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Government Stewardship for Health Care: A Scoping Review of Regulatory Frameworks for Health Care Providers

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Asian Development Research Institute

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List of Abbreviations

AP	–	Andhra Pradesh
AYUSH	–	Ayurvedic, Yoga, Unani, Siddha and Homeopathy
CE	–	Clinical Establishment
CEA	–	The Clinical Establishment (Registration and Regulation) Act, 2010
CMO	–	Chief Medical Officer
CMS	–	Center for Medicare and Medicaid Services
CQC	–	Care Quality Commission
DGHS	–	Director General of Health Services
DHS	–	Department of Health Services
DoH	–	Department of Health
ETALA	–	The Emergency Treatment and Active Labor Act, 1986
FT	–	Foundations Trusts
GoB	–	Government of Bihar
GoI	–	Government of India
HHS	–	Department of Health and Human Services
HMO	–	Health Management Organization
HSiT	–	Health System in Transition
IMA	–	Indian Medical Association
IMC	–	Indian Medical Council Act
INR	–	Indian National Rupees
IPD	–	In-patient Department
IPHS	–	Indian Public Health Standards
KPME	–	The Karnataka Private Medical Establishments Act, 2007
LMIC	–	Low and Middle-Income Countries
MBBS	–	Bachelor of Medicine & Bachelor of Surgery
MCI	–	Medical Council of India
MMR	–	Maternal Mortality Ratio
MoH	–	Ministry of Health
MoHFW	–	Ministry of Health and Family Welfare

MoPH – Ministry of Public Health
NABH – National Accreditation Board for Hospitals and Health Care Providers.
NCD – Non-communicable Disease
NCT – National Capital Territory
NGO – Non-Government Organization
NHFPC – National Health and Family Planning Commission
NHS – National Health Services
NICE – National Institute of Health and Clinical Excellence
NMC – National Medical Council
NPSA – National Patient Safety Agency
NQAS – National Quality Assurance Standard
NSSO – National Sample Survey Office
OECD – Organization of Economic Cooperation and Development
OPD – Out-patient Department
PCPNDT – Pre-conceptional and Pre-Natal Diagnostic Technique
PCT – Primary Care Trust
PHSRC – Private Health Services Regulatory Council
PMIRA – The Private Medical Institution Registration Act, 2006
PPO – Preferred Provider Organization
RTMR – Road Traffic Mortality Rate
SATCM – State Administration of Traditional Chinese Medicine
SDG – Sustainable Development Goals
SHA – State Health Agency
SMC – State Medical Council
TB – Tuberculosis
U5MR – Under 5 Mortality Rate
UK – United Kingdom
US – United States
USA – United States of America
UT – Union Territory
WBCERC – West Bengal Clinical Establishment Regulatory Council
WHO – World Health Organization

Executive Summary:

As per constitution of India, Improvement in public health, nutritional status and right to life for all citizen must be ensured by the Government. Health care for all is gaining priority in political and public discourse across the country. In all 29 states and six union territories, the health system is mixed of public and private sector; both in term of providers or health care facilities and financing. As a result of unregulated proliferation of mixed health systems, high inequity in access and low quality of care is gradually becoming a big challenge. Health care in union of India is a subject matter under jurisdiction of individual state. Bihar is one of the resource constrained state in the eastern part of India. The health system in Bihar is also mixed and unregulated. Majority of people access health care from private sector, even when the cost of treatment is much higher in comparison to public sector. Private health sector in the state is largely unregulated. In year 2010, state government brought a legislation to control and regulate private health facilities, which couldn't be implemented completely. In the same year, union government brought an act called "The Clinical Establishment (Registration and Regulation) Act (CEA) and notified the rule for the same in year 2012. The Government of Bihar immediately adopted this act and notified the rule in 2013. But, as per national list of clinical register, no health facility is registered under the act till January 2018. Therefore, private health facilities continues to be unregulated. Many factors can be contributing to this regulatory challenge, such as; limited role of government as steward of health care, insufficient institutional arrangements for effective regulation, lack of motivation, dominant role of doctors and professional associations in political economy of state and delay related to judicial procedures. This study was done with focus to understand regulation in health care, dominant regulatory framework globally and in other Indian states to document major learnings and suggest possible roadmap for regulation of health care in Bihar.

Adopting approach of scoping review of literature, the study was conducted in three phases to fulfill all objectives. Review was focused on understanding regulation of health care as concept, to study regulatory framework in six selected countries, to understand regulatory legislations and current status of implementation of regulation in other Indian states. Considering the complexity of entire health systems regulation, focus of this study was restricted to regulation of health providers and facilities.

One of best definition of regulation is *"sustained and focused control exercised by a public agency, on the basis of a legislative mandate, over activities that are generally regarded as desirable to society"*. Considering, massive market failure in health care, role of regulation is recognized as effective measure to control and establish fair exchange in health care market. Two broad approaches for regulation in health care are; administrative control and market harnessing methods. Most of the low and middle-income countries have tried

administrative control with little success. Evidence suggest that a mix of both approach can be useful for effective implementation.

Globally, effective regulation for health care exists in all high-income countries and regulatory framework is also being strengthened in LMICs. Among the six countries studied; Japan, UK (England), USA had quite comprehensive regulation. Other countries like, Thailand also has robust regulation for health care. Countries like China and Srilanka are introducing reforms to make regulation more effective. Most importantly, in all six countries, regulation is achieved by strong legislative mandate and decentralized institutional arrangement for implementation.

Regulation of health care providers (doctors) in India is though the medical council of India and other agencies via their state chapters. Regulation of health facility is responsibility of state government. Some of the states like; Maharashtra, West Bengal and Delhi have legislation in effect for more than 60 years, although implementation varies across the states. Some states like; Jammu and Kashmir, Madhya Pradesh, Punjab and Odisha introduced regulatory act at different time but implementation was very limited in terms of number and extent. Tangible momentum for felt need to regulate private sector was observed during first decade of new millennium after the enactment of legislation in Andhra Pradesh followed by Karnataka. The act introduced by Karnataka was major turning point owing to introduction of some provisions to display and control cost of treatment given by private sector. After the enactment of CEA by union government, almost all states, where an act was already in place were pushed to implement regulation more effectively. Currently, the central CEA is applicable in 10 states and all Union Territories, 12 other big states have legislation in place with inconsistent level of implementation. Some other states either have legislation in formulation process or no act is in effect.

Based on learning from this study, the suggestive way forward for government's stewardship role for health care in Bihar should have two important dimensions: continue to strengthen public health system and start regulating private health sector to connect their efforts to achieve larger health goals. The immediate knowledge and action required for this can be: to study the implementation challenges of CEA and to landscape the presence of private sector in the state.

Background and Rationale

India is the second most populous and economically one of the fastest growing countries of the world. With rising economic prowess, people's expectation from the government is also on the rise. As per article 37 (1) of the Constitution of India; India is a welfare state, where the welfare of people is the responsibility of the government. Article 14 of the Constitution provides equal rights to life for all Indian citizens and as per article 47, nutrition, standard of living and improvement in public health are the responsibility of the government.[1] Under the Indian constitution, the legislative power is clearly demarcated between the union and the states. The Parliament of India generally does not have the power to make laws applicable to states except for those issues mentioned in articles 249 and 250. Health care is included in subject under state list and hence under state government's jurisdiction.[1,2] Historically, the union government influenced health system of state by formulating newer policies or issuing guidelines.[3,4] Health, which was traditionally of low priority issue for both individuals and government, is slowly and steadily gaining greater priority in recent years.

The union of India is composed of 29 states, six union territories and one national capital territory of Delhi.[2] Health systems in these administratively distinct parts of India are at different stages of development. In all states, health systems experience some form of complexity due to the existence of many factors of which one universal phenomenon is the presence of parallel public and private health care providers. Private health sector in most of the states is largely unorganized, informal and unevenly distributed.[3] Regulation of private health facilities also vary among states; ranging from no regulation to partial to major regulation.[5]

Bihar is one of the most resource constrained states of India.[6] The health system is mixed with the private sector playing dominant role in health care provision. At present, due to limited public health infrastructure, private providers cater to the majority of the health care needs of the population.[7] Although catering to majority of the health care needs of people, the private sector is highly unorganized and almost totally unregulated. Historically, unlike in some other Indian states, no holistic attempt to regulate the private sector in Bihar was taken till the year 2010. In 2010, the state government enacted The Bihar Clinical (Registration and Control) act. But, even before this act could be implemented on the ground, the Government of India introduced a similar act called The Clinical Establishment (Registration and Regulation) Act, 2010 (henceforth CEA) with a strong advice for states to adopt this under the provision of article 252 of the Indian constitution. Government of Bihar (GoB) immediately adopted and enacted CEA and notified rules for implementation in 2013. This was an important step taken towards the regulation of health care facilities in the state.[8] But the private medical establishments and professional

association, such as Indian Medical Association (IMA) protested against the act and boycotted its implementation. Many litigations were filed against this act in the court of law. In one of the interim judgments, the court order restrained the state from taking any coercive measure against clinical establishments for not registering under the act.[9]

More than four years have elapsed, since the notification of CEA in the state of Bihar, implementation has not started as yet. As per the national list of clinical register, no clinical establishment in Bihar is registered under the act. The following important factors may have played significant roles in non-implementation of the act;

1. Limited role of Government as the steward of health care of people.
2. Insufficient institutional arrangement for implementation at state and district level.
3. Low motivation of health system functionaries in enforcing this act.
4. Dominant influence of physicians and professional associations in the political economy, and,
5. Judicial procedure and inherent delay.

Therefore, the current study aims to address why effective regulation of the private sector is required in the context of the pluralistic health systems in resource constrained settings to achieve larger health goals.

Specific Objectives

1. To understand regulation in health care.
2. To review the regulatory framework for health care in selected countries.
3. To examine health care regulation and its status in states of India.
4. To document major learnings and suggest ways for better regulation of health care facilities in Bihar, India.

Methodology

Since the research focus of the study is a complex issue with limited available evidences, we adopted a scoping review approach to understand the regulation and regulatory framework in selected countries and in Indian states. The scoping review "aims to map *rapidly* the key concepts underpinning a research area and the main sources and types of evidence available, and can be undertaken as stand-alone projects in their own right, especially where an area is complex or has not been reviewed comprehensively before".[10,11]

The study was conducted in three steps to address the four specific objectives :

Step 1: Review of literature was done to understand why regulation is important in health

sector, factors responsible for successful regulation, approaches and strategies of health care regulations. For this part, we did a comprehensive literature review on regulation of health care. Literature were searched using data bases including PubMed, google scholar and a generic google search. After the initial scanning, only selected literature was reviewed thoroughly to understand the meaning, economic basis and importance of regulation in health care.

Step 2: To understand regulatory framework for health professionals and facilities globally, case studies of six selected countries was done. The selected countries are; United Kingdom (England), United States, Japan, China, Thailand and Sri-Lanka.

For this review, the Health Systems in Transition (HSiT) reports were reviewed for United Kingdom (England), United States, Japan, China and Thailand. The HSiT report for England, United States and Japan were published by World Health Organization (WHO), Europe and European Observatory for Health Systems and Policies.[12,13,14] HSiTs for China and Thailand were published by WHO and Asian Observatory for Health Systems and Policies.[15,16] For case study of Sri Lanka, other published literatures were reviewed. [17,18,19]

Step 3: Step 3 of the study was further divided in two parts;

Part – 1: To understand the historical pathway of development of regulation for health care professionals and facilities in India.

For this objective, all published and grey literature were searched and websites of concerned government departments were also assessed to collect information.

Part – 2: To understand the status and challenges in implementation of regulation for health facilities in different states of India.

All published literature, selected reports, meeting minutes, other grey literatures and official documents were reviewed to understand regulatory framework. Official government websites were accessed to understand the implementation status of regulation in different Indian states.

Regulation in Health Care

What is Regulation?

Regulation is a broad term with diverse meanings, interpretations and applications depending on context. The main objective of regulation is to establish basic condition for fair market exchange. In the domain of health care, regulation is widely accepted as initiatives taken by government to correct market failure mainly through administrative control, although this somewhat restricts the domain of wider objectives, means and

outcomes.[20] Regulation of health care is very complex and inherent to the complexity of health systems itself.

Although there are many definitions of regulation, one widely accepted definition is given by a leading European analyst: "*sustained and focused control exercised by a public agency, on the basis of a legislative mandate, over activities that are generally regarded as desirable to society*".[21] Another definition given by Organization of Economic Cooperation and Development (OECD) says; *regulation means diverse set of instruments by which governments set requirements on enterprises and citizens. Regulations include laws, formal and informal orders and subordinate rules issued by all levels of government, and rules issued by non-governmental or self-regulatory bodies to whom governments have delegated regulatory powers.* In the context of health care, the OECD paper classified regulation into three categories; economic, social and administrative.[22] These two definitions are most relevant for health care.

Regulation in the context of health systems includes the range of factors exterior to the practice or administration of medical care, that influences the behaviour in delivering or using health services. While a traditional view of regulation sees it primarily as a preserve of government implemented through legislative and bureaucratic control, it is increasingly being realized that goals of regulatory policy can sometimes be achieved more efficiently by involving other actors in the regulatory mechanism.[20] Another definition for regulation of healthcare was given by Robert et al in their book "Getting Health Reform Right"*: regulation refers to the government's use of its coercive power to impose constraints on organizations and individuals. Under this definition, only legal rules, and not incentives or behaviour change are included under the heading of regulation*.[23] This definition is a little restrictive, because it identified coercive power and imposing constraint as important tools for regulation. After having reviewed what is regulation, especially in context of health systems, it is also very important to understand why regulation is required for health system.

Why Regulation for Health Care?

Baldwin and Cave (1999) in their pioneering work suggested that the motivation for regulating a market can differ from technical justification and reasons can vary from influence of market forces to chances of re-election of government. But strong technical justification also exists for regulating a market specially to address market failure. They proposed that if any of the condition such as: *monopolies and natural monopolies, windfall profit, externalities, information inadequacies / asymmetry, continuity and availability of services, anti-competitive behaviour and predatory prices, public good and moral hazards, unequal bargaining power, scarcity and rationing* exists, then there is a strong justification for bringing regulation to correct market failure.[24] Almost all these characteristics are overtly

manifested in an unregulated market of health care in mixed health systems especially in resource constraint settings. Moreover, the unregulated health market is a classic example of information asymmetry as described by Akerlof.[25]

Regulation is also described as one of the control knobs of health systems framework. Roberts J. et al, proposed that regulating health care in any area or region is essential due to following reasons: [23]

1. *Establish basic conditions for market exchange:* one of the primary aims of regulation is to create legal and regulatory framework to establish basic conditions for fair market exchange.
2. *Enhance equity*: regulation can be introduced to bring equity in health care provision in a free market.
3. *Correct market failure and to provide public and merit goods*: Government can bring regulation to correct these market failures; specially to help consumer make informed choices and protect the buyers from inadequate quality (this requires regulation of inputs, *control supplier-induced demand, counteract monopoly)*
4. *Ethical Reason:* regulation is also important for ethical reasons considered very important in health sector. An example of this is the Pre-conceptional and Pre-natal diagnostic technique (PCPNDT) act in India, which restricts determination of sex of a baby by any method to prevent discrimination.[26]

Roberts et al. also suggested four important determinants of regulatory success in health sector:[23]

1. *Cultural attitude (of both people and government)*
2. *Capacity of government,*
3. *Political support and*
4. *The design of regulatory process and institution.*

Bloom at el. also highlighted four broad policy objectives of regulation in health care; first, *to ensure quality of care,* second, *cost effectiveness,* third, *equitability* and fourth, *accountability.*[27]

Implications of un-regulated health care services in a mixed health system

A mixed health system is defined as "a health system in which out-of-pocket payments and market provision of services predominate as a means of financing and providing services in an environment where publicly-financed government health delivery coexists with privately-financed market delivery".[28] In most of the low and middle-income countries, health system is affected by what is often referred to as "mixed systems

syndrome", which is characterised by compromised quality and equity in health care delivery in a mixed health system".[28] Most of the Indian states exhibit the syndrome of mixed health system. The factors responsible are categorized into three: first; insufficient state funding for health, second; regulatory environment that enable private sector to deliver social services without a regulatory framework and third; the lack of transparency in governance of health system.[29]

In the state of Bihar, private sector is the care provider for majority of patients for both outpatient and inpatient care irrespective of the place of residence. Cost of hospitalized care in private health facility in comparison to public health facility is more than double in rural area and three times more in urban area of Bihar. Cost of hospitalization for child birth in private sector is more than seven times higher in rural area and more than six times in urban area **(Table.1)**.[7] It is evident that, health system in state of Bihar is mixed and private sector plays a predominant role in health care delivery. Cost of care in private health facility is much higher in comparison to public sector. In sum total, the state health systems exhibits classical symptoms of mixed health system syndrome and factors associated with them. The co-existence of both public and private health care is a reality which influences the health outcomes of people and overall health indicators of state.

Table.1: Utilization and cost of treatment at public and private health facility in India and Bihar:

	India		Bihar	
	Rural	**Urban**	**Rural**	**Urban**
Outpatient Care (Percentage distribution of spells of ailment treated during last 15 days)				
Government /Public Health Facility	28.3	21.2	14	12
Private Health Facility	71.7	78.8	86	88
Inpatient Care (Percentage distribution of hospitalised cases in last 365 Days)				
Government /Public Health Facility	42	32	42.6	38.8
Private Health Facility	58	68	57.4	61.2
Cost of Non-Hospitalized Care (Average total expenditure for non-hospitalised treatment per ailment during last 15 day) (In INR)				
Overall (Includes both public and private health facility)	509	639	729	604

Cost of Hospitalized Care Average total medical expenditure for treatment per hospitalisation case during stay at hospital (Last 365 days) (In INR)				
Government /Public Health Facility	5636	7670	6933	9232
Private Health Facility	21726	32375	15288	33072
Total	**14935**	**24436**	**13626**	**28058**
Cost for Child Birth Inpatient Average total medical expenditure per childbirth during stay at hospital (as inpatient) (Last 365 days) (In INR)				
Public	1587	2117	2197	2584
Private	14778	20328	16322	13795

Source: NSSO 71st Round - 2014

Therefore, in the spirit of article 42 of constitution of India, it is important for government to play the role of a steward for people's health care in addition to being a health provider. For this, the first stepping stone can be to bring effective regulation for health care providers including private health sector. There are many proposed and practiced strategies for regulation of health care, although none of them are perfect, so the selection of strategy must be context specific.

Strategies for Health Care Regulation:

Based on analysis of different approaches proposed by Baldwin and Cave, Ensor et al. and Bloom et al. health care regulations can be categorized in two broad strategies: *1. Administrative Control and 2. Market Harnessing Methods. Almost all the approaches for regulation can then be sub-categorized under these two broad strategies.*[20,24,27]

1. **Administrative Control:** Administrative control typically involves public or quasi-public agencies implementing rules backed by legal authority. Approaches can be:
   - Licensing and accreditation of providers and facilities.
   - Registration of medical products: drugs, vaccine, equipment etc.
   - Criminalization of malpractices.
   - Product surveillance.
2. **Market Harnessing Methods:** These methods are targeted to introduce competition among providers aiming to improve quality, efficiency and coverage. The potential approaches under this strategy can be:

- Market supply oriented:
    i. Self-Regulation: standards setting and compliance by professional associations of providers and suppliers.
    ii. Contracting: Government purchases services from provider at verified quality, quantity, and/or price standards.
    iii. Disclosure: Offenders and poor performers are "named and shamed"
    iv. Incentives and disincentives: funds or incentives provided for desired provider behaviour (location of service, quality of service)
- Consumer or Citizen oriented:
    i. Consumer education
    ii. Consumer rights
    iii. Citizen empowerment
    iv. Redressal mechanism
    v. Right to information by citizens
- Collaboration oriented:
    i. Partnership for transparency and accountability
    ii. Co-production (of regulation and services across providers)

Strategies of health care regulation highlight the different methods of regulatory control in health sector. While most of these strategies have similar end goals in mind, their approaches vary. All the same, the final approach that will be followed is determined by the strategy adopted by the regulator which is very context specific.

Regulating health system: where to start?

The next logical question for regulation of health systems is; where to start? Which building block of health system can be the starting point for regulation?

In most of the LMICs, the most common form of regulation is certification and licensing of health care providers. Another important regulation in LMICs, although not well developed is regulation of medicine, medical products and medical equipment. Some LMIC also introduced licensing, certification, accreditation of health facilities with varied success. Many LMICs have made efforts for improved access to health care for the poor by means of price control at wholesale or retail level of supply chain or by introducing subsidies for identified set of health services. Although, these controls are easier to implement in public health sector but difficult in private health sector due to weak

enforcement capacity on the part of the government and little incentive for compliance on part of providers.[27]

As evident, the overall approach for regulating health systems in LMICs is on the inputs used in producing health services. Ensor et al. proposed a framework of regulatory approach adopted and practiced to regulate input of health services. Bloom et al. modified that framework by Ensor et al. in their work and proposed a broader approach of regulating four broad domains of health systems; human resources for health, Infrastructure (health facilities), medicine and pharmaceutical products and medical equipments.[20,27] In this paper, the same approach is further modified and presented as a possible starting point for regulation in health sector (Table.2).

Table. 2: Objectives and Approaches of Regulation of Health Care in LMICs:

(Adapted and modified from Ensor et al. and Bloom et al.)

Objective	Approach			
	Human Resource for Health	Health Facilities	Medicines and pharmaceutical products	Medical Equipment
Volume	■ Restricting number of medical school and number of entry ■ Licensing of providers ■ Regulating types of providers	■ Approval and registration of facilities	■ Regulation on availability of drugs ■ Public procurement arrangement	■ Regulation of medical equipment purchase (approval, certification and limit)
Quality	■ Ensuring quality of medical education ■ Ongoing training and monitoring of providers	■ Setting standards for approval/process ■ Standards / licensing systems ■ Periodic monitoring of compliance	■ Control of process of sale of drugs for efficacy, safety and quality ■ licensing system	■ Licensing system ■ Restricted availability ■ Product and process standards
Price	■ Salary and incentives	■ Control on service prices ■ Mandatory services at subsidized price ■ Mandatory services	■ Price control ■ Subsidies on selected drugs ■ Promotion of essential drugs / generic drugs	■ Price control

Based on overall experience, the approaches should first target control of volume followed by ensuring quality and price control. For this study, our focus is on regulation of health care providers (medical professionals) and health facilities. In the next section, we have reviewed global experiences on regulation of health care providers and facilities.

Global Experience on Regulatory framework for Health Care Providers and Facilities:

To understand the trend on regulatory framework for health care providers and facilities, we reviewed regulations across six countries such as; United Kingdom (UK), United States (US), Japan, China, Thailand and Sri Lanka. These countries were conveniently selected considering geography, as well as, diversity in nature and characteristics of health system. The country cases highlight the health system characteristics, governance, regulation of health care providers and facilities. Main sustainable development goals (SDG) 3 indicators of the countries are also reviewed as a proxy for health status of people. Summary of country case studies are explained below and major observations are shown in Table.3:[12–16,30] for quick reference, India's health system is also summarized (Table 3).

- **United Kingdom (UK) (England):** Health care provision in the UK is completely nationalized, in addition, 13% of population have some kind of additional voluntary health insurance. Administration of health system at national level is spearheaded by Department of Health (DoH) which guide the National Health Services (NHS), public health and other services. At the regional level, there are 10 State Health Agencies (SHAs) which play a role to link DoH and NHS and develop a plan to improve health services in local area. At local level, Primary Care Trusts (PCT) are mainly responsible commissioning services for local geographically defined population. Health providers are regulated by various professional-led statutory bodies. Health care facilities owned by NHS are regulated by DoH directly through its agencies. Facilities owned by foundation or trusts are regulated by monitors. Other agencies having regulatory roles are (Table.3):[13]
    - Care Quality Commission (CQC): Responsible for regulation and inspection of all health care providers (NHS, private sector and voluntary sector).
    - National Institute of Health and Clinical Excellence (NICE): NICE is mandated to determine, whether interventions by the NHS (drugs and other technologies, procedures, clinical guidelines and to some extent, systemic interventions) are safe, effective and cost-effective.
    - National Patient Safety Agency (NPSA): Promotes culture of reporting.
    - DoH and SHAs – Issue guidelines and oversee regulations.

  Main SDG-3 indicators for the UK is one of the best in the world.[31] The strength of UK health system is nearly universal coverage, which is highly equitable. One important weakness is procedural delay due to presence of only one type of provider, which also tends to be monopolistic.

- **United States (US):** Health care in the US is provided pre-dominantly by private sector. The governance of health care is divided into three tiers. At the federal level; the Department of Health and Human Services (HHS) and its eight agencies are responsible for governance of health systems. At the provincial level; public health department, providers licensing boards, insurance commissioner and other minor agencies constitute the governing structure. Similarly, at the local level; public health department of counties and cities govern the health systems. Health care regulation is enforced by many private and public agencies at all levels. Regulation for health care providers exists at three levels; at central level, the Center for Medicare and Medicaid Services (CMS) regulates by setting criteria for re-imbursement; at state level, licensing board have the authority to issue and re-issue license for medical practice and also revoke or suspend license; Health Management Organization (HMO) and Preferred Provider Organization (PPO) also regulate physician's behavior and practice by defining standard protocol. Similarly, various government and Non-Government Organization (NGO) regulate health facilities. The Joint Commission is a NGO which issues certification for hospitals and medical institutions, CMS prescribes re-imbursement criteria, federal laws determine who must be treated in hospital. The Emergency Treatment and Active Labor Act, 1986 (ETALA) prescribe mandatory medical screening examination of all emergency medical conditions including active labour cases coming to any hospital, irrespective of their capacity to pay. SDG-3 indicators for US is although satisfactory but not as good as other developed countries. The most important strength of US health system is high quality of care and research. Weaknesses are high cost, coverage not being universal and inequitable (Table.3).[12]

- **Japan:** Japan could achieve universal health coverage by statutory health insurance, thus setting an example for rest of the world. Japanese health system is considered one of the best and most equitable health system. The health care delivery is by mixed public as well as private health care providers. Health governance at national level is led by ministry of health and labour welfare, at provincial level by public health centres of prefecture government and at local level by city or county public health department. Central ministry regulates health professionals directly and register and govern them. Ministry can suspend or revoke license for any misconduct and non-compliance to rules. Although, nurses are controlled by prefecture governments. Health facilities are regulated at two levels; central ministry set criteria for health insurance re-imbursement and prefecture government or city government in bigger cities enforce medical care act. Medical care act mandate registration and regulation of all health facilities, also set minimum standards for them and punish the violators.

The strength of Japanese health system is universal coverage, easily accessible and high-quality care. One of the important weakness is low priority on primary health care due to easily accessible secondary and tertiary care (Table.3).[14]

- **China:** Chinese health system is composed of three independent yet inter-dependent systems: a health financing system, a health service delivery system and a health supervisory system. Health providers and facilities are mixed, although majority of providers and facilities are in public sector. National health and family planning commission (NHFPC) and state administration of traditional Chinese medicine (SATCM) and many other agencies at national, provincial and local levels constitute network of health system governance agencies.

  Health providers are regulated by NHFPC directly, which sets rules for examination required for doctors to get license. Local health authorities organize these examinations. The NHFPC and provincial health and family planning commissions have established the postgraduate medical education council, which is responsible for research on specialist training, provides guidelines, coordinates activities and controls training quality of specialist doctors. Regulation exist for all aspect for health facilities; entry control, quality, practicing mode, pricing, cost management and patient health demands. NHFPC at national level is responsible for licensing of health facilities, setting standards, monitoring quality through third party evaluator. They also conduct periodic ranking and reviewing of health care facilities. Other regulatory mechanism includes, co-regulation by professional bodies and by third-party payer for health insurance mechanism. SDG-3 indicators for china is although not very good but still far better than those of India. The recent reforms and well developed primary health care delivery system are strengths of Chinese health system. Fragmented health care delivery is one of the most important weakness (Table.3).[15]

- **Thailand:** Thailand is much appreciated for accomplishing near universal health coverage. The health governance at national level is spearheaded by ministry of public health (MoPH) with administrative and technical centres at national and regional levels. Health governance at provincial level and district level are headed by provincial health offices and district health offices respectively.

  Health providers are regulated by respective statutory councils managed by professionals. There are separate councils for medical, dental, pharmacy and nursing midwifery. All public health facilities are exempt from accreditation and licensing. These are regulated by their governing agencies, which is either MoPH or another department/ministry. Private health facilities are regulated by The Bureau of Sanatorium and Art of Healing set up under the Sanatorium Act, 1998 (Medical

Premise and License act). The Bureau issues license which may be renewed annually in line with stipulated quality and standards. Although SDG-3 indicator for maternal and infant mortality is very good for Thailand, but other indicators are not as good. Biggest strength of the Thai health system is expanding coverage leading to universal coverage of health care. Over-dependence on general taxation as mode of health financing for universal coverage can become a bottleneck in the future (Table.3).[16]

- **Sri Lanka:** Sri Lanka is also cited as one of the success stories in Asia for improvements in health indicators, especially related to maternal and child health. The health system in Sri Lanka is mixed; but majority of health institutions, clinics, hospital beds and outpatient cases are under the public health sector. A majority of health expenditure (52%) is spent in the private sector. The health system governance is at three tiers; Ministry of Health (MoH) and its department of health services headed by director general of health services at the central level, eight provincial directorate of heath at provincial level, and divisional director general of health services or medical officer of health at the local level.

  Sri Lanka Medical Council is responsible for registration, maintenance of academic and professional standards, discipline and ethical practice of health professionals. Public health facilities are directly controlled either by central or provincial or local health department, hence, no specific regulations exist for them. Private health facilities are regulated by the Private Medical Institution Registration Act, 2006 (PMIRA). Private health services regulatory council (PHSRC) is the governing body for this act. Under this act; registration, certification, regulation, monitoring and inspection of private health facility is done. all private medical institution must get a certificate before starting operations. Sri Lanka has performed tremendously well in SDG-3 indicators such as maternal mortality ratio and infant mortality rate. The biggest strength of the health system in Sri Lanka is a very well developed public health care delivery system, and challenges are mushrooming of private sector with poor regulatory control (Table.3). [17–19]

Table. 3: Health system characteristics, governance, regulation of health providers and health facilities, and selected SDG-3 indicators of six selected countries.

	Health Systems Characteristics	Governance of Health Systems	Regulation of Health Providers	Regulation of Health Facilities	SDG-3 Indicator*	Strength and Weakness
United Kingdom (UK) (England)	Nationalized. Only 13% population has voluntary health insurance.	**National Level:** Department of Health. **Regional Level:** 10 State Health Agencies (SHAs). **Local Level:** Primary Care Trusts (PCTs) are mainly responsible for health services at local level.	**By Professionals led Statutory Bodies:** • Health Professional Council, regulating the members of 13 types of health professions • Nursing and Midwifery Council: • **Council for the Regulation of Health Care Professionals:** (known as the CHRE) to monitor health professional regulators	**NHS facilities –** directly by DoH, Secretary of State – Health • CQC • NICE • NPSA • SHAs. **Foundation Trusts (FTs)** – through independent board of Governors which include local residents **Monitors –** additionally to monitor financial health of FTs.	MMR – 9 U5MR – 6.5 TB incidence – 10 NCD Mortality – 11.0 RTMR– 2.9 Stunting among children - 0 Skilled Health Worker Density – 112.4	**Strength:** • Universal Access to care • Highly equitable **Weakness:** • Procedural delays • Monopolistic
United States of America (USA)	Predominantly private	**National Level:** Department of Health and Human Services (HHS) with its many agencies. **Provincial Level:** Public Health Departments, Providers Licensing Board and Insurance commissioners. **Local Level:** Public health department of Cities and Counties	**At three level:** **Federal Level:** through Centres for Medicare & Medicaid Services (CMS) – impose criteria for reimbursing practitioners. **State level Licensing Board:** New license, renew license, ensure basic standards by their power to suspend or revoke license to practice. **Health Management Organizations / Preferred Provider Organization (PPO):** Regulate physician's behavior and practice.	**Three Mechanism:** • Joint Commission (An NGO): certification • Federal Law: determine who must be treated at hospital • CMS: Provisions for re-imbursement criteria. • The Emergency Treatment and Active Labor Act (ETALA) 1986.	MMR– 14 U5MR – 6.5 TB incidence – 3.2 NCD Mortality – 13.6 RTMR – 10.6 Stunting among children –2.1 Skilled Health Worker Density –117.8	**Strength:** • High Quality of Care and • High quality of research. **Weakness:** • Inequitable and not universal access

	Health Systems Characteristics	Governance of Health Systems	Regulation of Health Providers	Regulation of Health Facilities	SDG-3 Indicator*	Strength and Weakness
Japan	Statutory health insurance Providers are public and private mix.	**National Level:** Ministry of Health, Labour Welfare – through Bureau of Health Policy **At Provincial Level:** Public health centres established by prefecture governments and city government in major cities **At local level:** Cities / Counties public health department:	**Ministry of Health, Labour and Welfare:** Register and govern all health professional **Prefecture government:** Govern enrolled nurses.	**Two tier regulations** Central Ministry: health insurance reimbursement Prefecture government / City administration: enforce Medical Care Act ● Regulation of health facilities / pharmacies ● Regulation of quality of care.	MMR – 5 U5MR – 2.7 TB incidence – 17 NCD Mortality – 8.8 RTMR – 4.7 Stunting among children – 7.1 Skilled Health Worker Density – 130.9	**Strength:** Near universal coverage at low expenditure **Weakness:** Less focus on primary care
China:	Mixed type of providers and financing majority in public sector In year 2011 – 48% of facilities (mainly clinics), 17.5% health personnel and 9.2% of hospital beds were in private sector.	**National Level:** National Health and Family Planning Commission (NHFPC) and other relevant ministries **State level:** State Administration of Traditional Chinese Medicine (SATCM) **Provincial Level:** Provincial ATCM, Provincial HFPC, and other allied agencies. **City / county / township level:** HFPC and ATCM.	**NHFPC:** Set rules for examination required for doctors to pass in order to obtain licence. **Local health authorities:** Organize practising doctors' examinations.	**Regulation exists for:** entry control, quality, practising mode, pricing, cost management and patient health demands. **NHFPC:** Licensing, define quality standards, monitoring of quality by third party evaluators, certification, ranking and reviewing **Professional associations, social organizations and Third-party payers for health insurance:** co-regulates	MMR – 27 U5MR – 10.7 TB incidence – 67 NCD Mortality – 18.1 RTMR – 18.8 Stunting among children – 9.4 Skilled Health Worker Density – 31.5	**Strength:** ● Well-developed primary health care delivery system. ● Recent reform to improve health financing and service delivery. **Weakness:** ● Fragmented health care delivery system.

	Health Systems Characteristics	Governance of Health Systems	Regulation of Health Providers	Regulation of Health Facilities	SDG-3 Indicator*	Strength and Weakness
Thailand	Mixed type of providers: pre-dominantly public. In 2010, 67% of hospital beds owned by public health system	**Central Level:** Ministry of Public Health (MoPH): secretariat at central and regional level: also have administrative and technical centres **Provincial level:** Provincial Health Office (PHO) **District:** The district health office	**Professional councils:** ● Medical, Dental, Pharmacy, and Nursing and Midwifery – are responsible for their national licence examination	**Public facilities:** exempted from accreditation and licensing Public health facilities owned by government department or local body self-regulate. **Private Sector:** The Bureau of Sanatorium and Art of Healing, Department of Health Service under the Sanatorium Act 1998 (Medical Premises License Act): issue license and relicensed annually in line with stipulated quality and standards.	MMR – 20 U5MR – 12.3 TB incidence – 172 NCD Mortality – 16.2 RTMR – 36.2 Stunting among children – 16.3 Skilled Health Worker Density – 24.7	**Strength:** ● Universal health coverage **Weakness:** ● Over-dependence on general tax revenue for health financing
Sri Lanka	Mixed type of providers: predominantly public Health Financing – 52% private and 48% public (2009) Health Facilities: 17 % of medical institutions, 6% of hospital beds, 5% inpatient, and 9% of outpatient are in private sector (2011)	**At Central Level:** Ministry of Health (MoH): Department of Health Services (DHS) and Director General of Health Services (DGHS) **At Provincial Level:** Eight provincial director of health services **Local Level:** Medical officer (MCH), divisional director general of health services or medical officer of health.	**Sri Lanka Medical Council:** ● Registration, maintenance of academic and professional standards, discipline, and ethical practice by health professionals.	**Public facilities;** Directly controlled by central, provincial and local health agency hence not regulated. **Private Sector:** Private Medical Institution (Registration) Act 2006 (PMIRA): Through Private health services regulatory council (PHSRC): Registration, regulation, certification, monitoring and inspection of private medical institutions.	MMR – 30 U5MR – 9.8 TB incidence – 65 NCD Mortality – 17.7 RTMR– 17.4 Stunting among children – 14.7 Skilled Health Worker Density – 24.8	**Strength:** Well organized Public health system **Weakness:** Poor stewardship and growing influence of private sector.

	Health Systems Characteristics	Governance of Health Systems	Regulation of Health Providers	Regulation of Health Facilities	SDG-3 Indicator*	Strength and Weakness
India	Mixed – Predominantly private in most of the Indian states. Health is a matter under jurisdiction of state/provincial government.	**At Central Level:** Ministry of Health and Family Welfare (MoHFW) through its agencies and directorates. **At Provincial Level:** Department of Health and Family Welfare of state governments. Organizational structure varies from state to state. **At Local Level:** By district health administration headed by chief medical officer or equivalent	**Professional Led statutory bodies:** **National bodies and their state branches** • Medical Council of India • Dental council of India • Council for Indian system of Medicine • Nurses council • Pharmacy council	**Inter – State variation:** • Central Act: The clinical establishment (registration and regulation) act, 2010 applicable in many states. • Other states have separate act. Enforcement and implementation not uniform	MMR – 174 U5MR – 47.7 TB incidence – 217 NCD Mortality – 23.3 RTMR– 16.6 Stunting among children – 38.4 Skilled Health Worker Density – 27.5	See details

★ MMR – Maternal Mortality Ratio – Maternal deaths per 100,000 live births

★ U5MR – Children under 5 years of age mortality rate per 1000 live births

★ TB Incidence – Incidence of Tuberculosis per 100,000 Population

★ NCD mortality – Probability of dying from any of cardiovascular disease, cancer, diabetes, chronic respiratory disease between age 30 and exact age of 70 in percentage (%)

★ RTMR – Road Traffic Mortality Rate per 100,000 population (death as result of injury due to road traffic accidents)

★ Stunting among children – Prevalence (%) of stunting (height for age <-2 standard deviation from the median of the World Health Organization (WHO) Child Growth Standards) among children under 5 years of age

★ Skilled Health Worker Density – Includes physicians (general and specialists) and nursing professionals (nursing and nursing associates) and midwifery (midwives and midwife associates) per 100,000 populations.

Regulation of Health Care Providers and Facilities in India:

History and Evolution:

History of health providers' regulation in India dates back to British rule. In 1934, Medical Council of India (MCI) was set up under the Indian Medical Council Act, 1933, in line with British General Medical Council. After India's independence, this act was repealed and replaced in 1956 by a new act called the Indian Medical Council Act, 1956 (IMC). Medical council of India (MCI) was re-constituted under this act. All physicians of western system of medicine are regulated through this central agency and its state chapters. In the same way, the practitioners of Indian system of medicine, dentistry, pharmacist and nurses are also regulated by separate acts and separate statutory bodies respectively. Since its

implementation, the IMC act has been amended many times as per requirement.[32] Very recently, a proposed National Medical Council (NMC) Bill with a provision to replace MCI with NMC is under consideration of Indian parliament.[33]

Health facilities regulation in India also has a long history. There is a huge variation in health facilities regulatory framework across states and the timing of their enactment also varies. The earliest act for regulation of health facilities by any state in independent India is The Bombay Nursing Home Registration Act, 1949, followed by The West Bengal Clinical Establishment Act, 1950 and The Delhi Nursing Home Act, 1953. Many other states also enacted such an act during different period of time **(Figure.1)**. But none of these acts succeeded completely in regulating private health sector.[34] Moreover, network of physicians trained in Indian system of medicine practicing western medicine and non-formal health care providers are always out of scope of these act.[35] Following on a Supreme Court verdict in 1996, health care service also came under the purview of The Consumer Protection Act,1986 (CPA). The 21st century brought movement in many states leading to enactment of act for regulating health facilities. This situation provided serious momentum to discussion on the need to have uniform act for regulation of health facilities, especially the private sector. Important factors which may have played a role for this momentum was rapid progress of private sector in health care and growing inequity in health indicators. Therefore, Government of India (GoI) enacted The Clinical Establishment (Registration and Regulation) Act in year 2010 (CEA). As per the constitutional provision, The CEA automatically became applicable to all union territories and to the states of Arunachal Pradesh, Sikkim, Mizoram and Himachal Pradesh. The act recommends other states to adopt, prepare rules and implement the same in their respective states. Some states, where similar act was already in force were exempted from adaptation of CEA. These states are; Andhra Pradesh, Maharashtra, Delhi, Madhya Pradesh, Manipur, Nagaland, Orissa, Punjab and West Bengal. The notification of the CEA and rules for CEA was issued in 2012.[36]

Figure.1: History of Health provider and Facilities Regulation in India.

Health Provider Regulation

- 1934: Medical Council of India under Indian Medical Council Act 1933.
- 1956: New Indian Medical Council Act, 1956 enacted. Medical Council of India established. Act slightly revised in 1964, 1993, 2001
- 1996: Health care service included in purview of Consumer Protection Act 1986.

Health Facilities Regulation

- The Bombay Nursing Home Registration Act, 1949.
- The West Bengal Clinical Establishment Act, 1950
- The Delhi Nursing Home Registration Act, 1953
- The Jammu and Kashmir Nursing Home and Clinical Establishment (Registration and Licensing) Act, 1963.
- The Madhya Pradesh Upchar Griha Tatha Rogoupchar Sambandi Sthapanaye (Registration tatha Anugyapan) Adhiniyam, 1973.
- The Orissa Clinical Establishment (Control and Regulation) Act, 1990.
- The Punjab State Nursing Home Registration Act, 1991.
- The Manipur Nursing Home and Clinics Registration Act, 1992.
- The Clinical Establishment (Registration and Regulation) Act, 2007 introduced in parliament but was referred for amendments.
- The Andhra Pradesh Allopathic Private Medical Care Establishment (Registration ad Regulation) Act, 2002.
- The Karnataka Private Medical Establishments Act, 2007.
- Bihar Clinical Establishment (Control and Regulation) Act 2007. Repealed and replaced later.
- The Clinical Establishment (Registration and Regulation) Act, 2010 approved by Parliament of India
- Form March 1, 2012. The Clinical Establishment (Registration and Regulation) Act, 2010 notified. Rules formulated.
- The Bihar Clinical Establishment (Registration and Regulation) Rules, 2013 notified.
- Bihar State council notified creation of District Registering Authority in 12 districts

Status of Health Providers and Facilities Regulation in Indian States:

It is clearly evident from the above description that health providers' regulation in India is uniform across states with MCI at national level and State Medical Council (SMC) playing anchor role at state level. For regulation of health facilities, the legislative provision varies from state to state. Currently, CEA is applicable for 10 states and six union territories. Separate act is in force in other 10 states and national capital territory of Delhi. In this section, we reviewed the prevailing legislations for health facilities regulation in states. For comparative analysis of different states, we reviewed the existing legislation, institutional mechanism and status of implementation. This review is based on official documents extracted from the websites, and live reporting available from government websites.

Bombay state was the first state to enact an act to regulate health facilities. After Bombay became the capital of Maharashtra state; this act is now applicable all over Maharashtra. The act is in effect till now but the implementation is not uniform and universal.[37]Currently, a draft clinical establishment Bill in line with the central CEA is under consideration in the state.[38] Second Indian state to enact such act was West Bengal, where the first act was enacted in 1950, known as The West Bengal Clinical Establishment Act, 1950. This act was implemented well but was replaced by another act in line with the central CEA. In the year 2010, the West Bengal government enacted The West Bengal Clinical Establishment (Registration and Regulation) Act, 2010. But this act was again replaced in 2017 by an entirely new act, The West Bengal Clinical Establishment (Registration, Regulation and Transparency) Act, 2017. This act has many ambitious provisions aiming at bringing transparency in private health care system in the state. A super regulatory body, West Bengal Clinical Establishment Regulatory Council (WBCERC) with constitutional powers was established to oversee the implementation. An act to regulate private health facility was enacted by the Delhi state in 1953, which is called The Delhi Nursing Home Registration Act,1953. The act has been amended many times since then, last amendment was done in year 2011. As per information available on website of the health department of Government of NCT, Delhi, a total of 933 nursing homes/hospitals are registered.[39] The state of Jammu and Kashmir has a similar act in effect since 1963 known as The Jammu and Kashmir Nursing Homes and Clinical Establishments (Registration and Licensing) Act, 1963 and the same is being implemented. Till 2017, in Kashmir division alone, total 1454 applications were received and 1246 licenses were granted.[40] In Madhya Pradesh, although the act was enacted in 1973, the rules for the same were formulated in year 1997. In March 2015, online portal with end to end solution for clinical registration and renewal was introduced which led to a surge in number of facilities registering under the act. Till October 2017, 2034 Allopathic, 1834 clinics of Indian System of Medicine, 23 yoga clinics and 622 other clinics (which include diagnostics, dental and physiotherapy clinic) were registered under the act.[41] Chhattisgarh

state was created by bifurcating Madhya Pradesh. The state enacted an act similar to Madhya Pradesh in 2010. Discussions with private sector and professional associations were done before enactment of the act. Until October 2015, only around 20% of the 7000 applicants of facilities could get license. As per the act, a clinic has to comply to a minimum standard in order to qualify for the license.[42] In Odisha, the act for health facilities regulation came into existence in 1990, known as The Orissa clinical establishment (Control and Regulation) Act, 1990. Many amendments were made in this act, the last one being in 2017 to include all provisions of CEA. As of year, 2017, 1235 health facilities were registered under the act.[43] The Andhra Pradesh Allopathic Private Medical Care Establishment (Registration and Regulation) Act, 2002 was enacted in 2002 but the rules for the same were formulated in 2007. For the first time, this act enforced mandatory display of rates for treatment and procedures by all allopathic medical establishment. The act was slowly being implemented in the state of Andhra Pradesh (AP) but faced resistance from private sector, especially professional bodies of physicians. In the year 2014, Andhra Pradesh state was bi-furcated and a new state, Telangana was created. Telangana didn't adopt this act and is mulling the idea of adopting the CEA 2010.[44] Similarly, in other southern state of Karnataka, The Karnataka Private Medical Establishment Act, 2007 (KPME) was enacted in 2007. This act also mandated display of cost of procedure and package by all private medical establishment. There is a provision for capping the maximum price for medical treatment and procedures. The act is implemented in the state but is also facing strong protest from private sector and professional associations.[45]

In Punjab state, The Punjab Nursing Home Act, 1991 is in place but due to non-availability of information, status could not be reviewed. In Tamil Nadu, the state with one of the best health indicators, an act called The Tamil Nadu Private Clinical Establishment Act, 1997 was passed in 1997.[46] But rules necessary for implementation could not be formulated till date. Recently, high court of Tamil Nadu directed the government to implement this act at the earliest.[47] In another southern state, Kerala which has one of the best health indicator, no act is in force till date. A bill along the lines of the national CEA is under consideration of the legislative body.[48] In Haryana, The Haryana Clinical Establishment (Registration and Regulation) Act, 2014 was enacted in 2014 but rules to implement the act could not be framed till date.[49] Draft rule was placed for public comments in 2015 but the same is not yet finalized.[50] In Gujarat state, no comprehensive legislation to regulate health facilities is in place **(Table.4).**

The status of regulation of private sector in health in five smaller states like; Goa, Manipur, Nagaland, Meghalaya, Tripura and one new state, Telangana were not reviewed for this study.

Table.4: Status of health facility regulation in states where state act is in effect:

State	Act in Effect	Major Difference from CEA 2010	Institutional Arrangements for Implementation	Current status
Maharashtra:	Bombay Nursing Home Act, 1949 Maharashtra Nursing Home Rules, 1973	• Only for Private Sector • Validity for three Years (31st March of year) • Basic infrastructure, standards and other provisions: not well defined • Only medical degree holder can own nursing home. • Notification of death. • Cancellation of registration for non-compliance • Non-Registration: Imprisonment for 6 months or Rs. 10,000 Fine or both	• District Civil Surgeon in district • Municipalities in bigger cities • Cantonment in cantonment area.	• More than 20% facilities not registered. • A draft Maharashtra clinical establishment (Registration and Regulation) Bill, 2014 is out for public opinion.
West Bengal	The West Bengal Clinical Establishments (Registration, Regulation And Transparency) Act, 2017 Replacing the older acts: The West Bengal Clinical Establishment (Registration and Regulation) Act, 2010 The West Bengal Clinical Establishment Act, 1950	• Only for non – govt clinics • Basic standards and terms and condition for licensures • No unethical / immoral practices • No detention of dead body • Public grievance cell • Help desk • E–prescription, e–medical records • Fixed rates to be displayed • Discourage un-necessary tests. • 100 bed hospital – May set up fair price medicine shop. • Hospital on govt. land – free 20% OPD and 10% IPD services • Non – discrimination amongst patients. • Participation in national and state health programmes. • Display of package cost. Package cost fixation by council.	West Bengal Clinical Establishment Regulatory Council (WBCERC): super body, Adjucating authority Director health services – state registrar of CE. Chief medical health officer (CMHO)– in all district are registering authority Assistant Director – for Kolkata city	Earlier act was implemented well. New act is being actively pursued. Discussion to fix package rates for health care procedure underway. Actual implementation status not known.
Delhi (National capital territory)	The Delhi Nursing Homes Registration Act, 1953 Delhi Nursing Homes Registration Rules, 1953 Updated by different amendments – Last in year 2006.	• Only for private. • OPD clinics exempted. Only applicable for nursing home and hospital. • Basic standards not well defined • Record of health care of all patient and maternity cases to be shared with government. • Intimation of death is mandatory	Supervising Authority: Director General of Health Services (DGHS) of Government of NCT of Delhi	933 registered nursing /maternity homes
Jammu and Kashmir	The Jammu and Kashmir Nursing Homes and Clinical Establishments (Registration and Licensing) Act, 1963	• Only for Private clinical establishment • Minimum standard specified but standards not well defined • Power to revoke / cancel license / Penalty • No clause for Emergency medical condition	• For City of Srinagar / Jammu: Committee headed by Dy Director Health services • For Districts: Committee headed by CMO of district is authority for registration	In Kashmir region: Till November, 2017: application received 1454 and license granted to 1246 clinical establishment. No information on Jammu region.

State	Act in Effect	Major Difference from CEA 2010	Institutional Arrangements for Implementation	Current status
Madhya Pradesh	The Madhya Pradesh UpcharGriha Tatha Rogoupchar Sambandi Sthapanaye (Registration tatha Anugyapan) Adhiniyam, 1973. Rules formulated in 1997	• Only for Private • Basic standards & human resource norms defined • Information of death • Information of communicable disease • Monthly report of communicable diseases • Participation in national and state health programme.	Chief Medical and Health Officer (CMHO) is registering and supervising authority in district Director of Health services – Appellant authority	Till October 2017- number of clinics registered are: Allopathy – 2034 Unani – 213 Siddha – 13 Naturopathy – 26 Homeopathy – 733 Ayurvedic – 849 Yoga – 23 Other (Diagnostic, Dental, Physiotherapy)– 622
Chhattisgarh	Chhattisgarh Rajya UpcharGriha and Rogoupchar Sambandhi Sthapnayen Adhiniyam Act, 2010	• Mandatory for all private • Mandatory notification of communicable diseases • Participation in national \state public health programmes • Mandatory information sharing and • Patient rights Grievance redressal mechanism • Stabilization of emergency condition.	At district level: District magistrate – Registering authority. District committee headed by CMHO: review, inspect and recommend for registration. Appellant Authority- Director – Medical education / health / AYUSH	As per October 2015, out of 7414 applications received only 21% were recommended for licensure. Many declared unfit.
Odisha	The Orissa Clinical Establishments (Control and Regulation) Act, 1990 Amendments – last Draft in 2017 (22 June)	• Only for private clinical establishment. • Only for establishment with bed • Provision of notification of death • Rejection / Revoking • Penalty for offences	• CMO Supervising – at district level. • Appellant Authority – at state level	1235 clinical establishment registered
Andhra Pradesh (A.P.)	The Andhra Pradesh Allopathic Private Medical Care Establishments (Registration and Regulation) Act, 2002	• Only for private sector. • District Registering Authority: application, temporary registration, inspection, permanent registration. • Minimum basic standards • Rejection of application • Duration - 5 years • Suspension or cancellation of registration • Display of rates for services and procedures. (updating annually on 1st June) • Medical audit • Penalty	• A.P Allopathic Private Medical Care Establishment Registering Authority(APMCERA) • State Level Advisory Committees (SLAC) • District Level Advisory Committees (DLAC) • State Level Appellate Board (SLAB) • District Registering Authority (DRA)	State division – Telangana and A.P. • Partially implemented in A.P. • Telangana: mulling idea of adopting the central act.
Karnataka	The Karnataka Private Medical Establishments Act, 2007 (KPME)	• Only for private establishment • Power to cancel / penalty • Maintenance of clinical record • Display of cost for procedure	District registering authority headed by deputy commissioner	Almost 50% implementation for private sector. Not applicable for public sector

State	Act in Effect	Major Difference from CEA 2010	Institutional Arrangements for Implementation	Current status
Punjab	The Punjab Nursing Home Act, 1991	Not reviewed	Not reviewed	Not reviewed
Tamil Nadu	Tamil Nadu Private Clinical Establishment Act, 1997	Rules not formulated	Not in place	Not implemented. High court has directed the Tamil Nadu government for Implementation of the act at the earliest.
Kerala	The Kerala Clinical Establishments (Registration and Regulation Bill, 2017.	Act not in effect/Bill under consideration		
Haryana	The Haryana Clinical Establishment (Registration and Regulation) Act, 2014	Rules not framed – Draft rule is kept for public comments since 2015.		
Gujarat	No comprehensive act in effect			

The Clinical Establishment (Registration and Regulation) Act, 2010:

Movement to regulate private sector in health-care by states received much needed momentum after the introduction of The Clinical Establishment (Registration and Regulation) Act, 2010 by the Government of India (GoI). The institutional arrangement for implementation of clinical establishment act is depicted in **Figure.2**. As per the constitutional provisions, the CEA was automatically applicable to four states and all eight union territories. Till December 2017, the act is adopted by six states; Bihar, Jharkhand, Assam, Uttar Pradesh, Uttarakhand and Rajasthan.

Figure.2: Institutional arrangement for implementation of CEA in India.

National Council for Clinical Establishment
[Headed by Director General Health Services (DGHS), all important stake holders as member]
Full-fledged secretariat within MoHFW
Role - Maintain national list of clinical register, minimum standards, classification of clinical establishments, statistics of clinical establishment

State Council of Clinical Establishments
Headed by Secretary / Principal Secretary, Health with Director, health as member secretary
all-important stakeholders as members
Role - Appellant against district registering authority, maintain state register of CE, sharing state CE list monthly to national council, publish annual report on CE

District Registering Authority
Chaired by district magistrate
District Chief Medical Officer (CMO) as member secretary and 3 other members.
Role - Grant / renewal of temporary / permanent licenses, publish updated list in the district, inspection, cancellation, penalty, district register

Implementation Status of CEA in States:

For understanding the implementation status of CEA, we assessed the national register for clinical establishment.[51] The CEA was implemented well in Himachal Pradesh and Arunachal Pradesh with considerably high number of clinical establishments (CE) being registered. But no CE was registered in states of Sikkim and Mizoram. All Union Territories, except Lakshadweep, implemented and registered numerous allopathic and other facilities **(Table.5)**.

Table.5: Status of implementation of CEA in States and UTs, where its applicable directly:

State	Notification of state rules	Notification of State / UT Councils	Notification of District Registering Authorities	Number of Clinical Establishment Registered as on January, 2017		
				Allopathic	Others	Total
Himachal Pradesh	Yes	Yes	Yes	3800	2645	6445
Arunachal Pradesh	Yes	Yes	Yes	13	3	16
Mizoram	Yes	Yes	Yes	–	–	–
Sikkim	Yes	Yes	Yes	–	–	–
All UTs						
Andaman and Nicobar Islands	Yes	Yes	Yes	123	58	181
Chandigarh	Yes	Yes	Yes	417	67	484
Dadra Nagar Haveli	Yes	Yes	Yes	145	88	233
Daman and Diu	Yes	Yes	Yes	127	92	219
Puducherry	Yes	Yes	Yes	369	57	426
Lakshadweep	No	No	No	–	–	–

Source: National Register of Clinical Establishment

Among the six bigger states which adopted the CEA and notified rules, the implementation varies. Maximum number of CE is registered in Jharkhand followed by Assam, Rajasthan and Uttarakhand. The number of CE registered in Rajasthan and Uttarakhand is very low compared to the size and population. In two of the biggest states; Uttar Pradesh and Bihar, no CE is registered as per national register of CE **(Table.6)**.

Bihar was the second state after Jharkhand to adopt this act and notify the rules in the year 2013.[52] The notification for formation of state council and district registering authority were also issued subsequently. But as per the national register of CE, no facility was registered under the act till January 2017.[51] Most important bottleneck for implementation of the act is opposition of health professionals and professional associations.[53] Many litigations were also filed in court by professional association of doctors against this act. The matter is still

under consideration of the Judiciary. Meanwhile, in one of the interim order in this litigation, the court has directed the state not to take any coercive action against any health care provider or facility for not registering under the act.[54] Since then, the court proceeding is underway and no progress in implementation could be achieved.

Table.6: Status of implementation of CEA in states where state adopted this act:

State	Year of Notification of Rule	Notification of state rules	Notification of State / UT Councils	Notification of District Registering Authorities	Number of Clinical Establishment Registered. (January 2017)		
					Allopathic	Others	Total
Bihar	2013	Yes	Yes	Yes	–	–	–
Jharkhand	2013	Yes	Yes	Yes	4100	371	4471
Uttar Pradesh	2016	Yes	No	No	–	–	–
Uttarakhand	2015	Yes	Yes	Yes	7	12	19
Rajasthan	2013	Yes	Yes	Yes	171	59	230
Assam	2016 (By Assembly resolution)	Yes	Yes	Yes	2611	686	3297

Source: National Register of Clinical Establishment

Conclusions and Way Forward:

In a mixed health system with multiple types of health providers and multiple ways of health financing, the role of private sector become important for achieving larger health goals. Incidentally, most of the times, the role of private sector is parallel and competitive to public health care delivery system. In most of the Indian states, the health system is mixed and complex with private sector being the preferred health provider for majority of the population. In the state of Bihar too, health care to majority is provided by the private sector. Major concerns of private health care include the cost of care, especially due to resource constraints. The per capita annual income in Bihar in 2015-16 was Rs. 29,190 and the average cost of a single episode of hospitalization in private health facility in urban areas of Bihar was Rs. 33,072 in 2014.[55,7] Government in most of LMICs and most of the states of India (including Bihar) largely play a role in the public health delivery system. Private health sector in such settings are neither governed nor regulated properly, leading to "laissez faire" market.[32] This is also complicated by the very high level of information asymmetry in health care, resulting in market failure. As per prevailing economic theories, for correcting market failure, introduction of some form of regulation is inevitable to establish basic condition for fair market exchange.[24,25] *Most important policy objective of*

regulation in health care is to ensure quality of care, to make services cost-effective, to bring equitability and ensuring accountability. To introduce regulation, Government can adopt either of the two broad approaches for regulation; administrative control or market harnessing methods. Although based on experiences of other LMICs, administrative control approach should precede market harnessing methods to avoid future complexities. Market and consumer-based approach is not in conflict with traditional approach but in fact is complimentary to them.[56] *The experience of health system development in advanced market economies shows that decision made early in this regard can have far-reaching implications for future health systems.*[27] In a welfare state, correcting market failure for health care is an mandated responsibility of the government.

Evidences from six-country case studies suggests that strong institutional mechanism which is fairly decentralized is present for overall governance of health systems in all developed countries. The institutional arrangements for health governance and regulation also evolved slowly over the period of time. However, health systems governance in newer economic super powers like China is still evolving, and the government is taking positive steps to build a favourable institutional mechanism for larger stewardship role for health care. Smaller Asian countries like, Thailand could achieve near universal health coverage by introducing gradual health financing reform, strengthening regulatory institutions and ensuring overall stewardship role of government. Stories from another South-Asian country, Sri Lanka is different in a sense that health indicators in Sri Lanka are at par with some of the developed countries; but the governance of health system and regulation of private sector is not very well developed.

Among the Indian states, the health system governance and institutional arrangements for health regulation varies widely. Existing legislation to regulate health facilities and its implementation also differs from state to state. The history of regulatory law for health facilities in some of the states dates back to 1950s, while some of the well performing southern states do not have effective legislations even today. The real watershed moment for health care regulation was enactment of CEA by the union government of India in 2010. CEA enactment brought momentum in health facilities regulation. This also led to an urgency in implementation of already existing legislations by many states. Many states used innovative approaches and harnessed technology to advance the implementation of legislations. The state of Jharkhand, Assam and Himachal Pradesh have implemented the CEA quite effectively.

Way Forward:

Based on our review, we propose that health sector regulation in all Indian States should be contextualized considering larger political economy. In Bihar, the possible approach towards larger stewardship role of government for health care can be multi-dimensional. Two dimensions which require immediate attention are: a). Government must continue to focus on improving access and quality of care by strengthening public health systems and b). Government must start taking steps to regulate private sector in order to maximize efforts to improve health outcomes in the state. The current scenario of regulation of health care providers and facilities are summarized in **Table.7** and suggestive roadmap is suggested in **Figure.3**. Possible steps in this direction can be:

a). Effective implementation of legislation (CEA) for regulation of private sector: A detailed study to understand the implementation challenges of CEA and case studies of states where the implementation is successful may help in future policy direction.

b). Engaging the stakeholders: For effective regulation, important step forward is to engage all stakeholders in the process.

c). Mapping of Private sector in health care: A primary study to understand the extent of private sector in health care in the state is an important step to engage them in service provisions.

d). Exploring policy options to constructively engage private sector for complementing public health care delivery.

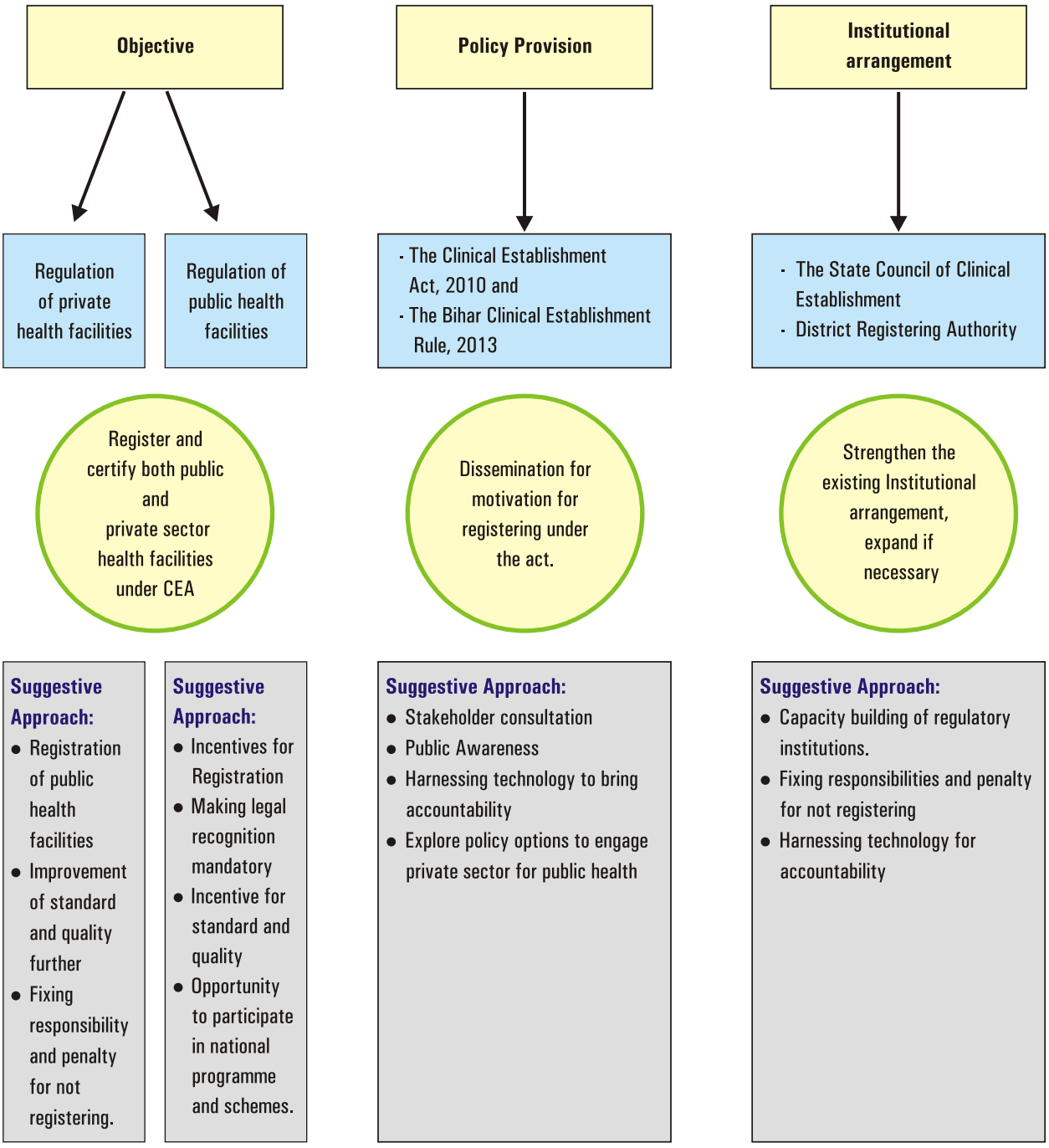
Table.7: Regulation of Health Providers and Facilities in Bihar: Current Scenario

<table>
<tr><th>Health Providers</th><th>Health Facilities</th></tr>
<tr><td rowspan="2">Regulated by Medical Council of India through
State Medical Council: executing body in the state.
• Registration of qualified (MBBS) doctors.
• Responsible for maintaining professional standards.

Central Council of Indian Medicine through state chapters: regulate Ayurveda, Siddha and Unani practitioners

Central Council for Homeopathy through state chapter: regulate homeopathy practitioners.</td><td>Public Health Facilities
Owned and run by Government:
• All facilities are listed under government record.
• All data and service provisions are recorded and reviewed.
Human Resources:
• Only qualified and trained personnel are hired.
• No accreditation system for human resources.
Infrastructure:
Voluntary accreditation through Government of India standards
• Indian Public Health Standards (IPHS)
• National Quality Assurance Standard (NQAS)
• Kaya kalp and many other government schemes
• Many other schemes to improve quality</td></tr>
<tr><td>Private Health Facilities
Any facility, not owned by Government or its allied agency:
• No registration system
• No record of human resource, infrastructure, service provisions and cost.
Human Resources: qualification, training and skill not known.
Voluntary Accreditation by Independent Agencies:
• International Organization for Standardization (ISO), National Accreditation Board of Hospitals (NABH), National Accreditation Board of Laboratories (NABL) and other agencies.</td></tr>
<tr><td>Ensuing Challenges:
Crosspathy: AYUSH practitioners doing allopathy practice.
Non-trained / non-formal health providers – not regulated</td><td>Ensuing Challenges:
Public Health facilities – not registered under the CEA.
Private Health Facilities: registration, compliance to standard, quality and human resource capacity not known.
• Extent of private sector not understood.
• Informal providers running health facilities
Crosspathy – AYUSH Practioners running Allopathic health facilities</td></tr>
</table>

Figure.3: Regulation of Health Facilities in Bihar: Suggestive Roadmap



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Notes

Notes

The Centre for Health Policy (CHP) at the Asian Development Research Institute (ADRI) has been set up with support from the Bill & Melinda Gates Foundation to strengthen the health sector in Bihar with a multidimensional and multi-disciplinary approach. Its aim is to engage in rigorous analysis of the health system and inform policy makers to fine-tune interventions for even stronger outcomes.

- Research and Analytical Studies

  It constitutes the core of CHP's activities. The areas of research include health infrastructure and delivery with emphasis on equity, health outcomes such as IMR, MMR, TFR and its predictors, health financing, private-public partnerships, regulatory framework and its implementation, and other issues which might emerge.

- Informing Policymakers on Strengthening the Existing Health System

  CHP aims to be the trusted partner of the state Government in providing evidence-based inputs in making the health system stronger, resilient and equitable.

- Sustainable Health Solutions

  CHP recognizes the need for establishing a strong health system which will be self-sustaining. It means immunity to natural disasters/calamities, financial uncertainties and other unanticipated factors. These pillars may be interrelated; CHP will provide a framework of synergy among actors working on these pillars.

- Collaboration

  CHP engages in collaboration with an extensive network of academic and policy research institutions both in India and abroad in health and the broader social sciences.