Mapping the Regulatory Architecture for Health Care Provision in LMIC Mixed Health Systems

A Research Tool and Pilot Studies in Two Indian States

**June 2011**



**Working towards a healthier India**

*‘Mapping the Regulatory Architecture for Health Care Provision in LMIC Mixed Health Systems’*

Report of a research project conducted by the **Public Health Foundation of India (PHFI)**

Supported by funds from the Nossal Institute of Global Health, University of Melbourne, Australia

**Research Team**

Dr Kabir Sheikh *(Principal Investigator)*

Prasanna Saligram

Lakshmi E Prasad

The views expressed in this report are solely those of the authors and not of their institutions. Correspondence may be directed to [kabir.sheikh@phfi.org](mailto:kabir.sheikh@phfi.org)

ACKNOWLEDGEMENTS: This study would not have been possible without the efforts and assistance of numerous friends and associates in Bhopal, Delhi and Melbourne. Foremost, thanks are due to the study participants – officials working in various regulatory organizations and departments – for contributing their valuable time and insights (they remain unnamed for purposes of confidentiality). Associates from the Centre for Public Health & Equity (CPHE), Bhopal helped facilitate fieldwork in Madhya Pradesh – to each of them we owe our gratitude. The authors also thank members of the Health Policy and Financing Hub of the Nossal Institute of Global Health, notably Ahmer Akhter and Shyamali Larsen, respectively for their academic partnership and for facilitating financial and travel support. Throughout the period of study, we benefited from the mentorship and guidance of Dr Kris Hort, Dr Thelma Narayan, Prof Sanjay Zodpey and Prof K Srinath Reddy.

*‘Mapping the Regulatory Architecture for Health Care Provision in LMIC Mixed Health Systems’*

This paper consists of:

* An **introduction** to mixed health care systems in low and middle income countries (LMIC), and the problems of health care provision necessitating regulatory policy
* A **review of the literature** on regulatory approaches for health care in LMIC mixed health systems
* A **policy research tool** to map and characterize the regulatory architecture for health care provision in a country or province, and identify gaps in the design and implementation of regulatory policy
* Detailed **reports of pilot studies** in two States of India – **Madhya Pradesh** and **Delhi** – demonstrating the use of the research tool
* An **assessment of the methodology**, detailing the process of development, strengths, weaknesses and utility of the tool

# SUMMARY

*LMIC Mixed Health Systems:* mixed health care systems in low and middle income countries are distinguished by significant heterogeneity in types of establishments and providers, a dominant unorganized private sector, and inefficiencies in government delivery of health services. Health care provision in these mixed systems is typified by high, often out-of-pocket, expenditures on health care by users, significant shortfalls in quality of available health care, frequent ethical digressions by health care providers and by wide variations and inequities in physical availability and accessibility to health care for users. These phenomena have negative significance for public health, health equity and health rights, and collectively impede progress towards the Millennium Development Goals. More effective regulatory policies and systems are necessitated in LMIC, to address these varied concerns around mixed health care provision.

*Regulating Health Care in LMIC Mixed Health Systems:* We review the existing literature on regulatory approaches in LMIC mixed health systems. In different LMI countries with mixed health systems, a combination of state-led and non-state mechanisms have been instituted to regulate different aspects of health care provision. These can be classified broadly as 1) Direct regulation – led by the state and enacted through the imposition of laws and bureaucratic structures and rules, 2) Market based approaches - incentivising providers to modify their behaviour to align with broader objectives, and 3) other approaches, including public-private partnership based schemes, contracting, and insurance. Each of these mechanisms have had limited success at scale, and regulation of health care provision remains one of the pre-eminent challenges for future health policy in LMIC. Yet, the specific institutional and systemic contexts for failures of regulatory policies in LMIC remain poorly explored, and represent a significant gap in the knowledge.

*Policy Research Tool:* The research tool proposed in this paper is designed to empirically map and characterize the prevailing regulatory architecture for health care provision in a particular geo-political unit (province or country). The tool combines the use of desk and field based methods and is founded on actor-centred frameworks of policy research including ‘empirical constitutionalism’ (Hjern and Hull 1982), and ‘backward mapping’ (Elmore 1982). *Actual* roles of state and non-state groups and organizations in enacting different aspects of health care regulation are elicited, and compared with the putative or *expected* architecture of regulation in the country / province. Consequently, gaps can be identified in the design and implementation of regulatory policies. The outputs of the research can be utilized to effect relevant modifications in the design of regulatory policies and institutions, to strengthen particularly aspects of implementation, and as a baseline against which to assess the success of regulatory reforms the country / province.

*Pilot Studies:* The research tool was applied to conduct pilot studies in two States in India, Madhya Pradesh and Delhi. The regulatory architecture for health care provision was mapped, and key design and implementation gaps identified in both States. In Madhya Pradesh, policy design gaps were most apparent for the domains of cost of care. Also key were the absence of a formal system for the control of quackery, of a community-based platform to address issues of grievances with care quality and conduct of providers, and of supportive or incentive-based approaches to improve provider distribution in rural areas. Major gaps in implementation included low coverage of policies for registering clinical establishments; and inefficiencies in implementing corrective procedures for erring establishments and medical professionals, and enforcing mandatory rural placements.

In Delhi State, design gaps identified included the absence of systematic approaches to regulate accessibility of care, and costs of care for non-EWS sections; and the absence of a formal mechanism to limit quackery, and of community-based platform to address issues of grievances with care quality and conduct of providers. Key implementation gaps included low coverage of schemes for social insurance and policies for registering clinical establishments; and inefficiencies in implementing disciplinary procedures for medical professionals and determining the locations of new hospitals.

Emerging underlying reasons for implementation gaps in both States included: 1) the pervasive influence of medical political interests (regulatory agencies are largely constituted of medical professionals, or reliant on their cooperation), 2) discordance in inter-departmental relationships and coordination within the State regulatory machinery, and 3) severe constraints in numbers and capacities of personnel for regulation.

*Assessment of methodology*: milestones in tool development included decisions to focus on a backward-mapping approach, and reject formal categories of regulatory strategies, to enlist policy contents from relevant documentation, and to expand the function of the tool to include a diagnostic component. Key strengths of the tool are its self-explanatory nature, coverage of regulatory domains, and adaptability to different policy areas, while limitations include problems in achieving comprehensiveness, lack of analytic depth below State level, the related issue of accounting for a complicated federal structure, and unresolved gaps in data collected. The tool has wide utility as a basis on which policy planners can redesign and re-delegate policy functions and plug unrecognized implementation gaps; for benchmarking institutional development; and for comparative research.

# TABLE OF CONTENTS

SUMMARY 4

TABLE OF CONTENTS 6

LIST OF ABBREVIATIONS 10

I. INTRODUCTION 11

LMIC Mixed Health Systems 12

*Diversity in health care provision* 12

*Dominant, poorly organized private markets* 13

*Compromised public services* 13

*Blurred public-private distinction* 14

Problems of Health Care Provision in Mixed Systems 15

*High costs of health care for users* 15

*Variable quality of care* 16

*Irregular ethical conduct of providers* 17

*Unequal availability of health care* 17

Role of Regulatory Policy 19

II. REGULATING HEALTH CARE IN LMIC MIXED HEALTH SYSTEMS 21

Direct Regulation 22

*Legal codes* 22

*Consumer law* 23

*Licensing and registration* 24

Providers 24

Establishments 25

Market-Based Regulation 26

*Voluntary accreditation* 26

*Educational bonds* 27

*Dual practice* 28

*Pay for performance* 28

Other Mechanisms 30

*Contracting* 30

*Co-production* 30

*Health insurance* 31

Summary 33

III. THE POLICY APPROACH AND RESEARCH TOOL 34

The Importance of Characterizing the Regulatory Architecture 35

The Policy Research Approach 36

*Policy-action relationship* 36

*Scope of the research tool* 38

The Research Tool 39

*Step 1. Outlining policy contexts* 39

Sources of data 39

*Step 2. Analyzing relevant laws and policies* 40

Sources of data 40

*Step 3. Analysing roles of organizations with regulatory functions* 40

Sources of data 41

*Step 4. Mapping the regulatory architecture* 41

*Step 5. Identifying gaps in regulatory policy* 42

IV. PILOT STUDIES 43

A. The National Arena 44

*1.* *Relevant laws and policies* 45

Targeted at: Quality of Care 45

Targeted at: Conduct of Providers 50

*2.* *Roles of regulatory organizations* 53

Targeted at: Costs of Care 53

Targeted at: Quality of Care 54

Targeted at: Conduct of Providers 55

B. Madhya Pradesh State 56

*1.* *Background and context* 56

Madhya Pradesh – The State 56

Health Profile of Madhya Pradesh 56

Health Care Services in the State 57

The Public Private Mix 57

*2.* *Relevant laws and policies* 58

Targeted at: Costs of Care 58

Targeted at: Quality of Care 59

Targeted at: Conduct of Providers 61

Targeted at: Accessibility of Care 62

*3.* *Roles of regulatory organizations* 63

Targeted at: Costs of Care 63

Targeted at: Quality of Care 63

Targeted at: Conduct of Providers 71

Targeted at: Accessibility of Care 75

*4.* *Regulatory architecture map: Madhya Pradesh State* 77

*5.* *Gaps in regulatory policy at State level: Madhya Pradesh* 81

Design of regulatory policies 81

Implementation of regulatory policies 81

C. Delhi State 83

*1.* *Background and context* 83

The State of Delhi 83

Health Profile of Delhi 83

Health Care Services in Delhi 83

*2.* *Relevant laws and policies* 85

Targeted at: Costs of Care 85

Targeted at: Quality of Care 86

Targeted at: Conduct of Providers 88

*3.* *Roles of regulatory organizations* 89

Targeted at: Costs of Care 89

Targeted at: Quality of Care 91

Targeted at: Conduct of Providers 95

Targeted at: Accessibility of Care 98

*4.* *Regulatory architecture map: Delhi State* 100

*5.* *Gaps in regulatory policy at State level: Delhi* 103

Design of regulatory policies 103

Implementation of regulatory policies 103

V. ASSESSMENT OF METHODOLOGY 105

Methodology Process and Milestones 106

Strengths of Tool 107

Weaknesses of Tool 108

Utility and Applicability 108

ANNEXURES 109

Topic guide for in-depth interviews with representatives of regulatory groups 109

Format for informed consent 111

Template for mapping the regulatory architecture 112

BIBLIOGRAPHY 113

# LIST OF ABBREVIATIONS

AYUSH: Ayurveda, Yoga, Unani, Siddha and Homeopathy

BPL: Below Poverty Line

CDMO: Chief District Medical Officer

CEA: Clinical Establishment Act

CHC: Community Health Centre

CME: Continuing Medical Education

CMHO: Chief Medical & Health Officer

CPA / CoPrA: Consumer Protection Act

DBCP: Delhi Bharatiya Chikitsa Parishad

DDA: Delhi Development Authority

DHO: District Health Officer

DHS: Directorate of Health Services

DMA: Delhi Medical Association

DMC: Delhi Medical Council

DME: Directorate of Medical Education

DoHFW: Department of Health and Family Welfare (of the Government of Delhi)

EWS: Economically Weaker Sections

GoI: Government of India

HIC: High Income Country(ies)

HOTA: Human Organs Transplantation Act

ICCM: Indian Central Council of Medicine

IEC: Information Education & Communication

IMA: Indian Medical Association

LMIC: Low & Middle Income Country(ies)

MCH: Maternal and Child Health

MCI: Medical Council of India

MoHFW: Ministry of Health and Family Welfare (of the Government of India)

MP: Madhya Pradesh

MTP: Medical Termination of Pregnancy

NABH: National Accreditation Board for Hospitals and Healthcare Providers

NCDRC: National Consumer Disputes Redressal Commission

NCMH: National Commission for Macroeconomics & Health

NGO: Non Governmental Organization

NHRA: Nursing Home Registration Act

P4P: Payment for Performance

PCPNDT: Pre-Conception and Pre-natal Diagnostic Tests (Act)

PHC: Primary Health Centre

PPP: Public Private Partnership

RBF: Results Based Financing

RSBY: Rashtriya Swasthya Bima Yojana (National Health Insurance Scheme)

SDM: Sub-divisional Magistrate

SHC / SC: Sub Health Centre

STP: Standard Treatment Protocol

# I. INTRODUCTION

## LMIC Mixed Health Systems

Health systems vary across different countries. In this paper we are concerned particularly with health systems in low and middle income countries (LMIC), which are considered to be mixed. Mixed health systems have been defined by Oxfam as entailing *“*centrally planned government health services that operate side-by-side with private markets for similar or complementary products and services” (Oxfam 2009). While most countries combine private and public health care provision to different degrees, LMIC mixed systems are typified by a distinct set of attributes and peculiarities, which are elaborated below.

### Diversity in health care provision

The landscape of health care provision in many countries of South and Southeast Asia, South and Central America, Central Asia and parts of Africa is deeply heterogeneous or pluralistic (Ramesh & Wu 2008, Rafei & Sein 2006, Bose 2005, Sheikh & George 2010, Pedersen 1989).  Health services are constituted by a diverse range of formal health care establishments in the public and private sectors, and also by a significant presence of providers who are either unrecognized by the state or whose legitimacy is contested or ambivalent, including purveyors of traditional and alternative systems of medicine, and untrained or less than fully qualified practitioners (Leslie 1980, Sheikh & George 2010).

Formal health care establishments in LMIC mixed health systems range from solo practices and nursing homes to multi-departmental corporate hospitals in the private sector; and primary health centres to speciality hospitals in the government sector (Oxfam 2009).  Many countries also have a significant presence of not-for-profit or charitable healthcare providers and establishments (NCMH 2005, Berman 2001).

The non-state health care sector in many LMI countries also includes a diverse mix of informal providers, including drug sellers, untrained practitioners of allopathic medicine and traditional healers. Statistical data on the informal health sectoring developing countries are particularly scarce, however there are indications that their services are widely utilized, often constituting well-established (if illegal) markets of goods and services (Bloom and Lucas 2000). In Bangladesh, it is reported that traditional and informal providers operate alongside NGO and private for-profit providers, with wide variations in population reach and quality of services (Standing & Chowdhury 2008). A provider mapping study in Madhya Pradesh State of India showed that 30% of all private providers were in the informal sector (De Costa and Divan 2007).

A poorly appreciated and particularly challenging aspect of LMI mixed health systems is the prevalence of (sometimes multiple) alternative and indigenous systems of medicine, and their interface with formalized western medical systems. Indigenous medical systems have achieved legal recognition and state support (Pedersen 1989) in some Asian countries (India, Bangladesh, Pakistan, Sri Lanka, and Burma). However, in spite of these official proclamations, it is likely that very little progress has been made in actually utilizing indigenous health practitioners, in national health systems, and these practitioners typically function outside the mainstream health architecture (Pillsbury 1982, Sheikh & George 2010).

### Dominant, poorly organized private markets

Nishtar has defined mixed health systems as those “in which out-of-pocket payments and market provision of services dominate as a means of financing and providing services in an environment where publicly-financed government health delivery coexists with privately-financed market delivery” (Nishtar 2010). This definition, like the earlier one speaks of the dually existing public and private health sector, but goes further to indicate a predominance of poorly organized private health markets.

While systematically collected statistical data on the public private mix of providers in LMIC are often unavailable or unreliable, Lagomarsino and colleagues (2009) highlight that “some data and much experience” suggest that non-state providers are more numerous and accessible in many locales, than public sector providers. In Bangladesh It is estimated that the public sector provides less than 20% of the curative health services consumed. (Standing and Chowdhury 2008). A World Bank study in India showed that 82% of outpatient visits occur in the private sector, and this dominance of the private sector in outpatient care is similar across income groups (Mahal et al. 2001). Proportionately greater utilization of the private sector for common illnesses is also reported in Vietnam, Indonesia, and several African countries (Limwattananon 2008).

The magnitude of out-of-pocket payments for health care is probably the best indication of a dominant, poorly organized private health sector (Berman 1997). Out-of-pocket payment is the chief financing mechanism for health care in several countries in South and South-East Asia, Africa, the countries of Central and Eastern Europe, and the former Soviet Union (Normand1999), and are a defining feature of mixed health systems (Nishtar 2010). Lagomarsino et al. (2009) report that in 34 countries in Asia and Africa, including many of the most populous nations (Bangladesh, China, India, Nigeria, Pakistan), more than half of total health expenditures are private out-of pocket transactions.

### Compromised public services

In low and lower-middle income countries, public expenditures on health care constitute no more than a third of total health expenditures (Nandakumar 200). Despite some growth in public health expenditure in the past decade, private health expenditure continues to dominate in low and lower middle income nations (WHO 2001). In many LMICs public financing for health is typically lower than what people pay directly out of pocket for health services (Nishtar 2010). Furthermore, given the relatively reduced level of government expenditure on health in LMICs, a disproportionally high amount is typically put forth towards large capital investments, leaving recurrent costs, including salaries and maintenance, under-funded (CMH 2005).

Furthermore many LMIC mixed health systems are characterized not only by low government spending, but also by inappropriate and inefficient application of government funds. It is widely observed that there are significant deficits in the management and oversight of government health care services in LMIC (CMH 2005, Peters 2002). These deficits result in a poor standard of essential services, and combined with concerns of lack of procedural transparency and accountability, contribute to their compromised credibility among communities (Nishtar 2010, Peters & Muraleedharan 2008). In many countries where governments provide free or nearly free health care services, users from all income groups including the poor avoid utilizing these services, and prefer instead to pay (usually out-of-pocket) to access care in the private sector (CMH 2005).

### Blurred public-private distinction

Another critical characteristic of mixed health systems is that the distinction between public and private health services is ambiguous. Both sectors have evolved from and co-exist in broader social, political and macroeconomic contexts, and overlaps in financing mechanisms and employment arrangements make strict public-private distinctions difficult (Lagomarsino et al. 2009, Nishtar 2010). According to Standing and Chowdhury (2008), the boundaries of the public sector in LMIC are ‘porous’, with private doctors often having links with government medical facilities. Dual job holding by government practitioners is a common practice in LMIC, in which publicly employed doctors (also nurses, midwives and other health workers) supplement their salaries through second, private jobs (Macq et al. 2001). A corollary to this observation is that out-of-pocket payments are often made to public providers holding dual jobs, and hence the proportion of out-of-pocket expenditure is not equivalent to the proportion of private provision (Lagomarsino et al. 2009).

Many government health systems engage actively in partnership with private providers to deliver services, notably preventive and primary curative services. These partnerships may be undertaken through formal contractual arrangement (Mills & Brugha 2002), or informally, such as the case of the Indian government giving vaccines to private providers and facilitating referral networks for tuberculosis care (Peters 2002, Dewan et al 2006). In instances the public and private sectors may pool financial and human resources for common ends, such as in many African countries where faith-based services receive government subsidies and manpower, and are integrated into national reporting and referral systems (Harding et al. 2003).

## Problems of Health Care Provision in Mixed Systems

The distinctive features of LMIC mixed health systems outlined in the previous section are the backdrop for a range of field level phenomena in health care including aspects of provider behaviour, which have adverse implications for users and communities, and the potential to undermine key developmental goals (Nishtar 2010). **Drawing from policy theorist Elmore, we orient our enquiry from the bottom up –with an understanding of field level phenomena and behaviours which generate the need for policy**. We start by asking: *what are the aspects of health care provision in LMIC mixed health systems, which necessitate better policies?*[[1]](#footnote-1)Four fundamental, interrelated sets of concerns emerge from the literature, which are of significance for public health, equity and health rights.

1. Unnecessarily high costs of health care for users
2. Variable quality of care provided
3. Irregular ethical conduct of health care providers
4. Unavailability / unequal distribution of health care providers

These are synopsized in the following pages:

### *High costs of health care for users*

The cost of health care has been cited as a major problem, and a key obstacle to access for users, especially poor users of health services (Mamdani 2004).Out-of-pocket spending on health in LMIC mixed systems accounts for the bulk of health expenditures in these economies, contributing directly to catastrophic spending and impoverishment (van Doorslaer et al, 2006, Killingsworth 1999).  Using expensive private services, especially for the treatment of chronic and long term conditions, is frequently a drain on the financial resources of LMIC households. The poor in LMIC are as likely to pay out of pocket as the rich, and spending on health care has been identified as a major factor driving families into poverty, and increasing the impoverishment of those already poor (Whitehead 2001). A study in Sierra Leone revealed that over 10% of the income of the poorest quintile of the population is often spent on medical care (Mills & Brugha 2002). Frequently this extent of spending compromises families’ ability to pay for future care needs, creating vicious cycles of impoverishment and deterioration in health (Whitehead 2001).

Costs of health care in the private health sector can be especially prohibitive, when associated with over-charging by private providers in a market with high information asymmetry, and the phenomenon of “price-gouging”– prescribing of unnecessary investigations, medicines and procedures, for financial gain (Lagomarsino et al 2009). Overspending on health care is also increasingly reported in the context of informal payments or bribes in public sector facilities. There is a growing body of evidence that such informal payments are a significant proportion of OOP payments (Whitehead 2001, Barber 2004).Profits from unofficial sales of medicines have also been reported to be an important part of health workers’ incomes in several LMIC (Wolffers 1995).

### *Variable quality of care*

There are extensive documented instances of substandard quality of care in both private and government facilities in LMIC worldwide, including irrational treatment of major diseases of public health concern (Abbasi 1999, Venkat Raman & Björkman 2008). Das and Hammer (2004) used observational methods to assess medical professionals’ practices in treating infant diarrhoea, pharyngitis, tuberculosis, depression and pre-eclampsia, observing a significant shortfall in quality of care among both private and government doctors in an urban Indian setting. Studies on the quality of primary care in LMIC have identified deficiencies in diagnosis, treatment, monitoring and counselling of patients for a range of clinical conditions including malaria, diarrhoea, and acute respiratory infections (Nolan 2001). In a study on quality of health care in five developing countries (China, El Salvador, India, Mexico, and the Philippines), using clinical vignettes and a quantitative measure of quality, the within-country range of quality of doctors was found to be 10 times as great as the between-country range (Peabody et al 2006).

Infringements of standard treatment practices for communicable diseases of public health concern have also been reported frequently in LMIC settings. There is evidence of widespread divergence from policy recommendations in the case of dengue diagnosis (Ng et al 2007) in Malaysia, and antimicrobial prescription for paediatric respiratory tract infections in Argentina (Aznar et al. 2005) and Trinidad (Mohan et al. 2004) respectively. Health professionals’ treatment of malaria in Kenya and Sudan respectively has been found to be reliant on outdated guidelines and medicines (Zurovac et al. 2008, Mannan et al. 2009). Somali and Pakistani practitioners have been reported to disregard global recommendations for tuberculosis management, in separate studies (Suleiman et al 2003, Marsh et al. 1996). Schneider and colleagues (2005) have reported aberrant treatment of STIs by practitioners in Gauteng, South Africa. These irrational treatment practices have significance beyond the care of the individual patient since they can lead to the spread of drug resistant strains, with potential adverse impact on the health of communities.

Lack of infrastructure, poor equipment and inappropriate technology have variously been cited as important contexts for the inability of primary providers in LMIC to provide quality care for a range of clinical conditions (Nolan2001). The lack of procedural transparency and internal accountability, as well as the absence of accountability to users of services are problems common to government and private establishments in many LMIC (Nishtar, 2010, George 2009, Mahapatra 2003), with significance for the quality of care provided in these establishments.

In countries where there are large numbers of practicing untrained health providers, it is to be expected that there would be significant concerns of quality in these sectors. However there is little data available on the actual quality of care provided by less than fully qualified health providers. The alternative systems of medicine, even when legitimated by national governments, are also beset by significant concerns around quality, but poorly developed standards and norms often make these deficiencies difficult to estimate (Unnikrishnan et al. 2010)

### *Irregular ethical conduct of providers*

Ethical conduct of health care providers – while having significance for both the quality and costs of care –emerges as a distinct and well documented problem in LMIC mixed health care systems. Health provider conduct has historically been the target of specific regulatory policies, i.e. professional self regulation founded on a tradition of distinct, stringent codes of practice for professionals (Freidson 1970), and hence warrants independent treatment.

Overspending on health care often has exploitative underpinnings, with providers utilizing information asymmetries to encourage or coerce patients into paying for unnecessary investigations and treatment (Radwan, 2005).  Informal payments, being unaccounted, are typically uncontrolled and exploitative (Tibandebage and Mackintosh 2002, TzPPA 2003). “Price gouging” and rent-seeking practices, such as taking kickbacks for unnecessary referrals, are commonplace and have been identified in a range of different LMIC settings (Mæstad & Mwisongo 2010, Anand 2008).

Standing and Chowdhury (2008) report that in South Asian health markets, there is widespread pressure on providers to shift to inappropriate and expensive procedures such as injections and pharmaceuticals, a sign of over-medicalization of care. Poor people in particular often receive ineffective or even dangerous treatment, including inappropriate or inadequate anti-tuberculosis treatment regimens (Udwadia et al. 2010) and contraindicated drugs for women in pregnancy (Krause et al 1999). Over-medicalization of this nature is not only ineffective or harmful to the individual, but can create drug resistant microorganisms posing a threat to public health. Health providers have also been implicated for their collusion in undesirable social phenomena, such as sex-determination linked to sex-selective abortions on a massive scale in India (Ahmad 2010).

Medical negligence in LMIC is widespread and unchecked, particularly affecting poorer and less literate segments of populations (Jesani et al. 1997). Discrimination and lack of respect by health workers towards the poor is another theme that emerges from a number of studies (Mamdani et al 2004, Tibandebage & Mackintosh 2002). Public sector health facilities have been implicated for health care workers lacking compassion, or being inattentive, dishonest, or disrespectful (Haddad & Fournier 1998). However, private facilities too are to blame for widespread discrimination and denial of care, such as with stigmatised diseases such as HIV&AIDS (Sheikh et al 2003, Rahmati-Najarkolaei et al. 2010).

### *Unequal availability of health care*

Geographical accessibility is a key determinant of access to quality health care, and as such, the asymmetrical geographical distribution of qualified health workers within countries presents a key obstacle to access for large segments of LMIC populations who live in rural areas. According to WHO’s global health report 2000, all countries report a disparate presence of qualified health personnel in urban and wealthier areas – a longstanding and widespread problem. Private health providers naturally favour areas where their clients are likely to be able to pay more (Lagomarsino et al 2009). However public sector providers too are loath to remain in rural areas – leading to significant vacancies in rural public sector facilities. This is ascribed to a combination of reduced opportunity for profit through informal payments and poorly developed infrastructure and support systems in villages (Dussault and Franceschini 2006; Serneels, Lindelow et al. 2007, Zaidi 1986). This problem of the public sector is compounded by the phenomenon of absenteeism, wherein health workers fail to attend their clinics for varying lengths of time, even while continuing to draw a salary (World Bank& PHFI 2008, Chaudhury et al. 2003).

In conclusion, these prevailing phenomena of health care provision in LMIC represent fundamental challenges for a country or province seeking to progress towards broader goals of public health, actualization of health rights and health equity (Mackintosh 2007, Bloom et al. 2008, Nishtar 2010) and hence represent the core targets for equity-oriented regulatory policy.

## Role of Regulatory Policy

According to Roemer, regulation is said to occur when a government exercises control over the activities of individuals and firms (Roemer 1993). More specifically regulation has been defined as the government’s “action to manipulate prices, quantities, and quality of products” (Maynard 1982). In reference to health services, regulation has been most commonly associated with the distribution of drugs and pharmaceuticals (Abraham & Reed, 2001; Danzon & Chao, 2000; Stenson et al. 1997, Vogel 1998, Wright 2004). Starting in the 1990s, the discussion on regulation expanded to include various facets of health services such as the monitoring of provider entry into the health sector and the registration and establishment of health facilities (Bennett & Ngalande-Banda, 1994; Hongoro & Kumaranayake, 2000; Muraleedharan & Nandraj, 2003; Yesudian, 1994), quality of care (Bennett & Mills, 1998; Bhat, 2000; Brennan, 1998; Loevinsohn & Harding, 2005), and cost of health care (Bhat, 1996a; Ensor & Weinzierl, 2006).

The growing recognition of regulation as an intervention in health systems was greatly catalyzed at a time when many low and middle income countries began to experience the growth of formal private health markets (Bloom et al. 2009; Kumaranayake, 1997; Mackintosh & Koivusalo, 2005; Zwi & Mills, 1995). This expansion gave way to questioning about the presence of quality and efficiency in the process of health service provision and delivery (Bloom et al. 2009; Kumaranayake, 1997; Mackintosh, 2007). Consequentially, the debate on regulation has since gained a steady momentum correlating with the gradual increased blurring of boundaries between the public and private health sector in LMICs.

The rationale for regulating health care has been argued by different authors based broadly on two complementary perspectives – the neoclassical economist’s view of regulation as a means to correct market failures; and more broad-based perspectives of regulatory policies as a means to promote equity in health. The market-oriented perspective stipulates that the occurrence of problems associated with quality and cost of care and inappropriate provider behaviour are fuelled in a health market by elements of economic uncertainty, externalities and information asymmetry, which are considered to be market failures (Bloom et al. 2009; Broomberg 1994). As a result, regulation is seen as having the ability to restore the balance, competition, and efficiency in the health market (McPake & Mills 2000). Regulation can alleviate market failures through the establishment of a basic set of rules that define the legal obligations of the various actors in the market transactions and delineate their responsibility and accountability to lower health costs and promote openness and honesty in health market (Roberts et al. 2004; Kumaranayake 1998; North 1990; Williamson 1985).

In recent years, a number of commentators have emphasized the significance of regulation in promoting inclusion and equity in order to allow individuals and communities access to affordable, quality, and comprehensive health services (McIntyre et al. 2007; Whitehead et al. 2001; Mackintosh & Koivusalo 2005; Cornwall et al. 2000). This is envisioned through the installation of appropriate rules and incentives, which can assure fair distribution of health resources, availability of appropriate provider behaviour, and adequacy in health staff, supplies and infrastructure. Regulation seen through this lens should effectively minimize the likelihood of individuals in experiencing adverse financial and health outcomes related to the access and usage of the health system.

*In this paper,* our understanding of regulatory policy in health care stems from a policy science perspective, and connotes a **diverse set of actions and arrangements undertaken by a range of state and non-state actors, to control and modify individual and organizational activity in the field of health care provision**.[[2]](#footnote-2) This definition draws from the policy sciences classification of four policy ‘types’ (distributory, redistributory, regulatory and constituent) (Lowi 1972),and denotes all aspects of policy associated with controlling the actions of individuals and organizations – not merely an instrument in the governance of health markets as it has been characterized by health economists (McPake & Mills 2000). We limit our scope of enquiry to **provision of health care in the most immediate sense (i.e. pertaining to health care providers and establishments)***,* and not the associated (but distinct in terms of regulatory interventions) domains of drug delivery and health care financing. Finally, the bottom-up approach oriented on the frontline problems of health care provision in mixed health systems – delineated above – is aligned to an understanding of the rationale of **regulatory policy as a means for achieving health equity, actualizing health rights and promoting public health***.* From this defined position, we seek a better, more systematized understanding of the prevailing regulatory architecture for health care provision in LMIC mixed health systems.

# II. REGULATING HEALTH CARE IN LMIC MIXED HEALTH SYSTEMS

Previous sections have outlined the problems posed in the mixed health systems of LMICs. Difficulties experienced by individuals and communities in relation to the quality of health services, behaviour of providers, costs associated with health services and the fundamental availability of services form the basis of the argument for increased regulation in these settings. The regulatory responses of different LMIC governments and societies to these field level phenomena have been varied, ranging from orthodox solutions of direct regulation by the imposition of bureaucratic power to broad-based pragmatism favouring modification of health care markets. Additionally, governments frequently engage in co-production and partnerships which are not primarily designed as regulatory instruments, yet contain built-in regulatory or quasi-regulatory provisions.

How much is known about actual processes of regulation in LMIC, the institutional structures that support them, and reasons for their successes and failures? What is the extent of empirical research in the area? In the following pages, we review the research literature on the implementation and impact of different regulatory approaches in the context of LMIC mixed health care systems.

## Direct Regulation

Conventional “command and control” regulation is characterized by the imposition of rigid standards, which regulate behaviour of various entities and their compliance with various standards through the use of strict legal sanctions (Stewart 1981; Aalders & Wilthagen 1997). The strategies used within direct regulation entail specific controls that are established through legislatively, administratively & bureaucratically, and are enforced through judicial mechanisms (Baldwin & Cave 1999; Tangcharoensathien et al. 2008). In LMICs, the majority of current regulatory mechanisms are in the form of legislated requirements focusing on registration/licensing requirements of health personnel and establishments, and curbs on the behaviour of health care providers (Bennett & Ngalande-Banda 1994; Kumaranayake 1997).

### *Legal codes*

Legal controls are considered to be the most stringent strategy of the direct regulation approach since their enforcement occurs within the purview of the judicial system (Moore 1961; Kumaranayake 1997; Ensor & Weinzierl 2007). A study by Peters and Muraleedharan in India revealed that prior to the establishment of consumer legislation for the health services, several cases of medical negligence and malpractice against individual providers were handled by purely legal instruments such as the Law of Torts and the Indian Penal Code (IPC). The Law of Torts, which applies to all public and private sector health providers, was found to be effective in awarding compensation for numerous cases related to the provision of emergency medical care, patient confidentiality and consent; however the application of the Penal Code was deemed to be ineffective (Peters & Muraleedharan 2008).

Another report from India found that the ruling of the courts in the cases of medical negligence have tended to rule in the favour of the providers, and in cases of serious medical negligence only minor sentences were imposed (Verma et al. 2002). A qualitative study in Zimbabwe elicited stakeholder perspectives and experiences to understand factors influencing the effectiveness of prevailing regulations, and found that there was a generalized lack of knowledge about relevant laws and regulations among government officials and private providers, unless it directly concerned them (Hongoro & Kumaranayake 2000). These observations underline that lack of awareness could have impeded the implementation of regulations, and also yielded a clear consensus from providers on the ineffectiveness of regulation enforcement. Similarly, in an article that considers the role of stakeholders in addressing equity and quality of health care concerns in India, it was stated that providers in India felt the legal provisions were not effective in protecting patients (Bhat 1996a).

Explanations for the limited success of conventional legal mechanisms for health care regulation vary. Inefficiencies in legal mechanisms have been widely attributed to lack of specificity and detail in the framing of relevant legislations (ibid; also Kumaranayake 1998). Additionally, in the event that legal controls are found to be well-established on paper, their actual implementation is often questionable (Peters & Muraleedharan 2008). Logistical issues and severe delays within the court system have been reported to dilute the effectiveness of these mechanisms (Bearak, B, 2000).

### *Consumer law*

In response to the concerns around conventional legal approaches, several countries have incorporated consumer-based legislations which purport to address many of the concerns of bureaucratic inefficiency and delay associated with the judiciary in LMIC. Consumer-based legal mechanisms are generally more established in HICs than LICs (Tangcharoensathien et al., 2008), but they do exist and operate in some LMICs like India, Nigeria, and Thailand. The consumer-based mechanism, which often roots from a consumer protection act, is used in the scope of health services to obtain redress for poor health services and medical negligence (Bhat, 1996b; Okojie, n d). In India, this approach came about due to the advocacy of consumer groups who felt that doctors approached the medical profession as a business, and therefore called for medical services to be covered as transactions, under the Consumer Protection Act. The effort for its inclusion under the CPA was also motivated by the ineffectiveness of medical councils in taking action against their members for instances of negligence and malpractice (Kumaranayake, 1997). In this vein, the Consumer Protection Act in India as an alternative mechanism for consumers in an environment where the traditional court system was stressed with inefficiencies and backlog (Peters & Muraleedharan, 2008).

The mechanism has been utilized by consumers as demonstrated by Muraleedharan and Prasad who showed that in 2001 over 1.57 million consumer complaints were ﬁled in the District Forums all over India since its inception in 1986, and 263,150 cases were ﬁled in State Commissions and the National Commission since their inception (Muraleedharan & Prasad, 2003). Medical cases accounted for less than 5% of the total cases ﬁled at all levels. The same study however showed that medical cases took much longer than the 3 months stipulated by law for an initial ruling, with nearly all cases taking longer than a year (Muraleedharan & Prasad, 2003), and it was found that as the number of pending cases increased, so did the time taken to process them. Consumer courts also face difficulties posed by insufficient staff and infrastructure, and the limited ability to bring parties to court (Muraleedharan & Prasad, 2003). Additionally studies on the effectiveness of the CPA have found that the vast majority of cases involving medical complaints that have been resolved in the Consumer Forums have ruled in favour of defendants (Bhat 1996; Muraleedharan & Prasad 2003; Ensor & Weinzierl 2007), hence their value as an effective instrument for regulating health care has also been challenged.

### *Licensing and registration*

Licensing and registration are legally supported strategies most often used in LMICs (Afifiet al. 2003). They can be described as mandatory controls that require adherence to minimum standards as a condition to practice. They are typically used to regulate the entry of professionals and facilities in the provision of health services, and their intention is to influence quantity, quality, and prices associated with health services (Bennett & Ngalande-Banda 1994; Ensor & Weinzierl 2007).

#### Providers

India, Egypt and Nigeria offer typical examples of physician licensing practices. In these countries a medical graduate from an accredited college is granted a license to practice medicine upon submitting an application and the completion of required course work. The failure of providers to comply with minimum standards of practice outlined by various licensing and registration standards can result in punitive action (Muraleedharan & Nandraj, 2003). The undertaking of this procedure is the responsibility of medical councils, and usually does not require periodic renewal or re-registration (Bennett & Ngalande-Banda, 1994). For the most part, however, the roles of these councils are largely limited to the inspection of colleges and assurance of graduation requirements, and do not sufficiently address standards of practice and care beyond graduation (Peters & Muraleedharan, 2008).

Licensing and registration controls differ from the purely legal mechanisms described above in their implementation and enforcement. The responsibility of implementation and enforcement is delegated to non-state autonomous body such as professional medical councils. These councils are seen as being better placed for the regulation of their members because of their relevant knowledge and capacity. In addition, they are more likely to be accepted as regulators by the providers, as compared to outside individuals and entities (Brugha & Zwi, 1998; Ensor & Weinzierl, 2007). Peters and Muraleedharan found that in India, a significant share of the professional regulatory functions is assigned to quasi-governmental agencies, such as the State Medical Councils under the assumption that these professional bodies have an interest in maintaining standards and building the reputation of the medical profession (Peters & Muraleedharan, 2008).

Failure in the efficient monitoring and enforcement of the licensing of practitioners is still prevalent, and sometimes this is attributed to the lack of funding. For example, a review of regulatory mechanisms in several Africa countries by Bennett and Ngalade found that in Ghana medical councils which were established during the 1950s, barely operated and were able to do so only recently when they began to receive funding from the government (Bennett & Ngalande-Banda, 1994).

Outside of the problem of limited funding the model of professional self-regulation has been criticized that medical bodies tend to remain loyal and self-interested, and are reluctant to operate against their own members (Ensor & Weinzierl, 2007). Referred to as regulatory capture this is a common occurrence in different parts of the world (Baldwin & Cave, 1999). As a consequence of regulatory capture, it was found that the Zimbabwean Medical Council failed to publicize any cases of medical malpractice for fear of damaging the reputation of the profession (Bennett & Ngalande-Banda, 1994). Similarly in India (Muraleedharan & Nandraj, 2003) and Thailand (Tangcharoensathien et al., 2008; Teerawattananon, et al. 2003) medical councils responded with disciplinary action towards accused members only as a reaction to unfavourable media attention. The self-interest of medical councils has been shown to extend beyond the scope of licensing implementation and enforcement, to the level where these medical councils and associations have cohesively lobbied against the efforts of governments and consumers to regulate different aspects of health care. This was demonstrated in the case of the State of Gujarat, India, where practitioners unsuccessfully opposed the introduction of the Consumer Protection Act in India, which handles cases of medical negligence (Bhat, 1996b).

#### Establishments

Licensing and registration mechanisms for health facilities and establishments typically focus on ensuring the presence of basic equipment and building infrastructure (Kumaranayake et al. 2000). For example, in Kenya, in order to receive licensing, a private clinic should keep in stock essential drugs and corresponding records, and should maintain a certain standard of repair in a non-residential building (Bennett & Ngalande-Banda, 1994). In India, the Bombay Nursing Homes Registrations Act in the State of Maharashtra mandates basic human resources and space for the establishment and operation of a private health facility (Yesudian, 1994).

An extensive 6-State literature and document review in India by Muraleedharan and Nandraj found a consistent absence of laws and regulations governing the practices of laboratories, poly clinics diagnostic centres, and the various other types of health facilities (V R Muraleedharan & Nandraj, 2003). In another study that aimed to explore the physical standards of rural health care in several districts of Maharashtra, Duggal and Nandraj found that there was no implementation of the facility registration regulation, as none of the hospitals in one of their study districts were being registered by local authorities. It was found that despite the absence of basic supplies and equipment in several facilities, these were still registered and continued to provide services (Nandraj & Duggal, 1997).

A study in Tanzania aimed at understanding regulations for for-profit providers revealed that Tanzanian law forbade the registration of new private pharmacies in areas considered as having an adequate prevalence of providers; however there is little clarity on how this was implemented (Kumaranayake et al. 2000). The study also looked at regulations in Zimbabwe, and found that the Medical Services Act authorizes the Minister of Health to regulate a wide variety of practices and actors related to the private for-profit sector. However, no specific measures were identified as being put into practice (Kumaranayake et al. 2000). Legislations that regulate health facilities are often not as prevalent or stringent as those that govern health personnel, and are often poorly outlined, implemented, and enforced.

## Market-Based Regulation

Given the limited successes of legal and bureaucratic interventions in health service regulation, there has been a growing interest in the use of incentives and other less costly, market-harnessing incentives to affect behaviour in health service delivery and utilization (Cassels, 1995; Kumaranayake, 1997; Saltman, 2002; Tangcharoensathien et al., 2008).Regulatory mechanisms that root from a market-oriented perspective aim to create a health market environment that increases the scope for competition between providers. Problems of poor health service quality, high cost of health care, and inadequate health infrastructure are seen as contributing to market failures, and regulation is seen as an intervention that can balance these problems (Bloom et al. 2009; Broomberg, 1994). This is done through the use of financial or non-monetary benefits for regulation compliance to consequentially stimulate improvement in the areas of health care quality, coverage and cost (Williams 2005; Ensor & Weinzierl 2007).

Incentives play a defining role in market-oriented regulation, where they are used as tools to provoke change in the behaviour of certain actors to produce these positive changes in the health market (Ensor, 2004). Incentives can exist in either monetary or non-monetary forms (Kumaranayake, 1997). It is a broad concept that can apply to individuals, and larger groups and organizations (Saltman, 2002). Incentive schemes are used in various LMICs; however there has been little study of the role of incentives in regulation within the health service provision. Proponents of incentives have stated that they are known to have an impact on behaviour, and are easier to implement since they are not resource intensive (Ensor, 2004).

Self-regulation is a strategy which involves the delegation of traditionally governmental responsibilities, such as standard setting, implementation, and enforcement to quasi-governmental or autonomous bodies. The rationale for doing so is to break down the boundaries between the regulators and the regulated to promote partnership towards a common goal. Self-regulation aims to pursue good for the public, by giving market players the flexibility to determine how to address the problem (Sugarman & Sandman, 2008). Self-regulation models may also be used in a health market environment to promote competition between various groups and organizations. Examples of self-regulation were stated earlier in the case of licensing and registration of health professionals, where the implementation and enforcement was in the hands of the medical councils. Self-regulation as a means for medical governance has been subject to the pitfalls of policy capture by vested interests (Tongcharoensathien et al. 2008). In some countries such as India, the functioning of self-regulatory councils has been defined by inflexible legal statutes and subjected to government intervention, making it barely distinguishable from direct regulation.

### *Voluntary accreditation*

Accreditation is a mechanism which increases benefits to providers for complying with quality regulations. It is often used in addition to a set of mandatory standards, and motivates better performance of individual and entities by enhancing the market position of well-performing providers (Ensor & Weinzierl, 2007). Accreditation can be used to improve the quality of health services through the oversight of a quality control evaluation body, which could be either governmental or private. The nature of the relationship between this ‘regulated’ entity and the evaluation body is purely voluntary, and not based on a contract (Kohn 1999, Patouillard2007). Accreditation can occur at several levels – at the provider level it can go beyond the basic mandatory licensing and registration of physicians; and at the facility level, hospitals and smaller health organizations can pursue accreditation to increase their market appeal and generate consumer demand (Ensor & Weinzierl, 2007).

The use of accreditation as a mechanism in health services is more common in high-income countries but is increasing in popularity in LMICs for a number of reasons that include medical tourism and growing wealth within a country (Ensor & Weinzierl, 2007; Tangcharoensathien et al., 2008). Evidence of increased use of accreditation of facilities is seen in Taiwan (Tangcharoensathien et al., 2008), and in Thailand, where private hospitals have obtained the ISO 9000 accreditation (Ensor & Weinzierl, 2007). Similarly, in India private super-specialty hospitals are also using the Joint Commission International’s accreditation standards to increase their marketability (ibid.).

There is a very limited data available on the effectiveness of accreditation in the improvement of performance, and of this much is limited to HICs and the regulation of individuals and general practice (Ranson et al. 2010). In the context of LMICs, one study examined the accreditation of hospitals has been implemented on a compulsory basis in Zambia (Bukonda, et al. 2002). Evaluation of this model suggested that the program had led to significant improvement in standards (Ensor & Weinzierl, 2007). Another study that looked at accreditation in Thailand, found that national level hospitals which had introduced accreditation showed progress in productivity and quality following an initial slow period (Tangcharoensathien et al., 2008). Questions frequently arise around how the voluntary nature of accreditation affects financial sustainability and inspection capacity. In addition, concerns have been expressed about whether the agencies in charge of norm enforcement have the legal support and standing to conduct their activities (Ensor & Weinzierl, 2007). Additionally, other problems recorded in Zambia were related to administrative and infrastructural issues in implementing national accreditation (Bukondaet al.2002).

### *Educational bonds*

In an effort to promote an equitable urban-rural distribution of health providers many countries introduced the medical educational bonds as a regulatory instrument. Several LMICs have utilized mandates to place medical graduates in rural, remote, and underserved areas for a set period of time, linked to the completion of their education and granting of a licence to practice. For instance, Egypt, Ecuador, Nigeria, and Malaysia assign and require new medical school graduates to serve one or two years in physician-scarce areas (Roberts et al. 2004). The failure of students to comply with these requirements can result in fines or the loss of the certificate to practice, as demonstrated by the policies of the States of Tamil Nadu and Meghalaya in India (Frehywot et al. 2010).

In other countries, the bond follows an incentive-based model. In Thailand recruited medical students received incentives in the form of heavy subsidies for working in remote areas following their graduation (Nitayarumphong et al. 2000). Indonesia uses a combination of compulsory and incentives and rural doctors receive double the salary than those working in urban areas, along with an increased opportunity for recruitment into the civil service (Chomitz, 1997). Recent graduates may also be offered preferential admission to postgraduate courses, based on their records of rural service (PHFI 2010).

Very limited evaluation has been conducted on the effectiveness of incentivized rural bonds (Ranson et al. 2010). Based on available evidence it is suggested that economic incentives can be effective in a short-term period, however its long term success is doubtful. This was evident in South Africa where financial incentives appear to have convinced some health workers to change their short-term career plans, yet the problem of understaffing in most rural hospitals remained unchanged (Reid, 2003; Serneels et al. 2007). Criticism of the effectiveness of enforcement of rural bonds and compulsory services is attributed to the lack of administrative capacity or the political will for enforcement in many countries (Dovlo, 1999; Reid, 2003). Additionally, problems of rampant corruption and favouritism have been reported to compound the problem of ineffective enforcement (Wibulpolprasert & Pengpaibon, 2003).

### *Dual practice*

Dual practice –public sector doctors engaging in private practice (Roemer, 1993) – is a global phenomenon and is typically seen as a problem because it has been associated with corruption and the unauthorized use of public resources (Brugha & A. Zwi, 1998). However, the argument has also been made to allow and utilize dual practice as a mechanism to not only increase consumers’ access to health services, but also to elevate the quality of services (Eggleston & Bir, 2006). While the advantages of dual practice have been stated in these papers based on the analysis of complex theoretical models (Rickman & A. McGuire, 1999, Biglaiser & Ma, 2003), it contradicts the discussion in policy circles, which is that allowing public sector physicians to practice privately can reduce the quality of services being provided in the public sector (Eggleston & Bir, 2006). In addition, empirical evidence on this in the context of LMICs is severely lacking and most available data is based in HIC settings. There is a minimal amount of evidence on dual practice in LMICs, which focuses predominately on reasons for the occurrence of dual practice (Roenen et al. 1997). Similarly, a study uncovered a variety of opportunities to change the current arrangements of Bangladesh’s mixed health system through changes in the physician incentive structure but did not examine the effects of these incentives on the cost or quality of services (Gruenet al. 2002). In the much of the developing countries the social effects of multiple job holding is not known.

### *Pay for performance*

Results-based financing (RBF) and pay for performance (P4P) are types of incentives that are used interchangeably to describe the “transfer of money or material goods conditional on taking a measurable action or achieving a predetermined performance target” (Oxman & Atle, 2008). A literature review by Petersen on the impact of financial incentives on the retention of health providers in rural areas has found that the goal of short-term retention was achieved, but a sustained long-term response was not successful, however this review was conducted in a HIC setting in Canada and the United States (Sempowski, 2004). Incentives are also used in different capacities and settings in the context of various partnerships in LMICs to increase the quality of health services by influencing behaviour; however there has been little study of its impact and effectiveness in health service provision. Most evidence that exists is based in HICs. A systematic review of empirical studies on the relationship between financial incentives and high quality care (Petersen, et al. 2006) found that financial incentives to providers were sometimes reported to have partial or positive effects on short–term behaviour (Beaulieu & Horrigan, 2005; Fairbrother et al.1999; Fairbrother et al. 2001; Safran et al., 2000). However the impact on a long-term basis is unknown due to the lack of evidence. Oxman and Atle have noted the unfeasibility of attributing the effect of RBF on quality improvement, due to the lack of rigorous quantitative data (Oxman & Atle, 2008).

## Other Mechanisms

### *Contracting*

Partnerships between the public and private sectors are approached as interventions in the overall structure and functioning on the health system (Muraleedharan & Nandraj, 2003). Contracting qualifies as one such partnership, and is advocated as an effective mechanism to improve health system performance in LMICs (Palmer, 2000). It is used by the government to acquire certain services at an agreed price from a specific private provider for a given period of time. Either clinical or non-clinical services can be acquired from private providers as a way to complement the public provision of health services in a country (Ensor & Weinzierl, 2007; Loevinsohn & Harding, 2005).

A wide range of contracting options exist as demonstrated by a qualitative research study that found arrangements ranged from private general practitioners in rural towns in South Africa who have been contracted by provincial health authorities to deliver a range of care, to private clinics serving low income workers and their families (Palmer & Mills 2005). More examples of contracting in health services are available from India where in Mumbai the contracting out of ancillary services such as catering, laundry, and hospital maintenance was found to be common. Similarly, the State of Tamil Nadu developed contracting arrangements for high-tech equipment in public hospitals, equipment maintenance services, and advertisements for the AIDS control program (N. Palmer, 2000). Contracting of clinical services is also carried out in LMICs either for specific services such as HIV/AIDS prevention and care or more comprehensive health service delivery at primary and hospital levels (Palmer & Mills, 2005).

Despite the increase in the use of contracting in LMICs (N. Palmer, 2000) little is known about it due to the scarcity of data. Based on available empirical evidence on the contracting of services in Mumbai (Bhatia and Mills 1997), Thailand (Tangcharoensathien et al., 1997) and Zimbabwe (McPake & Hongoro, 1995), which were carried out as part of a Collaborative Research Network on the Public/Private Mix for Health Care, it was found that there was inadequate monitoring of quality in these partnerships. One of the reasons for this was the lack of clarity on the quality standards to be achieved and the appropriate measurements to monitor them (Bennett & Mills, 1998). The biggest misconception about contracting is that the role of the government in facilitating this process is forgotten. While contracting is proposed as a solution to fill gaps of health service provision in health systems, it is sometimes forgotten that the government still has a large role to play in the areas of financial and information management, but in the case of many LMICs this has not always been seen as feasible (Mills, 1998).

### *Co-production*

Joshi and Moore defined institutionalized co-production as “the provision of public services (broadly defined, to include regulation) through regular, long-term relationships between state agencies and organized groups of citizens, where both make substantial resource contributions” (Joshi & Moore, 2004). They described it as an arrangement where the control of resources is divided between the government and other groups of citizens (Joshi & Moore, 2004).As indicated by Joshi and Moore, the search for cases of institutional co-production did not yield fruitful results. Peters and Muraleedharan did identify a few cases in India where this exists. For example, they highlighted Self-Employed Women’s Association (SEWA) in Gujarat, which provides health insurance schemes for its members. The authors stated that though the provision of insurance was made, the efforts to influence health provider behaviour or work with government regulators is not well developed (Peters & Muraleedharan, 2008).

In another example, Peters and Muraleedharan highlighted the Janani model based on the franchising of reproductive health services. The program trains unqualified health workers to offer basic reproductive and sexual health services, and to refer appropriate cases to qualified physicians. Clients pay a fixed fee for all services, and for every client referred to the doctors, who are franchised by Janani, the unqualified health workers earn a commission. (Peters & Muraleedharan, 2008).

### *Health insurance*

Health insurance has two aspects of use – in one it is used as a way to finance health services by raising money to pay for health care. In the case of LMICs, insurance is also used as a way to gain access to private health services due to the dissatisfaction associated with the public health system (Abel-Smith, 1992). Much work has taken place in HICs to understand the impact of insurance on different levels. The prevalence of health insurance, especially private health insurance is now growing in LMICs “in terms of premiums and numbers” (Gupta & Trivedi, 2005). At this point, much evidence has not yet been generated to study the impact and consequences of insurance use and insurance arrangements on the cost and quality of services in facilities in LMICs.

Based on studies and literature in HIC settings, the effect of insurance on the cost and quality of health services is said to depend on the type of scheme used. For instance in an insurance set-up where rates of services are not negotiated before-hand providers can determine their own charges for services that are provided to a patient who is fully or partially reimbursed for his/her expenses. Often times a bigger reimbursement from the insurance company encourages providers to over-test, over-prescribe, and therefore over-price patients (Abel-Smith, 1992).In a fee-for-service arrangement, which is used in HICs like Canada, Australia, New Zealand, Japan, South Korea, Belgium, Germany and Norway, there is no incentive to under-provide services as doctors have the freedom to test and prescribe according to their own volition (Abel-smith, 1992). This type of arrangement also potentially threatens the quality of services received by patients fuelled by unnecessary testing and treatment. For example, a study from the United States showed that “varying geographical rates of surgery seemed to be explained by the number of surgeons in each geographical area” (Abel-Smith, 1992). Furthermore, in the case of certain insurance set-ups providers might take this one step further and attempt to perform procedures with which they have not had recent or adequate experience just for the sake of receiving additional money (Abel-Smith, 1992; Bhat et al. 2005).

Most of these listed problems are prevalent within the private health insurance sector. Social health insurance has been deliberated as an option in the recent past, especially in LMICs as an important tool to extend health coverage to a majority of the population (WHO 2003a, WHO 2003b, Gupta & Trivedi, 2005). Peters and Muraleedharan highlighted that the efforts to influence health provider behaviour were not well developed in one social insurance scheme in India (Peters & Muraleedharan, 2008).However; further evidence is needed to understand how SHI works in respect to cost and quality of health services.

## Summary

The experiences of health service related regulations in many LMICs reveal that the existence of basic regulations does not automatically imply their adequate enforcement and performance (Kumaranayake 1997; Yesudian 1994; Bennett & Ngalande-Banda 1994; Mujinja 2003; Matsebula et al. 2005). Evidence for the effectiveness of various approaches, including provider re-licensing, regulations on dual practice, different models for regulation of private sector in LMICs, and how professional bodies can be made more effective in regulation of practice is scarce (Ranson et al. 2010). Different mechanisms have had limited success at scale, and regulation of health care provision remains one of the pre-eminent challenges for future health policy in LMIC, and for progress toward the Millennium Development Goals.

How is the limited success of regulatory policies in LMIC explained? A key issue that emerges across the board is the performance of the various institutions and groups expected to take a role in regulation, and their failure to fulfil these expected roles. Existing diagnoses for deficiencies in the regulatory response in LMIC include:

* Lack of institutional capacity, legal and organizational frameworks, and resources in the public sector for governance of mixed health services (Peters and Muraleedharan 2008, Balabanova et al. 2008)
* Misalignment of institutional roles and actions, and of formal and informal relationships in institutions, problems of inter-organizational coordination (Bloom et al. 2009, Sheikh 2008)
* Regulatory ‘capture’ of public institutions by vested interests (Tangcharoensathien et al. 2008, Gonsalves 1997)

While these are credible diagnoses, they are generic, supported only by a limited empirical research base, and tend to be drawn only from particular country contexts. The specific institutional and systemic contexts for failures of regulatory policies remain poorly explored, and represent a significant gap in the knowledge. The characteristics of regulatory institutions in different LMI countries and provinces are unique, and necessitate independent understanding. A particularly poorly explored aspect is that of the complementarity of different regulatory approaches, and the institutions that implement them. The rarity of empirical enquiry into how regulatory interventions are implemented in real-world institutional and systemic settings of low and middle income countries is remarkable, and typical of the neglect of health policy research in LMIC contexts (Raphaely &Gilson 2008).

In the following section, we outline an analytic approach and framework for empirical research to characterize the regulatory architecture for healthcare provision in a given country or province. The outcomes of the research can help to identify key gaps in design and implementation of regulatory policies in that country or province, and will also facilitate comparison across different country contexts.

# III. THE POLICY APPROACH AND RESEARCH TOOL

## The Importance of Characterizing the Regulatory Architecture

In their landmark WHO publication, “Systems Thinking”, de Savigny and Adam reflect that planned interventions in developing countries often fail to achieve their goals – not due to inherent flaws in the intervention, so much as to the lack of knowledge about the system through which they are implemented – its configuration, strengths and weaknesses. Systems which remain thus “unmapped and misunderstood” are likely to cause interventions to fail (de Savigny and Adam 2010). Regulatory systems for health care in LMIC are exemplary of this. The literature has tended to lump regulation in LMIC mixed health systems under broad descriptors of being inefficient, and lacking in capacity. These negative descriptors tell us little about the actual character of regulation in these different polities and societies – the nature of institutional arrangements and activities, cultures and values, and inter-organizational relationships remain largely undescribed and poorly understood, even as they are actually key determinants of policy success in a particular context.

In part this may be ascribed to the conventional “black box” perception of policy – as a simplistic equation of inputs and outputs, with little attention to process, power and institutional complexity (Easton 1965). “Black box” thinking is perpetuated by the dominant rational-managerial complex in which policymaking and implementation are regarded primarily as administrative functions separate from politics, and also by the methodological complexity of researching policy processes (Hjern & Hull 1982). A related explanation for the lack of attention to regulatory systems in LMIC is the dominant perspective among economists that organizational structures (and their inherent complexity) can be regarded interchangeably with market mechanisms as the apparatus of policy implementation (Elmore 1982). There are significant risks to a perspective which regards complex organizations mainly as barriers to the implementation of successful policy, and replaceable by the simplifying solution of modification of private incentives. Elmore emphasizes that organizations can be effective devices for working out difficult public problems, and advocate that their structures and processes require deeper and more specific understanding, so that they may be appropriately capitalized on and modified, in the pursuit of policy goals (Elmore 1982 p23). In low income contexts in particular, regulatory organizations in the state and non-state sectors can perform important roles particularly in furthering health equity goals. Organizations are also key loci of discourse and help shape social and political values (Fischer 2003).

How then can we better map and understand regulatory systems, so that this knowledge may be used in their improvement? The policy research approach provides a framework on which such meaningful enquiry can be conducted.

## The Policy Research Approach

Public policy analysis per se is not a new field of activity. As long as there have been governments and governance, policies have been scrutinized informally and formally. However, as a distinct entity, the field has seen an increase in interest in the second half of the 20th century (Hogwood and Gunn 1984). Policy approaches accommodate different disciplinary contributions in order to achieve a more complete understanding of actors and real-life policy processes. These include concepts from the political and management sciences, psychology, sociology, and economics (Walt 1994, Sabatier 1998), and in its more recent applications, from philosophy and critical theory (Fischer 2003). Further, its wide adoption in the literature of specific sectors (health policy, education policy, environment policy) also emphasises the status of policy analysis as a sub-constituent of each of those areas of study – i.e. within health studies, education studies etc. (Parsons 1995).

Analytical approaches vary based on the intended purpose of enquiry. The function of public policy analysis in its original conception was to generate specific knowledge to evaluate, support or contribute to government programmes or interventions. Such analyses “for” policy typically use targeted methods such as operational research and economic analysis to inform policy decisions (Parsons 1995). Subsequently however, research “on” policy, an approach with a more reflective orientation concerned with understanding the processes of formation and implementation of policy, has received increased attention. This approach was built on existing traditions of research into the functioning of government institutions, public administration and the role of interest groups (Gordon et al. 1977, Lasswell 1970 cited in Parsons 1995). In a contemporary sense however, distinctions of analysis *of* or *for* policy are no longer seen to be so clear. There is an increasing recognition of the diversity of roles of policy analysts in society and the variability of processes through which research influences policy change (Parsons 1995, Yanow 2000). Ritchie and Spencer (1994) identify four types of questions that are usually asked in applied policy research - contextual, diagnostic, evaluative or strategic questions - and stressed that most research, in intent or effect, addresses more than one of these types of questions.

The analysis we propose is both ***on* policy** and also ***for* policy,** and can be said to be **exploratory and diagnostic in nature.** It is ***not* evaluation research**, since it does not claim or attempt to assess the performance of organizations or the system against a standard.

### *Policy-action relationship*

In the early years of the emergence of policy studies, the focus was largely on understanding the nature of policy *formation*, in which context implementation, or the link between policy and action, was “assumed to be a series of mundane decisions and interactions” and not seen to have distinct significance as a subject of study by policy scientists (Van Meter and Van Horn, 1975 p450). Implementation was widely seen as a managerial function, and not integral to the study of policy, or to the policy process. Pressman and Wildavsky’s study of implementation of a federal programme for economic development in the USA in 1973 heralded the beginnings of the new sub-discipline. Since then, the literature on implementation has burgeoned and textbooks on implementation studies have been published, drawing on ideas from the political sciences, public administration and organizational behaviour (Grindle 1980, Barrett and Fudge 1981, Williams 1982, Younis 1990, Hill and Hupe 2002). “Implementation studies” developed as an umbrella under which academic thinking on the policy-action relationship was consolidated.

In its original conception implementation studies was conceived to address policymakers’ concerns about the ineffectiveness of policies, a problem variously described as “implementation deficits” (Pressman and Wildavsky 1973) “the implementation gap” (Dunsire 1978), and “policy failure” (Hogwood and Gunn 1984). The implementation process is viewed explicitly from the perspective of policy-makers, as part of a sequence following, and separate from policy formulation (Buse et al 2005). “Top-down” theorists have generally been preoccupied with identifying approaches and conditions which can lead field-level practices to more closely approximate original policy intentions (Sabatier and Mazmanian 1979, Hood 1976, Hogwood and Gunn 1984). Understanding why policies fail remains a core theme of implementation analysis, yet the top-down conception of the policy-action relationship has widely been contested and an alternative movement in implementation studies has also taken root, which is often collectively bracketed as *“action-centred”* or “bottom-up” approaches. Barrett and Fudge (1981) argued that there is no reason that the perspectives of policymakers should automatically be adopted by policy analysts, since in many instances action precedes or predates policy. Policy may be a response to pressures and problems experienced on the ground, or may be developed to control or build on an existing practice or phenomenon (ibid.).

There is an implicit assumption in the top-down perspective, also espoused in many health policy texts (Peters 2003, Duggal 2001), that decision-making is solely the function of policy-makers and hence decisional processes *end* with the formulation of policies by policy planners, and are then instrumentally “put into effect” by designated implementers. However there may be inconsistencies in this view of the policy process, and *action-centred* approaches offer an alternative view of actors’ participation in policy implementation. Reality may be more complex than is implied by a top-down model of a unitary central locus of decisions.According to Elmore (1982 p.20, also Lewis and Flynn 1979), the view that “policymakers control the organizational, political and technological processes that affect implementation” is a fallacy that is often not borne out by experience, observation and research. Groups who are designated as implementers continually reinterpret, modify and change policies in the process of implementing them (Barrett and Fudge 1981, Lipsky 1980). Further, groups and organizations involved in implementation are often autonomous or semi-autonomous, and not in direct hierarchical relationships with those making policy (Barrett and Fudge 1981). This makes it necessary, in exploring policy-practice gaps, to consider distinctly the decision-making processes of implementing actors, not just those of designated policy planners.

Core characteristics of action-centred approaches in studying the policy-action relationship are:

* They emphasise *action as the focal point of study*, rather than policy, focusing on “observing what actually happens or gets done, and seeking to understand how and why” (Barrett and Fudge 1981 p.12)
* They emphasise interactions and relationships *between actors* and organizations in the implementation process.
* They are often oriented on the *decisions and perspectives of actors involved in policy implementation*, other than policy-makers.

The two perspectives – top-down and action-centred – hence represent alternative ways of framing the problem of policy-practice gaps, and also reflect differing concerns and interests. In this paper, we subscribe to the latter, action-centred approach, as a way of characterizing the policy-action relationship.

### *Scope of the research tool*

We have framed the tool to focus on mapping the regulatory architecture at the **level of a province or State**. Health is a State-level subject in India’s federal system, and implementing organizations in the context of regulation of health care provision are concentrated in State capitals, which informed the consideration of restricting mapping to this level (notably however, several regulatory organs also operate at national level, or meta-State level, which we have analyzed separately in the pilot studies presented here). For smaller countries, in which regulatory organizations are located mainly at national level, the tool may be simply altered to focus on the national arena, and applied. While organizations with regulatory functions may also operate at sub-provincial level, including in districts, municipalities and even the regulatory functions of administrators in hospitals etc., this level of detail is considered outside the scope of this exercise. Analysis of such micro-level regulatory processes may be undertaken as part of a more in-depth study of implementation.[[3]](#footnote-3)

The architecture of a particular policy domain may be seen to be constituted by 1. Variously interlinked state and non-state actors – groups and organizations – that participate in the continuum of decision-making and implementation, and 2. The laws, policies and rules which guide their actions (Buse et al. 2005).In the case of the domain of regulation of health care provision at the level of a province or State, the policy architecture may hence be seen to be constituted by a range of organizations, bureaus and departments involved in making and implementing regulatory policies and by the contents of relevant policies, laws and guidelines.

Implementation theorists Hjern and Hull recognized that the roles organizations actually play in the implementation of policies frequently do not conform to formally expected norms. They suggested that this divergence in norms and behaviour is underpinned by the difference between the “living constitution” of policy – how policy problems are defined and addressed by relevant actors, from the “written constitution” – policy problems as defined by the political system. They advocated that organizational activities and interrelationships should be investigated through empirical research to understand what “actually happens or gets done, how and why”, rather than simply in terms of divergence from the norm

The proposed research tool, presented in the subsequent section, draws from these theoretical foundations (and also Elmore’s bottom up approach – see page 15). The tool primarily serves as a *first level* of analysis – i.e. mapping, consolidating knowledge about the configuration of the domain (regulation in this instance), and hypothesizing diagnoses of policy gaps.3It also proposes using field research methods to understand the *actual* roles of various state and non-state groups and organizations. The actual roles of these groups are then compared with the putative or *expected* architecture of regulation in that country or province – as outlined in written policies – to identify policy gaps (Hjern & Hull 1982).

The **aims of the research** can be summarized as:

* To characterize the regulatory architecture by charting the roles and functions of different regulatory groups and organizations and the contents of relevant policies, in a State / province.
* To identify key gaps and deficiencies in the design and implementation of regulatory policy

## The Research Tool

We propose a stepwise research process for mapping the regulatory architecture, involving a mix of methods and primary and secondary sources of data. The research may be undertaken by trained researchers (preferably policy analysts) independently or in commission to Ministries or Departments of Health of the relevant country / province. The framework is inherently flexible, and may (in other instances) be used to characterize other aspects of regulation such as pharmaceutical regulation, or indeed of other policy domains such as decentralization or distribution of resources.

Figure 1 Framework overview: steps, sources of data and outputs

### *Step 1. Outlining policy contexts*

Regulatory processes must be understood in the broader context of the status and organization of health services the respective province or country. An overview of health services in the province encompasses details such as the prevailing public-private mix of services and the human resources scenario, and may be prefaced by any remarkable particulars of the political system, the economy, demography or epidemiology, or of any situational, cultural or exogenous factors which have bearing on the issue of regulation (Leichter 1979).A combination of literature and document review, complemented by discussions with key informants and policy elites can be used to elicit the necessary information.

#### Sources of data

Literature and document review, discussions with policy elites and key informants.

### *Step 2. Analyzing relevant laws and policies*

The contents of varied formal policies represent the *de jure* context, or the “written constitution” of policy, based on which different regulatory groups are expected to act. Step 2 of the framework involves collating relevant policy documentation related to different aspects of regulation of health care provision, and extracting relevant sections and clauses that direct regulatory activities.

#### Sources of data

These include national or provincial level policies, and relevant laws of the land that contain details of the mandated responsibilities of different groups in the regulatory sphere.

### *Step 3. Analysing roles of organizations with regulatory functions*

The third step is to analyse the roles of all organizations with regulatory functions.

Step 3 A: Listing the organizations

In the first place, it is necessary to prepare a list of all regulatory groups, i.e. state and non-state organizations, departments and bureaux tasked with regulation of health care delivery. An attempt should be made to make this list comprehensive; however the list can be supplemented as the research progresses. It is useful to commence with a standard taxonomy of regulatory strategies, in order to identify the groups associated with each of these strategies. All the organizations that are mandated with developing and implementing each of these regulatory strategies are to be enlisted.

**Direct regulation**

Statutory licensing and registration agencies for providers

Statutory registration agencies for establishments

Medical and consumer law boards

**Market based**

Accreditation and certification boards

Departments implementing incentive schemes and bonds

**Other approaches**

**D**epartments handling service purchasing and contracting

Social insurance boards

Box 1 Groups and organizations associated with different regulatory approaches

Additionally, various mechanisms for engagement with health care providers are identified which are not instituted primarily to regulate, but have inbuilt regulatory provisions. Examples of such arrangements include:

* Health programme partnerships with independent hospitals and practitioners
* Mechanisms to contract ‘in’ and contract ‘out’ or to franchise private health facilities with public health goals of increasing access or expanding the scope of rational care
* Social insurance schemes for the poor which empanel private providers

The organizations associated with implementing the regulatory components of these schemes and strategies may be enlisted and merged with the list of regulators, to prepare a provisional list of groups with regulatory functions (Box 1).

Step 3 B: Describing regulatory activities

The most important step in the research entails describing relevant organizational activities in real-world settings, using field research methods including interviews and document review. Core areas of enquiry for this step are presented in Box 3, below. A detailed topic guide for interviews with health systems actors, and format for obtaining informed consent prior to interview are annexed.

Organizational activities corresponding to each regulatory “target” (cost, quality, conduct, access)

Regulators’ experiences of performance of each activity

Relationships and affiliations with other groups

Organizational goals and priorities

Box 2 Areas of enquiry

Transcripts of interviews and policy documents for each set of organizations are thematically organized and written up.

#### Sources of data

Discussions with policy elites and key informants may be used liberally to develop the groups listing. In addition, a review of relevant national / provincial level health policies, laws, acts and rules can assist in identifying departments and bureaux officially mandated to enact regulatory functions. The organizational arrangements and activities of each group as they pertain to a particular regulatory function are investigated primarily through in-depth interviews with organizational representatives. This may be supplemented by review of relevant organizational documentation (constitutions, rules and standard operating procedures, as well as internal circulars and communiqués, if available).

### *Step 4. Mapping the regulatory architecture*

No new data are required to be collected in this step. The documentation collected in Steps 3 and 4 is synthesized into a map or chart of the regulatory architecture in the country or province (see page 112). The chart is made up of six columns, as follows:

COLUMN 1: the targets of regulatory policy for health care provision are enlisted. These have been identified in previous sections (see page 15) as prevailing field level phenomena and behaviours in LMIC which are of significance for public health, equity and health rights, and which generate the need for regulatory policy - reiterated below in Box 3

High costs of health care for users

Variable quality of care provided

Ethical conduct of health care providers

Variable accessibility of health care

Box 3 Targets of regulatory policy for health care provision

COLUMN 2: groups with various regulatory functions are enlisted against each respective “target”.

COLUMN 3: indicates what type of authority is vested with that particularly group. Is it legally enshrined or statutory? In other instances, the type of authority may not be statutory, yet may be officially underwritten or bound by legal contract or agreement. Alternatively, the organization may have a voluntary interest in performing a regulatory function.

COLUMN 4: annotates the relevant policy document and clause which directs each of these regulatory activities

COLUMN 5: details the organizational relevant regulatory activities expected to be undertaken by that organization, in relation to each “target”. Since the listing of targets is fairly broad and in some instances overlapping, the following demarcation of activities is applied (see also page 15, section: Problems of Health Care Provision in Mixed Systems, for details):

* ‘Targeted at Costs of Care’: all regulatory activities aimed at reducing direct expenses of health care for the user
* ‘Targeted at Quality of Care’: all regulatory activities aimed at improving the quality of health care, including monitoring of management practices and reduction in irrational treatments, formative and continuing provider education, control of entry into health care professions, reducing or modulating practice by unqualified providers, and improvement of supporting infrastructure or process standards surrounding health care activity
* ‘Targeted at Conduct of Providers’: all regulatory activities aimed at reducing deliberately unethical practices of providers, including enforcement of codes of conduct, discipline and redress for medical negligence, and reduction in rent-seeking practices and in unnecessary and illegal diagnostic and therapeutic procedures
* ‘Targeted at Accessibility of Care’: all regulatory activities aimed at increasing the presence and active service of quality and qualified medical providers in hitherto underserved areas.

COLUMN 6: the sixth column represents relevant activities actually performed by the respective organizations.

### *Step 5. Identifying gaps in regulatory policy*

Analysis of the regulatory architecture charts will reveal that particular aspects of regulatory policy may be inadequately assigned, or not assigned to any group or organization. These are designated as *gaps in design* of regulatory policies. *Implementation gaps* are identified by comparing putative roles of different organizations from their actual roles as described in respondents’ accounts.

# PILOT STUDIES

## The National Arena

Under the federal system of the Indian constitution, health is a subject devolved to States. It is the prerogative of the States to regulate and enact the various laws pertaining to healthcare. However, certain laws and policies and certain institutions also operate at the level of the Union or the Centre. This section describes relevant laws and policies and regulatory institutions and schemes which are either operational at national level (and hence apply to all States), or are not specific to either of the States in this study. National-level policies and organizational structures are either directly applicable in the respective States, or are relevant in that they guide actions and operations of corresponding regulatory organizations at State level. Throughout this section, the putative roles of various National-level organizations are highlighted against a grey background.

### *Relevant laws and policies*

#### Targeted at: Quality of Care

Clinical Establishment Act 2010

Several States have mandated their own clinical establishments acts to regulate healthcare providers. However under a special provision of article 252 of the Indian constitution, if three States request the Union government to enact a particular law, the Union government can take necessary steps to enact such a law.[[4]](#footnote-4) Accordingly, the Union government passed a central Clinical Establishments Act in 2010. This is currently applicable to the States of Arunachal Pradesh, Himachal Pradesh, Mizoram, Sikkim and the Union Territories, and can be adopted by any other State.[[5]](#footnote-5) The definition of clinical establishments includes hospitals, maternity homes, nursing homes, clinic and any other institution of any stream of medicine, that provides care for illness, injury, abnormality, deformity or pregnancy. Also, in a first for the country, government-run clinical establishments are brought under the purview of this legislation.5

The Act provides for the establishment of a National Council at the level of the Union, and State Councils for the States for the regulation of clinical establishments. At State level, it recommends the establishment of a State council with the Director, Health Services of the State as ex-officio secretary. The putative functions envisaged for the National Council are compilation and publication of a national register of clinical establishments and development of a first set of standards for healthcare, within two years of the enactment of the Act; categorisation of the various clinical establishments; establishment and periodic review of minimum standards and collection of statistics from the clinical establishments. The State Councils would have the putative functions of compiling and updating the State Register for clinical establishments and sending monthly updates to the National Register; representing the State in the National Council; hearing appeals against the district registering authority; and annual publication of a report on the implementation of healthcare standards in the State.5

*Mandate:* The Act mandates minimum conditions of standards of facilities, services, personnel, and recording and reporting systems for each clinical establishment, requisite for registration*.* Once a clinical establishment has attained the standards it can register itself, on payment of a fee, with the district authority, following which it is permitted to render services. The district health officer (DHO) of the district, as the convenor of the District registration authority, is empowered to register establishments – s/he can issue a provisional registration certificate for a period upto twelve months; issue a permanent registration renewable every five years; cancel the registration if it is found that the establishment is not complying to the standards; conduct inquiry or inspect the facility as and when required, and penalise unregistered establishments which are rendering services (monetary penalties incurred range from rupees 50,000 for a first offence to 500,000 for multiple offences). The registration authority is obliged to supply the list of establishments to the State Council, to be entered into the State Register.5

Consumer Protection Act 1986

Consumer-based approaches to regulation takes into consideration that healthcare provision is a service and that the patient receiving the service is a consumer. India passed its Consumer Protection Act in 1986 (COPRA). This Act provides for the protection of consumer interests against deficiencies of quality of service and unfair trade practices. The Act brings within its purview all the services hired or availed by the consumer for payment.[[6]](#footnote-6) The provisions of the act do not apply to services provided by public bodies where there is no payment consideration. Various case-laws and rulings of courts in India have established the applicability of this Act to the services provided by private healthcare providers (Bhat 1996b).

The Act provides for a Central Consumer Protection Council at the Union Government level with the Minister in charge of consumer affairs as *ex-officio* chairman.6 The roles of the Central Council are to promote and protect the rights of the consumer on parameters of quality, quantity, standard, purity and so on of a particular good or service; right to protect the consumer against unfair trade practices and seek redressal against such practices, and right to consumer education. Similarly the Act provides for a State Consumer protection council with similar roles at the State level on the lines of the National Council, with the State Minister in charge of Consumer Affairs as its chairman.6

*Consumer disputes redressagencies* are to be set up at all three levels – National, State and District level and are to be called National Commission, State Commission and District Forum respectively. The National Commission is to be set up by the Union Government. The State commission and the District Forums to be set up by the State government.6 The District Forum consists of three members and is to be headed by a President who has the credentials to be a District Judge or who has been a District Judge. The other two members are persons known for their integrity and high social standing with adequate knowledge of law, commerce, industry and so on. At least one of these two members has to be a woman.

The District Forum has the role of receiving complaints when the residence of either the complainant or the defendant is in the district, and the value of the goods or services in the complaint or the compensation claimed does not exceed Rs 2 million.[[7]](#footnote-7) The State Commission also consists of three members with a sitting or ex-Judge of High Court as its President. The other two members are persons who are known for their integrity and high social standing with adequate knowledge of law, commerce, industry and so on. At least one of these two members has to be a woman. The State Commission receives complaints when the value of the goods or services or compensation claimed is between Rs 2 million and 10 million, and in cases of appeals against decisions of District Forums.6 The National Commission consists of a President who is or has been a Supreme Court judge and four other members known for their integrity and high standing with adequate knowledge of law, commerce, industry and related fields. The National Commission entertains appeals against rulings of State Commissions, and also complaints where the value of goods or services in question, or the compensation claimed is more than Rs 10 million.6,7

MTP and PNDT Laws

This section details some specific regulations that are passed by the Union government but are enforceable by State governments.

1. Medical Termination of Pregnancy (MTP) Act 1971, and Rules

This Act provides a legal basis for the termination of pregnancy. According to the Act, the medical termination of pregnancy (MTP) has to be done by a registered medical practitioner. It can be conducted on pregnancies upto twelve weeks if one medical practitioner is of the opinion that continuation of the pregnancy poses grave danger to the life of the mother or the chances of physical or mental deformities of the child born are significant; or from twelve weeks to not later than twenty weeks if two medical practitioners are of the same opinion. Medical termination is also envisaged when the pregnancy has occurred due to rape and if it is felt that the continuation of the pregnancy can cause injury to the mental health of the woman. Similarly termination can be done when unwanted pregnancy happens as a result of the failure of the contraceptive device and if it is felt that this might result in an injury to the mental health of the woman.[[8]](#footnote-8)

The Chief District Medical officer (CDMO) of the district in the case of the State of Delhi and the Chief Medical and Health officer (CMHO) of the District in the State of Madhya Pradesh are entrusted with the role of inspection, verification and approval of any private establishment for conducting MTP. The CDMO and the CMHO can also cancel the approval granted to the establishments if not maintained appropriately.[[9]](#footnote-9) The CDMO and CMHO are also entrusted with the role of soliciting monthly statements from the approved establishments with details of MTPs conducted.[[10]](#footnote-10)

1. Pre-Natal Diagnostic Techniques (PNDT) Act 1994

The Pre-natal Diagnostic Techniques Act of 1994, and its subsequent amendments, provide for the prohibition of sex selection before or after conception, and for the registration and licensing of genetic counselling centres, clinics and laboratories. The Act is established to prevent pre-natal sex determination leading to sex-selective abortions of female foetuses. The Act allows pre-natal diagnostics only for the purposes of detection of chromosomal abnormalities; genetic metabolic diseases; haemoglobinopathies; sex-linked genetic diseases; congenital anomalies and other such abnormalities or diseases.[[11]](#footnote-11) These procedures may be done at a registered centre, only on pregnant women who are above thirty five years of age; or have undergone two or more spontaneous abortions; or have been exposed to potentially hazardous drugs or radiation, or have a family history of mental retardation or genetic disease.

A central supervisory board is constituted according to the Act. The putative roles of the board is to advise the Government on policy matters on the Pre-Natal Diagnostic techniques; to review the implementation of the act; to create public awareness; and to prepare a code of conduct for the persons working with the Genetic Counselling centres, clinics and laboratories. The Act was amended in 2002 to provide for a State supervisory board with the role of creating public awareness; reviewing the actions of the appropriate authorities of the State; and monitoring implementation and suggesting appropriate remedial measures related to the regulation of Pre-Natal Diagnostic Tests.[[12]](#footnote-12) Appropriate authorities are to be established at State level for the purpose of implementing the Act. The Appropriate authority is a panel of members with an officer of the rank of Joint Director of Health and Family Welfare department of the State or above as chairperson, an eminent woman representing a women’s organisation, and an officer of the law department of the State government.12

The roles of the appropriate authority are to grant, suspend or cancel registrations of genetic counselling centres, laboratory or clinic based on their adherence to the Act, to enforce standards, to investigate complaints of breach of the provisions of the Act, and take punitive action. The Act provides for stringent punishment in the case of offences relating to pre-natal sex determination. The proprietor of a genetic counselling center, laboratory or clinic which contravenes the provisions of the Act is punishable with imprisonment of up to three years and a fine of Rs 10,000 for the first offence, and up to five years imprisonment and a maximum fine of Rs 50,000 for subsequent offences.11 The appropriate authority shall recommend immediate suspension of the registration of the offending practitioner, pending conviction, to the State Medical Council; and on conviction, shall recommend removal of the practitioner’s name from the Council Register for a period of five years (first conviction) and permanent removal of the name (second conviction).12

Medical Education Laws

One of the important regulatory activities in healthcare is the regulation of the quality of training of healthcare professionals, which has significance for the quality of services they provide. The legislations which regulate professional registration and conduct (previously discussed), also provide for the regulation of medical education for each of the systems of medicine.

1. Indian Medical Council Act 1956

The Indian Medical Council Act, apart from its function in regulating provider conduct, also seeks to regulate medical education for western or allopathic medicine (and hence, indirectly, the quality of care) through particular provisions which are applicable in the entire country. The Act provides for the constitution of a Medical Council of India (MCI) to oversee medical education. The Council consists of members from the States of the Union, universities and members nominated by the Union Government. The Council elects a President and Vice President, and constitutes an executive committee and other committees from among its members, as necessary.[[13]](#footnote-13)

*New Institutions and Courses:* A new medical college or new course in an existing medical college cannot be commenced without express permission from the MCI. Applications to open a new medical college or commence a new course in an existing college are to be submitted to the Central Government in prescribed form, acompanied by a fee. The application is forwarded to the MCI for its recommendations based on which the Government arrives at a decision. The Council is also required to periodically evolve minimum standards of medical education and revise standards for facilities, staff, equipment, accommodation, curricula, training and facilities needed to run a medical college, and offer relevant courses. A separate Post-Graduate Committee in the MCI oversees courses of higher learning.13

*Concurrent Inspections:* The MCI’s inspection committee appoints inspectors for the inspection of colleges, hospital, or universities according to prescribed standards. The inspector submits his/her report on the adequacy of standards which is then forwarded with comments to the concerned institution and to the Central Government. The committee can also depute visitors to inspect the process of examinations conducted by medical colleges. If recommended, recognition of the college or for a particular course offered by the college may be withdrawn.13

*Professional Registration:* the Act also provides for the establishment of an Indian Medical Register containing the names of all medical practitioners holding a recognized medical qualification in the country, which is an aggregation of the respective State registers. The Registrar of the Indian Medical Council is entrusted with the role of periodically updating the National Register, and Registrars of State Medical Councils are similarly mandated to report additions or deletions in their respective State registers. Any person who possesses a recognized medical degree is entitled to have his/her name entered in the State medical register, on application and payment of a fee. A listing in the Medical register entitles the person to practice medicine in the country; to issue medical and fitness certificates; and to give evidence in inquest in a court of law. Anybody found to be undertaking these activities without registration is liable to be imprisoned for up to one year.13

1. Indian Medicine Central Council Act 1970

The quality of training and entry of practitioners of Indian Systems of medicine is regulated through the Indian Medicine Central Council Act, 1970. This Act was passed for the first time by Union Parliament in December 1970 and is applicable for the entire country. Subsequently there have been further amendments to the Act, the most recent one being in September 2010. The Act defines Ayurveda, Siddha, Unani Tibb and Sowa-Rigpa as the Indian Systems of Medicine.[[14]](#footnote-14) The Act provides for the constitution of a Central Council of Indian Medicine to look into affairs of the Indian medicine in the country. The Council shall consist of five members from States representing Ayurveda, Siddha, Unani Tibb and Sowa-Rigpa respectively; three members from universities of the Ayurveda, Siddha, Unani Tibb and Sowa-Rigpa systems; and members of high repute from the Indian systems of medicine nominated by the central government, not exceeding thirty percent of the total number of members.[[15]](#footnote-15) The council appoints committees for each system of medicine, and vice-presidents corresponding to the respective systems to head these committees.

*New Institutions and Courses*: No institution or a new course or degree in an existing institution can be started without permission from the Central Council.[[16]](#footnote-16) Only those medical qualifications entered in a centrally maintained schedule are recognised. In case of a new qualification, the specific institute may apply for its recognition and inclusion in the schedule. The Central Council also prescribes minimum standards of education in Indian Medicine for corresponding qualifications granted by universities, colleges or boards in India. Each committee of the Indian system of medicine shall from time to time revisit the standards prescribed and report to the Central Council regarding efficacy of the regulations and recommend any amendments if necessary.15

*Concurrent Inspections:* The central council is entrusted with the power to summon, from time to time, such information from the colleges as to the courses offered, duration of the course, examinations held and such other prerequisites for obtaining a qualification. The central council can also depute inspectors for the inspection of examinations conducted by colleges, hospitals or institutions teaching Indian medicine. Similarly, the council can revoke institutional registrations if they are found to be diverging from prescribed standards.15

*Professional registration:* The central council shall maintain a Central Register of providers of Indian Medicine pertaining to all systems of Indian Medicine. This Register shall consist of registered practitioners of the Indian Medicine who are at that particular point in time enrolled either in the state register or the central register. Such a register shall maintain separate parts for the Ayurveda, Siddha, Unani Tibbi and Sowa-Rigpa practitioners of medicine. Any person registered either in the state register or the central register of Indian Medicine is entitled to practise it in any state, to sign medical or fitness certificates, or provide evidence in a court of law; and a person practising in contravention to this shall be punished with an imprisonment of one year, a fine of Rs 1000 or both.15

#### Targeted at: Conduct of Providers

Indian Medical Council Act 1956 (and subsequent Amendments) and Regulations (2002)

The Indian Medical Council Act of 1956 *makes specific provisions, which seek to regulate the professional conduct of health care providers* practising modern allopathic medicine by the precription of a uniform code of ethics and elaborate roles and responsibilities of providers, including the primacy of service to humanity.[[17]](#footnote-17) The Regulations detail the nature of violations by the provider that constitute professional misconduct, and other related strictures.[[18]](#footnote-18) They are both applicable and binding from the time of completion of medical education through registration as a medical practitioner.

*General conduct regulations* include the following: that the provider must maintain proper records of inpatients and outpatients, and medical certificates issued by him/her. The provider is required to display his registration number and also his/her qualifications prominently at the place of practice. Physicians shall expose any misconduct or unethical practice by members of the profession. Fees are to be displayed prominently and declared to patients before treatment, and not after or during the procedure. Those physicians who provide services on behalf of the state are not expect any remuneration for their services from the patients. Physicians are to abide by the various laws and regulations regarding practice of medicine, set forth by the regulators from time to time in the country. The practitioner can engage with the pharmaceutical industry as a consultant or researcher or as a treating doctor provided the involvement ensures professional integrity, patient's interests are not compromised, and such associations are completely transparent and fully disclosed. Endorsements of any drug or product of the industry are not permitted.18

Also detailed are *regulations pertaining specifically to the care of patients*: practitioners should handle the patients with due care, patience and sensitivities; no patient shall be neglected and should be treated in case of emergency. The physician shall neither exaggerate nor underplay the condition of the patient. Unnecessary, unwanted investigations and consultations are to be avoided, and where specialists' expertise is needed, proper referral procedures to be followed. To the extent possible, he/she shall prescribe only generic drugs. The physician shall respect the Human Rights of the patient and shall not aid or abet torture or any such inhuman acts. Before engaging in medical research, the physician is to ensure that the proposed research has received due permission from the concerned authorities, has cleared the ethical clearances at all levels, source and amount of funding is publicly disclosed, and due care is taken in case of human volunteers. 18

A medical practitioner of modern medicine violating regulations shall be construed as *professional misconduct* and shall be liable for *disciplinary action*. In case of professional misconduct by the practitioner a complaint can be lodged with the concerned State Medical Councils by any person for appropriate disciplinary action. The concerned Medical Council shall hold an enquiry giving due chance for both the parties to present their cases. In case of the establishment of the misconduct by the practitioner, the Medical Council shall direct appropriate action and also order removal of the name of the practitioner, either permanently or temporarily from the registry, depending on the severity of the offence committed. The deletion of the name must be publicized widely in various publications, medical associations and other bodies. The action against the practitioner shall be taken before the expiry of six months of the complaint being lodged. In the event that the concerned State Medical Council does not decide upon the complaint within the period of six months, the Medical Council of India shall take it upon itself either to impress upon the concerned State Medical Council to expedite the matter within a time-bound schedule, or may withdraw the case from the State Medical Council and refer it to the Ethics Committee of the Medical Council of India and take steps to expedite the same within the six months of the registration of the complaint at the Medical Council of India.[[19]](#footnote-19) Any person aggrieved by the decision of the Council has the right to appeal with the MCI against the ruling within the 60 days of the Council's order. In the case that the concerned Medical Council orders for the removal of the erring practitioner's name from the register for a specific period, then it shall be incumbent upon the concerned Medical Council to take necessary steps to restore the name of the practitioner in the medical register at the expiry of the said period of time.18

The Indian Medicine Central Council Act 1970, and Regulations (1982)

The Indian Medicine Central Council Act, 1970 provides for the regulation of the conduct of the providers of Indian systems of medicine, and prescribes independent standards for the conduct of these professionals.[[20]](#footnote-20) In accordance with this provision provided in the central act, a practitioners of Indian Medicine (Standards of Professional Conduct, Etiquette and Code of Ethics) Regulations, 1982 was passed. Broadly similar to the provisions of the Indian Medical Council Act, these regulations outline the responsibilities of the practitioner as a renderer of service to humanity.[[21]](#footnote-21)

*Conduct regulations* include prohibition of advertisement of services and direct or indirect solicitation of patients. A practitioner is required to display qualifications clearly at the place of practice. Contracts of the nature of 'no cure, no payment' with patients are prohibited. The practitioner is required to respond to emergencies and to not discriminate between patients on the basis of caste, class, religion or any other such attributes. The practitioner shall handle patients delicately and with utmost patience and sensitivity. The practitioner shall, if need be, participate in public health work and shall notify the authorities on communicable and non-communicable diseases.21

The Act provides for *disciplinary action against professional misconduct*. When the actions of the practitioner run contrary to the foregone provisions then it is construed as professional misconduct, and disciplinary action is warranted. Action is also taken against the practitioner in case of adultery or improper conduct with the patients or conviction in a court of law for criminal offences or violations of the Drugs and Cosmetics Act, 1940. In case of complaints of professional misconduct, the Council shall take note of this and institute an enquiry giving opportunity for the practitioner to be heard. If the practitioner is found guilty of professional misconduct then his/her name is removed from the register, either for a fixed time or permanently as the case may be. If the practitioner applies to the Central Government for restoration of his/her name in the State medical register, and the central government are in concurrence with the central council for the same, it can overrule the State council or board.21

### *Roles of regulatory organizations*

#### Targeted at: Costs of Care

Health Insurance Schemes

The health insurance sector in India has a role to play in the regulation of the cost of health services. While various health insurance companies exist both privately and publicly it is predominately the government health insurance schemes that currently maintain a wide reach in coverage and number of policy holders. In order to qualify with an insurance company a hospital must meet and maintain a certain set of pre-defined input parameters that relate to their facilities and their services. The agreed-upon payment packages between insurers and hospitals differ across providers based on the level of quality of care provided. Insurance companies also regulate the cost of services provided within these facilities through the establishment of pre-defined and pre-paid packages for procedures and drugs. Hospitals that aim to be listed under an insurance company must agree to these arrangements from the beginning. Pre-informed packages are especially prevalent in government health insurance schemes.

The Rashtriya Swasthya Bima Yojana (RSBY) is one example of a government insurance scheme that operates under these conditions. RSBY is India’s national social health insurance program, which was launched in early 2008 to provide health insurance to individuals living below the poverty line. Beneficiaries are entitled to hospitalization coverage of up to Rs. 30,000 for most diseases. Beneficiaries need to pay a fee of only Rs. 30 as the registration feel, and the national and State government pays the premium to the insurer. RSBY covers the cost of secondary care hospitalization and utilizes cashless transaction method where the beneficiary can avail services with the swipe of a Smart Card.

RSBY is administered by *nodal agencies* under the aegis of the Ministry of Labour and Employment in different States. RSBY contracts the task of beneficiary enrolment to insurance companies. There are 11 different insurance companies in 24 States. The government also takes the responsibility of choosing the various hospitals to provide services. Interested hospitals must meet certain basic parameters, which address infrastructure, access to supplies, and adequate human resources. In order to qualify for the scheme the hospital must also have a formal relationship with pharmacy to provide medicines to RSBY recipients. Once a hospital has been empanelled it can provide pre-authorized services, without having to obtain approval from the insurance company prior to conducting a procedure. The risk of inflated claims for procedures by the hospitals is reduced through a system of checks and balances where the insurance company oversees hospital transactions. Additionally, in order to prevent the occurrence of insurance fraud insurance companies have set up a database that contains details on beneficiary hospital activities.

To date there are 19.5 million smart cards in 24 States and approximately one million users. Presently, across the country approximately 6000 hospitals are empanelled with the RSBY scheme with a third of them being public facilities and two-thirds of them private. According to respondents, initially hospitals were reluctant to pursue RSBY empanelment due to its stringent standards and efforts for start-up, but over time they have found a business model in it that they have found beneficial. Large tertiary care hospitals are less likely to enlist in the RSBY program. Most of the interested facilities consist of smaller nursing homes. The scheme is present in the rural and urban setting, which has also contributed to the availability of health services. Some cases of fraud were reported in the form of collusion between the beneficiary and the facility. At the time of the interview approximately 60 hospitals had been de-empanelled for this reason. The government is currently working to build mechanisms to reduce fraud in the RSBY program.

#### Targeted at: Quality of Care

Medical Council of India

*(See page 48 for details of the putative roles of the MCI in regulating the quality of medical education, in accordance with the IMC Act 1956 and Amendments.)*

Indian Central Council of Medicine

*(See page 49 for details of the putative roles of the MCI in regulating the quality of medical education, in accordance with the IMC Act 1956 and Amendments.)*

National Accreditation Board for Hospitals and Healthcare Providers (NABH)

Accreditation is regarded as a mechanism that will encourage establishments to voluntarily create systems for quality control and accountability. The focus of accreditation is a continuous process of improvement that is relevant to systems, processes, and most outcomes. The National Accreditation Board for Hospitals and Healthcare Providers (NABH) is a constituent board of the Quality Council of India, set up to establish and operate an accreditation program for private and governmental health care organizations. The NABH is a statutory and autonomous body that was established in 2006 with a board comprised of 19 people, with 30% from government, 30% from industry, and 30% as consumer representation. As per its constitution at the time of set up, half of the NABH’s funding came from the government and half from industry. However, over time the amount of funding from the government has significantly decreased.

NABH has different sets of standards for hospitals, laboratories, radiological facilities, blood banks and urban primary health centers. The standards are the same for both public and private facilities. In order to get accredited a health care facility must undergo an assessment by a team of trained professionals, which includes nurses, administrators, and clinicians. NABH has compiled an exhaustive list of health care standards for accreditation for hospitals and healthcare providers, which includes over 500 objectives. The accreditation standards focus on established processes that begin from the point of registration, and include admission, surgery and hospital discharge protocols. In addition to the clinical aspects hospital governance and management is also examined. Approximately 60 percent of the standards are clinically related and 40 percent are managerial. If facilities fail to continually meet standards then the NABH has the authority to withdraw the accreditation. In addition to the process of accreditation, the NABH also runs awareness campaigns, newsletters, school education, and other advocacy initiatives.

According to representatives of NABH: 70-80 government hospitals across the country are under preparation for accreditation. 20 had been pre-assessed at the time of the study, and 5 government hospitals have received accreditation. In the private sector there have been approximately 50 accreditations. Of those that had applied 3 had been refused accreditation because they did not meet standards. No facility has yet been de-registered.

National Consumer Disputes Redressal Commission

The National Consumer Disputes Redressal Commission (NCDRC) is a quasi-judicial regulatory mechanism that was constituted in New Delhi in 1988.  It was established under the auspices of the Consumer Protection Act (CPA) of 1986, which intends to safeguard the interest of consumers, protect them from exploitation and to save them from adulterated and sub-standard goods and services. The NCDRC is headed by a sitting or retired Judge of the Supreme Court of India as its President, along with eight other distinguished judicial members. The NCDRC is delegated with administrative authority over the State Commission, which must report periodically to the National Commission on its activities and case activity. The NCDRC also has the authority to determine procedures in the hearing of matters in the State and district commissions and in general oversight to ensure that the objectives and purpose of the Act are served.

The NCDRC deals with cases where the claims value over Rs 10 million. In the case of health services, the majority of cases dealt with by the National Commission are those of death or disability of an individual due to medical negligence. The cases are heard by the 9-member panel, and expert medical opinions are solicited as appropriate by qualified authorities and experts in the field. The final judgment regarding the case is then taken by the 9-member panel.

#### Targeted at: Conduct of Providers

Medical Council of India

*(See page 51 for details of the putative roles of the MCI in regulating the conduct of allopathic medical practitioners, in accordance with the IMC Act 1956, Amendments and Rules & Regulations)*

Indian Central Council of Medicine

*(See page 51 for details of the putative roles of the ICCM in regulating the conduct of practitioners of the Indian systems of medicine, in accordance with the IMCC Act 1982, Amendments and Rules & Regulations)*

## Madhya Pradesh State

### *Background and context*

#### Madhya Pradesh – The State

Madhya Pradesh is a vast State with an area of 308,245 sq km - it has 50 districts, 313 blocks and 55,393 villages.[[22]](#footnote-22) The State has the highest area of forest coverage in the country at 154,497 sq. km (nearly 50%),[[23]](#footnote-23)and has a large tribal population with 28% of the blocks declared as tribal blocks.[[24]](#footnote-24) According to last Census held in 2001 the State contains nearly 23% of India's tribal populations and there are 46 tribes identified who dwell either in the forests or on the fringes of the forests. The population is predominantly rural with three-fourths of the population living in rural areas.[[25]](#footnote-25) The population density of the State is just 195 persons per sq. km whereas that of India is 312 persons.[[26]](#footnote-26) Madhya Pradesh is also one of the poorer States. The per capita income of Madhya Pradesh was Rs. 8000 in 2004-2005 whereas that of India was nearly Rs. 12000.[[27]](#footnote-27)

#### Health Profile of Madhya Pradesh

Madhya Pradesh is characterized by poor health status indicators. Life expectancy at birth in the State is 59 years for male and 58 years for female27 while the corresponding figures for the country are 63 years and 66 years respectively.[[28]](#footnote-28) The estimated birth rates, death rates and infant mortality rates in 2008 for Madhya Pradesh (India) were 28.0 (22.8), 8.6 (7.4) and 70 (53) respectively.[[29]](#footnote-29) The Maternal Mortality ratio is 335, against the national figure of 254.[[30]](#footnote-30)Seventy four percent of the children in MP suffer from Anaemia, second of all the States in the country. 47% of the children below the age of three years are stunted (low height for age), 40% are wasted (low weight for height) and 58% of the children are underweight (low weight for age).[[31]](#footnote-31)

#### Health Care Services in the State

The difficult terrain of Madhya Pradesh provides a formidable challenge to the delivery of healthcare services. The State has a mixed healthcare provision of services. It consists of public, private and missionary and non-governmental organizations. The rural public health system at the primary level consists of sub health centres (SHC), primary health centres (PHC) and community health centres (CHC), expectedly for populations of 5000-6000, 30000 and 100,000 respectively. The corresponding population standards for tribal and remote areas are 3000, 25000 and 80000, respectively. In 2008, there were 8834 SHCs, 1149 PHCs and 270 CHCs in Madhya Pradesh.[[32]](#footnote-32) At secondary level there are 50 district hospitals in each of the district headquarters and 54 civil hospitals at sub-district level. Cities in MP are serviced by 96 Urban Family Welfare centres, 80 Urban Health Posts and 92 Civil Dispensaries.[[33]](#footnote-33)The public health system is characterised by significant deficiencies of infrastructure and human resources. There is a total shortfall of 1568 SHCs, 521 PHCs and 147 CHCs. 574 SHCs (36.6%) have no designated female health worker, 262 PHCs (22.8%) have no doctors, and there are 727 specialists' positions (67.3%)vacant in the CHCs and District Hospitals in the State.33

#### The Public Private Mix

Ninety-two percent of the hospitals in rural areas are government-run (657 / 714), whereas private facilities are dominant in urban areas with 69.8% (1080 / 1546) of listed hospitals. The private sector, however, is completely dominant in the primary and outpatient sectors, with 133,412 clinics compared to the 10,160 government SHCs, PHCs, Urban Health Posts and Civil Dispensaries. Practitioners of all the systems of medicine (Allopathy, Ayurveda, Unani, Siddha and Homeopathy) also work in the state. Out of the total 24,807 qualified doctors in the states, 77.3% serve in urban areas. In cont rast, qualified non-clinical professionals (paramedics, pharmacists laboratory technicians etc) number 71.5% (67153 out of 94019) of service providers in rural areas (De Costa and Diwan 2007).

### *Relevant laws and policies*

This section describes relevant laws and policies which are operational in Madhya Pradesh State. Throughout this section, the putative roles – regulatory activities expected – of various State organizations (as mandated by State laws and policies), are highlighted against a grey background.

#### Targeted at: Costs of Care

Janani Sahyogi Yojana

Madhya Pradesh government launched this scheme as part of its innovation under the National Rural Health Mission (started by the Union government in 2005 throughout the country) in October 2006. Through this scheme, private and non-government service providers are enlisted for providing safe motherhood and childcare services to families of the economically weaker sections (Below Poverty Line of BPL) free of cost. Through a government order, private service providers are solicited to provide the ante-natal care services, sonography, pathology services, normal and complicated delivery services, blood transfusion, Caesarian section deliveries, Caesarean hysterectomy and post-partum examination. Other services included are the medical termination of pregnancy services and child health related services. The private facilities are reimbursed on a fees-for-service basis (previously capitation payments were used, which reportedly led to problems of moral hazard).[[34]](#footnote-34) The fees for each of the above services is pre-determined and the private facilities are reimbursed accordingly. In order to get enlisted for this scheme, the private facilities have to fulfil certain regulatory conditions. In the first place, the private facility must be a registered clinical establishment. Facilities are classified based on location and number of beds. Each facility should have a resident gynaecologist 24 hours a day, and a paediatrician and anasthetist are required to be available on call.[[35]](#footnote-35)

The private facilities are required to submit weekly report to the *CMHO* over email, detailing the various cases handled by the facility during the week. This report is to be further forwarded by CMHO to the Divisional Joint Director and the State Directorate. 10% of the cases handled by the private facilities are to be physically verified for authenticity, failing which necessary actions in accordance with the contract signed by the private facility. The facilities are to be constantly monitored and in case that caesarian section deliveries exceed 35% in any facility, then this is stipulated to warrant physical verification by the monitoring authority before the payment is reimbursed.35

#### Targeted at: Quality of Care

Madhya Pradesh Upcharyagriha Tatha Rajopchar Sambandi Sthapanaye (Rajistrikaran tatha Anugyapan) Adhiniyam 1973

The State of Madhya Pradesh enacted its Clinical Establishments Act in 1973. Its official title is the Madhya Pradesh Upcharyagriha Tatha Rajopchar Sambandi Sthapanaye (Rajistrikaran tatha Anugyapan) Adhiniyam, 1973 which translates to Clinical Establishments Registration and Licensing Act. The Act provides a statutory and legal basis for the regulation of the clinical establishments with regard to physical infrastructure and personnel.

Every clinical establishment which aims to offer healthcare services must apply for registration or renewal, in the prescribed form and fees, to the *Chief Medical and Health Officer (CMHO) of the respective district*. The act excludes clinical establishments run by either the local self government, state government or the union governments from the purview of the respective Acts. The CMHO is the supervising authority designated for granting the certificate of registration and renewal of the clinical establishments. The CMHO may grant the certificate on being satisfied that the proposed clinical establishment is fulfilling all the necessary standards with regard to its construction, staff qualifications and their requisite numbers, accommodation requirements and equipments or reject on the conditions not being satisfied. The clinical establishment is mandated to maintain record of each patient and also of each child born in the prescribed format and also notify any death of the patient in its premises within 24 hours.[[36]](#footnote-36) The CMHO can cancel the registration, upon conviction, if it is being run in contravention to the provisions of registration. The CMHO is empowered to impose penalties where the establishment is operating without a proper registration. The quantum of penalties are also determined with a sum of fifty thousand rupees for first offence, and subsequently one lakh rupees for a repeat offence. The establishment or its records can be subjected to inspection either by the CMHO or any officer deputed by the State Government.[[37]](#footnote-37)

Madhya Pradesh Ayurvigyan Parishad Adhiniyam, 1987

The Madhya Pradesh Government enacted the legislation Madhya Pradesh Ayurvigyan Parishad Adhiniyam, 1987 (Madhya Pradesh Medical Council Act, 1987) in July 1990. This Act establishes the *Madhya Pradesh Medical Council* in the State, with the official title of Madhya Pradesh Ayurvigyan Parishad. The Council shall consist of five members elected from among the enrolled members in the State medical register; Director of Medical Services and five members to be nominated by the State government of which one shall be a representative from Indian Medical Association, one from the medical faculties in the State, two persons from the state health services and one Dean of a medical college. The Director of Medical Services is to be the ex-officio President and the Dean of the Medical College, the ex-officio Vice-President. The council shall meet for a minimum of 2 times in a year.[[38]](#footnote-38)

Registrars shall be appointed to have the functions of both the secretary and treasurer of the council. The Registrar has the putative function of preparing and maintaining the State Medical Register; to receive completed registration applications for entry into the State Medical Register from persons who have completed the recognised medical qualifications in the prescribed form and accompanied by prescribed fees and Issuance of registration certificates (including a provisional certificate for a period of maximum of 1 year) for every registered person; registration of the additional qualifications of the medical practitionersand submitting the updated list of the State medical register to the Indian Medical Register.[[39]](#footnote-39) At present there is no provision for the renewal of the registration after a certain period of time. The Madhya Pradesh Medical Council also has no role to play in the approval of medical colleges, the specific courses or curriculum of the courses.

Madhya Pradesh Ayurvedic, Unani and Prakritik Chikitsa Vyavasayi Adhiniyam 1970

The *Madhya Pradesh Ayurvedic, Unani tatha Prakritik Chikitsa Vyavasayi Board* was constituted by the Madha Pradesh Ayurvedic, Unani tatha Prakritik Chikitsa Vyavasayi Adhiniyam, 1970 (Madhya Pradesh Ayurveda, Unani and Natural Medicine Practitioners Act) which first came into being on January 30, 1969. One notable attribute of this act is that it precedes the Indian Medicine Central Council Act, 1970 and hence recognizes Ayurveda, Unani and Natural Medicine (natural remedies) streams as well [[40]](#footnote-40). This is the main difference between the Madhya Pradesh Act and the Central Act. The Act provides for the constitution of the Board. The Board shall consist of a Joint Director of Ayurveda; Assistant Director, Ayurveda; a registered practitioner of Indian Medicine from each of the divisions elected from among themselves; five to ten persons nominated by the government from among the professors in Ayurveda or Unani or natural remedies in government colleges.[[41]](#footnote-41) The president and vice-president to be elected from among the members of the Board. The Board has to meet a minimum of two times in a year.

The Board shall have a Registrar as the secretary for the board. The Registrar has the putative function of registration of the practitioners of Indian Medicine on due verification of the practitioner's qualification. The Registrar shall also maintain and update the register with additions and deletions. The qualified practitioners have to submit their application for the registration, in prescribed form and fees, to the registrar. Additional qualifications can also be subsequently registered. There is scope for provisional registration for training and internship purposes.40

Quality Assurance Procedures for Reproductive & Child Health Services

The Madhya Pradesh Department of Health has started to implement the Quality Assurance Procedures for its Reproductive and Child Health services since 2006. Quality is sought to be improved by systematic monitoring and improvements in delivery of services. The goal is to enhance quality assurance through the District level management by continuously monitoring the quality of delivery of the reproductive and child health services provided by the Sub-Health Centres (SHC), Primary Health Centres (PHC) and Community Health Centres (CHC) and to work towards progressively improving the shortfalls identified during the monitoring.[[42]](#footnote-42)

The *District Quality Assurance Group (DQAG)* are formed at the District level to work towards Quality Assurance at that level. The DQAG shall be a group of people drawn from both the district health services people and the district program management unit. The DQAG shall consist of 3-4 officials from the District supervisory level, out of which one shall be a woman and another from the Rogi Kalyan Samiti of the District Hospital, a District Quality Assurance in-charge (DQIC) - drawn from the senior district level officials - designated by the Chief Medical and Health Officer (CMHO) of the District and a representative of an NGO which is active in the District. The Chief Medical and Health officer of the District shall be the Chair and the District Quality Assurance in-charge shall be the member secretary of the group.

The putative functions of the secretary of the DQAG are planning of the QAG visits to the facilities; making necessary preparations for the visits, compilation of the findings; preparing a district summary report; providing feedback to the facilities with guidance for corrective action and forward the minutes of CMHO and also to the Deputy Secretary, Maternal Health with the Directorate of Health Services. In addition to the above, training on all aspects of Quality Assurance for the members of DQAG and all the levels of personnel in the public health system is envisaged, which includes sensitisation of the personnel to the quality aspects. The same team is also involved in monitoring the implementation of the Standard Treatment Guidelines in the case of maternal and child health. Standard Treatment Guidelines with the accompanied flow-charts are prepared for various conditions of labour. Similarly there are flow charts of standard treatment guidelines for conditions of anaemia during pregnancy, for ante-partum haemorrhage, eclampsia, puerperal sepsis and prolonged labour.42

#### Targeted at: Conduct of Providers

Madhya Pradesh Ayurvigyan Parishad Adhiniyam, 1987

The Madhya Pradesh Medical Council follows the Madhya Pradesh Ayurvigyan Parishad Adhiniyam (MP Medical Council Regulations) for regulation of the professional conduct of allopathic medical practitioners.

On receipt of a complaint against the practitioner, or if a practitioner has been convicted in a criminal offence by a court, the *Madhya Pradesh Medical Council* shall conduct an in-camera inquiry giving an opportunity for the practitioner to be heard in person. If found guilty of the conduct by a two-thirds majority verdict in the council voting, the council shall order for the suspension of the registration of the practitioner for a specific period, or permanently as the case may be. The Council shall also take steps to restore the temporarily suspended names on expiry of the term.[[43]](#footnote-43)

Madhya Pradesh Ayurvedic, Unani tatha Prakritik Chikitsa Vyavasayi Adhiniyam, 1970

The State Act for professional conduct of practitioners of Indian systems of medicine does not provide for all of the exhaustive provisions that the Central Council stipulates for the regulation of practitioners of Indian Medicine for professional misconduct.

The Act provides for the de-registration of the practitioners of Indian medicine in the case of an adverse ruling against the practitioner in a court of law; if the practitioner is found to have submitted false certificates and in case of establishment of professional misconduct. On proof of guilt by the practitioner, the Board shall remove the name of the practitioner from the register for a specific period of time or permanently as the case may be. The practitioner has a chance to appeal to the State government in case he/she is not satisfied with the order within three months of the passage of the order. Practice of Indian Medicine by non-registered practitioners is not allowed and can be punished with a fine upto rupees one thousand.[[44]](#footnote-44)

#### Targeted at: Accessibility of Care

Rural Medical Bonds

The government of Madhya Pradesh has made it explicit that the students who have been selected for Bachelor in Medicine, Bachelor in Surgery (M.B.B.S) and Bachelor of Dental Surgery (B.D.S) courses in Government medical colleges have to execute a bond at the time of their selection. The Bond specifies that they have to serve with the Government of Madhya Pradesh in rural areas for a specified period after completion of their internship. The Bond amount in case of failure to adhere to the above rule is Rupees 0.5 Million for general candidates and Rs 0.3 Million for students of Schedule Castes (SC), Scheduled Tribes (ST) and Other Backward classes (OBC). The period of service shall be as notified by the Government from time to time.[[45]](#footnote-45) Students selected in the open category for Postgraduate or for Post-Graduate Diploma admission to any Government Medical or Dental Collegeare subject to a similar Bond for at least 2 years service under the State Government in rural areas failing which the candidates have to pay an amount of Rupees 1 Million in the case of Postgraduation and Rs 0.8 Million in the case of Post-graduate Diploma. In-service candidates, who are working on a continuous contractual basis with the State department of Public Health and Family Welfare have to execute a Bond that after successful completion of his/her course, shall serve for 5 years under the State Government in rural areas in the case of Post-graduation or 3 years in the case of Diploma, failing which the candidates have to pay an amount of Rupees 1 Million in the case of Post-graduation and Rs 0.8 Million in the case of Post-graduate Diploma.

Deans of the respective medical colleges are required send the list of candidates appearing for their final examinations, to the *Commissioner of Health Services* three months before the candidates appear in the exams. The Commissioner of Health Services shall make arrangements for the placement of the students. Upon successful completion of the course, the students have to be offered an appointment before the expiry of three months of the declaration of the examination results failing which the bond shall become null and void.45

### *Roles of regulatory organizations*

This section describes various regulatory organizations and structures which are operational in Madhya Pradesh State, and their *expected* and *actual* activities, based on first-hand accounts of representatives of these organizations, and review of relevant documents. Throughout this section, the putative roles – regulatory activities expected – of the various organizations, are highlighted against a grey background, and their actual activities are highlighted by the use of square borders.

#### Targeted at: Costs of Care

Madhya Pradesh Directorate of Health Services

*(The Office of the Chief Medical and Health Officer (CMHO) of the Directorate of Health Services is mandated with the task of implementing the Janani Sahayogi Yojana [see page 58]. Details of the constitution, financing and other functions of the DHS are presented in the sub-section on Quality of Care.)*

In terms curtailing costs of maternal health care, the Janani Sahayogi Yojana has been a way to enhance access to institutional deliveries. At a minimum a private facility must have a minimum of 6 nurses, an in-house gynaecologist, hired aesthetic and paediatrician, ambulance facility. Non-traditional and market-based mechanisms such as these are slowly making their presence known within the public health system context through steadily increasing public-private partnerships. There are currently 20 hospitals in the State that run the JSY scheme, and at the time of conduct this study, there was not enough experience of its implementation at scale, for implementers to comment on.

#### Targeted at: Quality of Care

Madhya Pradesh Directorate of Health Services

The Directorate of Health Services (DHS) of the Government of Madhya Pradesh is the body in charge of formulating and implementing health care policies to increase the presence and purpose of the public health system in the State. It is a governmental entity, equipped with the capacity and responsibility to undertake various aspects of health care regulation, which aim to increase availability and quality of health care provision under the banner of the public health system. In various instances, these also include public-private partnerships in health care within the State.

The DHS has an elaborate organizational structure that ranges from the level of the Chief Minister of the State at the head to the Sector Level Medical Officer at the field. The different levels of the DHS engage in a variety of activities that range from the formulation and administration of policies, addressed by higher level Secretaries, Joint Directors and Deputy Directors, to implementation of these policies by those engaged at the district level. The DHS serves more as a technical body, and focuses on the oversight and management of the policy process, while at the district level; the Chief Medical Health Officer (CMHO) is the primary appropriate authority in charge of policy and program implementation. There is one CMHO per district, and he/she reports directly to the Regional Joint Director of Health Services. The CMHO works in collaboration with various NGOs, external consultants, and other authorities at the district level, such as the District Collector and District Magistrate to implement defined health programs and policies. Partnerships with external entities are becoming increasingly ubiquitous within the health system, and in many cases seen as necessary to fulfil health system needs.

The DHS follows a traditional approach to the regulation of health services and predominately employs legal controls such as the Clinical Establishments Act (CEA), Medical Termination of Pregnancy Act (MTP), and Pre-Conception and Pre-natal Diagnostic Tests Act (PCPNDT). The following section will aim to outline the various regulatory measures undertaken by the DHS, and briefly outline the experience in the implementation of these measures.

1. Clinical Establishments Act

The MP Clinical Establishments Act (CEA) was established to ensure that through registration and licensing of private health facilities, basic requisites of infrastructure, equipment, and qualified human resources would be present at health establishments as to provide a minimum standard of quality. The administrative responsibility of the CEA lies with the Hospital Administration Cell within the DHS, with the role of enforcement and implementation being in the hands of the Chief Medical and Health Officer (CMHO).

On receipt of an application from an interested facility for registration, a team from the CMHO office is dispatched to conduct an on-site inspection. Once it is ensured that basic standards are met the facility is granted registration by no later than the following day. If registration is rejected then the facility is informed of its shortcomings and can re-apply at a later date.

The CMHO office undertakes routine inspections along with a team comprising the Sub-divisional Magistrate, a doctor, and a police representative. Five teams from the CMHO’s office are assigned to CEA related tasks. Each team is assigned approximately 20-30 establishments for inspection for registration and renewal. The CEA mandates renewal of registrations of clinical establishments every 3 years. At the time of the renewal inspection, if the basic standards are not upheld then the registration is not granted. In the event a facility is being run in contravention of the provisions of registration, the CMHO can cancel the registration or impose penalties.

The CMHO, as part of a similar team comprising the SDM, a physician and a police officer, are also mandated to identify unregistered and unqualified practices and shut them down. These inspections may be routine, or pursuant to complaints received from the general public.

The process of registration under the CEA in MP is yet to occur in its full capacity. Although the Act was introduced in 1973, the Rules were not framed until 1992, and its implementation did not begin until 2007. The Act was highly contested at the High Court level, due to opposition against its strict rules by various entities. It was only after 28 amendments were made to the original act that it was put into motion. Therefore, at the time of the interview the process used for registration holds interested establishments accountable only to some key points of the CEA in order to grant registration, not all of the requirements listed in the amended Act.

It was stated that the effort to inspect facilities and to conduct monitoring of the CEA were catalyzed in the recent past largely due to the petitions put forth by various social organizations and NGOs. *Human resource constraints* were reported to be a severe impediment to the CMHO in conducting inspections. Due to shortage of medically qualified staff in particular (a required member of the team conducting inspections); practitioners from various district hospitals are frequently solicited for their participation in this effort, often unsuccessfully, since they are unable to spare time. The other members of the team – sub-divisional magistrate and police officer, were also reported to be frequently unavailable. Once a team is mustered, inspections are conducted in accordance with the Rules, and the nursing home in question is intimated of shortcomings, and asked to rectify them.

Putatively, if a nursing home does not rectify its shortcomings, it is liable to be de-authorized (de-registration). However, this seldom occurs, partly due to long-drawn and frequent contestations by the establishments, and partly because de-registration is sometimes regarded as a low priority concern by higher authorities. The respondent indicated that Nursing Homes frequently contest de-registration notices. In one instance 15 diagnostic laboratories were proposed to be de-registered. According to rules, one medical pathologist may run no more than 2 such diagnostic laboratories; however it was observed that in some instances, individuals were running 6-7 laboratories, some of which also did not meet the criteria for registration. These de-registrations were hotly contested by the owners, and the CMHO offices faced widespread criticism. A respondent from the DHS offices reported how at one time, de-registrations were delayed due to a departmental drive to compile statistics for swine influenza. Further, deregistration was reported to be something that ‘had to be handled delicately’, as the DHS is sometimes reliant on private health establishments for health information data.

De-registration of an establishment is merely a notional procedure, and while it is expected to be followed by closure of the establishment, in actuality this does not always take place. Actual orders for closure must emanate from the SDM’s office, and the physical act of closing down an establishment is to be undertaken by the police – these procedures are frequently delayed due to busy schedules and the requirement of coordination between multiple departments. Similar difficulties were reported for the allied activity of identifying un-registered establishments for closure. Since registration is a paid activity without very tangible benefits to the establishment, it was common for establishments to function without seeking registration. Respondents indicated that this was being corrected through awareness campaigns, but the difficulty of identifying all such establishments made it difficult to enforce the registrations. The CMHO offices also attempt to increase awareness of the requirement for *renewing* registrations, and about the mandatory conditions for registration, through periodic meetings with the medical fraternity. Some establishments reportedly have been proactive in initiating the renewal process themselves.

Under the CEA, facilities are also mandated to submit periodic health information reports in/outpatient records for births and deaths. Only about 50 percent of the registered facilities were said to comply with these standards, and those which did not were sent warning letters.

It was also reported that the lack of technical regulations for establishments run by practitioners of Indian Systems of Medicine & Homeopathy, was an obstacle to their regulation. In the absence of written specifications of practice, said one respondent, court authorities did not permit for these establishments to be held liable for anything other than practicing the wrong system of medicine.

1. Medical Termination of Pregnancy Act

The Medical Termination of Pregnancy (MTP) Act provides a legal basis for the termination of pregnancy by a registered and qualified medical practitioner. An MTP can be conducted on pregnancies up to twelve weeks if there is one medical practitioner, or from twelve weeks to not later than twenty weeks if two medical practitioners are of the opinion that the continuation of the pregnancy poses great danger to the life of the mother or the chances of physical or mental deformities of the child born are higher. Medical termination is also envisaged when the pregnancy has occurred due to rape and if it is felt that the continuation of the pregnancy can cause injury to the mental health of the woman. Similarly termination can be done when unwanted pregnancy happens as a result of the failure of the contraceptive device and if it is felt that this might result in an injury to the mental health of the woman.

In the State of Madhya Pradesh, the CMHO is entrusted with the role of inspection, verification and approval of private facilities wanting to offer MTP services. At any point if the standards within the facility, as outlined by the MTP Act are not maintained the CMHO has the authority to cancel the registration of that establishment. As is the case with the PCPNDT Act, periodic reporting on the number of procedures performed is to be regularly sent to the CMHO by registered facilities. Upon compilation of this data it is sent to the Deputy Director in charge of the RTI, who oversees the administration of the MTP Act.

Inspections of laboratories for suspected violations of the MTP Act are conducted following complaints, which are rare. Routine and surprise inspections too are rarely undertaken, and regulation is largely passive through receipt of periodic reports from the establishments doing MTP. MTPs were assessed to be more frequent in actuality than are reported by respondents, and it was also reported that aspects of the MTP act, such as the requirement of two doctors assent to the MTP at the time of the procedure, are difficult to ensure. Critically also MTP was regarded to be a low-priority subject for the DHS, being superseded in importance by PCPNDT, among others.

Similarly to PCPNDT, a key bottleneck to implementation of the Act is that it is predicated on the assumption that the establishment is registered under the CEA, which is not always the case. There are also numerous quacks reported to be doing MTPs, which remains broadly unregulated.

1. Department of Maternal and Child Health – Standard Treatment Protocols

The Department of Maternal and Child Health within the Directorate of Health Services of Madhya Pradesh utilizes defined Standard Treatment Protocols as a mechanism for ensuring a consistent level of quality in maternal and reproductive health services. The Standard Treatment Protocols used by the MCH department are guidelines issued by the Government of India for Skilled Birth Attendants (which include doctors, nurses, LHVs, and ANMs – who provide services at the PHC level and below). There is also a module specifically designed for Medical Officers who operate at Emergency Obstetric Care facilities, which includes a step-wise flowchart procedure for what to do in the case of Post Partum Haemorrhage. There are also Standard Treatment Protocols for Newborn Care Units in setting of district hospitals. This protocol falls under the purview of the Child Health department, and was formulated with the help of experts from the Indian Paediatrics Association, WHO, and AIIMS.

This effort is overseen by the Deputy Director of MCH, who is accountable to the Divisional Joint Director. The Deputy Director is in charge of the MCH initiative and is supported by an NGO-based consultant, to conduct post-training follow-up and monitoring of the quality of training. It is the responsibility of the CMHO to make sure this is implemented.

In an effort to increase the quality of services provided in the context of MCH, training of trainers have taken place over the last 3 years. In addition, written IEC materials have also been developed for the STPs for display in various parts of the labour delivery room. Doctors’ case sheets are monitored for details, and a checklist for monitoring use of the STPs. However there is no procedure for corrective action, if it is found that the STPs are not being followed.

Madhya Pradesh Medical Council

The Madhya Pradesh Medical Council, established in 1996, is a legislative and self-regulatory mechanism that regulates the entry of practitioners into medical practice by overseeing provider licensing and practices in the State. As per the provisions fixed by the Directorate of Medical Education Madhya Pradesh Act 1987 only those individuals with medical qualifications recognized by the Indian Medical Council Act, 1956 can be registered to practice modern scientific medicine in the State of MP. Additionally, the Council seeks to regulate the professional conduct of the providers through the implementation of regulations for ethical conduct of the providers (see page 71).

The Medical Council in Madhya Pradesh consists of an appointed President, an ex-officio member from the Directorate of Health Services; an appointed Registrar, who is also posted at the Directorate of Health Services, and a Deputy Registrar. Both, the President and Registrar divide their time between the DHS and Council responsibilities and are accountable to an elected Executive Board, consisting of a representative from the MP Medical Association, a medical faculty member, and a member from the Directorate of Health Services. Unlike the President and Registrar, members of the Executive Board are chosen through election.

The MPMC falls within the purview of the national level body, the Medical Council of India (MCI), which loosely dictates its activities. While it receives basic funding from the MCI to carrying out routine operations, other activities can occur only through the means of self-financing that is generated predominately through granting of registrations for the practice of medicine.

The function of provider license registration for government and private practitioners of allopathic medicine is carried out by the Registrar and Deputy Registrar throughout the year, and are updated at the national level every quarter of a year. At present the registration of practitioners is a one-time procedure, with no provisions in MP that mandate the renewal of medical registrations. However, an amendment to the present provisions of the Madhya Pradesh Medical Council Act, 1987 has been proposed to include the renewal of registration as a requirement every 3 years to 5 years.

A variety of registrations for medical practice within the State are provided, and include Permanent Registration, Provisional Registration, Registration of Additional Qualification, and an Issue of Good Standing Certificates for doctors going abroad. The explicit purpose of introducing mandatory periodic renewals of registrations is to introduce a mechanism that can indirectly address the quality of health services provided. However, the underlying and practical reason is for the generation of funds. This is with the hope to mitigate the hindrance caused the ongoing shortage of funds in the planning and implementation of activities that relate to Continuing Medical Education for providers and to enable expansion of services provided by the Medical Council to members.

Madhya Pradesh Board for Ayurveda, Unani, and Natural Medicine

The MP Board for Ayurveda, Unani, and Natural Medicine, which was created under the MP Ayurveda, Unani, and Natural Medicine Practitioners Act, 1970 functions very similarly to the Homeopathic and Medical Councils. Its main activity is also to regulate the entry of practitioners of Indian Systems of Medicine through their registration. The registry is annually updated at the national level every April, and the responsibility lies with the Registrar. The board also includes a Vice-President and President, who oversee the processes. The President and Vice-President are elected members, and the Registrar is appointed.

Registrations are conducted as a one-time process, on the applicant’s successful completion of the degree, and the submission of an application and fees; and cancellation occurs in the case of misconduct, relocation of the provider to a different State, or death of a provider. Registration can be obtained by providing a fee of Rs. 100 and a donation fee of Rs. 500. The Board also undertakes the task of provider verification, where an average of 60 requests are sent per year by the district Chief Medical Health Office to mitigate prevalent quackery. Quackery is viewed as a major problem with a majority of ISM people practicing allopathic medicine.

The council registers approximately 5000 providers per year, and includes practitioners in the Ayurveda, Unani, and Naturopathy streams. In order to carry out its operations, the Board is provided with Rs. 5,00,000 per annum from the Central Council, and the remainder is generated through registration fees. As is the case with the other Councils, funding is seen as problematic, and even with registration fees there is trouble with recovery. The funding shortage is a hindrance to the hiring of additional staff members, and to the expansion of the scope of activities.

Madhya Pradesh Homeopathic Council

The MP Homeopathic Council was established in 1959 based on the MP Homeopathy Parishad Adhiniyam Act 1976. The State council, located in the capital city of Bhopal has similar roles and operations to its modern medicine counterpart, to oversee the entry of Homeopathic practitioners into the field. The Council is an autonomous body responsible for the generation of its own funding to finance its operations and activities. At one point, however, the Council did receive one-time financial assistance from the State to aid in its establishment. Funding is gathered based on the fees charged to applicants for registration, which is carried out by the Registrar. While the Registrar oversees the registration activities, the overall functions of the Council are overseen by the Council Administrator. Individuals are chosen for these positions through a formal process of appointment rather than an election, and serve for a period of 5 years.

Once a student successfully completes his/her homeopathic education and prior to pursing a year-long internship, he/she applies and is granted provisional registration. Upon completion of the internship and presentation of the completion certificate, provisional registration and application form the student then receives full registration to practice homeopathy independently. The Council is not mandated to conduct the re-registration of providers, but since 2009 through a process of ‘updating’ every 3 years. It is the responsibility of the provider to update this registration with the Council in order to continue the practice. If the updating process is not undertaken by the provider then his/her registration automatically expires, and the provider is considered to be un-registered and unable to practice. Subsequently, the Council sends the registry to the national Central Council every year.

In actuality, however there is failure to implement this effectively due to the lack of a functional space for hearing the case within the Council. Suspension and de-registration occurs as a response to cases tried by the Medical Council and legal system when a provider of Homeopathy is found guilty of practicing allopathic medicine. The Council does not make proactive efforts in identifying quack providers of any kind primarily because it does not exist in their mandate, but also due to the shortage of staff and funding to carry out these activities, however it does respond to complaints received from the DHS, Medical Council and the public. The lack of funding is seen as a barrier for expansion of scope and activities of the Council. One example of this manifests in the lack of Continuing Medical Education efforts. In order to address this, the Council is currently seeking funding from the Central Council. Overall the Council’s functions and scope for expansion are limited. The perceived disparity between modern medicine and Indian Systems of Medicine which is prevalent at the policy and ground level is seen as a large hindrance to the growth of the Homeopathic Council and the practice of Homeopathy in general. Much dismay has been expressed over this disparity as it seen as diverting funding away from the Council and having far-reaching consequences on the morale of providers and quality of care provided.

Madhya Pradesh Medical Association

The Madhya Pradesh Medical Association (MPMA) was established in 1921 in the city of Jabalpur, seven years prior to the formation of the national level Indian Medical Association (IMA). The MPMA is a non-statutory and autonomous body that prides itself as one of the largest not-for-profit service organizations of doctors of Modern Scientific System of Medicine in India. The Association was initially intended as an intellectual platform for physicians to discuss issues of clinical importance. Four State branches of the Medical Association are present in the capital city of Bhopal with a strength of approximately 300 members, and 65 active branches of the Medical Association with about 6000 members exist within the entire State. However, not all branches are active in carrying out election and other member-related activities, despite being established and having members. The branches operate distinctly and independently from each other in all operations and activities. Inter-branch collaboration is minimal; however, members of one branch are not prohibited from participation in activities organized by another.

The culture of the Association evolved over time, from a smaller and more informal entity to what is one of the largest and most pervasive professional networks in the country. Predictably, the role and priorities of the Association also evolved, and the main focus of the Association at present is to organize Continuing Medical Education activities for its members, social service missions and day camps with other organizations, and social gatherings for members and their families. In trying to keep with one of its stated mission of keeping doctors updated with the latest developments in the medical sciences, the branches organize CME meetings. The individual branches independently determine the topics of these CME sessions, and periodic activity updates are subsequently reported to the State and national Associations.

Funds generation occurs at the individual branch level with most branches soliciting pharmaceutical companies for financial assistance. This continues to occur despite an advisory sent out by the IMA in New Delhi in 2009, asking doctors to refrain from taking expensive personal gifts and payments in cash from pharmaceutical companies. The dissemination of periodic bulletins from the IMA, that sometimes include scientific articles of common interest, and such guidelines and advisories are not always effectively communicated, received and/or implemented. The individual branches are faced with the continuous challenge of identifying and acquiring funds for their operations, which consequentially has affected the scope, quality and frequency of the MPMA’s activities. For instance, CME activities are limited to more intimate dinner meetings, as opposed to large formal lectures. Minimal financial means is also said to affect the way in which the activities are planned, where MPMA related work is to be undertaken within the homes and offices of the elected members, as there is no space dedicated office space or resources.

While the overarching goal of the Association has always been to update the technical capacities of member doctors, it also aims to protect the interests of individual physicians and the interests of the fraternity at large. For instance, the Association is loyal to its members and provides support to them in instances where someone has been accused of medical negligence or provider misconduct. At the macro level, the Association in MP has demonstrated its commitment to the interest of doctors through its advocacy for the State’s Health Personnel Protection Act (also referred to as the Doctor Protection Act). It was one of the leading organizations that opposed the enforcement of the Clinical Establishments Act in MP, and took a strong stance against the implementation of the Consumer Protection Act on Medical Professionals.

The MPMA has a strong relationship with the Madhya Pradesh Medical Council, as both organizations share a common commitment to uphold the interest of medical doctors.

Madhya Pradesh Nursing Home Association

The Nursing Home Association (NHA) is an autonomous body located in the State capital Bhopal that serves as a common platform for the owners and operators of private health establishments in the State. Membership in the association is voluntary and is open to any establishment that is registered under the Clinical Establishments/Nursing Home Registrations Act. The individual who represents the establishment has to be a qualified MBBS doctor or a qualified BDS dentist, and must work as a full-time staff member in that facility. Those establishments that apply to be a part of the association, which are not registered under the CEA are reported to the authorities by the NHA for illegal practice. Member establishments are diverse and range from individual sole-proprietary practices to larger hospitals. Across the State there are approximately 850 registered facilities with 75 percent of them being NHA members, and 146 member facilities in Bhopal.

The primary purpose of the NHA is to help educate establishment operators on the procedures of overseeing and running a facility through periodic workshops. Most sessions are on the running of establishments and include topics such as income tax, electricity, facility accreditation, and the Consumer Protection Act. The workshops are organized State-wide every alternate year and are attended by approximately 200 members. In addition, the Association organizes a conference every 2 years for its members to serve as a networking venue.

The NHA in the State of MP was a pivotal organization in fighting against the adoption and implementation of the Clinical Establishments Act in 1973. They pushed for amendments to the Act within the High Court as they felt that the provisions of the act were too stringent and irrelevant for the State of MP, especially for smaller establishments that have only a few beds. They also were strong advocates and worked towards the formulation of the State’s Doctor Protection Act. The NHA views itself as a self-regulatory mechanism that addresses the quality of services provided at private health facilities, by ensuring that facilities maintain basic standards as outlined by the CEA, and also by conducting informal awareness raising workshops for its members about facility improvement.

#### Targeted at: Conduct of Providers

Madhya Pradesh Medical Council

*(See also, description of constitution, financing and other functions of MP Medical Council in the sub-section on Quality of Care)*

The second stated function of the MPMC is to handle ethical misconduct and negligence complaints against registered individual providers through committee hearings and investigations, as per the guidelines of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002. The MPMC has formulated an ethical committee which consists of the Director of Medical Education, the Dean of a medical college, subject experts, a legal expert, the MPMC President and Registrar, who meet approximately 4 times a year, or as necessary to resolve such cases. The Council commonly receives these complaints against registered providers through the Directorate of Health Services (DHS), which are forwarded by the Chief Medical Health Officer at the district level.

On receipt of a complaint and a criminal complaint against a practitioner the Council conducts an inquiry, which gives the practitioner an opportunity to present his/her case. In the event that a practitioner is found guilty of medical negligence, the Council can order for the suspension of the registration of the practitioner for a specific period or even permanently. In explicit cases of medical negligence that result in criminal offense through the violation of provisions in specific acts, such as the PCPNDT, Medical Termination of Pregnancy Act and the Nursing Home Registrations Act the Council can permanently deregister a provider.

The engagement of the Council with disciplinary activities is minimal - no data were available on actual numbers of doctors who had been subjected to disciplinary action. The role of handling medical negligence complaints is seen as problematic by members of the MPMC, given the number of diverse actors currently deal with issues of medical negligence (such as the Consumer Courts and other formal legal mechanisms) which are seen as diluting the process. The council feels that this process should be consolidated.

The council aims to protect the domain of doctors, and does so through action against unqualified providers of allopathic medicine. When the Council receives a complaint of a non-qualified or quack provider of health care, it bears the responsibility of forwarding the case to appropriate authorities as a criminal case. The MPMC is neither formally mandated nor proactively involved in the pursuit of and action against unqualified practitioners and charlatans; however it views anti-quackery efforts as imperative for the well-being of the patients at large.

Madhya Pradesh Board for Ayurveda, Unani, and Natural Medicine

*(See description of constitution, financing and other functions of MP Board for Ayurveda, Unani, and Natural Medicine in the sub-section on Quality of Care)*

In the scope of provider misconduct, the role of the Board is to suspend and de-register providers found to be guilty of misconduct by the MP Medical Council. In some instances cases are brought to the Board to be heard by a committee that consists of the President, VP, and 18 other members who meet every 6 months at a minimum.

The Board’s engagement with disciplinary activities for misconduct and negligence, as mandated by the relevant Act, are minimal, and their focus of activities is primarily on advocating for the Indian Systems of Medicine.

Madhya Pradesh Homeopathic Council

*(See description of constitution, financing and other functions of MP Homeopathic Council in the sub-section on Quality of Care)*

In regards to provider conduct, the Homeopathy Central Council Act, 1973 outlines that it is the responsibility of the Council to take appropriate action in the suspension or de-registration of the individual if a provider is found guilty of misconduct, convicted in a criminal court or is seen as violating guidelines.

The Council’s engagement with disciplinary activities for misconduct and negligence, as mandated by the relevant Act, is minimal, and their focus of activities is primarily on advocacy for Homeopathy.

Madhya Pradesh Consumer Disputes Redressal Commission

The Madhya Pradesh Consumer Disputes Redressal Commission, also known as the State Commission, was established in 1990 under the auspices of the Consumer Protection Act (CPA) of 1986 (see page 46), which intends to safeguard the interest of consumers, protect them from exploitation and to save them from adulterated and sub-standard goods and services. The CPA mandated the establishment of Consumer Councils and other authorities for the settlement of consumer disputes and other related matters. Through this the State Commission intends to provide a space for speedy and inexpensive settlement of consumer disputes through a quasi-judicial machine, but with a fully judicial process where the laws are laid down by the apex court.

The State Commission consists of a deputed President, formerly a Judge of a High Court with 5-year tenure, and two other members, one of whom must be a woman. Unique to MP, the State government also created an additional post in the State Commission in 2005 for a Registrar. The State Commission has administrative control over the District Forums, while the National Commission oversees the State Commissions on the matters provided in Section 24B of the Act. MP presently has 24 District Forums, four of which were established after 2003. It is reported that since the establishment of the State commission and up to 31st December 2004, 19712 cases, including original complaints, appeals, revisions and other miscellaneous applications, were instituted.   Out of these 17433 cases were disposed, making up 88 percent of cases.

In respect to funding, the Central Government in the past directed a one-time grant of Rs.50 million for infrastructure to the State Commission and for the District Forums.  Outside of this, the State Government must bear the expenditure of the State Commission and the District Forums.

Legal provisions for cases of medical negligence and provider misconduct in the delivery of health services are not explicitly outlined in the CPA. Instead these instances are considered within the context of a “deficiency in service”, which must occur as a result of a paid transaction between a health service provider and paying patient. In reference to health services, this automatically precludes providers and services provided by the government and public health structures. In this capacity, the function of the CPA and State Commission is to serve as amelioration to the consumer through the determination of appropriate compensation.

The scope of cases dealt with by the State Commission in the realm of health services includes those against private nursing homes for issues such as misdiagnosis, faulty procedures and operations, and cases against insurance companies, and unqualified providers and quacks. While the focus of the State Commission’s action is on the practice of the provider it also touches upon aspects of health facility infrastructure and management in instances where this has contributed to the act and outcome of medical negligence and misconduct. The State Commission does not see itself as a regulatory body per se but as a judiciary instrument that makes decisions based on presented data and evidence. The determination of negligence occurs in a two step process: 1) whether the doctor was negligent, and 2) whether the negligence caused the outcome. In regards to cases of medical negligence and provider misconduct, the forum is highly dependent on presented evidence, rather than the consequences of an accused action.

Prior to May 2010 the State Commission utilized the Bolam Test as the model to facilitate decision-making for cases of medical negligence and provider misconduct. Through this model the State Commission consults a medical body of experts to determine whether negligence and misconduct occurred. The experts often consulted for these cases are those housed in the Dean Medical College in Bhopal. At the State level experts were called upon from different medical colleges and hospitals, and effort was made to reduce the conflict of interest by calling in experts from different places who do not know each other. If the body of experts supported the practice of the accused provider then no breach of standard of care was considered.

It was reported that through the process of the Bolam Test, “doctors have a tendency to not be frank, so we reverted back to the system of coming to the conclusion ourselves.” The State Commission found that the control being put in the hands of the expert panel of doctors who were suggested to rule typically in the favour of the defendant, unless there was obvious evidence against him/her. In addition, the State Commission found their own role to be obsolete in this process, even in cases of obvious negligence where consultation of an expert panel was not necessary. Since May 2010 however, a contrary judgment [Kishan Rao vs. Nikhil Super Specialty Hospital] determined that the Bolam Test was no longer necessary for all cases of medical negligence handled by the Consumer Forums. The consultation of a body of medical experts could be sought at the discretion of the State Commission in cases where the determination of medical negligence is not obvious. Otherwise, the State Commission can handle the cases and decisions itself (based on CPA Section 13). The MP State Commission sees this contrary judgment as a positive change that put the decision-making power back in the domain of the consumer courts, once again giving purpose to the State Commission in handling cases of medical negligence and misconduct. The recent change in the medical negligence determination process has kept the power of the final decision in the hands of the State Commission. This was seen as a favourable change as it could help to not “make it an issue, when you can immediately decide it”.

The State Commission has witnessed an increase in the number of medical negligence cases that are brought forth to the forum, which is attributed to increasing awareness among consumers. Consumers approach the forum oftentimes through the help of a civil society organization or through a lawyer, and receive assistance from them in filing the necessary paperwork. The consumers that approach the State Commission come from diverse backgrounds that cross cut geographic and socio-economic strata. The increased use of the State Commission to resolve cases of medical negligence and misconduct, while seen as an advantage for consumers, is also viewed as a hindrance to the creativity of doctors, which can lead them to practice defensive medicine. Additionally, the increase in cases has been seen to have contributed to the pile-up of cases due to the infrequent occurrence of case turnover. Human resources and staff capacity was however seen as adequate.

Madhya Pradesh Directorate of Health Services (DHS)

*(See also, description of constitution, financing and other functions of Directorate of Health Services in the sub-section on Quality of Care)*

1. Pre-Conception and Pre-Natal Diagnostic Tests Act (PCPNDT) Act

The PCPNDT Act came about as a means to prohibit the practice of pre-natal sex-determination in an attempt to reduce the number of female feticides occurring in the country, with the ultimate goal to balance out the male-female sex ratio. Therefore, this Act mandates the registration and licensing of all privately operating genetic counselling centres, clinics and laboratories.

Periodic reporting by doctors of their time spent in a registered PCPNDT facility is also required for monitoring purposes. This information is to be submitted to the CMHO office for its compilation into a quarterly report. The implementation and enforcement of the PCPNDTA occurs at the district level and falls under the purview of the CMHO and his team. When an interested facility seeks registration, a team from the CMHO’s office and from a local NGO is dispatched to inspect the said facility to ensure that required equipment and IEC signage is appropriately and adequately posted. In order for a provider to register the PCPNDT facility, the provider should have a minimum of an MBBS degree plus 1 year of training. In the State of MP there are around 250 facilities where the inspections should be conducted and approximately 40 sonography centres.

In the event that a complaint is lodged against a particular facility or provider for illegal testing an investigation is conducted by the CMHO who checks for whether the facility meets basic infrastructure, equipment, and staff standards, and looks into the number of abortions that have been conducted within that facility. This is done to investigate whether sex-selective abortions are being conducted at the facility. In addition to these monitoring and investigative activities, the CMHO conducts awareness workshops for physicians on the PCPNDT Act. For consumers IEC materials are produced and publicly posted in multiple spaces within the establishment.

Inspections of laboratories for suspected violations of the PCPNDT Act are conducted following complaint, and with the help of local NGOs. Accordingly 40 ultrasound centres had been enlisted for inspection in the upcoming quarter. A ten member committee is expected to adjudicate on violations. A key bottleneck to implementation of the act is that it is predicated on the assumption that the establishment is registered under the CEA, which is not always the case. Since many laboratories offering ultrasound diagnostics are not registered, these fall outside the net of routine inspections. It is also difficult to establish violations of the PCPNDT Act, since the information about the sex of the foetus can be conveyed verbally. A respondent cited future plans to undertake exit interviews with clients.

Madhya Pradesh Directorate of Medical Education (DME)

*(See also, description of constitution and other functions of the MP Directorate of Medical Education in sub-section on Accessibility of Care)*

One function of the DME is to implement the Human Organ Transplant Act, which is carried out through the formation of an authorization committee that consists of the district Collector, representative, lawyer, and 2 senior doctors. The committee conducts the registration and inspection of private facilities that are interested to provide organ transplant services of the cornea, kidney, and liver. Eye banks and medical and private colleges and nursing homes, if they have an ophthalmology set-up, are also registered under this act. In the event of an ethical violation of the HOTA, a committee consisting of a dean of a medical college, the Collector, a lawyer, and 2-in service professors conduct a hearing and a effective action is taken against the provider in the form of facility deregistration or provider negligence.

The information available about the actual role of the DME in implementing the HOTA was limited and inconclusive.

#### Targeted at: Accessibility of Care

Directorate of Medical Education

The Directorate of Medical Education (DME), Madhya Pradesh is the arm of the State Government responsible for the administration of medical and dental education and graduate examinations in the State. It oversees 6 government medical colleges and one of 13 dental colleges, and is headed by the Director of Medical Education. The DME operates independently from the Directorate of Health Services, and does not cover the various streams of Indian Systems of Medicine.

In the aspect of regulation, one of the DME’s main functions addresses the issue of health care accessibility and seeks to balance the urban-rural disparity in modern medicine health service availability through the administration of the Medical Rural Bond. The rationale for the implementation of the rural bond as per the DME is two-fold: the first based on the need to increase the number of providers in rural and medically underserved areas, and secondly, for students to compensate for their highly subsidized public medical education. According to the DME, the cost of a government medical college education of Rs. 35,000 is borne by the State. Those students who pursue post-graduate medical studies receive a stipend of Rs. 24,000 per month. In addition, 50 percent of the seats for government medical education are reserved for candidates of Scheduled Castes and Tribes and do not demand any fees. Therefore, since students utilize state resources it is seen as their responsibility to give back to the state through service in vulnerable areas. If a student is unwilling to serve the Medical Rural Bond then he or she can be waived out with a payment. Students from private dental and medical institutions are excluded as they pay out of pocket for their education fees.

The DME began its implementation of the Rural Medical Bond in MP with the 1997 batch of medical students who passed out in 2003. Based on several lists of students received by the Deans of various medical colleges, the DME compiles a final list of students who are required to complete the Rural Bond component. This list is subsequently delivered to the Commissioner of Health Services who directs the order for rural bonds and conducts the placements.

Despite the compilation of lists of eligible candidates postings have not been properly assigned over the past 2 years, which a DME official ascribed to inability of the Directorate of Health Services (DHS) to place the students in relevant postings.

The issue of the medical rural bond has been heavily contested in the State of MP, and has driven many groups of junior doctors to strikes, protests, and to the High Court to appeal against this mechanism. In its response, the High Court initially ruled that the failure to fulfil the rural bond requirement would result in a cancellation of the registration to practice. Other negotiations between student unions, the DME and the DHS have taken place and have resulted in various amendments to the Bond guidelines in favour of the students.

### *Regulatory architecture map: Madhya Pradesh State[[46]](#footnote-46)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Target of Regulatory Activity | Group(s) tasked with relevant activities | Type of authority invested with group | Relevant policies and clauses | Relevant activities expected of the organization | Relevant activities actually performed by the organization (and additional activities in *italics*) |
| *COSTS OF CARE* | Directorate of Health Services:  Office of the Chief Medical and Health Officer (CMHO) of the District | Official (government scheme) | Janani Sahayogi Yojana (JSY)  *Source:* Government of Madhya Pradesh, Department of Public Health and Family Welfare, Directorate of Health Services,  Government Order  RCH/MH/09/160 dated 01.07.2009 and RCH/MH/10/638 dated 16.06.2010, Bhopal | Assessment of applications of interested private sector providers, physical verification by a committee headed by the CMHO, and granting of accreditation | (Not enough data, since scheme recently initiated) |
| Receipt of weekly report of from accredited providers, forwarding report to State Directorate |
| Physical inspection of a minimum number of accredited providers, periodically. |
| Cancellation of accreditation in case of private provider’s non-compliance to minimum standards |
| *QUALITY OF CARE* | Directorate of Health Services:  Office of the Chief Medical and Health Officer (CMHO) of the District | Statutory | Madhya Pradesh Upcharyagriha Tatha Rajopchar Sambandi Sthapanaye (Rajistrikaran tatha Anugyapan) Adhiniyam, [Clinical Establishments Act] 1973; § 4(1) & (2), § 7, § 8 ff, § 5, § 6, § 19 | Registration of private clinical establishments in accordance with infrastructure and personnel standards | Numerous amendments to Act, following contestation. Several original conditions for registration diluted or absent in present iteration. Registration not universally implemented, many establishments function unregistered. |
| Periodic inspections of facilities to assess adherence to norms | Inspection routine severely impeded by manpower shortages / unavailability, and by requirement of coordination with magistrate and police. |
| Imposition of penalties for non-compliance to norms, issuance of notifications for rectifying faults | Conducted, frequently contested by establishments. |
| Cancellation of registrations due to non-compliance and conviction | Possibly infrequent or delayed, as a result of contestations. Further action leading to physical closure of establishment is often delayed. |
| Receipt and processing of applications for renewal of clinical establishments, every 3 years | Recently introduced. Qualified cooperation from nursing homes. |
| Maintenance and receipt of records of births, deaths and infectious diseases | Partial compliance by establishments. |
| Medical Termination of Pregnancy Rules, 2003. § 6 ff., § 7 ff., § 4 (5). | Inspection, verification, and approval of private establishment for conducting MTP | Not undertaken fully, due to low prioritization of issue. Cancellation predicated on prior registration under CEA, which is not always the case. |
| Cancellation of approval of facility to conduct MTPs in case of non-compliance |
| Soliciting weekly statements from approved facilities about MTPs conducted | Likelihood of frequent under-reporting, non-adherence to norms. |
| Directorate of Health Services  District Quality Assurance Group  Department of Maternal and Child Health | Official (government policy) | Government of Madhya Pradesh, Department of Public Health and Family Welfare, 2006. *'Quality Assurance procedures for Reproductive and Child Health Services in Public Health System'*, Bhopal, 2006 | Plan visits of Quality Assurance Group to public facilities, undertake inspections, compile findings, prepare reports | QAG visits, training and dissemination of STPs conducted. Some deficits in providing feedback and undertaking corrective action. |
| Feedback to the facilities with guidance for corrective action, forward minutes to CMHO and Deputy Secretary, Maternal Health |
| Training and monitoring the implementation of Standard Treatment Protocols for maternal health |
| MP Medical Council | Statutory | Madhya Pradesh Ayurvigyan Parishad Adhiniyam, 1987. § 10 (1),§ 11 (3), § 13 ff, §22,  Indian Medical Council Act, 1956 | Registration of graduates for practice of allopathic medicine, registration of additional qualifications, submission of updated list to the National Medical Register | Registration activities ongoing as mandated |
|  |  |  | *Issuing certificates of good standing for emigrating doctors* |
| Madhya Pradesh Ayurvedic, Unani, and Naturopathy Board | Statutory | Madhya Pradesh Ayurvedic Unani Tatha Prakritik Chikitsa Vyavasayi Adhiniyam, 1970. § 21 ff,§ 27, § 24  Indian Medicine Central Council Act, 1970 | Registration of the practitioners of Ayurveda, Unani, and Naturopathy, registration of additional qualifications, submission of updated list to central Register of Indian Medicine | Registration activities ongoing as mandated. |
| Madhya Pradesh Homeopathic Council | Statutory | MP Homeopathy Parishad Adhiniyam  Central Council of Homeopathy Act, 2002 | Registration of the practitioners of Homeopathy, registration of additional qualifications, submission of updated list to central Register | Registration activities ongoing as mandated. |
| MP Medical Association | None (Voluntary body) | Indian Medical Association Charter  <http://www.imampstate.com/> accessed on 25th July 2010 | Provides Continuing Medical and Health Education to doctors through privately organized events | CME activity through private events. |
|  |  |  | *Providing support to doctors accused of misconduct* |
| *Opposing the institution of regulatory legislations (CPA and CEA) (historical)* |
| Nursing Home Association | None (Voluntary body) | - | Educating nursing home owners on legal requirements and procedures | Educating nursing home owners on legal requirements and procedures |
|  |  |  | *Opposing the institution of regulatory legislations (CEA) (historical)* |
| *CONDUCT OF PROVIDERS* | MP Medical Council | Statutory | The Madhya Pradesh Ayurvigyan Parishad Adhiniyam, 1987.  § 15 ff, § 16 (1) & (2), § 16 (3) ff. | Receipt of complaint against practitioner or taking cognizance if the practitioner has been convicted in the court. | Members ambivalent about value of disciplinary role, given other mechanisms such as CPA. No data on disciplinary procedures undertaken. |
| In-camera hearing and adjudication by disciplinary committee |
| Suspension or cancellation of practitioner from the State medical register, if guilty |
| Restoration of the suspended name on expiry of the term of suspension |
|  |  |  | *Receipt of, and forwarding complaints about non-qualified providers* |
| Madhya Pradesh Ayurvedic, Unani, and Naturopathy Board | Statutory | Madhya Pradesh Ayurvedic Unani Tatha Prakritik Chikitsa Vyavasayi Adhiniyam, 1970. § 29 (1) ff,§ 35 | Removal of the name from the Register either for a fixed term or permanently for proven misconduct. | Minimal emphasis on disciplinary role and procedures. |
| Madhya Pradesh Homeopathic Council | Statutory | Homeopathy Central Council Act 1973 | Removal of the name from the Register either for a fixed term or permanently for proven misconduct. | Minimal emphasis on disciplinary role and procedures. |
| State Consumer Disputes Redressal Commission, District Forums | Statutory | Consumer Protection Act, 1986. § 11 (2) ff, § 17 (a) (ii)  Consumer Protection (Amendment) Act, 2002, § 7, § 13 | Adjudicating cases of medical negligence under consumer law, and consequent redress | Numerous cases adjudicated. Some concerns around application of Bolam test, which has since been deemed unnecessary |
| Entertain appeals against adjudications of the District Forum (State Commission) |
| Directorate of Health Services  Office of the Chief Medical and Health Officer (CMHO) of the District | Statutory | Pre-conception and Pre-natal Diagnostic Techniques Act 1994  §17 (4) (a),§23 (1), §17 (4) (i), §19 (3)  Pre-conception and Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Act, 2002. §14 ff. | Registration and licensing of Genetic counselling centres, clinics and laboratories | Registration activities conducted as mandated. |
| Investigation of complaints of breach of the provisions of the Act and suspension / cancellation of registration of Genetic counselling centre, laboratory or clinic for non-compliance to standards. | Concerns over methodology for investigation, since infringements difficult to establish. Cancellation predicated on prior registration under CEA, which is not always the case. |
| Renewal of existing licenses | Renewal activities conducted as mandated. |
| Directorate of Medical Education | Statutory | Transplantation of Human Organs Act, 1994  § 13 (3) i), § 13 (3) ii), § 13 (3) iii) , § 13 (3) iv) | Registration of hospitals to perform organ transplantation (cornea, kidney, and liver transplants) | (Data on actual activities inconclusive) |
| Enforce standards, investigate the breach of conditions of Act, cancel registration of hospitals found to breach conditions |
| *ACCESSIBILITY OF CARE* | Directorate of Medical Education | Statutory | Madhya Pradesh Medical and Dental Undergraduate Entrance Examination Amendment Rules, 2009.§11.  Pre-Post Graduate Test Rules (Amendment) 2009. §9 ff,§12 ff | Compilation of list of eligible graduates for mandatory rural service (rural bond), delivery of list to DHS for postings. | Limited implementation due to inability to make appropriate placements, and due to extensive legal contestation of Bond provisions by medical fraternity. |

### *Gaps in regulatory policy at State level: Madhya Pradesh*

#### Design of regulatory policies

Madhya Pradesh has no known laws or regulatory policies for the curtailment of costs for users of health care, other than the recently introduced Janani Sahayogi Yojana (Scheme) in which private providers are franchised to provide free obstetric services. There are however numerous policies and schemes aimed at improving the quality of care in existing health services. These include the MP Clinical Establishments Act which mandates minimum infrastructure and personnel standards for hospitals, rules and procedures for ensuring the quality of reproductive health services or of specific interventions such as medical terminations of pregnancy, professional self-regulatory councils’ control over qualification requirements to practice medicine, and voluntary medical association’s efforts to boost continuing medical education. Conduct of healthcare providers is putatively regulated through the quasi-judicial processes of the professional self-regulatory councils, and increasingly through the recourse of consumer courts. There are also specific laws for ethically contentious areas such as pre-natal sex determination, and transplantation of human organs. For both quality of care and conduct of providers, the absence of a credible community-based forum for grievance redress emerges as an apparent gap in design. Inequalities in health workforce distribution contributing to variability in accessibility of care, is putatively regulated by means of a mandatory rural service policy for graduates of government medical colleges. There are no alternative policies or schemes based on incentivizing or supporting rural health practice, or improving working conditions in rural areas.

#### Implementation of regulatory policies

Costs of care

The JSY is a recently introduced scheme in MP, and representatives of implementing organizations were unable at the time to provide informed views on their experience.

Quality of care

The MP Clinical Establishments Act (CEA) has been subjected to repeated modifications since its original implementation, and even in its present, diluted form, its *implementation is partial*. Unregistered establishments flourish, and may outnumber registered establishments. Regulation of registered facilities is impeded by *personnel constraints* and further difficulties are posed by the need to coordinate inspections with the police and a magistrate. Reports of inspections are frequently contested, and physical closure of establishments is rare, since this again requires *inter-departmental coordination* and can compromise the health departments’ relationships with hospital-owners, whose cooperation is required for other functions. The implementation of special laws such as MTP and PNDT is also partial, predicated as it is on establishments being previously registered under the CEA.

The registration of medical practitioners is broadly implemented as mandated, by the professional self-regulatory councils. The role of voluntary medical associations however is complicated by their history of taking an active *stance against strengthening regulations* including opposing the institution of the CEA and other regulatory laws, and their active support to doctors accused of medical negligence, even though they are active in promoting and conducting continuing medical education programmes.

Conduct of Providers

Medical self-regulatory council’s commitment to their disciplinary functions is ambivalent, and made problematic by their close relationships with medical associations who have an avowed interest in opposing regulation. Their engagement with voluntarily adopted, additional tasks such as reducing quackery is greater than the *minimal performance of their disciplinary roles*. Consumer forums were apparently more prolific in adjudicating cases of medical negligence and misconduct.

Accessibility of Care

The implementation of rural medical bonds was hampered in the first place by extensive *contestation of the conditions by doctors’ groups*, and by problems in *coordination between government departments*, essential for placing graduating students in appropriate rural centres.

## Delhi State

### *Background and context*

#### The State of Delhi

Delhi State is an urban agglomeration in northern India, part of which, New Delhi, is the national capital of India. Delhi has an area of 1483 sq. km making it one of the smaller States in the country. According to the national census of 2001, the population of Delhi was 13.85 Million with 3.85% annual growth rate and 47.02% decennial growth rate during 1991-2001. It has a total of 9 districts and 27 sub-divisions. The population is predominantly urban with the rural population of Delhi comprising only 6.99% in 2001. The per capita income of Delhi in 2007 was Rs. 60189,[[47]](#footnote-47) significantly higher than the national average in 2007 of Rs. 12000.[[48]](#footnote-48)

#### Health Profile of Delhi

Delhi State has better health indicators than many other States in the country. Life expectancy at birth at 69.6 years is higher than the national average.[[49]](#footnote-49) The birth rate, death rate and infant mortality rate in Delhi (India) are better than national averages at 18.4 (22.8), 4.8 (7.4) and 35 (53).[[50]](#footnote-50)The maternal mortality ratio for Delhi is 172, again an improvement on the national MMR of 254.[[51]](#footnote-51)

#### Health Care Services in Delhi

Delhi is home to some of the best healthcare facilities in the country. The profile of public sector establishments ranges from dispensaries and urban health centres at the primary level to multi-speciality medical colleges and hospitals. Government agencies such as the Directorate of Health Services (DHS) of the Government of National Capital Territory of Delhi, Municipal Corporation of Delhi (MCD), New Delhi Municipal Corporation (NDMC), Railways, Cantonment Board, Employees State Insurance (ESI) and Central Government Health Services (CGHS) provide services to the various segments of the people of Delhi. Spending on the health sector by the Delhi government is one of the highest in the country at nearly 9.45% of the total outlay of the government in 2008-2009 and approximately 1.19% of the State Gross Domestic Product (SGDP). There is also a dense concentration of private clinics and networks of corporate hospitals providing healthcare services. In 2009, nearly half of the total hospital beds (42% of 36352 beds) in Delhi were in the private sector.[[52]](#footnote-52)In spite of the favourable numbers compared to other States, primary health care infrastructure in Delhi is significantly deficient. In March 2008, there were only 41 Sub Health Centres in the State, against the population norm of 188. Similarly there were only 8 Primary health centres as against the mandated 31, and there were no Community Health Centres when there are expected to be seven.

### *Relevant laws and policies*

This section describes relevant laws and policies which are operational in Delhi State. Throughout this section, the putative roles – regulatory activities expected – of various State organizations (as mandated by State laws and policies), are highlighted against a grey background.

#### Targeted at: Costs of Care

Subsidies for Private Hospitals to Treat Poor Patients

In 1986, the Delhi Development Authority and Land and Development office of the Government of India had offered lands at concessional rates to registered societies and Trusts for establishment of hospitals on the condition that the treatment of certain percentage of in-patient beds in these hospitals would be kept free for patients from Economically Weaker Sections (EWS). Likewise, a certain percentage of out-patient cases (OPD) also had to be earmarked. The percentage of earmarked in-patient beds varied from ten per cent to seventy per cent. But in 2000, following the recommendations of a High power committee, *the Directorate of Health Services (DHS)* in order to bring in uniformity fixed the condition of ten per cent in-patient beds and twenty five per cent OPD to be earmarked for free treatment of patients from EWS. The hospitals shall be liable for action to be taken under the law if found to be charging the patients duly identified as EWS. The hospital shall maintain complete records including the name of the patient, disease, treatment given, expenses incurred and so on pertaining to the treatment to such patients.[[53]](#footnote-53)

The guideline provides for an *inspection team* consisting of three individuals, including the Medical Superintendent of Dr. Ram Manohar Lohiya Hospital. The putative role of this inspection team would be to periodically check the records maintained by the private hospitals. The hospital has to also send a quarterly report to the DHS before the expiry of the first week of the fourth month. The hospital has to send the information regarding the availability of free beds to the DHS and also to the nearby linked government hospital twice daily. In addition to the above, *a special committee* comprising of the Chief Secretary GNCT Delhi, Finance Secretary GNCT Delhi, the Director Health services and the Medical superintendent of the government hospital in the specified areas. The role of this special committee is to look into the issue of such of those trusts or societies which have not constructed hospital on the concessional land provided and to ask for repayment to the authorities.53

#### Targeted at: Quality of Care

Delhi Nursing Home Registration Act

The State of Delhi enacted a Clinical Establishments legislation in 1953. It is called the Delhi Nursing Homes Registration Act, 1953. The Act provides a legal basis for the regulation of the clinical establishments with regard to physical infrastructure and personnel.

Every clinical establishment which plans to offer healthcare services must apply for registration or renewal, in the prescribed form and fees, to the supervising authority.[[54]](#footnote-54)The *Nursing Home Cell, of the Directorate of Health Services*is established as the the designated supervising authority for the State of Delhi. The main function of this cell is the registration, and renewal of registrations, of the clinical establishments within the national capital territory of Delhi.[[55]](#footnote-55) The Cell consists of 2 Medical Superintendents at the Directorate level assisted by a district level team comprising of Chief Medical Officer and other secretarial staff.[[56]](#footnote-56)

The Cell has the powers to register the clinical establishment subject to its achievement of standards with respect to the situation of the establishment, its construction, staff qualifications and their requisite numbers, accommodation and equipment; the Cell is also vested with the powers to impose penalties where the establishment is convicted of operating without a proper registration. The Cell can cancel the registration, upon conviction, if it is being run in contravention to the provisions of registration. The establishment has to submit an application in Form 'B' for renewal of registration every third year before January 31st of that year.[[57]](#footnote-57) The establishment or its records can be subjected to inspection either by the Cell or any deputed person by the Cell. The clinical establishment has to intimate in the prescribed proforma, within 24 hours, any death of the patient occurring in its premises to the Cell.54

In times of natural calamity or a disaster, the Cell can requisition the services of the clinical establishment to provide medical assistance.[[58]](#footnote-58) The Act does not provide for the mandatory treatment of the emergency cases that might present themselves at the establishment. In addition to the above, the Cell is also mandated to assist the State mental health authorities in carrying out inspections and registration of psychiatric centers / hospitals.54

Delhi Medical Council Act 1996

The Indian Medical Council Act, 1956 provides for the establishment of the State Medical Councils to cater to the regulations of the medical profession at the State level. Accordingly the Delhi Medical Council Act, 1996 was passed by Delhi State Assembly in 1997.[[59]](#footnote-59) The Act provides for the constitution and incorporation of the Delhi State Medical council.[[60]](#footnote-60) The Council shall consist of four members nominated by the State government, representations from each of the medical colleges of the State government, nine other members elected from among the registered practitioners including one representative from the Delhi Medical Association. The President and Vice-President of the Council shall be elected from among the members. The Act provides for the formation of an Executive Committee as also other sub-committees as may be necessary from time to time. A Registrar and Sub-Registrar are appointed by the Committee and the Registrars shall be a registered medical practitioner. The Registrars shall act as the Secretary of the Council.60

The Registrar has the putative functions of receipt of the applications of medical practitioners in the prescribed form and fees for registrations into the State medical register; registration of the medical practitioner into the medical register, the qualification obtained from the particular medical college and University and periodic updating with deletion or addition of names in the State Medical Register;60 submitting the updated list of the State medical register to the Indian Medical Register; annual publishing of the updated State medical register; sending out notices of renewal to the registered practitioners once in five years, soliciting renewal applications from them in the prescribed form and fees and renewal of the registration.[[61]](#footnote-61)

Delhi Bharatiya Chikitsa Parishad Adhiniyam 1998

The Delhi Bharatiya Chikitsa Parishad (DBCP) was instituted by the Government of Delhi through the Delhi Bharatiya Chikitsa Parishad Adhiniyam, 1998 to look into the affairs of the Indian Systems of medicine in the State of Delhi. The three systems of medicine are Ayurveda, Siddha and Unani Tibb. The Parishad (Council) constitutes of 21 members comprising Director-Indian Systems of Medicine, three principals, from teaching institutions from each of the Indian systems, nominated by the government, one representative from the Central Council, six prominent Vaidyas (Ayurvedic/Siddha practitioner) and Hakims (Unani practitioner) to be nominated by the Government, ten persons registered with the Parishad who get elected from among the registered practitioners. The President and the Vice-president shall be elected from among the members of the Parishad.[[62]](#footnote-62)

The putative functions of the Parishad consist of maintaining live register and registration of the qualified providers; to hear and decide appeals against any decisions of the Registrar; to provide protection to its members in discharging their professional duties and to take action against unregistered practitioners of Indian Medicine. The Parishad shall appoint a Registrar who shall be the secretary for the Parishad and treasurer as well if need be and the Registrar shall be a graduate in the Indian System of medicine. The functions of the Registrar is to be the secretary of the Parishad, attend all the meetings of the executive committee, prepare proceedings of the meetings and keep accounts of the Parishad.62

The Registrar shall prepare and maintain the State Register of Indian Medicine. The Registrar shall receive the applications from the qualified persons in Indian medicine wanting to practice in Delhi, in the prescribed form and accompanied by prescribed fees, and after due verification shall have the name of the practitioner entered in the State Register. The Registrar shall issue certificates of registrations to the registered practitioners and the certificate shall be displayed prominently by the practitioner at the place of his/her practice. The Registrar shall have the function to update the register periodically adding and deleting the names as the case may be. The Registrar shall also have the function of printing and publishing the updated Register annually and such an updated register shall act as a conclusive evidence in case of disputes. Any person aggrieved by the decision of the Registrar shall have the chance to appeal before the Parishad within one month from the date of the order. The Act also provides for an additional body called the Examining Body to conduct qualifying examinations for paramedical personnel in Indian Systems of medicine.62

#### Targeted at: Conduct of Providers

Delhi Medical Council Act 1996

In addition to the India level regulations of the professional conduct of the practitioners, the Delhi State medical council also has provisions for regulating the professional conduct of the practitioners which is similar to the regulations at the national level.[[63]](#footnote-63)

A *disciplinary committee* is established within the Council to look into the professional misconduct by the practitioners in the State. The committee shall comprise of the chairperson nominated by the council, a member of the legislative assembly of the State, a legal expert, a specialist doctor pertaining to the complaint, a representative from Delhi Medical Association who has been a member for a minimum of 10 years.60On receipt of a complaint, or if she/he is convicted for criminal acts in a court of law and has violated the code of ethics, an enquiry is instituted regarding misconduct by practitioner. After due enquiry by the disciplinary committee,if the practitioner is found to be guilty of misconduct then the council can take steps to either warn the practitioner or direct the name of the practitioner to be removed from the State medical register for a specific period or direct the name of the practitioner to be removed from the State medical register permanently depending on the individual case.60 If the council later finds that the practitioner has been erroneously implicated, it shall order for the restoration of the name of the registered practitioner in the State medical register.60

Delhi Bharatiya Chikitsa Parishad Adhiniyam, 1998

The Delhi State Parishad for the purposes of implementing the code of conduct and ethics among practitioners of Indian Systems of Medicine has decided to follow the conduct and code of medical ethics as prescribed by the Central Council described earlier in this report (see page 51).62

The Delhi State Parishad has established a set of regulations for handling the cases of professional conduct. On receipt of complaints of professional misconduct the Parishad shall institute a disciplinary committee comprising a nominated chairman; a legal expert nominated by Parishad; one legislative assembly member from the State of Delhi; an eminent public person nominated by the Government; an eminent Indian Medicine specialist from the branch pertaining to the complaint nominated by the Parishad and a member representative from the Indian Medicine related Association with at least ten years standing in practise of Indian Medicine. After conducting due inquiry held by the Parishad, the practitioner is found to be guilty of professional misconduct then the Parishad shall issue a warning letter to the practitioner or direct that the practitioner's name shall be removed temporarily for a specified period or to be removed permanently as the case may be. In case at a later point in time either of its own volition or through the upholding of the appeal by the practitioner concerned the Parishad finds that the grounds of the complaint do not exist any more then the Parishad shall take steps to restore the name of the practitioner in State register. Alternatively in case the suspension was for a specific period then the Parishad shall restore the name of the practitioner in the register on the expiry of the specified period.62

### *Roles of regulatory organizations*

This section describes various regulatory organizations and structures which are operational in Delhi State, and their *expected* and *actual* activities, based on first-hand accounts of representatives of these organizations, and review of relevant documents. Throughout this section, the putative roles – regulatory activities expected – of the various organizations, are highlighted against a grey background, and their actual activities are highlighted by the use of square borders.

#### Targeted at: Costs of Care

RSBY Nodal Agency

*(See description of the constitution and functions of the RSBY nodal agency on page 53)*

The Office of the Labour Commissioner is the designated RSBY Nodal Agency for Delhi State. They facilitate and coordinate the implementation of RSBY in the State. The Commission’s primary aim to provide health insurance for in-patient care to the poorest of the poor and the most vulnerable populations, firstly by active efforts to enrol participants in the program, who can join by paying only Rs. 30 for the year, with an annual premium of Rs. 541. The activity of user enrolment is directly implemented by an insurance company empanelled by the Labour Department.

Private healthcare establishments are empanelled with the RSBY, and each one of these is expected to have an RSBY desk which helps the patient navigate the system to access care. Once care has been provided and treatment has been received the user’s RSBY card is swiped, and the treatment paid for. This is meant to ensure that there is no motivation for the provider to charge extra fees or overprescribe because the packages are pre-defined and negotiated by the government. RSBY is funded 75 percent by the national government 25 percent by the State government. It is purely a government initiative.

The respondent stated that RSBY regulates costs of care through financial protection for health care for the poorest segments of society. The RSBY insurance scheme currently includes coverage for inpatient expenses for 780 disease conditions and 90 empanelled hospitals. The target for the year for enrolment is 400,000 people, and at the time of interview 12,000 had been recruited. Some instances of fraud were reported, and 3 such incidents had led to the erring hospitals being de-empanelled. The respondent also indicated that regulatory mechanisms to ensure quality of care, prevent unnecessary procedures, and identify fraudulent reporting by private establishments were yet in the process of development.

Directorate of Health Services

The Directorate of Health Services (DHS) is the largest agency related to health care delivery under the Department of Health and Family Welfare, Government of the National Capital Territory of Delhi. It coordinates the provision of services through health care facilities at the primary and secondary level through various health outlets, such as dispensaries, health centres, school health clinics and mobile health clinics. The DHS is a government body, equipped with the capacity and responsibility to undertake various aspects of health care regulation, which aim to increase availability and quality of health care provision under the banner of the public health system. The DHS is headed by Director of Health Services and comprises of various departments, including a Nursing Home Cell, Hospital Cell, and Continuing Medical Education Cell. At the district level, the 8 Chief District Medical Officers (CDMO), under the administrative control of the DHS, are responsible for monitoring the functioning of the health facilities within their respective districts. The DHS also liaises with other State-level entities in various capacities to carry out its functions; these include the Delhi Medical Council, the Delhi Bharatiya Chikitsa Parishad, and the Delhi Development Authority.

Part of their extensive regulatory mandate is to ensure, through the institution of committees, that beds legally allocated to those patients who live ‘below the poverty line’ are actually provided. These hospitals must submit a quarterly report of the treatment of such patients and the expenditures incurred to the DHS. The DHS has the power to inspect hospital records pertaining to the treatment of such patients.[[64]](#footnote-64)*(See details of administration of subsidies for private hospitals on page85)*

According to reports: In recent years, the number of subsidies to private hospitals has increased greatly, due to policies to undertake more public private partnerships (PPP). This has been the context for a tacit contestation of organizational tasks between different departments within the government and a succession of role shifts, which has decreased the efficiency of the regulatory process. To elaborate: administering PPPs is the domain of the Government Department of Health & Family Welfare (DoHFW), and these are centrally funded through the Planning Commission. However the day to day tasks of inspection of private facilities are mandated to the implementing body, the DHS (which is subordinate to the DoHFW).[[65]](#footnote-65)As more PPPs were undertaken, the balance shifted from mainly public to a mix of privately and publicly provided care, and consequently the financing for Government health departments was broadly reduced. Paradoxically, these wholesale reductions also decreased the capabilities of the DHS for *regulation* of those private establishments with which agreements were made. Hence even as the power to undertake PPPs is increasingly centralized within the government, the implementation machinery to regulate them is compromised.

Following a controversial law suit against a private hospital for failing to uphold this stipulation, the Supreme Court mandated that a new regulatory body, called the Social Jurist, should regularly monitor the availability and provision of these beds in private hospitals around to city. The committee includes a lawyer, the medical superintendent of nursing homes from the DHS Nursing Home Cell, among others.

#### Targeted at: Quality of Care

Directorate of Health Services

*(See detailed description of the constitution of the DHS on page90)*

1. Delhi Nursing Homes Registration Act

The NHRA, also referred to as the Clinical Establishments Act, was established in Delhi in 1953 to ensure that through registration and licensing of private health facilities, basic requisites of infrastructure, equipment, and qualified human resources would be present at health establishments as to provide a minimum standard of quality.

The administrative responsibility of the NHRA lies with the *Nursing Home Cell* in the DHS, with the role of enforcement and implementation at district level being in the hands of the CDMO. The main function of the Nursing Home Cell is the registration, inspection and renewals of clinical establishments every 3 years. It consists of 2 Medical Superintendents at the Directorate level, who are assisted by a team at the district level led by the CDMO. The Cell has the power to grant registrations, impose penalties in cases of non-compliance, and the ability to cancel registrations. *(See full details of expected regulatory activities on page 86)*

Inspections are conducted initially when an establishment applies for registration. In the 2010-2011 annual cycle, 96 new nursing homes had been registered and 15 de-registered, and there were a total of 679 nursing homes registered with the Cell. This was reported to be well short of the actual number of nursing homes and hospitals in Delhi State (one official estimated this number at more than 5000), hence it could be stated that the implementation of the NHRA is partial. An official recounted how at one point, a petition by 2 establishments regarding one of the clauses of the Act had led to a court stay order (cessation of regulatory activities). This official regretted that there was so much opposition to regulations from the medical fraternity, and that “political aspirations often transcended sense of duty”. Since a majority of officials in government health service are physicians themselves, this would indicate that regulation was generically seen as being detrimental to the interests of the medical community. The contents of the Act had been regularly contested in the past few decades, whenever an attempt was made to implement it, leading to a dilution of several standards (including minimum mandatory size of an operation theatre) and removal of some clauses. Another respondent indicated how the contents of the DNHRA were “primitive”, since they focused only on infrastructure standards, and only marginally on aspects that would have direct impact on the quality of care provided.

The physical task of inspections of facilities is devolved to the district level (CDMO). One respondent indicated that staff shortages and lack of motivation among existing staff hampered the routine conduct of inspections. According to an official, the regulatory system was passive in its functioning – “the system waits for a complaint to be made” and such complaints either from civil society or citizens were rarely forthcoming.

The institutional ethos in the DHS was more closely aligned to the goals of providing health services through public facilities, than of regulating private health services.

1. Continuing Medical Education

The purpose of the *Continuing Medical Education (CME) Cell* within the DHS is to undertake the continuing medical education of the health staff throughout the city/State, as per the Delhi Medical Council’s curriculum, with the intention to promote the quality of care by medical providers. Despite the existence of a CME Cell within the DHS, the Government of Delhi does not require or mandate periodic CME for providers within the public health system.

The execution of the CME activities is irregular at the DHS, and the minimum CME hours to be fulfilled by providers are frequently not met. This is attributed to the general lack of interest in the medical fraternity in conducting and attending the workshops.

*Note (relationship with Delhi Medical Council)*: The DHS and DMC have a formal relationship based on common interests in undertaking continuing education and reducing quackery, which is further strengthened by the Director of Health Services holding an ex-officio position within the DMC. It is was estimated that 20,000 quacks operate in Delhi, and since the DHS does not have the mandate formal mandate or the manpower to address these issues the complaints are forwarded to the DMC. Similarly, complaints received from the public for provider negligence and malpractice are directly forwarded to the Delhi Medical Council.

Delhi Medical Council

*(See detailed description of the constitution, financing and other functions of the Delhi Medical Council on page95)*

The function of provider license registration for government and private practitioners of allopathic medicine is carried out by the Registrar of the DMC throughout the year for the National Capital Territory region, and with the registry updated at the national level every quarter of a year. Registrations are handled for interns, MBBS doctors as well as those completing their post-graduate studies. Since health is a State subject, those individuals who are interested in practicing in Delhi must register with the DMC in addition to being registered with the MCI. A variety of registrations for medical practice within the State are provided, and include Permanent Registration, Provisional Registration, Registration of Additional Qualification, and an Issue of Good Standing Certificates for doctors going abroad. Re-registration for the practice of modern medicine in Delhi is mandated every 5 years.

DMC offers provisional registration to those doctors who are in the internship phase. For instance, individuals who have studied under another State medical council, but would like to do an internship in Delhi are granted this. As evidence the MBBS certificate and verification from the medical college is needed. The process usually takes a month, and is similar for a non-provisional/regular certificate. Once the certificate is granted to the provider, it must be publicly displayed in the place of practice. In some instances, hospitals have sent requests to the DMC for the registration confirmation of specific providers.

In 2008 DMC received a list of 8 doctors from a hospital for verification, during which it was discovered that 7 of 8 of them had used forged documents. In such an event the doctor is arrested and the case is registered with the legal authorities. Following this incident other hospitals in the city also began to conduct this procedure of provider authentication. In the last year and a half the DMC has found 25 providers operating with forged certificates as a result of this process.

It was also reported that the DMC’s ruling that practitioners needed to obtain a minimum number of CME hours, in order to re-register themselves, had not been implemented.

The council also aims to protect the domain of doctors through *action against unqualified providers* of allopathic medicine. When the Council receives a complaint of a non-qualified or quack provider of health care, it bears the responsibility of forwarding these cases to appropriate authorities as a criminal case. The DMC is neither formally mandated nor proactively involved in the pursuit of and action against unqualified practitioners and charlatans; however it views anti-quackery efforts as imperative for the well-being of the doctor community and patients at large. Complaints against quacks are verified across the 9 districts in Delhi by the Chief District Medical Officer. Identified quacks are brought to the DMC to meet with anti-quackery committee and are subsequently made to shut down their practice. If the person continues to practice, then a case is filed in the courts. The DMC also plans raids with the CDMO, during which an authorized member of the DHS’s anti-quackery cell can seize the drugs as evidence.

The Council has taken on the additional duties of providing *protection to the members in discharging their professional duties*. The Council’s website states that it shall take steps to provide guidance and protective measures in order for the practitioner to continue his/her practice in a non-threatening atmosphere, and this was confirmed by an official.[[66]](#footnote-66)

Delhi Bharatiya Chikitsa Parishad

*(See also detailed description of the constitution, financing and other functions of the Delhi Bharatiya Chikitsa Parishad in the subsequent section on Conduct of Providers)*

The DBCP maintains a central, live register of qualified practitioners who practice Ayurveda, Yoga, Unani, or Siddha streams of Indian medicine. The Homeopathic Council separately governs the practice of Homeopathy in the State.

In the registration process DBCP verifies the identity of the individual and the successful completion of his/her degree from the college. Once the registration is approved a license to practice is granted for a period of 5 years. Registered practitioners are presented a certificate to display in their establishment to ensure their qualifications. The Registrar reports an updated version of the register to the Central Council once a year. This list can be considered as conclusive evidence in all Courts according the provision of the DBCP Act, and the absence of the name of any person is considered to be unregistered and a quack, until proven otherwise. The DBCP also takes active measures to eliminate quackery in Delhi through unannounced monthly and sometimes bi-monthly checks across 9 zones of the city for survey and inspection. Individuals found to be practicing illegally are fined and are made to shut down their practice.

In recent times 9 quack practitioners were fined Rs. 27,000 for their illegal practice. Fine money is received by DBCP in the form of cheques and demand drafts and is put towards financing the operational activities of the organization. In some cases, the DBCP encounters practitioners who are qualified with degrees, but do not have proper registration. The Directorate of Health Services also forwards complaints against providers practicing quack medicine to the organization. DBCP also carries out advocacy efforts and drives in the public domain to raise awareness about quackery and how to report it. Occasionally, complaints are received by DBCP directly from the public.

Quackery is a contentious issue among providers of Modern and Indian Systems of Medicine. There is active contestation between the two streams of medicine as allopathic providers do not want ISM providers to practice any allopathic methods. From the viewpoint of the modern medicine community this is viewed as quackery. However, ISM providers consider quackery to occur when an individual provides services with no qualifications whatsoever. “These days modern systems of medicine are included in an Ayurvedic education, therefore many allopathic elements are treated. Ayurvedic providers practice integrated medicine; by default they use some modern medicine techniques. This is not quackery.” The question about hypocrisy is raised about whether a provider of modern medicine can be considered a quack if he/she prescribes herbal medicines.

Delhi Medical Association

The Delhi Medical Association (DMA) was established in 1914. It is a non-statutory and autonomous body that prides itself as one of the largest not-for-profit service organizations of doctors of Modern Scientific System of Medicine in India. With 13 branches across the capital city and over 10,000 members, the organization includes members from the public and private sector. Each branch maintains its autonomy through its own office bearers, elections, members and executive body. The Association was originally intended as an intellectual platform for physicians to discuss issues of clinical importance. Predictably, the role and priorities of the Association also evolved to include the organization of activities such as various mass scale vaccination efforts, health check-up camps, measles and pulse polio programs; awareness generation against quackery and its eradication, and the facilitation of continuing medical education workshops for members. The DMA is able to carry out its designated functions through various self-financing mechanisms, which include funds generated through membership fees, solicitation of donations from various other organizations, and through partnerships. Although the State-level branches do not receive funding from the national level Indian Medical Association the IMA does maintain its authority to oversee the branches’ operations and policies.

One of the primary functions of the DMA is to protect the domain of doctors and the general well-being of the public at large through aggressive anti-quackery efforts. The objectives of the Eradication of Quackery committee are to sensitize members and public about the problems of quackery and to liaise with government agencies and NGOs to adopt and implement anti-quackery measures.

The DMA is committed to protecting the territory of doctors, and in its efforts identifies and reports cases of quackery to the DHS for action to be taken by the DMC. The DMA itself does not have the statutory power to take action on its own. This has yielded some dissatisfaction on the part of the DMA who feels that the response of the government to quackery is too mild and infrequent. “We can only report cases to the government, but they don’t do anything.” Although not explicitly outlined as an objective of the DMA, the organization advocates for the protection of doctors and takes action against manhandling of physicians and threats from patients.

The DMA has a strong relationship with the Delhi Medical Council, as both organizations share a common commitment to uphold the interest of medical doctors, and share some members.

#### Targeted at: Conduct of Providers

Delhi Medical Council

The Delhi Medical Council was established in 2000 under the DMC Act 1997. It is a legislative and self-regulatory mechanism that oversees the entry of practitioners into the medical profession through provider licensing and registration in the State. The Council also seeks to regulate the professional conduct of the providers through the implementation of regulations for code of ethical conduct. The DMC consists of 20 members, 8 of whom are formally elected through a general election, 4 nominated by the Delhi Government, 6 from medical colleges, an ex-officio member from the Directorate of Health Services (DHS), and 1 who is the dean of faculty of medical science. The DMC’s major activities are performed by the Registrar, who has been appointed by the health department of the Delhi State government. General meetings of the Council are held once a month and are attended by all the members. There are various sub-committees to perform the functions of the Delhi Medical council like Committee for protection of doctors; Ethics Committee; CME Committee; Anti-Quackery Committee; Disciplinary Committee; Land & Building Committee; Newsletter Committee; Finance Committee; Constitutional Amendment Committee; Nursing Homes Committee; Staff welfare Committee; Diagnostic Committee [[67]](#footnote-67).

The DMC falls within the purview of the national level body, the Medical Council of India (MCI), which oversees the State Council’s activities. The organization receives basic funding from the MCI to carrying out its routine operations; however, other activities can only be made possible through self-financing mechanisms. The granting of registrations for the practice of medicine is one of the main sources of finance for the DMC, according to the respondent.

The DMC also handles ethical misconduct and negligence complaints against registered individual providers through committee hearings and investigations, as per the guidelines of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002. The Council receives these complaints from the public and the Department of Health Services. Following a hearing and based on the concluding decision made by the disciplinary committee action against the practitioner is initiated. This can range from the issuance of a warning to the practitioner to suspension or permanent de-registration. In the experience of the DMC, in most cases suspensions occur for a temporary period of 1 to 3 months.

The DMC handles complaints of medical negligence which they receive from the police, the court and the MCI. The disciplinary committee of the DMC studies the case and then decides on course of action. The respondent indicated that some practitioners had been de-registered following an unfavourable adjudication of the disciplinary committee, although actual numbers were not forthcoming. However the punitive action meted out was typically temporary suspension for between 1 and 3 months.

Delhi Bharatiya Chikitsa Parishad

The Delhi Bharatiya Chikitsa Parishad (DBCP) was established under the Department of Health and Family Welfare as per the DBCP Act of 1998. The act provisions for the maintenance of a registry of practitioners for the Indian Systems of Medicine (ISM), for the prescription of a code of ethics for the regulation of professional conduct, and for the assurance that the practice of ISM is undertaken only by qualified providers. DBCP exists in parallel to the Delhi Medical Council, which falls under the jurisdiction of the health secretary of the MoHFW National Capital Territory. Unlike the DMC, DBCP is a part of the Directorate of Indian Systems of Medicine (ISM), Government of National Capital Territory.

The DBCP is a State-level statutory and autonomous body, and is made up of several committees that include Legal Affairs, Registration, Anti-Quackery, Disciplinary, and an Executive Committee. The Executive Committee consists of 21 members and oversees the administration of the DBCP functions. Elections for the Executive Committee take place every 5 years, with regularly meetings every 2-3 weeks. The members are nominated by the government from amongst qualified persons and then are elected for a period of up to 3 years. The daily operations of the DBCP are governed and carried out by a President and Vice President, who are on the Executive Board, and a Registrar and Deputy Registrar. The generation of funds for operational activities occurs through the collection of provider registration fees. This amount has been insufficient and leaves a difference between the organization’s revenues and its expenses exists, which is then covered by funds directed from the Central Council of India, the overarching body of the DBCP that also regulates ISM education in the country.

Complaints against a provider for medical negligence or professional misconduct, often received from the public is handled by the DBCP’s Disciplinary Committee comprising of a chairman, legal expert, member of Delhi’s legislative assembly, a specialist provider, and association member. The Committee determines whether the provider is guilty of misconduct and takes appropriate action taken based on the decision, which can either range from the issuance of a letter or warning or the de-registration either temporarily or sometimes permanently.

The Board’s engagement with disciplinary activities for misconduct and negligence, as mandated by the relevant Act, are minimal, and their focus of activities is primarily on advocating for the Indian Systems of Medicine, and reducing quackery.

Delhi State Consumer Disputes Redressal Commission

The Delhi State Consumer Disputes Redressal Commission, also known as the State Commission, was established under the auspices of the Consumer Protection Act (CPA) of 1986, which intends to safeguard the interest of consumers, protect them from exploitation and to save them from adulterated and sub-standard goods and services. The CPA Rules were framed in Delhi in 1987. The CPA mandated space for the establishment of Consumer Councils and other authorities for the settlement of consumer disputes and other related matters. Through this the State Commission provides for speedy and inexpensive settlement of consumer disputes through a quasi-judicial machine, but with a fully judicial process where the laws are laid down by the apex court.

The State Commission in Delhi State consists of a deputed President, formerly a Judge of a High Court with 5-year tenure, and two other members. A law background is not required for either of the members; however, one of them must be a woman. A full-time member receives a consolidated honorarium of Rs. 10,000 per month, or Rs. 500 per day of sitting if appointed on a part-time basis. In addition members receive Rs. 9,000 per month to cover their transportation costs. These expenses are defrayed out of the Consolidated Fund of India. The State Commission has administrative control over the District Forums, while the National Commission oversees the State Commissions on the matters provided in Section 24B of the CPA.

In Delhi, the scope of cases dealt with by the State Commission in the realm of health services includes those against private nursing homes for issues such as misdiagnosis and faulty procedures, and cases against insurance companies, and unqualified providers and quacks. Approximately 5 percent of cases handled by the State Commission were said to be of medical negligence. The determination of negligence occurs in a two step process: 1) whether the doctor was negligent, and 2) whether the negligence caused the outcome. In regards to cases of medical negligence and provider misconduct, the forum is highly dependent on presented evidence, rather than the consequences of an accused action. Legal provisions for cases of medical negligence and provider misconduct in the delivery of health services are not explicitly outlined in the CPA. Instead these instances are considered within the context of a “deficiency in service”, which must occur as a result of a paid transaction between a health service provider and paying patient. In reference to health services, this automatically precludes providers and services provided by the government and public health structures. In this capacity, the function of the CPA and State Commission is to serve as amelioration to the consumer through the determination of appropriate compensation.

The Privy Council initiated a counsel about 8 years ago, where matters of provider misconduct and medical negligence are to be handled through the Bolam Test. Under the Bolam Test, the advice of a panel of experts in the field must be solicited and should inform the decision of the case. The expert panel often consists of professors from local government medical colleges and sometimes also includes private ones. There are no empanelled experts, each case is unique and experts are identified based on the needs of the particular case. When hospitals do not have faculty, the case is referred for expert opinion to another hospital, however, this is not seen as a problem in Delhi. If the expert panel reports that medical negligence occurred then the State Commission proceeds to take appropriate action for compensation, or else the case is dropped. Documents that are used in medical negligence cases as evidence for negligence often include prescription papers. The State Commission does not hold any formal relationships with doctors associations or councils.

The Bolam Test was said to be well received by the doctor community, as is the case with the expert panel referral process and the yielded decisions. It was stated that the community of doctors associations and councils have not been “annoyed with the decisions made by the State Commission”, partly because an unfavourable final decision can always be appealed.

The nature of medical cases is seen as being complicated, due to the view that if a doctor is not palpably wrong in his/her treatment then action cannot be taken, “You can only find a defect if it is visible, if it can be felt”. Furthermore, the nobility associated with the medical profession should ensure that “one who practices medicine has ethics in mind… a doctor will never like it if his patients suffer”, therefore the occurrence of negligence is largely due to the limitations of the human mind. However, negligence cases due to an obvious lack of reasonable care are viewed differently, and not attributed to natural “human error”. While there is some difficulty in determining what is actual negligence versus what is due to human error, the pursuit against a doctor for malpractice by a consumer is fuelled by the view that health is an emotive issue. When reports from the expert panel are returned the State Commission, various advocates who, if unsatisfied by the panel’s decision can re-submit the case to an alternate panel for evaluation.

#### Targeted at: Accessibility of Care

Directorate of Health Services

*(See detailed description of the constitution of the DHS on page90)*

1. Planning and Establishment of Hospitals

The mandate of *the Hospital Cell* of the Directorate of Health Services is to increase the average hospital bed population ration from 2.5 to 5 through the establishment of more hospitals. The Cell consists of 4 staff members, who at the time of interview handled 12 projects worth Rs. 9000 million. The planning and establishment of hospitals falls under the Hospital Cell of the DHS, and is directly supervised by the Director of Health Services. The broad functions of the Hospital Cell involve site inspections of the proposed area and monitoring and coordination with different agencies that are related to the establishment of hospitals. The financial aspects of upcoming hospitals are also taken care of by the Hospital Cell. These tasks include the preparation of budgets and cost estimates of hospitals relating to manpower, equipment and other vital components required for the establishment of hospitals.

The first step of a ‘needs assessment’ is conducted by a District Health Committee headed by the CDMO, to determine whether the proposed area would benefit from the construction of a hospital. This is done in a participatory process to gain an understanding of the surrounding community, with relevant inputs from the local Member of Legislative Assembly. If the proposed site for the hospital does not fit into the currently outlined master plan of the city, a ‘no objection’ approval must be sought from the Development Department Authority (DDA) first. The DDA is vested with the authority to approve or disapprove the establishment of a hospital, with the DHS playing only a technical role. The plan must also pass muster from various committees including those investigating environmental and legal viability.

Improving the bed to population ratio is the driving force for the institution of more hospitals in Delhi. In early 1990s the DHS held full responsibility for the construction of most public hospitals, however, due to unfavourable changes in funding and policies increasingly favouring privatization, hospitals are now frequently being constructed and operated on a Public Private Partnership basis, reducing the extent of control they have over the location of services.

In the present context, the agreement to provide land for establishing a private hospital was seen to be the remit of the DDA. Reportedly, an advisory committee exists which investigates if the interested hospital company is qualified to build the hospital in accordance with norms, however the committee’s findings are not binding, as the DDA has the final word in such agreements. In this matter it is not mandatory for the DDA to consult with the DHS.

### *Regulatory architecture map: Delhi State[[68]](#footnote-68)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Target of Regulatory Activity | Group(s) tasked with relevant activities | Type of authority invested with group | Relevant policies and clauses | Relevant activities expected of the organization | Relevant activities actually performed by the organization (and additional activities in *italics*) |
| *COSTS OF CARE* | Rashtriya Swasthya Bima Yojana (RSBY)Nodal Agency | Official (government scheme) | Government of India, Ministry of labour and Employment, *‘Rashtriya Swasthya Bima Yojana’*, <http://www.rsby.gov.in/about_rsby.aspx> accessed on 10th Nov. 2010 | Empanelment of private facilities based on minimum standards, ensuring adherence to norms and standards, de-registration in case of breach | 90 private establishments enrolled, Indirect regulatory mechanism: contracted insurance company as intermediary has financial interest in minimizing gross expenditure, but not directly in reducing costs to users. Does post-facto monitoring of the records maintained by private establishments. Identification of fraud in some instances and 3 hospitals de-empanelled. No direct oversight to prevent fraud and unnecessary procedures. |
| Enrolment and allocation of smart cards to RSBY eligible members, dissemination of information to RSBY members about eligible facilities for health services | Enrolment lower than targeted, possibly due to low awareness of programme among beneficiaries |
| Directorate of Health Services:  Nursing Home Cell | Official (State government policy) | Guidelines for provision of free treatment facilities to patients of EWS category in private, 2007 <http://www.delhi.gov.in/wps/wcm/connect/3cd0a5004d9238eeaa5eaf09e0ee946a/guidelines.pdf?MOD=AJPERES> accessed on 24.05.2010. § A 5, § A 10,§ A 5, § A 16 & 17 | Monitoring of the free treatment for 10% in-patient beds and 25% of Out-patient to the Economically Weaker Sections (EWS) by the Private Hospitals that have been allotted land on concessional rates by the inspection committee. Inspection of the records, solicitation from private facilities of twice-daily report on the availability of free beds, and three-monthly report on utilization of free beds. | Inadequate regulation of subsidy conditions widely recognized, attributed to lack of role clarity between departments, and resource limitations. Litigation against private establishments reneging on subsidy conditions was followed by creation of new body: Social Jurist, to oversee subsidy conditions. |
| *QUALITY OF CARE* | Directorate of Health Services: Nursing Home Cell, and district CDMOs | Statutory | Delhi Nursing Home Registrations Act, 1953. § 4 (1),§ 9 ff, § 7 ff, § 6, § 8  <http://www.delhi.gov.in/wps/wcm/connect/doit_health/Health/Home/DHS/Nursing+Home+Cell> accessed on 24.05.2010 | Registration and renewal of private clinical establishments in accordance with infrastructure and personnel standards. | Multiple contestations and subsequent dilutions of standards, current focus mainly on infrastructure standards. Registration not universally implemented many establishments function unregistered. |
| Inspections of facilities to assess adherence to norms, periodically, and in response to complaints | Inspections inadequately performed, typically only in response to complaints, attributed to lack of capacity, motivation, political factors within medical fraternity. |
| Cancellation of the registration, imposition of penalties in case operating without registration | Cancellations of a small number of establishments. Action in case of non-registration rare, attributed to lack of capacity, motivation, political factors within medical fraternity. |
| Directorate of Health Services:  Continuing Medical Education Cell | Department policy | - | Organization of CME for government practitioners, dissemination of information regarding training programmes | CME undertaken in various technical domains, however overall execution of CME reported to be inadequate. Attributed to lack of official mandate, coupled with inadequate follow up by DMC. |
| Delhi Medical Council | Statutory | Delhi Medical Council Act, 1996. § 15(3),§ 22 ff,  § 15 (2),  Indian Medical Council Act, 1956. § 22 | Registration of graduates for practice of allopathic medicine, maintenance of State Medical Register, periodic reporting of the registry to the National Register | Registration activities ongoing as mandated. Several forged certificates identified in previous months, leading to arrest of culpable parties |
| Notifying registered practitioners for renewal of registrations every 5 years contingent on CME credits, receipt and processing of renewals from practitioners | Enforcement of renewals of registration inadequate, CME credits rule not implemented |
|  |  |  | *Receipt of complaints of non-qualified providers, forwarding to authorities, and anti-quackery advocacy* |
| *Guidance to, and protective measures for practitioners in discharging their professional duties* |
| Delhi Bharatiya Chikitsa Parishad | Statutory | Delhi Bharatiya Chikitsa Parishad Adhiniyam, 1998. § 10(a), § 25 ff, § 33 ff, § 10(h).  Indian Medicine Central Council Act, 1970. § 24 | Registration of the graduates for practice of Indian medicine, maintenance of State register of Indian Medicine, reporting to Central Council | Registration activities ongoing as mandated. |
|  |  |  | *Active identification of, and receipt of complaints of non-qualified providers, forwarding to authorities, and anti-quackery advocacy* |
| Delhi Medical Association | None (voluntary body) | Indian Medical Association Charter | Continuing Medical and Health Education to doctors through privately organized events to promote and advance medical and allied sciences | CME in a number of topic areas, efforts to involve more practitioners in public health efforts, such as vaccination and health camps |
|  |  |  | *Active reporting of cases of quackery to the government, anti-quackery advocacy* |
| *Protection of doctors against physical threats and violence* |
| *Advice and support to doctors accused of medical negligence* |
| *CONDUCT OF PROVIDERS* | Delhi Medical Council | Statutory | Delhi Medical Council Act, 1996. § 21 (2) ff. § 21 (3) & (4). | Receipt of complaint against practitioners. | Complaints from aggrieved patients received and processed. Some instances of rulings against doctors, typically followed by minimum punitive action, i.e. suspension for 1-3 months. Precise data of de-registrations not made available. |
| In-camera hearing and adjudication by disciplinary committee |
| Suspension or cancellation of practitioner from the State medical register, if guilty |
| Restoration of the suspended name on expiry of the term of suspension |
| Delhi Bharatiya Chikitsa Parishad | Statutory | Delhi Bharatiya Chikitsa Parishad Adhiniyam, 1998, § 23 (2) ff.  § 23 (4) ff. § 24 (2) | Receipt of complaints on ethical misconduct, conduct of enquiry by disciplinary Committee. Suspension of practitioner or removal from Register on establishment of the misconduct | No evidence of disciplinary action forthcoming. Minimal emphasis on disciplinary role and procedures. |
| Reinstatement of the name in the register if found that the implicated charges are found to be false, or expiry of suspension period |
| State, District Consumer Disputes Redressal Forums | Statutory | Consumer Protection Act, 1986. §11(2)ff, § 17(a) (ii)  Consumer Protection (Amendment) Act, 2002. §7, §13 | Adjudicating cases of medical negligence under consumer law, and consequent redress | Numerous cases adjudicated. Subjective nature of the cases related to medical negligence makes it difficult to determine the ruling. Reportedly the “benefit of doubt” is often given to doctors. |
| *ACCESSIBILITY OF CARE* | Directorate of Health Services:  Hospital Cell | Official (State government policy) |  | Planning and establishment of hospitals, under supervision of DoHFW, following assessment of need and due inspections | Reduced control over location of hospitals due to emerging PPP policies, and greater controlling influence of Urban development authority. |

### *Gaps in regulatory policy at State level: Delhi*

#### Design of regulatory policies

Policies for reducing the costs of care for the majority of users of care in Delhi have been based on the recognition that the majority of care is sought in the private medical sector. The national social insurance scheme (RSBY) and through government subsidies for free care both aim at reducing costs of private care for the Economically Weaker Sections (EWS) of society. They do not address the attendant issue of high incident costs of care in public facilities, or the financial protection of the middle class and those in poverty, but who are not officially designated as EWS. There is no direct control of costs of care for packages of interventions, nor is there any agency apparently tasked with regulation of competition in health markets. The mandate of regulating quality of care is divided between the State health department’s oversight of standards of establishments, self regulatory councils’ control over qualification requirements to practice medicine, and voluntary medical association’s undertaking to boost continuing medical education. There is no credible regulatory mechanism to limit the practice of medicine by unqualified providers. Conduct of healthcare providers is putatively regulated through the quasi-judicial processes of the professional self-regulatory councils, and increasingly through the recourse of consumer courts. For both quality of care and conduct of providers, the absence of a credible community-based forum for grievance redress emerges as an apparent gap in design. The concern of equal accessibility of care is not addressed through a distinct act or policy of the State.

#### Implementation of regulatory policies

Costs of care

The implementation of the RSBY is as yet very partial, being impeded by significant information asymmetries resulting in slow uptake by target communities. The scheme is run mainly through contracting of insurance companies and by way of an elaborate electronic system to maintain and audit records. Instances of fraud and abuse of the system have been reported. The *absence of a stringent regulatory component* of the scheme which monitors real-world health care processes and relationships between stakeholders may diminish the success of the programme in reducing costs for end-users.

Government policies to subsidize private hospitals on the condition that they provide some services free to EWS individuals are largely unimplemented; a phenomenon underpinned by *inter-departmental dynamics* within the State health sector, and *reduced investment in regulatory capacity* of relevant departments.

Quality of care

The Delhi Nursing Homes Registration Act may be characterized to be widely ineffective. This can be attributed in part to multiple contestations of its contents by interests representing the medical fraternity, leading to a *dilution of the standards* it proposes. Secondly, very few establishments are actually registered, and inspections of those which are registered are infrequent – these failures of implementation result from *personnel constraints* and *organizational inertia* of the relevant State health department. Medical politics may underpin both of these phenomena, with the doctors’ fraternity exerting their influence to reduce regulatory interference which is seen to adversely affect commercial interests.

Professional self-regulatory councils are expected to play a largely instrumental role in this domain, by maintaining registers of practicing professionals. However they also participated in additional unmandated activities including action against unqualified medical practitioners and protection for doctors who are under threat of violence. Councils appear to have undergone a *transformation in organizational identity* to be focused less on their putative role of a highly neutral regulatory body, and more on protecting the rights of individual practitioners, and the sanctity of the medical profession. This divergence of identity is further complicated by the close relationship between the council and the largest voluntary medical association, which has a principal interest in advancing the interests of their doctor members. The Medical Association undertakes CMEs, and is also actively involved in efforts to eradicate quackery, protect doctors from physical harm, and provide advice and support to doctors accused of negligence.

Conduct of Providers

Professional councils are mandated to uphold standards of conduct among medical practitioners through enforcement of a code of ethics, and the disincentive of disciplinary action. However councils were observed to be less engaged with this function and more with their voluntarily added functions of providing leadership and protection to the medical community. This may have been a factor in determining that *instances of disciplinary action taken were infrequent*, and *punishments to doctors found culpable of negligence or misconduct were often of the lowest order*. Consumer forums were apparently more prolific in adjudicating cases of medical negligence and misconduct, but may have also been influenced, by the subjective and specialized nature of medical knowledge, to more frequently rule not to indict doctors.

Accessibility of Care

The implementing role for determining the *location of new hospitals is mandated to the urban development authority*, with the health department playing only an advisory, and hence non-decisive, role. New hospitals are primarily being constructed through the conduit of public–private partnerships, which further reduces the influence of the State department in determining location.

# ASSESSMENT OF METHODOLOGY

## Methodology Process and Milestones

The process of drafting the tool, implementing it for pilot case studies in Delhi and Madhya Pradesh, and refining it, based on experiences from the field and theoretical inputs, represented a continuous cycle of learning, adaptation and re-testing, with small and large feedback loops. Initial drafts of the tool were built around linking goals of regulation with regulatory strategies or mechanisms, and exploring respective roles (actual and expected) of regulatory organizations corresponding to each regulatory strategy (see Figure 2)

|  |  |  |  |
| --- | --- | --- | --- |
| **Goals of regulation** | | High quality, accountable, ethical and equitable health service delivery | |
| **Regulatory strategies** | | Controlling market entry of professionals, of establishments, quality of care standards, ethical conduct, process standards and transparency, grievance management, controlling prices | |
| **Organizations / groups / bureaus**  **Their putative and actual roles in regulation**  **Their interlinkages** | | Professional councils, health departments at national and state level, accreditation bodies, professional associations, consumer groups, insurance agencies | |

Figure 2. Preliminary conceptual framework

Key milestones in refining the design of the tool included:

* *Eliminating the consideration of regulatory strategies.* While a list of regulatory strategies was found to be useful in generating a list of organizations, it tended to obfuscate the relationship between real-world actions and regulatory goals, and added a layer of unnecessary complexity. Both putative and actual roles of regulatory organizations did not easily fit into categories of different regulatory strategies and approaches, as described in theory and literature. For example professional medical councils in the literature are widely regarded as emblematic of a self-regulatory or market-based mechanism for regulation, however in the Indian context these councils are partly constituted by government actors, hence their putative roles could be interpreted to be closer to a command-and-control strategy.
* *Backward-mapping emphasis*: We decided instead to rely entirely on the backward-mapping approach, in which organizational roles were not linked to ostensible regulatory mechanisms, but instead, directly to regulatory ‘targets’ representing field level phenomena of concern, identified from a literature review of mixed health systems. This approach was found to be relatively more successful in achieving coverage of all domains of regulation and establishing a clear unfiltered view of the regulatory architecture, linked to desired outcomes.
* *Diagnostic function:* A key milestone in refining methodology was to expand what was a primarily exploratory tool, to include clear diagnostic and explanatory functions. Distinction of the putative regulatory architecture (as defined by documents) and actual regulatory architecture (as defined by actors), as separate columns (5 and 6) in the tool matrix (see Annexure), denotes this expansion of functions. Identification of design and implementation gaps (diagnostic function) and summation of factors underlying these gaps (explanatory function) were enabled in this manner.
* *Mapping policy content*: Early iterations of the tool did not consider the importance of contents of policy documents. An early refinement was to list relevant policy contents from policy documentation as a distinct step (Step 2), before listing relevant organizations (Step 3). Focusing on policy content helped achieve greater coverage of organizational actors, and precision in defining their putative roles, and correspondingly, divergences from these putative roles.

## Strengths of Tool

Key strengths of the research tool include:

* *Self-explanatory nature*: the steps in the tool, and also the map matrix – as the key outcome of implementing the tool – are simple and self-explanatory. The matrix follows a universal log-frame design, and demonstrates both the mapping function and the diagnostic function of the tool (gap identification) with good effect.
* *Domain coverage*: within the limited purview of health care provision, the backward mapping approach effectively covers a majority of regulatory activities and policies, which can be attributed to the backward-mapping approach of focusing on field phenomena requiring policy intervention.
* *Adaptability*: the tool is inherently flexible, and members of the research team have adapted part of it to address other policy domains including 1) mainstreaming of indigenous health providers[[69]](#footnote-69), and 2) community participation for health[[70]](#footnote-70), as part of other institutional activities at the Public Health Foundation of India. The tool awaits field testing in other country settings, and in other States of India.

## Weaknesses of Tool

Key limitations or weaknesses of the tool include:

* *Comprehensiveness:* while the researchers attempted to enlist all the relevant organizations and policies, the pilots threw up listings which were short of being comprehensive – representatives of some organizations were unavailable and in other instances, policies relating to the activities of some regulatory organizations are not in the public domain, and could not be accessed. For example, after the study was completed, team members identified the presence of the Competition Commission of India, a national level body which should necessarily have constituted part of the putative regulatory architecture for health care provision, but which was omitted while conducting the pilot study.
* *Surface analysis:*  the tool maps regulatory activities at the level of the Province or the State, but not at lower levels. Far richer analyses of implementation gaps an be expected through more in-depth study at lower echelons or regulatory institutions. India’s complicated federal structure, whch frequently features sharing of roles between twinned national and State-level organizations, or splitting of functions across the State and the Union, is a source of ambiguity. While these distinctions and relationships are explicated in the running text, the map matix does not effectively depict how the State regulatory architecture links with the national regulatory architecture.
* *Data gaps*: In a few instances, no information about organizational activities was forthcoming from the participants. While these are technically unresolved gaps in the data, triangulation revealed that these refusals frequently reflected organizational deficits – the inability of a State Medical Council to furnish data on doctors’ being subjected to disciplinary proceedings, is likely to have been linked to that organization’s inattention to performance of their putative functions in this area.

## Utility and Applicability

The research outputs consist of a research report for the province or country being investigated, supported by detailed charts of the prevailing regulatory architecture in that province / country, and diagnoses of gaps in design and implementation of regulatory policy. These outputs may be utilised by policymakers at provincial, national and international levels, and by researchers:

* To redesign and/or modify institutional arrangements for regulation (design gaps)
* To strengthen relevant aspects of institutional implementation (implementation gaps)
* As a baseline against which to assess the success of future reforms and improvements in regulatory policy
* To compare the architecture of regulatory systems across different countries or provinces
* As the preliminary stage of an in-depth exploration of implementation of regulatory policies

# ANNEXURES

## Topic guide for in-depth interviews with representatives of regulatory groups

*<Name of Research Organization>*

*<Year>*

**Characterizing the Regulatory Environments of Mixed Health Care Systems in Low and Middle-Income Countries (LMIC)**

***Case Study:*** *<Name of Country / Province>*

**TOPIC GUIDE – POLICY ACTORS**

* *Introduce self and engage respondent*
* *Provide information on the study and objectives, confidentiality and further information as detailed in the consent form*
* *Take informed consent for interview*

**Commence the interview**

1. Personal designation and role within the organization/department
2. Administrative structure, oversight and financing of the organization/department
3. Legal status of the organization/department
4. Affiliations and interlinkages with other bodies/organizations, if any
5. Goal and philosophy of organization/department
6. Designated functions of the organization/department
7. Designated functions of the organization/department in regulating health care (corroborate with putative roles)
8. Experiences of executing each of these functions
9. Shortfalls and obstacles in executing each function
10. Interactions with other organizations and departments for each of these functions
11. Additional tasks and activities undertaken in sphere of health care regulation
12. Position or stance of organization/department vis-à-vis regulation of health care
13. Opportunities to strengthen/modify role of organization/department in regulating health care
14. Avenues for strengthening/modifying regulation of health care in the State

*Obtain / reconfirm the following details*

* Full name of respondent \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Designation of respondent\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Close the interview with thanks**

*Leave contact details with respondent*

Points to remember while conducting interview:

* Take time to build rapport and comfort
* Cover all the topics carefully, as the interview proceeds although not necessarily in sequential order
* Encourage detailed narratives of experiences, probe carefully to encourage - not interrupt - narratives
* Focus on *experiences* of specific events and phenomena, not on hypothetical or abstract examples
* Encourage respondents to provide explanations of their experiences, rather than opinions which are not linked to specific experiences
* Probe appropriately, introduce new topics naturally in the course of conversation
* Avoid leading questions, do not pre-empt responses
* Always be respectful, adopt a neutral tone and consciously avoid expressing judgment, even if you do not agree with the respondent

## Format for informed consent

*<Name of Research Organization>*

*<Year>*

**Characterizing the Regulatory Environments of Mixed Health Care Systems in Low and Middle-Income Countries (LMIC)**

***Case Study:*** *<Name of Country / Province>*

**Verbal Consent Process and Form**

*Information to be conveyed to the respondent prior to obtaining consent:*

We are doing a research study exploring the issue of regulation of healthcare systems. The study is being conducted by < Name of Research Organization>, with financial support from <Name of Funding Agency>.

We are hoping to talk with you for about 30 minutes to one hour. Please talk to us freely and frankly and let us know if there are any issues we bring up that you do not want to discuss. At any time, you may terminate an interview or request that interview data be removed from the study. Please let us know how we should cite your statements, in our reports and publications:

- Under your own name and designation / under an alias

- Name of institution cited / name of institution withheld

Your participation in this study, and all records about your participation, remain confidential unless you expressly indicate otherwise. All data will be stored in secure locations and available only to study personnel. None of the information obtained will be identified with you, or your office of work.

If you have any questions now I will answer them, and if you have questions later you can contact us.

Statement of the person administering consent

I have fully explained to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ the context, purpose, procedures and risks that are involved in the above-described study. I have taken free and informed consent from him/her to participate in the interview, without suggestion or coercion. I have answered all questions to the best of my ability.

\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date Signature (Person Administering Consent) Name

*Witnessed by:*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature (Witness) Name

## Template for mapping the regulatory architecture

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| COL 1. Target of regulatory policy | COL 2. Group(s) tasked with relevant activities | COL 3. Type of authority invested with group | COL 4. Relevant policy(ies) and clauses | COL 5. Relevant activities expected of organization | COL 6. Relevant activities actually performed by organization |
| *COSTS OF CARE* | 1. |  |  |  |  |
| 2. |  |  |  |  |
| *QUALITY OF CARE* | 1. |  |  |  |  |
| 2. |  |  |  |  |
| *CONDUCT OF PROVIDERS* | 1. |  |  |  |  |
| 2. |  |  |  |  |
| *ACCESSIBILITY OF CARE* | 1. |  |  |  |  |
| 2. |  |  |  |  |

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1. Our approach is presaged on Elmore’s assertion that one’s ability to influence a problem is proportionate to one’s closeness to it [↑](#footnote-ref-1)
2. As such, we limit use of the term ‘regulation’ due to its (flawed and) limited connotation of government action to contain markets, instead preferring the broader ‘regulatory policy’. Further, ‘regulatory policy’ avoids the presumption that this wide-ranging sphere of policy activity is solely the domain of government, with a variety of non-state and societal actors also involved in regulatory processes (even as they would not be classified as ‘regulators’ or agents of ‘regulation’ in the orthodox understanding of the term). Here we draw on the emerging ‘new’ institutionalism in the policy sciences (distinct from new institutional economics – (Williamson 2000)), which integrates societal and state-oriented models to achieve an understanding of how policy is made (John 1998, Scott 1995). [↑](#footnote-ref-2)
3. A second, deeper level of implementation research may be conducted as a follow up to such a mapping exercise, to achieve a more in-depth understanding of regulatory processes in real world settings. [↑](#footnote-ref-3)
4. Government of India, Constitution of India, Article 252 [↑](#footnote-ref-4)
5. Clinical Establishments Act, 2010 [↑](#footnote-ref-5)
6. Consumer Protection Act, 1986 [↑](#footnote-ref-6)
7. Consumer Protection (Amendment) Act, 2002 [↑](#footnote-ref-7)
8. Medical Termination of Pregnancy Act, 1971 [↑](#footnote-ref-8)
9. Medical Termination of Pregnancy Rules, 2003 [↑](#footnote-ref-9)
10. Medical Termination of Pregnancy Regulations, 2003 [↑](#footnote-ref-10)
11. The Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 [↑](#footnote-ref-11)
12. The Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Act, 2002 [↑](#footnote-ref-12)
13. The Indian Medical Council Act, 1956 [↑](#footnote-ref-13)
14. The Indian Medicine Central Council Act, 1970 [↑](#footnote-ref-14)
15. The Indian Medicine Central Council (amendment) Act, 2010 [↑](#footnote-ref-15)
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67. <http://www.delhi.gov.in/wps/wcm/connect/doit_health/Health/Home/Regulatory+Councils/Delhi+Medical+Council> accessed on 20th November 2010 [↑](#footnote-ref-67)
68. Caveat: may not be comprehensive. Contents of table are derived from analysis of subjective accounts of policy actors, and review of documents. [↑](#footnote-ref-68)
69. Sheikh, K, Nambiar, D, Sathyanarayana, TN, Lakshmi, JK, Narayan, V, Gayathri, K, Porter, JDH. *Engaging Traditional, Complementary and Alternative Medical Providers in the Delivery of Health Services: Implementation Analysis of Integration Strategies in Four States of India*. PHFI Working Papers. New Delhi: Public Health Foundation of India, 2011. [↑](#footnote-ref-69)
70. Public Health Foundation of India. *Guidelines for the Constructive Participation of Communities, Local Elected Representatives, NGOs, and the For Profit and Not-for-Profit Sectors in the Delivery of Health Care.* Recommendations on Universal Health Coverage of the High Level Expert Group appointed by the Planning Commission, Government of India, June 2011 [↑](#footnote-ref-70)