodies have **very weak representation of civil society organizations, health activists and patient interest groups, and such citizen representation explicitly ensuring gender and social inclusivity**, is absent in bodies at district level.

50 <https://timesofindia.indiatimes.com/city/nagpur/IMA-calls-off-satyagraha-on-health-ministers-word/articleshow/49761803.cms>

51 <https://phmindia.org/2015/11/21/309/>

52 <https://www.thehindubusinessline.com/news/health-activists-resist-ima-move-to-exempt-hospitals-from-licensing-under-cea/article7903939.ece>

53 <https://www.ahrq.gov/talkingquality/measures/types.html>



## REVIEW OF DELAY IN IMPLEMENTATION OF REGULATION IN SELECTED STATES

In this section we look into the reasons for the delay in enforcing the act in selected states, while analysing the challenges in implementation.

**BIHAR:** The CEA 2010 was adopted in Bihar in 2011, and the rules were framed in 2013. A petition opposing the Act was filed by the Bihar Health Services Health Association (BHSA) in the Patna High Court in 2016, pointing out that the Act was adopted in its entirety by the state government without any changes to make it more feasible for healthcare providers in the state.<sup>54</sup> The petition stated that the CEA was amended to the local context before being adopted in many other states. Bihar had, however, accepted the Centre's categorisations of Clinical Establishments and all the provisions as such, without considering the ground reality that small hospitals, single doctor establishments, particularly in remote rural areas would find regulatory compliance with certain provisions related to staffing and infrastructure very challenging. It was argued that the Act should have been implemented only after due consultations with all stakeholders on all its provisions, as was done in other states. IMA Bihar supported the petition, highlighting concerns they had about certain clauses in the Act such as the condition of free treatment to emergency patients till they stabilise, stating the smaller hospitals would not be able to bear the cost of such treatment. They also objected to the high monetary penalties in the Act for not adhering to the rules.

**CHHATTISGARH:** The CEA Act was passed in 2010 in the state of Chhattisgarh. Following consultations with CSOs and representatives from associations of PMEs, the Act omitted certain provisions after stiff opposition from the PMEs. The rules and standards for the Act were notified in August 2013. However, the Act did include crucial provisions on Patients' Rights and Grievance Redressal.

A study<sup>55</sup> conducted to understand process of the implementation of the Act in Chhattisgarh brought forth the following findings:

- The process of registration of Clinical establishments was not streamlined and licensing depended to a great extent on the Chief medical and health officers, and District health committee, with a lot of flexibility in standards, especially in underserved areas.
- Private for-profit practitioners perceive the CEA as yet one more way of interference and harassment from the Government. They complained of time wasted in getting mandatory certificates and licensing.
- Many doctors felt that they would not be able to provide affordable treatment if they had to comply with all the standards, and would be forced to pass on the extra cost to their patients.
- Not-for-profit hospitals meanwhile faced serious challenges in licensing their nurse-run outreach clinics, which were the only health facilities available to people in remote and underserved areas.
- There was also the perception of differential treatment between government and private hospitals, since government hospitals were deemed as licensed without any process or inspection. Privately practicing doctors perceived this as differential treatment and insisted that government health facilities should be made to adhere to the same standards and go through the same process of inspection as private hospitals.

<sup>54</sup> <https://www.telegraphindia.com/states/bihar/relief-for-hospitals-in-clinical-act-case/cid/1357840>

<sup>55</sup> Nandi S, Joshi D, Dubey RUNRAVELING THE CLINICAL ESTABLISHMENT ACT IN CHHATTISGARH: A CAMPAIGN AND A STUDY. *BMJ Global Health* 2016;1:A40-A41. [https://gh.bmj.com/content/1/Suppl\\_1/A40](https://gh.bmj.com/content/1/Suppl_1/A40)

### INSTITUTIONAL BARRIERS

- Interviews with the district health administration revealed challenges at their end. The lack of a dedicated implementing agency has meant a lot of extra unpaid work and uncoordinated action for authorities responsible for implementing the Act.
- Officers opined that compliance with standards is rigid and impractical, especially those pertaining to infrastructure, and that the process has to allow for flexibility in standards, especially in underserved districts.
- CSOs revealed their concerns about the lack of any government initiative to create awareness about the CEA or to release information about the clinical establishments registered under the Act.
- The CEA stipulates the formation of multi-stakeholder institutional bodies; however, it is noteworthy that CSOs are not a part of any mandated committees under the Act. Attempts at using grievance redressal processes have proved challenging.

**ODISHA:** In May 2018, the All Odisha Private Medical Establishment Forum (AOPMEF) called for a one-day cease work strike across the state, protesting against the delay in amending the Odisha Clinical (Control and Regulation) Establishment Act 1990.<sup>56</sup> The forum asked for the renewal process for registration of private medical establishments to be simplified. It also demanded relaxation of fire safety norms after proceedings for non-compliance of fire safety norms were initiated against 13 private hospitals in 2016.

As a response, the government of Odisha launched an online registration system in January 2020 to enable private clinics to avail fresh registration, fire safety certificates and documents related to renewal of license. Small private clinics having less than a two-storey structure with no ICU and less than 30 beds could apply for online registration along with an affidavit. The registration process would not take more than 30 days.

Following lobbying by the private doctors and their associations, the fee structure for registration of small establishments was revised from Rs 5000 to Rs 3000. The validity of the registration was extended from 2 to 5 years, with late fees being waived. The penalty for violating the provisions of the Act was however, made more stringent, with the fine being increased to Rs 25 Lakhs and imprisonment up to 3 years.

**UTTAR PRADESH:** Similar to other states, there have been protests by private healthcare providers in Uttar Pradesh, where over 5000 doctors went on a dharna in June 2016, to protest against the impending CEA. Doctors alleged that certain provisions of the Act had critical implications for small and medium-sized hospitals and single practitioner led private clinics, which are the bedrock of primary and secondary care in most places.

For example, the Act stipulates that every clinic should have a separate clinic nurse and a pharmacist, a condition that was exceedingly difficult to fulfil, given the state-wide shortage of nurses and para-medical staff. Eventually, the cost of retaining extra manpower would have to be passed on to patients, making even basic healthcare costly. Doctors also questioned the feasibility of clauses such as provision of free emergency treatment in all clinical facilities—pointing out the cost of life saving equipment and its maintenance. Besides, not all doctors and specialists were trained in emergency care.

Doctors in U.P. portrayed the Act as being 'Anti-Doctor' and 'Anti-People', alleging that the government was implicitly supporting the growth of corporate hospitals by enforcing the CEA without considering the constraints of the majority of practicing doctors. Doctors also wanted a medical professional, such as the District CMO or Director Health to head the clinical inspection of facilities, saying that the designated authority as per the act was the DM (District Magistrate), who did not have any medical background.

<sup>56</sup> <https://medicdialogues.in/odisha-private-hospitals-call-off-strike-after-assurance?infinitiescroll=1>

## CASE STUDY: KARNATAKA PRIVATE MEDICAL ESTABLISHMENTS (KPME) AMENDMENT BILL 2017

The concerted pressure campaign run by private medical establishments (PMEs) against the so-called “draconian” Karnataka Private Medical Establishments (KPME) Amendment Bill 2017 is emblematic of the wider resistance of the private healthcare sector in India to effective regulation of clinical care, especially when it comes to capping of rates. Associations of medical establishments and nursing homes in Bengaluru and across the state called for bandhs in November 2017, to which more than 50,000 doctors from private and corporate hospitals responded by downing shutters and ceasing work for over 5 days. They were protesting against certain amendments to the original 2007 bill, which were based on recommendations by the Justice (Retd.) Sen committee to make the act ‘citizen-centric’ and to curb unethical practices and profiteering in PME:

- Cap on prices of various medical procedures
- Abolition of the proposed district and metropolitan grievance redressal committees as there were multiple forums already existing for the same – State medical council, Medical Council of India, Consumer court, Civil court
- Increase in jail term of doctors in the event of medical negligence
- Non-inclusion of the public health system in the Bill

PMEs pushed back stating that the bill was unfair towards small and medium-sized PMEs and the high costs of regulatory compliance would threaten their survival and promote corporatisation of the medical sector. Increased liability would force doctors to practice defensive medicine and increase cost of healthcare ever more for patients. Capping costs of treatment in private hospitals in the absence of any tax concessions in setting up PMEs would lead to compromises in quality of healthcare and discourage the youth from joining the medical profession due to high costs of running PMEs.

Following the outcry, the government constituted an 18-member joint select committee of the legislature to look into various controversial aspects of the bill and heard the submissions of several citizens’ groups and private hospital associations. The committee ignored most of the doctors’ demands and recommended retaining most of the original provisions. However, the IMA and other PME associations mounted a concerted social media misinformation campaign about the provisions in the bill and their impact on doctors and patients; high profile influential doctors backed by corporate hospitals lobbied with politicians to support the demands of the private healthcare sector. Health and health rights CSOs, public health researchers and senior medical professionals attempted to counter the fake news and to address the concerns of the medical fraternity, but they were no match against a powerful medical behemoth with a slick coordinated PR campaign.

The government finally succumbed to pressure and passed a diluted version of what was intended to be a progressive pro-people act of legislation. The clause of cost regulation was restricted to publicly-funded health insurance schemes. Imprisonment for medical negligence was scrapped and deterrent clauses for filing of baseless complaints of medical negligence were included in the bill. The district level grievance redressal authority was reconstituted to include representation from the private sector. The KPMEA experience shows that PME associations can force governments to dilute regulatory provisions in clinical establishment acts through agitations and strikes, putting the industry above the interests of the public. The vice like grip of the private healthcare sector state on policymakers and its all pervasive influence on the drafting of the CEA points to “regulatory capture” of the healthcare landscape in India.

## REGULATORY STALEMATE: RESISTANCE AND ROADBLOCKS

By far the most contentious issue regarding implementation of CEA type regulation so far has been that of regulating **rates of healthcare services** in the private healthcare sector. The Central Clinical Establishment Rules, which provide details for implementing the Central Clinical Establishment Act (CEA), stipulate that clinical establishments shall charge the rates for procedures and services fixed by the central government in consultation with the state government. Though the rules were framed in 2012, the central government has not fixed the rates despite the issue being discussed in several meetings of the National Council for Clinical Establishments. The Central CEA and some similar state level acts talk about “**transparency of charges**” in the private sector, but any mention of **capping of prices** is met with fierce opposition.

In 2018, the Competition Commission of India (CCI) even issued a policy note<sup>57</sup> on “making markets work for affordable healthcare” which acknowledged the lack of transparency in healthcare services. The policy note specifically pointed out the high pricing of drugs and consumables at in-house pharmacies and diagnostic labs. It emphasized that information asymmetry and lack of agency further compromised the interests of patients as consumers and called on the government to introduce **regulation in rates, accreditation of facilities and a uniform regulatory framework for pharmaceutical sector**.

Major **political parties** in India included the provision of affordable and even free healthcare in their manifestos for the parliamentary elections in 2019. However, they were all silent on the issue on rate regulation in private hospitals.

Here it may be observed that **regulation of rates is in many ways the crux of regulation of the private healthcare sector**, since this is the foremost area of concern for most patients and caregivers. Further, such effective regulation would have multiple

positive spinoffs – once the rates for treatment of each medical condition are fixed, the incentive for performing unnecessary investigations, medications etc. to earn additional revenue vanishes. Also, the scope for various specialist doctors and hospitals to aggressively offer competitive ‘commissions’ to lure referring doctors reduces, since the financial margin available for giving such cuts is narrowed and standardised. Rate regulation is also an inherently progressive measure, since higher-end corporate and large private hospitals which cater to the upper middle class would be more impacted by rate regulation, compared to genuinely charitable and smaller providers. However, in a predominantly market economy, characterised by an overwhelmingly large private healthcare sector (compared to the public health sector), such rate regulation is also contentious and difficult.

Drawing upon various experiences until now, we can identify certain **major factors which have contributed to stalling the implementation of Central CEA, and diluting / delaying similar state level acts**, which include the following:

### **GOVERNMENTS NOT ADOPTING A DIFFERENTIAL APPROACH TO REGULATING THE PRIVATE HEALTHCARE SECTOR**

This has enabled the powerful private medical lobby to rope in numerically preponderant individual practitioners and smaller hospitals in their campaigns to resist regulation. Allegations that regulation would lead to corporatisation of healthcare appeal to smaller providers, since they apprehend that they might be unable to invest heavily in hiring of skilled and qualified healthcare workers, equipment and infrastructure, provisions which would be favourable for larger private hospitals with corporate funding.

This has fuelled an ‘anti-regulation’ narrative which has

<sup>57</sup> [https://www.cci.gov.in/sites/default/files/press\\_release/PressRelease.pdf](https://www.cci.gov.in/sites/default/files/press_release/PressRelease.pdf)



been repeated ad infinitum by the private sector lobby, while drowning other voices of reason even within the medical profession. Bodies like the IMA have often used this argument as a wedge to reject all form of regulation, instead of submitting concrete suggestions to address concerns related to smaller providers, while accepting the need for regulation.

The **Central government, and most State governments, on the other hand have done little to build consensus over contentious provisions, and to educate or inform the average medical practitioner about actual provisions in the Act.** Governments need to display readiness to be flexible and adopt a progressive stage-wise approach to regulation, which could accommodate some of the genuine concerns especially of smaller and individual providers, while furthering public interest by adhering to the core public principles of regulation.

### **LACK OF POLITICAL WILL TO ALLOCATE SUFFICIENT FUNDING AND RESOURCES FOR THE PUBLIC REGULATORY APPARATUS**

As previously stated, CEA 2010 mentions the establishment of national and state councils and the district registering authority. However, beyond this mention, there is **no clear stipulation of dedicated staff and funds to operate the regulatory process.** This will leave the existing staff to pick up the additional burden of management and arbitration. This is typical of a **neo-liberal approach to regulation, where the state is reluctant to expand its own capacity,** which must be based on additional regular staff and adequate public resources. In this situation, even in states which have adopted the Central CEA, besides delays in notification of standards and other legal hurdles, the regulatory infrastructure is inadequate for handling massive number of private healthcare providers with varying sizes and levels of complexity, with the regulatory process having many technical aspects.

### **LACK OF POLITICAL AND ADMINISTRATIVE LEADERSHIP FOR EFFECTIVE REGULATION**

When it comes to regulation of the healthcare sector, a state subject in India, the key driver of change within the government is political and administrative leadership. This leadership needs to be responsive towards the needs of people and willing to engage all stakeholders in a consultative process to solve certain

impasses, while ensuring that public health goals and equity are promoted in a progressive manner, without compromising on principles.

Currently, CEA 2010 either must be adopted by state governments in totality, or not at all. Hence, many State governments have drafted their own Acts in order to introduce specific provisions, based on consultations with stakeholders. However, it **falls to the state political leadership to ensure that the Act is drafted in a manner so as to reflect the core regulatory principles** given in the Central CEA 2010, while accommodating certain genuine concerns of the medical community and patients groups in the state. Most state governments have also failed to take up this challenge as a political priority.

We need to keep in mind that **political will is also influenced by vested interests of politicians** who often have stakes in private hospitals and medical colleges, and may have links with the powerful lobby of the medical industrial complex. Hence, it would require sustained and collective mobilisation and engagement by health movements, civil society and citizens to push state governments out of their inertia, and to make them overcome the resistance of the private healthcare sector, while responding to pressing social demands and concerns related to healthcare.

Given this entire background, moving forward for ensuring much more effective regulation of private healthcare would include effective implementation of CEA 2010 (which is definitely a step forward despite certain limitations) or similar state level acts, which **would require action by the Central Health Ministry and State governments on certain key, inter-related fronts:**

- Addressing certain genuine concerns of private healthcare providers, especially individual practitioners and smaller providers, by ensuring that infrastructural standards are not unduly demanding, and allowing transition period for fulfilling manpower standards.
- Bringing in wider social support for the regulatory process by strengthening patients' rights and process standards, along with providing stronger representation to civil society groups in councils at various levels.
- Expanding multi-stakeholder governance bodies, adding district level councils, and making these



participatory platforms much more functional and visible to ensure social backing for the regulatory process. This would also help to reduce the scope for corrupt practices by inspectors and officials, due to oversight by multi-stakeholder bodies.

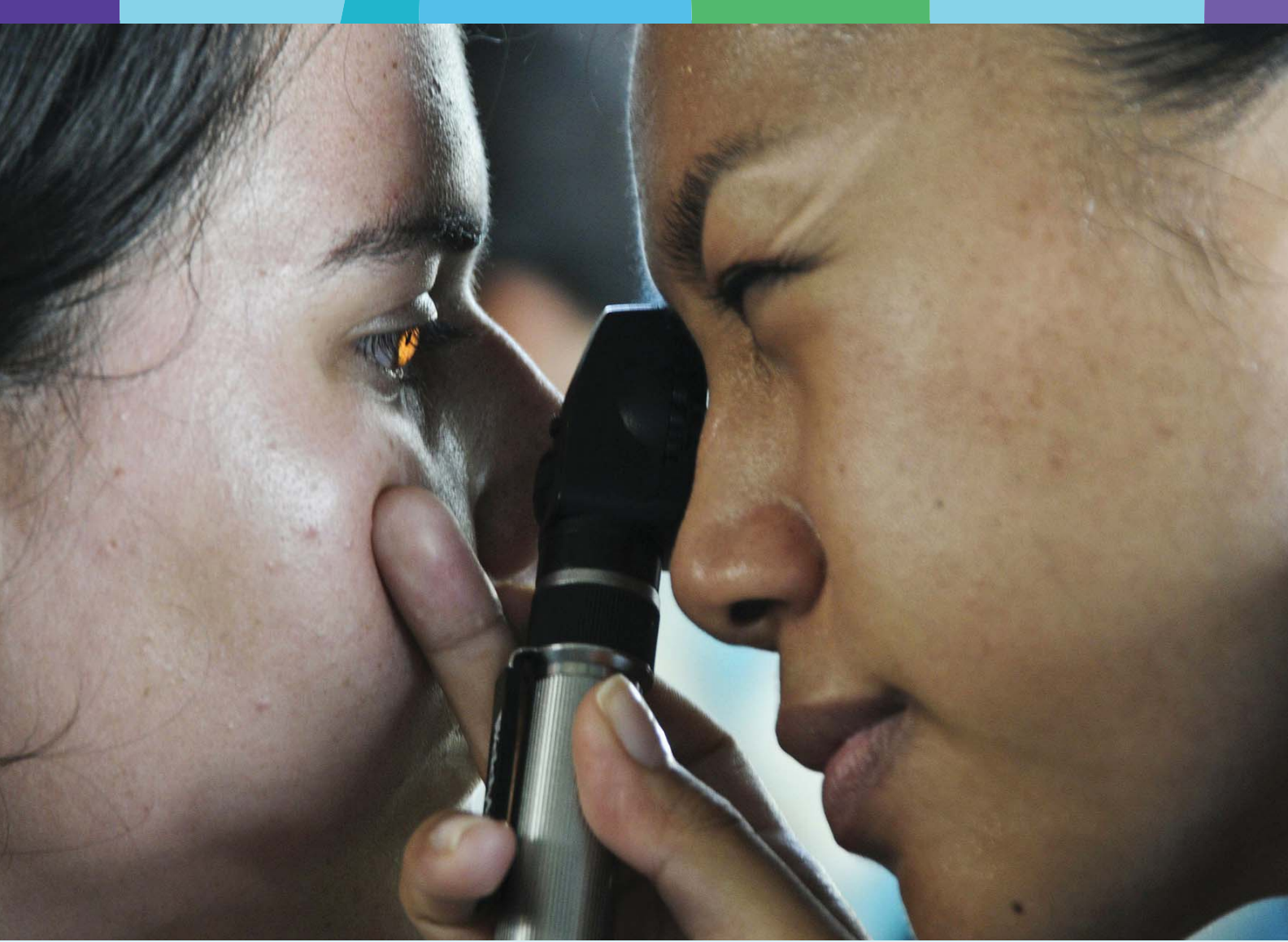
- Providing greater flexibility to State governments (while maintaining core principles of regulation) for modifying certain aspects of rules in keeping with state level situations. Bringing in many more state governments to implement the act in a proactive, partnership mode.
- Ensuring substantial additional resources and dedicated and skilled manpower for the regulatory apparatus at various levels, which is essential to ensure any effective regulation.

Finally, as we will argue in the concluding section, *the purely 'enforcement' based approach to regulation has so far met with major resistance from the private healthcare sector* (barring exceptional situations like the current COVID epidemic), and may need to be replaced by a **more 'interventionist' approach to regulation**, which does not stand apart from the

market, but actively intervenes in ways to reshape the market in the direction of greater equity and public interest. In its publication, "Universalising Health Care for All<sup>58</sup>", the Jan Swasthya Abhiyan (JSA) has elaborated on this approach, which would see private resources being used for public benefit as follows:

*".....A section of such providers will have to be contracted into Public Health Systems in significant numbers, at least for urban areas, regulated by certain terms and conditions, and in a manner that strengthens or complements efforts to expand the public health system... Such contracting-in of a section of private providers would have to be based on appropriate regulations and guidelines, due to which these contracted doctors would act more as an extension of the Public Health System. They would be so regulated that they conform to scientific, ethical medicine in tune with the logic of social medicine. Under this contract, it should be mandated that while they have a decent and secure income, contracted private providers too would have to practice rational care, and that they will have to tune their clinical practice with the goal and logic of Public Health."*

58 <http://phmindia.org/wp-content/uploads/2015/09/universalising-health-care-for-all.pdf>



## **SECTION III: CONCLUSIONS, RECOMMENDATIONS AND WAY FORWARD**

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## POLITICAL ECONOMY CONTEXT TO BE ADDRESSED WHILE CRAFTING REGULATION

The delayed movement on implementing Central CEA and similar state level regulatory Acts has to be viewed through the larger prism of political economy of the private healthcare sector, which has been evolving over the past several decades, characterised by trends of commercialisation from 1980s onwards, and then corporatisation from the early 2000s:

*“The overall trajectory of the Health sector in India during the last three decades has been of increased commercialisation of health care, accompanied by stagnation and weakening role of public health services. The dominant discourse in India during 1950s to 1970s treated the healthcare sector as a set of socially embedded institutions – mostly public or charitable hospitals, along with individual private practitioners – whose primary logic consisted of responding to health care needs of the people they served. From 1980s onwards, commercialisation of healthcare gathered momentum with rise of private nursing homes and smaller private hospitals; health care was being converted into a market-based commodity, and profit making emerged as an important dynamic. This set the stage for the next phase – from the turn of the millennium, large private and corporate hospitals have emerged as significant players, whose overwhelming driving logic is maximization of profits. Corporatisation of health care has emerged as a process which while centred on corporate hospitals, is also influencing other players in the sector in various ways – including individual practitioners, small, medium, large and charitable private hospitals<sup>59</sup>.”*

The past two decades have seen a major shift in the nature of practice of medicine, with the rapid growth of corporatisation encompassing hospitals and diagnostic chains, combined with powerful pharmaceutical and

biomedical device industries, all of whom together now form the powerful **medical industrial complex** which has massive financial and political clout to influence policymakers. Healthcare is now regarded as a profit-making industry and incentive-based referrals have become the norm, not the exception. Healthcare has been accorded the status of an industry in India in 2019 and has been treated as a commodity in the open market, assuring handsome returns on investment to the tune of 16-17% of Compounded Annual Growth Rate (CAGR)<sup>60</sup>. With 70% of healthcare being provided in the private sector, **the powerful private medical lobby is often in a position to dictate terms to the government, as has been observed repeatedly over the past 10 years through their actions to veto the implementation of the CEA 2010.** This is a major factor shaping the entire regulatory process in the current situation.

At the same time, ordinary citizens are becoming increasingly vocal about their dissatisfaction with the status quo in the private healthcare sector. The rise of a relatively affluent, vocal middle class during last couple of decades, which has access to information, resources and often globalised aspirations, yet is often dissatisfied with overcharging and questionable quality of private healthcare, is an important factor which can help pave the way for effective regulation. With the advent of digital connectivity, social media platforms and regional news media, instances of exploitation, medical malpractice and negligence in the private health sector across India are coming to the fore like never before, and so is the demand from citizens to curb the profiteering and corruption. It is clear that the government must act and implement substantial reforms which will not only correct the current imbalance of power, but also eliminate the increasing hostility and friction between frontline healthcare providers and consumers.

59 SATHI, Pune and King’s College, London, Growing Corporatisation of Private Healthcare in India and its Implications. Policy brief, 2019

60 <https://www.investindia.gov.in/sector/healthcare>



# REGULATION OF PRIVATE HEALTHCARE – STREAMLINING THE MARKET FOR BUSINESS INTERESTS OR RESHAPING THE MARKET FOR PUBLIC INTEREST?

Regulation can be considered as an attempt to control or influence private behaviour in the desired direction by imposing costs on or proscribing undesirable behaviours.<sup>61</sup> Accordingly, there may be three major objectives for regulatory interventions concerning the private sector:

- **To streamline the market, and checking anti-competitive practices** such as preventing abuse of monopoly power, ensuring basic quality and control of standards (for example independent regulatory boards which exist for the telecom sector, electricity, insurance, aviation, gas, ports).
- **To prevent market failure**, a condition in which the market mechanism fails to allocate resources efficiently to maximise social welfare. Market failure occurs in the provision of public goods, in case of natural monopolies or asymmetric information. This is particularly relevant for the healthcare sector.
- **To promote public interest**, for ensuring fair access, non-discrimination and affirmative action. This objective is again highly relevant in relation to healthcare, especially in context of public health goals such as achieving Universal Health Care.

Here we need to understand that the limited framework of regulation defined only by the first objective, which we may term as the **Enforcement Approach**, may be sufficient for certain other economic sectors, but is completely insufficient for the healthcare sector. Healthcare is a public good, which must be made available to all, free of cost. Private healthcare providers, who have historically grown through large

scale direct and indirect public subsidies, have a larger obligation to society, which should be enforced by the state. Because of the inherent information asymmetry and the moral imperative, **healthcare must not be treated as a market commodity, but should rather increasingly become a public good.** Viewed from this perspective, achieving the second and third objectives also becomes very important, which necessitates more of an **Interventionist Approach** to regulation. Writing in context of largely unregulated commercialisation of low-income primary care, it has been noted that -

*“Fee-for-service systems create incentives to over-treat and over-charge the better-off while, where users lack information and ability to pay, the market incentives become focused on reducing quality while charging what people are able to pay ... Faced with acute problems of exclusion and quality, resources for regulation through formal rule setting and enforcement are very limited ... Rule based standard setting in these contexts is largely ineffective at the provider level ... It seems that in this context it is the interventionist, more negotiated style of regulation – including alliances with professional, user and activist citizen groups – have the best of hope for exercising some influence.”<sup>62</sup>*

In a national workshop on ensuring accountability in the private health sector in India, organised by SATHI and Jan Swasthya Abhiyan in November 2019<sup>63</sup>, public health expert Dr Anant Phadke pointed out that many western capitalist countries like Japan, UK, Canada have all adopted frameworks that provide for universal health care, thus **effectively taking healthcare off the market and subsidising the cost of care, while**

61 <https://www.oecd.org/gov/regulatory-policy/44925979.pdf>

62 Maureen Mackintosh, Planning and market regulation, Health Systems Knowledge Network, 2007

63 Marathe, Shweta – Ensuring accountability and responsiveness of the private health sector in India: National workshop report. **Indian Journal of Medical Ethics**, [S.l.], v. V, n. 2, p. 158-160, apr. 2020. ISSN 0975-5691.

*also implementing comprehensive regulations, accountability and transparency.* Healthcare providers do make limited profits, but there are stringent checks and penalties in place to prevent profiteering and cheating. If health care is indeed to become a public good, then purely enforcing legal regulation would face certain limitations, which can be overcome by simultaneously moving towards a system of Universal Health Care. This would involve major expansion and strengthening of public healthcare provisioning, effective regulation combined with insourcing of private healthcare providers, and operationalising mechanisms for social accountability of the entire system. UHC systems developed in countries like Thailand can give us useful pointers for moving in such direction.

In India, the government has signalled its **commitment to achieving 'Universal Health Coverage' by 2030**, which includes financial risk protection, access to quality essential healthcare services, affordable essential medicines and vaccines for all.<sup>64</sup> To this effect, the government has committed to increasing its public health spending from 1.28% to 2.5% of its Gross Domestic Product (GDP) by 2025. Against this background, a regulatory framework involving public and private healthcare providers should extend beyond merely streamlining the market (limited to 'enforcement' type regulation of physical standards) and relying on optional, contractual obligations through public and privately funded insurance schemes, since these depend purely on the wish of the providers, who have the freedom to opt out of such schemes if terms and conditions are perceived as being unfavourable. Examples of *denial of care in private hospitals to insured people during the past six months of the*

*COVID-19 epidemic illustrate the limited efficacy of the commercial insurance-based model.*

Instead, *the process of regulation needs to be combined with a powerful movement to bring the healthcare sector under social control, while using public funding as an influential lever.* Otherwise, using traditional regulatory efforts limited to establishing legal enforcement are in themselves, not likely to achieve their desired aim of mitigating an environment of regulatory uncertainty, due to resistance of the politically and numerically powerful medical lobby, as shown over the past decade.

Governments in alliance with broad spectrum of public interest groups and ethical elements within the medical profession need to outline a clearly defined trajectory for moving from the currently chaotic, unregulated and often exploitative private health sector, to a more regulated and socially accountable health sector. This process will require the government to negotiate with different interest groups and come up with innovative and pragmatic solutions that are acceptable to diverse constituencies. Learnings from research<sup>65</sup> on the UHC movement in eleven countries show the importance of managing interest group politics, as in the example of Turkey's drive towards UHC. The government conducted an initial scoping exercise to identify interest groups who would most likely be opposed to the proposed health care reforms and understand their motivations and political influence. It then developed strategies to manage opposition from varied groups such as unions, medical professionals, health insurance industry etc. It simultaneously tried to increase public support for the reforms by announcing patient-friendly measures.

64 <https://www.mea.gov.in/press-releases>

65 Reich MR, Harris J, Ikegami N, et al. Moving towards universal health coverage: lessons from 11 country studies [published correction appears in Lancet. 2016 Feb 20;387(10020):750. Cashin, Cheryl [added]; Araujo, Edson C [added]]. Lancet. 2016;387(10020):811-816. doi:10.1016/S0140-6736(15)60002-2

# DIRECTIONS FOR GOVERNMENT ACTION ON REGULATION AND SOCIAL HARNESSING OF PRIVATE HEALTHCARE

This process for effective regulation and progressive socialisation of private healthcare will require integrated and simultaneous action on the following five fronts.

## LEGAL REGULATION

The government should consider this step in two stages, which could be carried out in a parallel manner:

- **Ensure proper and effective implementation of the existing Clinical Establishment Act, 2010 after notifying minimum standards, and promoting similar state specific legislations.**

Central features of such acts should include regulation of rates in private hospitals, transparency in charges, Standard Treatment Protocols and checking malpractices. States which have adopted the Central CEA 2010 should have regulatory flexibility to amend the Act as per their priorities, a move that will encourage other states to adopt the Central CEA.

- **Expansion and strengthening of these regulatory Acts to improve their effectiveness,** keeping in view developments over the past decade, consultations with stakeholders, and the lessons from the COVID 19 pandemic.

The government should undertake a **scientific, cross cutting, comprehensive analysis about costing of healthcare** in order to come with evidence-based data that can be cross-referenced with recent studies on healthcare costing<sup>66</sup>, which attempt to demystify healthcare costs and make a series of recommendations for policy reform related to pricing, such as adopting a model based on differential pricing for stratified provider groups. Such evidence can be

used to **formulate viable pricing options that are cost - effective and assure optimal quality of care and health outcomes in hospitals and are acceptable to large sections of the private healthcare sector.**

However, the responsibility of policymakers does not end with enacting the rules and setting the standards. They also need to ensure that **doctors and hospitals across all categories comprehend the regulations, their rationale and processes involved in compliance.** The government also needs to adopt innovative approaches and affirmative action plans to improve compliance and overcome deeply entrenched attitudes against public regulation in the private sector. This may include building the capacity of private providers through **training to meet standards through setting regulation related milestones such as ensuring transparency of rates, followed by capping of rates in private health facilities and fostering a culture of accountability, transparency and good governance in the healthcare sector.** There is also a need to acknowledge and take measures to resolve certain genuine regulatory impediments put forth by the private healthcare sector such as their demands for a single window mechanism for registration and grievance redressal, and flexibility in infrastructural and human resource standards, particularly in rural and remote areas.

A notable example of **enabling governance comes from Jharkhand**, which currently has the highest number of provisional registrations of clinical establishments in the country. Provisional registrations were around 2500 in 2016, when a state consultant for the CEA was appointed by the National Health Mission department. Advocacy workshops were conducted for doctors, hospital owners, administrators and IMA chapters in each district of Jharkhand, explaining the Act, its provisions and required documentation in detail and even sharing formats. Over 80 advocacy workshops

66 <http://fikki.in/spdocument/23028/FICCI-Paper-Demystifying-Healthcare-Costs.pdf>

have been conducted so far, resulting in around 7,500 provisional registrations and 10,000 applications, proving that disseminating information and facilitation are essential for improving regulatory compliance, particularly in the initial stages.

In particular, the regulatory process will also need to adopt a differential approach to different kinds of private providers, taking into consideration the genuine issues faced by individual practitioners, smaller clinical establishments while meeting infrastructure and human power standards, and their ability to meet the costs of regulatory compliance.

### **UNIVERSAL IMPLEMENTATION OF THE PATIENT RIGHTS CHARTER**

Most state governments have taken no action so far to operationalise the abridged 13-point Patient Rights Charter, that was circulated to all States and UTs on 2 June 2019.

The 17 point NHRC Patient Rights Charter should **be included in standards related to the Clinical Establishment Act 2010** as well as **existing Clinical establishments Acts or Nursing Home Registration Acts in various states**, and be **made legally mandatory** in all clinical establishments. The government should also respond to the demands of health activists and patients' rights groups who have pointed out the inefficiencies, biased nature and convoluted workings of currently existing grievance redressal mechanisms for victims of medical negligence and malpractice. It should establish a single window Patient Grievance Redressal mechanism which is uniform, easy to access, prompt and people friendly.

### **STRENGTHENING OF PUBLIC REGULATORY CAPACITY**

Moving beyond the framework of 'minimum government', it is necessary to ensure the legal formation of a **well-staffed public regulatory authorities** functioning at national, state and district levels, which will regulate the standards, rationality, quality and costs concerning healthcare in all private hospitals and health facilities.

Regulatory provisions need to clearly articulate allotment of sufficient resources in terms of required

number of regular posts to be filled with trained human resources, to operate regulatory agencies like the National and State Health councils and District Registering Authorities, along with additional staff for inspections and grievance redressal. This would make it feasible for them to enact, monitor and enforce regulatory provisions in the CEA in an efficient, independent and transparent manner. Regulatory agencies should also focus on designing efficient compliance-friendly processes in regulatory structures, which would minimise abuse of power by regulatory authorities.

### **PROGRESSIVE PUBLIC IN-SOURCING OF PRIVATE PROVIDERS USING FINANCIAL LEVERAGE**

**Governments should progressively in-source the private healthcare sector by bringing a large proportion of beds in all private hospitals above a specified minimum size, under public direction.** This publicly-funded measure could replace the problematic PMJAY scheme, which has proved to be inadequately effective in general, and specifically for dealing with the challenge of the COVID-19 epidemic.<sup>67</sup> The cost of maintaining engaged beds would be properly and promptly reimbursed by the public system to the concerned private providers. These would be utilised as an extension of the public health system, to provide tax-funded and free healthcare to a progressively increasing proportion of the Indian population.

### **DEVELOPING MULTI-STAKEHOLDER GOVERNANCE PLATFORMS WHILE PROMOTING SOCIAL ACCOUNTABILITY**

Governments must create spaces for civic engagement in healthcare governance, by ensuring multi-stakeholder representation in health councils at district, city and state levels.

Regulatory governance bodies such as councils should go beyond tokenistic representation of non-official actors, and should be converted into **truly inclusive platforms for diverse stakeholders** including government health officials, healthcare providers, representatives of frontline doctors, nurses and health staff from public and private hospitals, civil society

<sup>67</sup> <https://indianexpress.com/article/india/pm-jay-saw-57-pc-fall-in-surgeries-46-pc-in-medical-care-during-lockdown-6469988/>



**"SOCIAL ACCOUNTABILITY REFERS TO FORMAL OR INFORMAL MECHANISMS THROUGH WHICH CITIZENS AND/OR CIVIL SOCIETY ORGANIZATIONS BRING OFFICIALS OR SERVICE PROVIDERS TO ACCOUNT. 'SOCIAL REGULATION' REFERS TO ACTION-ORIENTED APPROACHES DESIGNED TO REINVENT AND DEMOCRATIZE REGULATION, WITH GREATER PARTICIPATION AND ACCOUNTABILITY OF THE REGULATORY PROCESS TO USERS AND THE PUBLIC. PATIENT'S RIGHTS CAN BE USED AS A FULCRUM FOR SOCIAL MOBILIZATION RELATED TO REGULATION AND DEMANDING SUBSTANTIAL REPRESENTATION OF CIVIL SOCIETY, CITIZENS, ESPECIALLY FROM MARGINALISED COMMUNITIES IN THE REGULATORY FRAMEWORK.**<sup>68</sup>

organisations, health rights and patients' groups and consumer forums. These councils should also include a **gender and inclusivity component**, that takes into account the gendered and socially marginalised vulnerabilities in healthcare, and create an enabling environment for them to represent their concerns. The experiences and lessons from **Participatory Health Councils in Brazil<sup>69</sup> and Health Assemblies in Thailand<sup>70</sup>** can provide useful inputs in creating spaces for meaningful engagement of people with policy making processes. Based on the principle of participatory governance of health systems, such platforms would help to:

- monitor delivery of quality healthcare services
- facilitate social accountability of public and private healthcare sectors and preventing corruption and mismanagement by monitoring of health budget spending
- address genuine concerns of healthcare providers and rights of staff
- represent and address healthcare concerns of the most vulnerable and marginalized communities

### **REGULATION OF PRIVATE HEALTH SECTOR SHOULD BE INTEGRATED WITH PUBLIC HEALTH SYSTEM STRENGTHENING AND MOVEMENT TOWARDS UNIVERSAL HEALTH CARE**

As mentioned previously, the processes of regulation and progressive socialisation of private healthcare

will need to proceed in tandem, for each to be fully effective. Public in-sourcing will be ineffective if not accompanied by ensuring standards of care, however imposing regulatory standards will be easier if accompanied by use of public funds and authority to leverage care from private providers; *'Those who pay the piper, can call the tune'*.

Governments will need to move towards Universal Health Care systems, which will be significantly based on **expanded and strengthened public provisioning**, which in itself can prove to be a major check and counter-balance to arbitrary behaviour by private healthcare providers. Further, bringing private healthcare resources under public management and control through in-sourcing of private healthcare providers can be developed as part of various 'building blocks' for UHC. One such major step could be **provision of free healthcare to all formal and informal sector workers** (including rural cultivators and workers, and self-employed), which could move much beyond and replace the current PMJAY scheme. Similarly tax funded, free primary healthcare services may be provided universally for maternal and child health, and for the elderly. These actions would help to create a realistic and popularly supported foundation for a system of Universal Health Care, which is publicly funded and organised, and is free of cost to ordinary people.

68 [https://www.copasah.net/uploads/1/2/6/4/12642634/working\\_paper-pvt.\\_sector.pdf](https://www.copasah.net/uploads/1/2/6/4/12642634/working_paper-pvt._sector.pdf)

69 Mayka, L. (2019). Brazil's Health Councils: Successful Institution Building through Sweeping Reform. In *Building Participatory Institutions in Latin America: Reform Coalitions and Institutional Change* (pp. 98-139). Cambridge: Cambridge University Press. doi:10.1017/9781108598927.004

70 Rajan D, Mathurapote N, Putthasri W, et al Institutionalising participatory health governance: lessons from nine years of the National Health Assembly model in Thailand *BMJ Global Health* 2019;4:e001769.

## BRIEF REVIEW OF SELECTED CIVIL SOCIETY ACTIONS FOR ACCOUNTABILITY AND REGULATION OF PRIVATE HEALTHCARE

The role of civil society networks, people's organisations and media is critical in the movement for accountability of the healthcare sector, as they represent diverse voices responsive to people, and are able to advocate for vulnerable sections of society, who may not have access to the tools and the space to be heard. Creation of stronger civic spaces and engagement is key to challenge the capture of the decision making process by powerful and influential medical lobby, while strongly highlighting the need to promote public interests. Hence, it will be worthwhile to briefly review selected civil society actions for social accountability of private healthcare over the last couple of decades, before moving to suggested strategies for action.

An overview of the people's movement for regulation and accountability of the private healthcare sector in India (with focus on actions taken in Maharashtra state) is documented in a chapter of the book *'Healers & Predators? Healthcare corruption in India'* (Shukla in Nundy et al).<sup>71</sup> Citizen groups like Medico Friends Circle and Forum for Medical Ethics Society in Maharashtra started to engage with the issue of commercialization and malpractice in the healthcare sector in the nineties. In 2005, as the Bombay Nursing Home Registration Act (BNHRA) of 1949 was being amended, Jan Arogya Abhiyan (JAA – Maharashtra circle of Jan Swasthya Abhiyan) mobilized public opinion and played a crucial role in drafting provisions in the draft rules to promote patients' rights and accountability of private hospitals. However, the powerful medical lobby vetoed the adoption of these provisions, despite a sustained civic society campaign for their inclusion.

Following the adoption of Clinical Establishments Act, 2010 by the Union government and associated rules in 2012, the JAA advocated for an improved version of Maharashtra Clinical Establishments Act (CEA) with

key additional provisions to ensure 'social regulation' through district level multi-stakeholder bodies and protection of patient's rights. In December 2013, the official decision was taken to draft a Maharashtra Clinical Establishments Act, on the lines of the national CEA, but duly modified to address concerns of both patients and doctors. After months of deliberations by a drafting committee, a draft MCEA was prepared in mid-2014 which explicitly included a charter of patients' rights and district-level grievance redressal bodies. However, the critical provision for regulation of rates was dropped in the state draft bill, due to resistance from medical associations. Though the draft bill was endorsed by the Directorate of health services and Health minister, it could not be enacted due to change in Maharashtra state government in October 2014.

At the national level, from 2010 onwards, organized efforts across various states also emerged to promote awareness and act on various aspects of this issue. SATHI and JSA conducted a series of regional workshops on 'Promoting Patients' rights and ensuring social accountability of Private medical sector' across India in 2013–14. Subsequently, health activists begin to raise patients' rights issues and systematically document patient's rights violations in certain states like UP and Chhattisgarh. JSA also focused on advocacy to ensure inclusion of patients' rights in the national standards for CEA, and participated in some of the sub-committees involved in developing various aspects of the standards for clinical establishments. This did lead to inclusion of some of the patients' rights-related provisions in the standards for hospitals at various levels.

In parallel, there have been notable initiatives focusing on specific areas of regulation related to certain practices of the private healthcare sector. Starting from Madhya Pradesh, a health rights organisation -

71 Shukla A. Healthcare Corruption: Responses from People's Health Movement in: Nundy S, Desiraju K, Nagral S eds. *Healers or Predators? Healthcare Corruption in India*, Oxford UP, 2018pgs 462-481

Swasthya Adhikar Manch, documented irregularities and unethical practices in clinical trials, based on which they filed a public interest litigation<sup>72</sup> (PIL) in the Supreme Court (SC) in 2013, alleging gross violations of patient's rights in clinical trials such as enrollment of participants without proper informed consent, lack of adequate compensation for trial-related adverse effects. In response, the SC recommended stringent controls on the conduct of clinical trials and directed the Central Drugs Standard Control Organisation (CDSCO) to undertake regulatory reforms to ensure participant safety.<sup>73</sup> The subsequent adoption of New Drugs and Clinical Trials Rules in 2019 was a significant step towards regulation of clinical trials by private hospitals across the country.

In 2012, SAMA - Resource group on Women and Health published a study on commercial surrogacy in India<sup>74</sup>, a highly flourishing and poorly regulated market since 2002 and highlighted the risks and inherent exploitation faced by vulnerable surrogate mothers. Sustained engagement by human rights and women's health groups led to a ban on commercial surrogacy in 2015, and regulatory reform in the form of the Surrogacy (Regulation) Bill, 2016, introduced again in Parliament in 2019 after it lapsed.

A landmark achievement by a citizen activist, Delhi-based lawyer Birender Sangwan was the rate regulation of cardiac stents, an area marked by profiteering to the estimated tune of 3500 crores per year. Based on his PIL to regulate the prices of life saving stents in 2014<sup>75</sup>, which was persistently supported by research and media advocacy led by civil society networks such as All India Drug Action Network (AIDAN), the Department of Pharmaceuticals and the National Pharmaceutical Pricing Authority (NPPA) were moved to take a decision<sup>76</sup> to cap a ceiling on stent prices in February 2017,

bringing down their costs for the consumer on an average by over 70%.

Another notable campaign for pro-people regulatory legislation concerning the private healthcare sector started in June 2017 with the tabling of the KPME (Amendment) Bill in Karnataka. The bill was hotly debated for months thereafter<sup>77</sup>, with a spirited campaign by civil society, citizen activists, public health researchers, patient victims who allied to counter the organized opposition put up by professional medical associations.<sup>78</sup> Though critical provisions were diluted in the rules - a testament to the major clout of the private health sector, the people's movement for the implementation of the KPME Amendment Bill was significant in terms of the scale and nature of people's participation. As Akhila Vasan, from the organization Jan Aarogya Chaluvali put it "*the story of the KPMEA amendment is a story of citizens' battle against the exploitative profiteering private health sector. This is not so much about what was "achieved" but about the immense possibilities when the health rights discourse is democratized, of what ordinary citizens can do when drawn into the health rights discourse*".<sup>79</sup>

In 2015, the National Human Rights Commission's (NHRC) decision to conduct public hearings on the right to healthcare across the country in collaboration with JSA gave further impetus to the movement for patients' rights, with around 30 workshops held across the country to orient activists on documentation of the denial of patients' rights in private hospitals, along with recording instances of health rights violations related to the public health system. The first in the series of NHRC-JSA hearings on right to healthcare, covering the western region of the country, was organized at Mumbai in January 2016 with around 650 participants. While cases of denial related to public health services

72 <https://www.legitquest.com/case/swasthya-adhikar-manch-and-ors-v-union-of-india-uoi-and-ors/184c8a>

73 Roy Chaudhury R, Mehta D. Regulatory developments in the conduct of clinical trials in India. *Glob Health Epidemiol Genom.* 2016;1:e4. Published 2016 Feb 23. doi:10.1017/ghg.2015.5

74 <http://www.samawomenshealth.in/birthing-market/>

75 Lawyer with a heart: Birender Sangwan's fight to cap price of coronary stents-<https://www.hindustantimes.com/india-news/meet-the-man-who-fought-to-cap-coronary-stent-price-at-rs-30-000/story-8Nbn7MSAH1NBy17TZjJdUP.html>

76 <https://health.economicstimes.indiatimes.com/news/medical-devices/coronary-stents-prices-slashed-by-85-govt-tells-delhi-high-court/57441134>

77 <https://www.epw.in/engage/article/political-interests-and-private-healthcare-lobby-collude-stifle-patients-rights-karnataka>

78 <https://medium.com/the-dialogue/why-do-patients-and-social-movements-support-kpme-amendments-bill-2017-in-karnataka-c6d6e52a7bf9>

79 [https://www.copasah.net/uploads/1/2/6/4/12642634/working\\_paper-pvt\\_sector.pdf](https://www.copasah.net/uploads/1/2/6/4/12642634/working_paper-pvt_sector.pdf)



were given a hearing, when patients who had suffered violations in private hospitals— which had been duly registered by NHRC—attempted to speak, they were refused a hearing on the grounds that such cases were beyond the commission’s mandate.

Developments from 2016 onwards such as the publication of the book, *Dissenting Diagnosis* (Gadre and Shukla 2016) highlighted the prevalent medical malpractices across the country, substantiated by powerful testimonies from ‘whistleblower’ medical professionals. This joint articulation of ‘voices of conscience’ by a section of doctors and the positive public reception to this book resulted in the formation of a pan- Indian network of doctors called the Alliance of Doctors for Ethical Healthcare (ADEH), whose members are committed to ethical, rational healthcare and advocate for major reforms, including regulation of the private healthcare sector.

Formation of Citizen Doctor Forums in cities like Mumbai and Pune in the past few years are signs of increasing civic engagement with these issues, and the desire to develop alternatives to the current model of profit

oriented healthcare. Simultaneously, citizen activism by victims of medical negligence and their families has also resulted in creation of Patient Rights organizations like People for Better Treatment (PBT) and All India Patient Rights Group (AIPRG), thus contributing to the visibility and momentum of the campaign for Patient Rights in India.

The emergence of social media platforms as a powerful tool for advocacy and the unprecedented reach of digital connectivity has enabled civil society to reach out to far more communities than before, and make them a part and the face of India’s struggle for affordable and quality healthcare. In February 2019, Jan Swasthya Abhiyan and several health networks came together to launch an online petition and also organized a demonstration<sup>80</sup> at Jantar Mantar in Delhi to demand adoption of the NHRC Patient Rights Charter by the government, regulation of rates in private hospitals and an effective grievance redressal mechanism for patients. Sustained engagement on this issue did ultimately result in the adoption of a Patient’s Right Charter by the MOHFW later that year, albeit in a diluted version.

80 <https://thewire.in/health/patients-health-workers-protest-breach-of-rights-at-private-hospitals>



## FURTHER STRATEGIC APPROACHES FOR CIVIL SOCIETY NETWORKS AND ORGANISATIONS

Given this entire background and the current situation, civil society networks and organisations will now need to develop large-scale social action by integrated attention to **Alliances, Demands and Strategies**, to effectively further the agenda of regulation of private healthcare sector.

### BUILDING ALLIANCES: STRENGTHENING SOCIAL COALITIONS FOR REGULATION OF PRIVATE HEALTHCARE

Building alliances of diverse sections of people, cutting across classes and social strata, is essential to create an organised and impactful collective constituency, which can powerfully demand accountable healthcare services. CSO networks working in the health sector should specifically reach out to the following constituencies, which have a stake in pro-people regulation of private healthcare:

- **Patient victim's groups and individual patient victims** who have suffered from gross negligence and exploitation in private hospitals. Such patients and their families are highly motivated and have compelling first hand stories. Their lived experiences form the narrative for the struggle for patient rights, and can motivate other affected people to speak up and join the movement.
- **Patient support groups** such as People living with HIV/AIDS (PLHA) networks, Hepatitis C and Mental health support organizations who are already engaged with issues of discrimination and violation of health rights.
- **Nurses and healthcare workers in the private sector** who are facing the consequences of commercialisation and corporatisation of healthcare as employees in private hospitals, and also would support regulation and improved standards which would lead to better working conditions.
- **Trade unions and organisations of informal workers, women's networks, and rural and urban**

**mass organisations, including those working with Dalit and Adivasi communities** who increasingly find their members faced with medical deprivation and exploitation related to private healthcare, and would be interested in greater accountability and regulation of this sector.

- **Socially active and sensitive sections of the middle class**, who are experiencing the pinch of unaffordable and largely unaccountable private healthcare, and have the voice to influence public opinion.
- **Academia and public health researchers**, whose work can help to support evidence-based advocacy action.
- **Independent media houses** who document human rights stories, social media influencers who comment on current socio-political issues, especially in regional languages. In an increasingly digital world, their involvement is important for reaching out to a younger and politically active, media-savvy population and involve them in the movement.

Further, there is **need for alliance building with sections of rational, socially responsive doctors**. *"Since primary resistance to regulation of the private medical sector comes not from the state but from the medical profession, without moderating this resistance, while ensuring elements of participation in the regulatory process, it may not be possible to develop effective regulation. Hence, along with citizen mobilisation, there is an ongoing need to work with the medical profession, towards developing voices for social responsiveness. These voices would include doctors concerned about the negative impacts of gross commercialisation. The involvement of physician advocates can both reshape regulation, by ensuring that the critical concerns of doctors are taken on board, and also helps overcome resistance to regulation from mainstream medical associations."<sup>81</sup>*

81 Shukla A, More A, Marathe S. Making private health care accountable: mobilizing civil society and ethical doctors in India. *The IDS Bulletin*; 49:129-46

Amplifying the voices of conscience within the medical community through network building like the Alliance of Doctors for Ethical Healthcare (ADEH), and engaging responsive doctors in dialogue through Citizen-Doctor Forums can help to build consensus and support within the medical community regarding regulation of the healthcare sector, for correcting distortions which have emerged due to unbridled commercialisation.

Health sector CSOs should also reach out to unions of medical students and residents to sensitise them regarding advantages of social regulation to check commercialisation of healthcare, linked with movement towards a UHC framework. A regulated and publicly organised UHC system would offer medical professionals the freedom to work in a secure and stable environment, leading to improvement in doctor patient relationship, and cessation of violence and abuse of frontline healthcare professionals.

Such a 'grand alliance' of diverse people's organisations and progressive healthcare professionals can help in fore-fronting the discourse on regulation of the private healthcare sector. Their combined presence could provide the social counterbalance to check the power and privileges of the private healthcare lobby, which has traditionally resisted regulation. Organized people's movements can influence policymakers, as was observed in the long drawn out struggle to pass a pro-people amended regulatory legislation in Karnataka.

### KEY DEMANDS: SETTING THE AGENDA FOR CHANGE

As is obvious from the preceding analysis, there are a wide range of demands which need to be raised for ensuring comprehensive reform of the healthcare sector. Here we will only highlight a few core demands related to Clinical Establishments Act, which may be focussed upon in the near future, while further strategies would unfold over time. Health being a state subject, major demands have to be made at the National and State levels.

#### KEY DEMANDS AT THE NATIONAL LEVEL:

- **Union Health Ministry (MOHFW) must rapidly notify the CEA Minimum Standards** and thus ensure that the stalled implementation of CEA 2010 in number of states and UTs, which have adopted the act, can now proceed as soon as possible.

- **MOHFW must immediately revive the process of standardisation of rates for private hospitals**, which has been shelved by the National council for clinical establishments, by delegating this complex process to the states governments. This will enable fixation of rates in private hospitals across all states, which have adopted CEA 2010, and will also provide guidelines for other states.
- **MOHFW should endorse all 17 rights from the NHRC Patient Rights Charter, and include this expanded charter in the CEA Minimum standards for hospitals.** This would make the Patient Rights Charter legally enforceable in all states which have adopted CEA 2010.
- Considering the widespread violations of patients' rights in the COVID 19 epidemic, **MOHFW should also recommend that States which have not adopted the CEA 2010, but have adopted other regulatory acts, must legally implement the Patients' rights charter through their existing acts.**

#### KEY DEMANDS AT THE STATE LEVEL:

- **All State governments which have adopted CEA 2010 must now move for its effective implementation**, completing any statutory steps which are pending in some states, asking the Central government to notify long pending standards, and with this notification proceeding with permanent registration process for all clinical establishments.
- **In states which have implemented the CEA 2010, governance bodies like the State Councils and the District Registering Authority should be expanded with multi-stakeholder representation**, ensuring that they have a gender and social inclusivity component.
- **States which have not adopted the Central CEA and are in the process of amending existing regulatory legislations or drafting new legislations, should pass/amend these State level acts as soon as possible**, while ensuring that these Acts do not dilute key provisions of central CEA in spirit and principle, and include key provisions related to rate regulation, district and state level multi-stakeholder governance bodies, and implementation of Patients' rights.



- **All states must ensure that all their clinical establishments display and implement the Patients' Rights Charter.** Display of the charter should be made mandatory for provisional registration in states which have adopted CEA 2010, and should be included as a provision in existing state level regulatory legislations in other states.
- **States should develop a more effective and accountable mode of publicly engaging private providers, which should replace existing insurance scheme based models.** Drawing on the experience during the COVID-19 epidemic, where some states insured a certain percentage of private beds for treatment of COVID 19 patients, states should consider bringing under public direction 60 to 80% of beds in private hospitals above a certain size, and reimburse them directly whilst ensuring that they are effectively regulated and accountable.
- **State level regulations should consider the concerns of small sized and individual clinical establishments** by providing them some flexibility and transition period for fulfilling physical and human resource standards, reflecting the constraints they face due to their location, size and financial capacity. This should be done while not compromising on core process standards, standard treatment guidelines and patients' rights.

## ANNEXURE 1: TIMELINE OF STATE AND UT LEVEL NOTIFICATIONS RELATED TO CEA 2010

S.N.	Name of State and UT	Date when CEA 2010 adopted or came into force	Date of Notification of State Rules OR UT Rules	Date of Notification of State Council OR UT Council	Date of Notification of District Registering Authority (DRA)
1	Chandigarh	01.03.2012	08.11.2013	01.07.2020	22.01.2013
2	Daman & Diu	01.03.2012	04.09.2014	15.04.2011	18.09.2013
3	Dadar & Nagar Haveli	01.03.2012	10.11.2014	27.11.2013	27.11.2013
4	Lakshadweep	01.03.2012	06.02.2017	31.08.2011	31.08.2011
5	Andaman & Nicobar Islands	01.03.2012	06.03.2013	06.03.2013	South Andaman- 23.07.2013 ; North & Middle Andaman – 23.12.2013 ; Nicobar-21.09.2013
6	Puducherry	01.03.2012	05.03.2014	07.05.2014	07.05.2014
7	Arunachal Pradesh	01.03.2012	31.05.2012	31.05.2012	All districts notified between year 2012 to year 2015; all 17 notification confirmed on 03.02.2015
8	Mizoram	01.03.2012	27.05.2014	16.07.2014	16.07.2014
9	Himachal Pradesh	01.03.2012	20.12.2012	17.11.2012	28.08.2012
10	Sikkim	01.03.2012	19.04.2012	19.04.2012	19.04.2012
11	Haryana	-	-	-	-
12	Assam	10.12.2015	14.10.2016	03.11.2016	03.11.2016
13	Uttarakhand	29.03.2011	22.03.2013	18.08.2011	23.11.2012
14	Jharkhand	08.02.2012	30.05.2013	27.02.2013	23.05.2012
15	Rajasthan	29.08.2011	05.06.2013	05.06.2013	05.06.2013
16	Bihar	16.08.2011	28.11.2013	-	-
17	Uttar Pradesh	11.02.2011	11.07.2016	Not Done	Not Done
18	Punjab	01.07.2020 Through Ordinance	Pending ratification in State Assembly		

Source: [www.clinicalestablishments.gov.in](http://www.clinicalestablishments.gov.in); Operational Guidelines for Clinical Establishment Act



## ANNEXURE 2. NATIONAL REGISTER- TOTAL PROVISIONAL REGISTRATIONS DONE TILL 31ST AUGUST 2020

State	Allopathy	Ayurveda	Unani	Siddha	Homeopathy	Yoga	Naturopathy	Sowa-Rigpa	Total
Andaman & Nicobar Islands (UT)	125	20	0	1	24	4	1	0	139
Arunachal Pradesh	64	5	0	0	12	0	2	0	77
Assam	4376	687	34	14	223	65	22	1	4562
Chandigarh (UT)	600	121	3	1	34	7	8	1	651
Dadra & Nagar Haveli (UT)	217	54	1	0	63	0	1	0	297
Daman & Diu (UT)	181	47	5	0	80	3	0	0	260
Haryana	439	52	8	4	46	24	12	0	448
Himachal Pradesh	4371	2421	132	26	213	54	55	12	6429
Jharkhand	7277	397	67	6	294	68	43	0	7636
Mizoram	7	0	0	0	3	0	0	0	8
Puducherry (UT)	745	39	0	38	30	6	4	0	7990
Rajasthan	1460	109	21	7	104	35	25	2	1557
Uttarakhand	861	199	34	1	78	32	77	0	1122
<b>Total</b>	<b>20723</b>	<b>4151</b>	<b>305</b>	<b>98</b>	<b>1204</b>	<b>298</b>	<b>235</b>	<b>16</b>	

Source: [www.clinicalestablishments.gov.in](http://www.clinicalestablishments.gov.in); accessed on 31st August 2020

\*The difference in total is due to the fact that Clinical Establishments may have more than one operational system of medicine.

## ANNEXURE 3: SELECTED NATIONAL LAWS AND REGULATIONS APPLICABLE TO PRIVATE HEALTHCARE, CONCERNING QUALITY OF CARE AND PATIENT SAFETY

S.N	Name of the Act
1	Clinical Establishments Act – 2010
2	State Fire Prevention and Safety Acts & National Building Code of India, 2016 , Part 4 - Fire and Life Safety
3	The Drug and Cosmetics Rules - 1945 (Amendment 2005)
4	Blood Bank Regulations under Drugs and Cosmetic (2 <sup>nd</sup> Amendment) Rules – 1999
5	Indian Medical Council Act, 1956
6	Indian Medicine Central Council (IMCC) Act, 1970
7	Homoeopathy Central Council (HCC) Act, 1973
8	Indian Medical Council (professional conduct, etiquette and ethics) Regulations- 2002
9	Registration of Medical Practitioners with State Medical Councils
10	Transplantation of Human Organs Act – 1994 (Amendment 2011) & Rules 2014
11	Pre Conception and Pre-Natal Diagnostic Techniques (prohibition of sex selection) (PCPNDT) Act -1994 & Rules – 1996
12	Medical Termination of Pregnancy (MTP) Act – 1971 (Amendment 2020)
13	Biomedical Waste Management Rules -1998 (Amendment 2018 )
14	The Consumer Protection Act – 1986 (Amendment 2019)
15	New Drugs and Clinical Trials Rules, 2019
16	National Medical Commission Act, 2019

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