HSTP

Health Systems Transformation Platform

Webinar Report

Regulation of Clinical Establishments in India – The Train is Still Only Inching Forward

28 October 2021

Objectives

Health Systems Transformation Platform (HSTP) is a not-for-profit organization based in New Delhi, India. Our mission is to enable Indian researchers and policymakers to conduct research and translate evidence for achieving Universal Health Coverage. We carry this out in collaboration with Indian and global expertise by strengthening stakeholders' capabilities for health systems redesign, validating interventions, and fostering policy dialogue.

HSTP identified health systems governance and regulation as one of the building blocks of the health system that has not received adequate attention. The instruments for health systems regulation have a high impact on institutions, processes, and outcomes, but currently, these are poorly understood and utilized. Health facilities in India were not regulated in many states until the Clinical Establishments (Registration and Regulation) Act (CEA) came into being in 2010. The CEA 2010 spurred many states to enact or update their own state Acts which were outdated to the needs and inadequate in scope. The CEA 2010 prescribes minimum standards for infrastructure, human resources, supportive services, medical equipment etc. Challenges of adoption and implementation of the clinical establishments regulations combined with the absence of legislative mechanisms for fixing the cost of services, conducting audits, and ensuring patients' rights, has led to weak regulation of health care services.

A webinar 'Regulation of Clinical Establishments in India – The Train is Still Only Inching Forward' was organized by HSTP on 28th October 2021 to deliberate upon the present status of legislation to regulate clinical establishments in India and the regulatory challenges. The focus of the webinar was to share information by the Central and State governments regarding the implementation of clinical establishment regulations in India, challenges and the way ahead.

Shri. Rajeev Sadanandan, Chief Executive Officer, HSTP gave an overview of the objectives of HSTP and challenges observed in regulating clinical establishments in India. Dr. Rakesh Sarwal, Additional Secretary, NITI Aayog, GOI delivered the keynote address and Dr. Anil Kumar, Additional Deputy Director, DGHS, GoI explained the reason for bringing in a central Act for regulating clinical establishments, provisions of the CEA 2010 and its Rules, the status of implementation of the Act and way forward. State nodal officers for clinical establishments regulations from nine states namely, Arunachal Pradesh, Delhi, Himachal Pradesh, Jharkhand, Karnataka, Kerala, Maharashtra, Rajasthan and Tamil Nadu presented the current status of clinical establishments regulations in their states and key issues they face in implementing them.

The panel discussion included Ms. K Sujatha Rao, Former Secretary, MoHFW, GoI, Dr. RV Asokan, Ex-Secretary General, Indian Medical Association, Dr. Alexander Thomas, National President, Association of Healthcare Providers (India) and Shri. Sunil Nandraj, Advisor, HSTP, moderated by Shri. Rajeev Sadanandan. Panelists shared their experiences and reasons for the slow implementation of clinical establishments regulations and lack of participation by professional associations. Ms. Pallavi Gupta, Specialist, Health Systems Governance anchored the webinar and was assisted by Dr. Sonali Randhawa, Research Associate, Health Systems Governance.

Summary & Learnings

Shri. Rajeev Sadanandan welcomed the participants. He shared that the webinar aims to review the status of the Clinical Establishments Act, 2010, and similar legislations enacted by the states. Further, it would help to understand the challenges in the implementation of the legislations from the point of view of different stakeholders. He stated that learnings from the webinar will guide the way forward for strengthening regulations to provide quality health care.

Dr. Rakesh Sarwal delivered the keynote address and congratulated HSTP for selecting a subject that is crucial to improve the quality of health care. He emphasised that standardisation is the focus of the Central legislation, and we need to move beyond the number of establishments registered since registration by itself would not improve the quality of outcomes. We have both statutory standards (CEA standards) and voluntary standards (IPHS or NABH accreditation standards) for clinical establishments but because of lack of culture of standardisation/ accreditation, or perhaps the standards are set too high for the hospitals, only 7% of the clinical establishments are accredited in the country compared to 76% in the United States. Dr Sarwal recommended that realistic standards (especially the entry-level accreditation standards) be developed, and a culture built among the providers to adopt such standards and be more transparent. He also recommended that the stress should be on voluntary compliance and not on coercion.

Dr. Anil Kumar shared the reasons behind enacting the central Clinical Establishments Act 2010 - multiple media reports indicated the functioning of several fake laboratories and clinical establishments, patients' death because of medical negligence or substandard clinics/ hospitals delivering services, private hospitals charging unreasonably high prices for treatment. Providing the status update on the implementation of CEA 2010, he said that currently the Act is applicable in 11 States (Arunachal Pradesh, Himachal Pradesh, Mizoram, Sikkim, Uttar Pradesh, Uttarakhand, Rajasthan, Bihar, Jharkhand, Assam and Haryana) and 6 UTs (Andaman & Nicobar Islands, Dadra and Nagar Haveli and Daman and Diu, Lakshadweep, Chandigarh, Puducherry, Jammu & Kashmir), Ladakh is in the process of adopting it and other states have their own state Acts. Approximately 28,832 clinical establishments are registered online and 2,148 offline as of 27 October 2021. The Central government has undertaken several steps to promote the implementation of the Act such as conducting a survey to assess the ground situation of clinical establishments in 61 districts, advocacy and training workshops, nodal officers and coordinators at the state and district level, a website with online registration facility, and providing budget and ongoing support to the states. He highlighted some of the reasons for the slow implementation of CEA 2010 by the states such as shortage of specialists, nurses and paramedical staff compared to CEA standards; lack of interest and ownership by the state; registration on the state portal but not on the dedicated CEA portal developed by the Central government; limited capacity for online registration; and lack of participation by professional associations.

This was followed by presentations from the nine states on the implementation of clinical establishments regulations. The state representatives shared the number of clinical establishments that have applied for registration, numbers that are registered under the respective Act and some presented the number of applications that are pending approval.

- **States following their own Act**: Delhi follows Delhi Nursing Home Registration Act 1953 for the registration of clinical establishments and is in the process of finalising the Delhi Public Health Bill. Kerala passed the Kerala Clinical Establishment Act in 2018 and the English version of the Rules was notified in

2021. The Karnataka Private Medical Establishments Act 2007 that repealed the Karnataka Private Nursing Home (Regulation) Act 1976 regulates only private medical establishments in the State. Maharashtra has one of the oldest Acts for the registration of nursing homes and maternity homes called the Mumbai Nursing Home Registration Act 1949 which applies to the whole of Maharashtra state but does not cover small clinics, dialysis centres, pathology labs, physiotherapy or daycare centres. In 2018, a draft Maharashtra Clinical Establishment Bill 2018 was submitted to the government. Tamil Nadu Private Clinical Establishments (Regulations) Act was passed in 1997 (amended in 2018) to regulate the private clinical establishments in the State.

- **States that adopted CEA 2010**: Arunachal Pradesh, Himachal Pradesh, Rajasthan and Jharkhand have adopted the central Act and presented the status of implementation in their states.

The issues highlighted by the states in the webinar were:

- Objections raised by professional associations such as the Indian Medical Association, Indian Dental Association on issues like displaying treatment rates in hospitals, publication of inspection reports in the public domain, and their non-representation in the registering authority. Implementation delays due to delay in notifying minimum standards, and delay in applying for provisional registration mainly by the private sector were shared. Clinical establishments are required to apply for several licences (such as fire safety, building stability, bio-medical waste management, etc.) which causes a delay in their registration under the CEA 2010 or state-specific Act.
- Ineffective implementation because states have limited capacity and resources. For example, Arunachal Pradesh pointed out issues of poor infrastructure, poor connectivity with lack of internet facility in many places, lack of human resources in several districts, difficult terrain along with the unavailability of vehicles make it difficult for the staff to make visits for inspection and regular monitoring. Himachal Pradesh and Rajasthan highlighted the challenges faced in operating the online CEA portal for the registration of clinical establishments.
- Rules in some states were inadequate as they cover only the registration of nursing homes and private hospitals.
- The minimum standards under the Act do not cover issues relating to accountability of quality and price.
- The absence of a database that captures the actual number of clinical establishments functioning in the state (panchayat or district wise).

The Covid-19 pandemic drew attention to several issues such as violation of patient confidentiality, human dignity, privacy during treatment, overcharging by the private providers, services being delivered by an increasing number of unregulated, non-registered online health service aggregators (especially online laboratory and diagnostic services). Given all these issues, National Council for Clinical establishments issued a directive on “Patients’ Rights” to the States and UTs where the CEA 2010 is adopted, recommended that only registered clinical establishments should be allowed to provide online laboratory services and stressed the need to fix the cost of health care services.

The National Commission for Allied and Healthcare Professions Act 2021 permits certain allied healthcare professional categories such as physiotherapists to “practice independently” in contrast to CEA 2010 which allows them to provide services based only on “prescription or referral from a licensed medical doctor”. It will have to be seen how such contradictory provisions will impact service delivery.

The panel discussion followed the presentations by Central and State governments to understand the views and experiences of other stakeholders involved in the implementation of CEA, moderated by Shri Rajeev Sadanandan.

- Some of the panelists were of the view that CEA is an anti-medical profession and adopts a bureaucratic approach to overregulate clinical establishments. They shared their concern that such regulation would lead to the closure of small and mid size private health facilities such as small hospitals and single or couple doctor clinics as was observed in the USA and Malaysia. There is gross infringement by the CEA on the rights of a medical professional to prescribe treatment to patients and how it must be delivered.

- However, this was refuted by other panelists who believed that practitioners often do not want to be accountable and therefore are opposed to regulation. Several episodes have been highlighted where peer regulation did not work in case of medical negligence, hence self-regulation could not be a recommended approach for India.

- One size (central Act) will not fit all (types of clinical establishments) and recommended to use different strategies such as accreditation, self-regulation, and local governance structure to regulate the health care sector. Doctors who have small hospital setups or single doctor clinics need not be covered under the CEA. They can be regulated differently such as adopting entry-level NABH accreditation, and the option of peer regulation by the medical council could also be explored. Fixing rates and their display should not be mandatory.

- Clinical establishments include not only allopathic hospitals but also institutions that provide services for diagnosis, treatment and care for illnesses through yoga, ayurveda, homoeopathy and other recognised systems of medicines. Hence, the argument that the medical council can self-regulate clinical establishments takes a narrow view of the health care sector.

- Though in existence for almost ten years, knowledge about CEA is scant among various stakeholders. CEA 2010 enactment was the first step in regulating clinical establishments in order to capture who is practising what, in what kind of set up and where is it located, through registration. But, even after a decade of CEA implementation, the rate of registration is low.

- The present pandemic exposed the unregulated nature of the health sector, especially the private sector. The issues of accountability, transparency and outcome data are lacking from both the government and private hospitals.

- Along with regulatory tools, there is a need to develop collaboration between organisations and individuals; prioritise transparency of rates charged; build accountability mechanisms among regulators and providers; and facilitate strong consumer institutions and redressal platforms for patients.

Around 90 practitioners, academicians, government representatives, researchers and civil society members participated in the webinar. Participants raised concerns over the poor status of implementation of regulations, delay in notifying minimum standards for hospitals, the possibility of delays and corruption in implementation of the act and absence of rate regulation to date even after the horrifying experience of overcharging by providers during Covid-19 and emphasised that any health care reform should have patient-centeredness as a key value.

Way Forward

Several steps are being taken by the Central government for implementation of CEA, 2010 such as the development of the new portal, Clinical Establishments Registration and Regulation System (CERRS) which will also have a grievance redressal module, notifying the minimum standards and patients' rights, regulating online health service aggregators and providers, and bringing in reforms that promote ease of doing business such as single-window clearances, availability of relevant resources online, etc.

The need to engage more closely with the private health sector to improve the quality of health care services through an error-free, reliable and safe system that follows standard processes and protocols was emphasised. The webinar brought together stakeholders with different perspectives and provided an opportunity to learn about the concerns in the implementation of clinical establishments regulations. Based on the discussion during the webinar, there is a need to:

- Initiate discussion with Central and State government officials to provide technical support to strengthen the implementation of clinical establishments regulations.
- Build partnerships and work in collaboration with other stakeholders, civil society organisations, professional groups.
- Build capacity of young professionals to work on health regulation.

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The webinar report 'Regulation of Clinical Establishments in India - The Train is Still Only Inching Forward' is developed by Health Systems Transformation Platform (HSTP) to share the summary of proceedings of the discussion.

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