Regulation as a part of Management Reforms

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The background paper on regulation is divided into three sections:

**First section**
The first section examines the key definitions and inter-disciplinary perspectives on regulation, discussing its common conceptual understanding in theory and practice. It also describes various instruments and tools of regulation and how together they create a system of equity and accountability in health care delivery, while ensuring improved quality of care.

**Second section**
The second section is a broad sketch of the existing regulatory mechanisms and their effectiveness in India and countries worldwide, particularly focusing on low and middle income and developing countries.

**Third section**
In the third and the last section there is discussion on the key lessons of regulation, focusing on the opportunities and challenges that are before government and policy makers interested in scrutinizing existing regulatory practices and developing new ones. The discussion in this section focuses on the need for effective regulation of the health care sector in India and the governance mechanisms required to attain universal health coverage (UHC) coverage for the Indian population.
Section 1

The Need for Regulation
Public health systems around the world have evolved extensively with governments adopting new measures to deliver better health care services to their people. Demographic transition and the epidemiological shift in disease burden have led to the advent of new medical technologies and health care financing mechanisms, also resulting in the entry of new players into the health care market. The role of the private sector is ever expanding, but its activities need to be monitored closely to ensure ethical conduct, improved health care outcomes and patient safety.

A dramatic upsurge in the core health activities along with peripheral supplies and services has transformed health care around the globe, which means that governments can no longer function as the sole benefactor and provider of health care services. What is now needed of government is to expand its role in driving the health sector, accordingly increasing the scale, scope and sophistication of the responsibilities and functions required of such a role.

Since the early 1990s, the state’s supervisory role has evolved manifold, so that the term stewardship is being applied to its overall policy and management responsibilities. The stewardship role of governments can go a long way in ensuring better management of health care services. Since regulation is an important tool for the achievement of public policy goals, an appropriate regulatory apparatus needs to be instituted to keep a check on the system and incorporate quality control measures. Regulation is indispensible for safeguarding ethics and streamlining control processes within the system. The unique character of health care as a social as well as a private good reinforces the importance of the regulatory role in the health sector (Saltman in press).

Key Definition(s) of Regulation
There have been many conflicting and confusing view points. As per the Organisation for Economic Cooperation and Development (OECD), regulations include laws, formal and informal orders and subordinate rules issued by all levels of government, as well as rules
issued by non-governmental or self-regulatory bodies to which governments have delegated regulatory powers. (OECD report 1997)

Chinitz suggests that regulation looks different from the viewpoints of economics, management, law and politics. Baldwin et al. (1998) have tried to compile the various definitions of regulation found in academic literature into three basic categories, depending on the range of control exercised:

- According to the first definition regulation is setting forth mandatory rules that are enforced by a state agency. This puts regulation in an economic or social perspective without imposing on it the criminal justice system or any type of sanctions unless the court decides so.

- The second definition takes a political viewpoint on regulation, incorporating all efforts by state agencies to steer the economy. This board view includes state ownership and contracting, as well as taxation and disclosure requirements.

- The third and broadest definition of regulation states that regulation includes all mechanisms of both intentional and unintentional social control. These are social regulations, which protect public interests such as health, safety, the environment, and social cohesion. This environmental approach to regulation emerges when societal norms and values bond with intentional policy initiatives.

Lately responsive regulation, which takes into account the culture of those being regulated, is gaining ground. Responsive regulation is an approach that values trust, transparency and professionalism. It aims to transcend the polarized choices between punishment and persuasion.

Research on magnet hospitals (so termed because of their success in attracting and retaining nurses) has generated enough research evidence to make a case for responsive regulation.
Allocating Regulatory Roles to Different Actors
A wide range of different public sector bodies can be involved in regulation. The three major pillars of a democratic state that play a clearly delineated role are:

- The Legislature (Parliament)
- The Executive (Government and government administration)
- The Judiciary (the Courts)

Other governmental, quasi-governmental and non-governmental actors may also be expected or designated to act as regulators. Some countries transfer public responsibility to either regional (county, state, autonomous community) or local (municipal) authorities, while others delegate ‘self-regulatory’ authority to various private-sector entities (licensure to medical associations, insurance to sickness fund associations).

To carry out the regulation some countries utilize independently managed national agencies (National Board of Health, Office of Prices and Tariffs, National Insurance Fund, etc.) which are responsible for the activity being regulated, the segment of the health system being regulated (hospitals, physicians, etc.), the capacity of various actors within that segment and other factors including institutional structure and cultural traditions. **Regulatory activity itself, in the health sector as elsewhere, consists of legislation, implementation, monitoring and evaluation, enforcement and judicial supervision.**

Mechanisms of Health Sector Regulation
Health sector regulation is aimed at two aspects of health policy-the policy objectives and managerial mechanisms to achieve them, each with specific functions, yet closely connected in order to achieve national health goals.

**The first aspect of regulatory activity can be termed as social and economic goals.** It is normative and value-driven in nature, concerned with specific policy goals and with the broad public interest in mind (which may be seen differently in different countries). Such value-driven decisions tend to change only infrequently, typically as a consequence of major historical events such as wars (the foundation of the British National Health Service in
1948), the end of dictatorships (the change from social insurance to national health-type systems in Portugal and Spain) or as a result of political revolutions (as in central European countries after 1990).

The second aspect of regulatory activity can be termed as health sector management mechanisms. This level is what concerns us most; it is practical and operational and is concerned with the specific regulatory mechanisms through which decision-makers seek to attain policy objectives. These management mechanisms (as listed below) are technical in nature and emphasize effective and efficient management of human and material resources. They may or may not have a direct impact on the ability of the overall health system to achieve its broad policy objectives. These managerially oriented mechanisms may have a mixed public/private character, reflecting the number of different provider arrangements across the health sector. Their managerial focus means that they tend to emphasize micro-level activities at sub-sector or even at facility/institution level.

<table>
<thead>
<tr>
<th>Health sector management mechanisms</th>
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<tr>
<td>• <strong>Regulating quality and effectiveness</strong>: assessing cost-effectiveness of clinical interventions; training health professionals; accrediting providers</td>
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<td>• <strong>Regulating patient access</strong>: gate-keeping; co-payments; general practitioner lists; rules for subscriber choice among third-party payers; tax policy; tax subsidies</td>
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<tr>
<td>• <strong>Regulating provider behaviour</strong>: transforming hospitals into public firms; regulating capital borrowing by hospitals; rationalizing hospital and primary care/home care interactions</td>
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<tr>
<td>• <strong>Regulating payers</strong>: setting rules for contracting; constructing planned markets for hospital services; developing prices for public-sector health care services; introducing case-based provider payment systems (e.g. diagnostic-related groups); regulating reserve requirements and capital investment patterns of private insurance companies; retrospective risk-based adjustment of sickness fund revenues</td>
</tr>
<tr>
<td>• <strong>Regulating pharmaceuticals</strong>: generic substitution; reference prices; profit controls; basket-based pricing; positive and negative lists</td>
</tr>
<tr>
<td>• <strong>Regulating physicians</strong>: setting salary and reimbursement levels; licensing requirements; setting malpractice insurance coverage</td>
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Source: *Regulating Entrepreneurial Behaviour in European Health care Systems, European Observatory on Health care Systems Series.*

The specific choice of mechanisms as well as the balance among them differs from country to country. It largely depends on the broad policy
objectives and the overall health sector design. For example, in the post-1977 competitively structured health systems in the Netherlands, anti-trust concerns were far greater than in Germany which has predominantly corporate arrangements. The definition of regulation adopted by the policy makers and the rationale that countries adopt to justify or reject specific regulatory mechanisms, play an important role in the overall regulatory design adopted.

Bennett et al. provided a comprehensive framework of health care regulation incorporating the above mentioned health sector management mechanisms. Regulators exert power over the regulated through various mechanisms, e.g. entry to market, quality and safety, quantity and distribution, price, public information and advertising. Teerawattananon et al. later adopted this framework to study health sector regulation in Thailand.

**Conceptual Framework of Health care Regulation**

![Conceptual Framework of Health care Regulation](image)

Approaches for Regulating Quality of Care

Quality can be seen from the viewpoints of technical quality and quality of and patient care. Lack of well defined laws often leads to poor quality of health care. Even if laws exist, delay in their enforcement and or lack of self regulation by the medical community is a constant challenge for improvement of health outcomes. Three main approaches to quality regulation traditionally used by governments and professional bodies to ensure, maintain, and improve the quality of health care are Licensing, Certification, and Accreditation. Each of the three approaches has a distinct purpose but they are not mutually exclusive. Together, they can contribute to a country’s overall strategy for ensuring quality of health care services.

Similarities in the approaches:

- All three are based on external assessment or evaluation against explicitly defined standards.
- All three approaches share a common goal of ensuring public safety and promoting the quality of health care by striving to create uniformity of practice by service providers and health care delivery institutions.

The three approaches also differ strikingly on:

- whether they are mandatory or voluntary
- differing in the character of the issuing or enforcing organization
- with respect to who is the object of evaluation
- in the level of detail of requirements and the scope of standards
- in the frequency with which evaluation is carried out
- in the assessment methodology used

Approaches targeting health care providers and health care facilities vary. The quality evaluation of health care facilities, for example, may assess the level of compliance with established standards for structure (e.g., presence of policies, facilities, equipment), work processes of staff as a whole (e.g., overall adherence to clinical guidelines, staff supervision), or outcomes (e.g., infection rates, case fatality rates) for the facility as a whole or for
individual departments, though not for individual providers within the facility.

Of these three approaches, accreditation requires a detailed understanding from a theoretical perspective. Accreditation is one process in a range of different approaches for checking and standardizing the quality of health care delivered by health service organizations (Scrivens 1996). Until the 1980s, the term ‘accreditation’, when applied to health care organizations, was used to describe a voluntary, health service based activity that allowed all organizations, and particularly hospitals, to compare their organizational processes and procedures against accepted good practice. Frequently, the emphasis was on safety of procedures, the aim being to provide an environment in which clinical effectiveness could be maximized (Scrivens 1995). Traditionally, accreditation bodies have been self-funding and, in most cases, organizations seeking accreditation pay a fee. The end result of the accreditation process is the award of a grading or score denoting the degree of compliance with the standards. The grade is determined by the number of years that are allotted before the next survey is required. The better the degree of compliance found in the institution the longer the period before the next survey is required and the higher the grade assigned to it. (Scrivens 1995)

How the regulatory framework is operationalized depends on whether participation in the accreditation process is voluntary or compulsory, whether there are standards that have to be met and whether there is a scoring system that denotes a pass or a fail.

Section 2

Regulation in India

Current Scenario

The Indian health care system has made great progress in terms of overall achievement; however the current health care market has a transformed dynamics with multiplicity of players. A World Bank publication released in October 2010 remarks that inadequate regulation undermines India’s health care. Concerns have been raised on the dominating private sector and its poor quality in service provision and the failure to enforce
regulations. Although India has a strong legal framework (see Annexure) there has been an absence of structured health care regulation as this regulation through the bureaucracy does not seem to be working well.

Public safety in health sector is not guaranteed and service delivery and financing are neither transparent nor accountable, making the delivery of health care prejudiced against the poor. Potential harm to the public is inevitable considering the advent of new technologies and pharmaceuticals (Bloom, Lloyd and Standing, 2008). India’s current regulatory approach, therefore, does not address its highly unregulated market.

Experiences from other countries also highlight the limited capacity of governments to oversee the private sector. Attempts to formally intervene in the public sector have done more to increase transaction costs than achieve public policy goals (Leonard, 2000). Many transactions occurring in private health care go unnoticed because of the lack of government oversight. The 2002 Health Policy by the Indian government called for implementation of ‘statutory regulation’ and the ‘monitoring of minimum standards’ in the private sector. However, such a conventional approach fails to achieve the over arching goals of equity, efficiency, accountability and social justice.

The National Health Bill of 2009 promulgates setting up National and State Health Boards to oversee the implementation and monitoring of the public health sector. The Board shall perform several regulatory functions like regulation of clinical research, field trials and health technology assessments; regulation of public and private clinical establishments and other health service providers; regulation of the Health Impact Assessment; regulation of health care insurance companies and providers. The Bill also proposes the establishment of a national level health service regulatory body to ensure compliance with the aforementioned standards, protocols, norms and guidelines, and lays down the rules/regulations for its functioning. The regulatory body will not only set standards but also review them every five years.

**Although the bill proposes elaborate actions it fails to specify how they will be implemented, making their outcome dubious.**
The Clinical Establishments (Registration and Regulation) Act, 2010 is a good move for regulation of the private sector and must be enforced effectively. To date, however, only four states and the Union Territories have adopted this Act, whereas the remaining states also need to quickly bring the highly unregulated private health care establishments under the scanner.

The table below summaries India’s regulatory experience citing evidence, wherever available.

<table>
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<tr>
<th>Regulatory Experiences of the Indian Health Sector</th>
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<td><strong>Regulatory Domains and Actors</strong></td>
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| **Role of Professional Bodies in Regulation** | • Poor record in ensuring continued good behaviour (Jesani, Singhi and Prakash 1997)  
• Poor initiatives undertaken for developing professional self regulation  
• Medical associations have acted more as unions than as organizations interested in promoting quality of care  
• No sanctions against traditional health system practitioners (AYUSH) practicing modern (allopathic) medicine  
• No premium on continuing education or examinations for already qualified doctors |
| **Health Care Legislation** | • The Nursing Home Registration Act was adopted in three states - Delhi, Maharashtra and West Bengal but the emphasis was more on registration, overlooking quality of care  
• The Consumer Protection Act (COPRA) expanded the voice of citizens against poor quality of care and medical negligence which include some of the following:  
  o long delays due to the Indian court system, allowing massive backlog of cases  
  o transaction costs of processing medical complaints through medical forums are enormous  
  o consumer redress mechanism at health facilities are |
poorly developed in both private and public sectors (studied in three cities by Misra). Nevertheless the private sector is more responsive towards patient complaints than the public sector

- effective enforcement is hampered by doctors’ unwillingness to depose against their peers (Bhat 1996; Jesani, Singhi and Prakash 1997)
- COPRA has led doctors to practice defensive medicine safeguarding their interests

Despite these hurdles, however, COPRA has played a pioneering role in redressing consumer related complaints of medical negligence and insurance

| **Unregulated private sector** | • Asymmetry in the relationship between the provider (the agent) and the patient (the principal)
• Even independent regulatory bodies often fail to identify the opportunistic behaviour of agents
• Out-of pocket payments provide better opportunity to agents to increase the volume and intensity of their services and to enhance their income (Mills et al., 2001)
• There is strong need for regulation, but regulation is not easily achievable
• Quality, costs and accessibility of care provided in the private sector are questionable and are central issues for regulation (Nandraj, Muraleedharan, Baru, Qadeer and Priya, 2001; Peters et al., 2002)
• The private sector poses the risk of unnecessary services, high prices and skimping on quality
• There is incomplete data on number of health care facilities and practitioners
• The greater challenge of enumerating informal providers who are not registered and work part-time
• Even though Registered Medical Practitioners fall under the regulatory cover, courts intervene only in serious cases
• Lack of accountability in the health system is a big stumbling block |
| **Unregulated Health Insurance** | The private health insurance health sector has largely remained unregulated  
| | The IRDA bill contains no reference whatsoever to the health sector or to health insurance (Government of India 1999a)  
| | Problem of adverse selection remains unresolved  
| | Regulating the insurance sector is paramount for achieving social agreement |
| **Professional Self Regulation: An Uncharted Territory** | Low consumer trust among providers and the regulatory agency makes professional self-regulation in India difficult (India Today, 2000; Yesudian, 1994)  
| | Corruption in the health sector is rampant (Thampi, 2002)  
| | Government doctors practicing in their own private clinics at the cost of their duty at government institutions is a common sight  
| | Frequent absenteeism is observed among doctors and nurses  
| | Taking informal payments for hospital beds, frequent hospital admissions or for getting subsidized drugs are quite common (Thampi 2002)  
| | Accreditation by some large private hospitals is gaining ground but is not yet a widespread practice (Ensor and Dey, 2003) |
| **Role of Civil Society organizations** | Civil society, NGOs and consumer groups play a role in raising patient safety and health care quality concerns, and are found to be doing well in Mumbai and Bihar  
| | Media is an important advocate, having the ability to synergize the actions of consumer groups and civil society organizations |
**Regulation: Experiences across the Globe**

The health care industry in volatile global markets is changing every day. Escalating health care costs and technological advancements are compelling governments to exercise strict regulatory regimens. The Boston Consulting group reports, ‘scarcely a month passes without a striking regulatory change in one European health care system or another’. Similarly in the United States, a variety of regulatory approaches have evolved at the Federal and State levels. Many OECD countries have initiated regulatory reforms to stabilize markets and restrict competition and control costs.

The table below summarizes the regulatory experience of a few developed and developing countries detailing existing regulatory mechanisms and issues arising within them. **Regulation themes largely focus on self regulation, role of regulatory bodies, accreditation and health insurance control mechanisms.**

<table>
<thead>
<tr>
<th>Country</th>
<th>Experiences</th>
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| **Europe** | • Europe’s steer-and-channel regulation has been a response to increased entrepreneurial activities  
• Across Europe a range of Quality Assurance approaches have been implemented  
• France’s standards-based accreditation system seeks compulsory participation but offers a qualitative report rather than a rigid assessment  
• Dissemination of results of all external reviews and inspections in the public domain is being mandated by most governments |
| **Australia** | • Self regulation by practitioners and hospitals, their own licensing, certification and accreditation is common  
• Private hospitals benchmark their own performance against accreditation benchmarks set by the Australian Council on Health care  
• Self regulation has been useful in providing information to patients about care performance, quality and safety, without recourse to government regulatory interventions |
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<th>Brazil</th>
<th>Thailand</th>
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<td></td>
<td>• Stringent pharmaceutical regulations affecting pharmaceutical production, distribution and retail exist</td>
<td>• Regulations cover almost all relevant private and public organizations including individuals</td>
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<td>• The early regulation model focused on the control of expenditures of the private sector, supported by an excessive number of norms, imposition of rules and flows</td>
<td>• A regulatory framework for drug control, registration and licensing of health care organizations</td>
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<td></td>
<td>• Private providers were profiled and work related guidelines and standard operating procedures were developed</td>
<td>• Professional organizations assume a regulatory function, mostly through rules and standard setting, enforcement and ethical control</td>
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<td></td>
<td>• Types of regulation practiced: commercial regulation, administrative regulation, financial regulation and assistance regulation</td>
<td>• Provision for sanctions through reprimand and probation for mild cases; suspension and revocation of licenses for severe</td>
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<td></td>
<td>• Commercial and payment relation with the accredited network of health professionals defined health care standards and relation</td>
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<td></td>
<td>• Health Information Systems were established</td>
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<td></td>
<td>• Information on the number of hospital beds, therapeutic services, consultations and ambulance services is collected</td>
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<td></td>
<td>• The national data bases form essential instruments for the control, evaluation and auditing functions</td>
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<td></td>
<td>• Heath system enjoys exclusive and well-articulated command over the three governmental levels</td>
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<td></td>
<td>• All three levels have definite prerogatives and responsibilities in public regulation</td>
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<td></td>
<td>• Private sector contracts are regulated by stringent legislation</td>
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<td></td>
<td>• Process flows and approvals are governed by special commissions having representation from all levels</td>
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<tr>
<td></td>
<td>• The contracting process is followed by the monitoring of the invoicing (billing), quantity and quality of services rendered (Brazil, 2003)</td>
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</table>
Almost all regulators are government organizations
Almost all the health-care purchasers are influenced by government officers who are on the boards of their professional organizations
Regulations control only the private sector, not the public sector providers
There is need for better enforcement of the existing regulatory framework; changing the incentive structures of professional councils, and health-care providers

| Zimbabwe and Tanzania | Most regulations focus on the entry requirements of health personnel (licensing)
Zimbabwe has regulations for traditional health practitioners. Regulations also exist for the entry and quality of health facilities
Acts to restrict and regulate the private sector including pharmacies, nursing homes and practitioners have been passed by both countries
Enforcement of Acts has largely been weak
Few regulations to control prices
Market level regulations mostly limited to the sale and import of drugs into the local market
Tanzania too has a Consumer Protection Act as in India
No controls to check market-level problems of competitive pricing in the private sector
Problems of self-referral have been well documented in Zimbabwe
Approach to regulation largely ‘social’ rather than ‘economic’
Legislation has been the main instrument of regulation but focuses more on individuals rather than the health system organization
Lack of explicit control on quantity, price, and distribution
Regulation fails to address patient rights issues
| China | China has regulatory mechanisms for its rural health care markets and insurance
Annual licensing system exists at the provincial level, for
village based health care providers
• Failure to clear examination debars doctors from running their clinics
• Campaigns are carried out by the local health department for closure of unlicensed clinics
• Township hospitals have regular meetings and monitoring visits, although resource constraints adversely affect the schedule of the visits
• Two-to-three year courses for village doctors have been introduced by a few counties
• County-level voluntary insurance scheme present
  o Creation of institutional arrangements to ensure prescribed utilization of funds emphasized in early years of the scheme
  o Public opinion on fairness of the scheme sought regularly
  o The emphasis has been on financial audit and on winning public support for the reimbursement system
  o Supervision committees have been established with representation from government, anti-corruption office and local bodies
  o Local processes to review claims for reimbursement introduced to monitor inappropriate charges by hospitals
  o County health bureaus also monitor the achievement by health facilities on agreed-upon performance targets
  o Computer-based billing systems have been established to record the details of treatment
• Pertinent regulatory issues are over prescription of drugs; high cost of treatment of certain kinds of health problems; and potential differences in capacity to use services (based on geographical location and household income)
Section 3

Opportunities, Challenges and Future Pathways

There are a few principles of good regulation applicable across sectors as outlined by the OECD report on regulatory reforms 1997, drawing on the 1995 OECD Recommendation on Improving the Quality of Government Regulation. Some of the key aspects of good regulation are:

(i) Minimize costs and market distortions;
(ii) Promote innovation through market incentives and goal-based approaches;
(iii) Be clear, simple, and practical for users;
(iv) Be consistent with other regulations and policies; and
(v) Be compatible as far as possible with competition, trade and investment principles at domestic and international levels.

Once we understand what good regulation is, it is important to reiterate some important lessons in the context of health care regulation and identify the opportunities and challenges that developing countries would encounter on the road to regulation.

1. Balance and Vigil: Regulation can be like walking a tight rope. In its negative aspect it can result in greater bureaucracy and costs and impede the creative responses of the private sector. On the other hand, regulation enables monitoring of quality to reach into the private sector, providing a significant incentive for providers to practice quality assurance. It also enables the gathering of comparable health service data for sector-wide planning.

2. Consistent review of regulatory frameworks and regimens: There is need to review the framework and nature of existing regulations to avoid duplication of authorities and functions. Clarifying roles and responsibilities at the Federal level is important for clear administration of legislation and regulatory approaches. Ensuring that the roles of each level in regulation are clearly defined has been a recurring issue in many countries. Problems arise where the roles are not well defined so that there are either gaps or overlaps. In South Africa, for example, a
consequence of decentralization is that health services are simultaneously accountable to the local and national government (McIntyre and Klugman 2003). The need for documentation of regulatory effectiveness and innovations and continuing policy research on favourable models of regulation for low and middle income countries has been emphasized and reinforced across literature and practice.

3. **Self-Regulation and Voluntary Approaches:** Self-regulation and voluntary approaches need to be carefully monitored as they come with the risks of undue influence by private interests, barriers to competition, and lack of transparency and accountability. These risks need to be rigorously managed by programme design and application of competition policies.

4. **Public-private Partnerships:** Public–private partnerships can be forged as a move to regulate the quality of health care, and this can be backed by the payment of incentives based on performance and adherence to standards. Voluntary regulation and self regulation by private health providers who update their technical knowledge and promptly conform to applicable legislations can be a way forward.

5. **Incentives Better than Command:** New policy tools are based on the idea that incentives are better than commands. The incentives can include information disclosure; economic incentives such as taxes breaks; voluntary agreements; and the creation of new markets through tradable property rights. Changing the incentive structures of those organizations which enforce regulations, notably the Professional Councils, as well as health-care providers, serves as a good policy option.

6. **Continuous Education and Recertification to Regulate Human Resources:** Laws and protocols governing human resource regulation need to be revisited and developed to accommodate the huge influx of human resources into the flexible and fluid health markets. The development of continuing education and recertification programmes for all health care providers presents a significant opportunity for developing a better workforce (Ross et al. 2000; Bolis 2001). Management and new programmes should not only target technical health care providers, but also other key personnel in the health care delivery system, such as administrators and support staff. Experts have highlighted the need for continuing education of doctors and re-
examination for renewal of registration for doctors, especially in the rural areas.

7. **Building Public Trust:** For building public trust the government needs to design new mechanisms so that misinformation between patients and providers is reduced and new partnerships are forged between organizations of providers, community groups and civil society. Information disclosure on quality, pricing, equity and efficiency of health services, if provided in both private and public sectors empowers individual consumers to make more informed decisions about health care choices.

8. **Citizen Groups, Media and Civil Society Organizations can play a key Role:** Government can involve and encourage citizen groups to disseminate consumer education on expected standards of care, medical negligence, and legal protections available to consumers. Professional organizations should include consumer representatives in their committees in order to improve transparency. The participating consumer can represent the consumer side and simultaneously monitor the roles of professionals on the supply side. This will also improve the reputation of the professional councils giving them greater respect and public sanction and enable the lessening of government’s regulatory vigilance. The media, too, has a key role in narrowing information gaps and asymmetries.

9. **Patient’s Rights Legislation:** Patient’s rights legislation is an important way to establish consensus about patients’ rights among policymakers and health system leaders, and to provide a legal basis for enforcement. However, patients must be made aware of these rights to in order for there to be an impact on service delivery. Quality assurance strategies can include consumer groups and initiate a dialogue on patient rights, giving them a platform to voice opinions and concerns. Health care seekers having more options means expanded information on good hospitals, qualified doctors and affordable health care with no compromise on quality. For this, confidence building measures need to be put in place.

10. **Information Technology:** Information technology can play a lead role in enhancing quality assurance even in public health facilities. As in the Brazilian regulatory framework, database structures and information pathways can be effectively developed. Because of the well developed
information systems in many countries consumers can read up on the ranking and specialty of a hospital, get information on surgeons and/or procedures, interact with earlier patients of the chosen doctor and check the credentials and affiliation of providers. In developed countries like Canada, United States and the United Kingdom, individuals are able to monitor the risk-adjusted mortality rates of hospitals, and in some cases individual surgeons, which are publicly reported at regular intervals.

11. **Regulation of Insurance Companies:** Regulation of insurance companies includes a range of strategies from mandating basic service packages, to setting minimum and maximum fees, to disallowing services by non-licensed providers, to requiring that policies be offered to certain beneficiary groups. Developing countries like India should pay attention to enforcement and revision of existing strategies and provisions for regulating the markets for private health insurance.

12. **Continually Assess and Develop Capacity of the Regulators:** Those who are regulating and those being regulated need to be continually assessed and upgraded to make regulation more effective. Control without any supportive measures defeats the regulatory process and encourages bureaucracy and corruption. Thus, emphasis should be on training and continuing education, provisions for certification and rewards and incentives for those who show progress. The regulatory authorities thus need to overcome substantial skill shortages for better enforcement of regulatory functions.

In conclusion, a **tripartite model, involving not just the government and providers but empowered consumers, is needed for effective regulation.** In an effectively regulated model, the government should distance itself from the provider role while providers should compete as well as cooperate to create higher-value health care systems. Health care policies should be better informed by health policy research. Such a model could go a long way in reforming the existing management of health systems in India and providing valuable guidelines for UHC coverage for all Indians through carefully planned regulation, looking to the interests of all parties while at the same time delivering positive health outcomes.
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Annexure

Table 1: Legislations related to Standards in the Indian Health Sector

<table>
<thead>
<tr>
<th>Legislation</th>
<th>Objective</th>
<th>Powers and Functions</th>
<th>Quality Controls</th>
<th>Implementing/Monitoring Authority</th>
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<tbody>
<tr>
<td>The Bureau of Indian Standards Act, 1986</td>
<td>Provide for the establishment of a Bureau for the harmonious development of activities of standardization, marking and quality certification of goods</td>
<td>Co-ordinate activities of any manufacturer or association of consumers engaged in standardization and improvement of quality; Grant, reserve, suspend, or cancel licenses for use of standard mark; Inspect samples, establish laboratories for standardization and quality control; Address consumer complaints about quality of a product</td>
<td>Establish and publish Indian standards in relation to any article or process; Specify a standard mark to be called the “Bureau of Indian Standards Certification Mark”</td>
<td>Bureau of Indian Standards</td>
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<tr>
<td>Drugs and Cosmetics Act, 1986</td>
<td>Quality control of drugs</td>
<td>Power to debar a drug misbranded, adulterated, spurious and to prohibit import, manufacture and sale of certain drugs</td>
<td>Define standards of quality, adulterated, misbranded and spurious drugs</td>
<td>Inspectors for this purpose appointed by central and state governments</td>
</tr>
<tr>
<td>Nursing Home Registration Acts (Delhi, Maharashtra, Bengal)</td>
<td>Registration of private hospitals</td>
<td>Maintain a register of private hospitals; may enter and inspect a nursing home; inspect any record; cancel registration if not meeting the provisions of the Act.</td>
<td>None specified</td>
<td>Municipal Authority/State Government</td>
</tr>
<tr>
<td>Indian Medical Council Act/Nursing Council Act, 1947/Pharmacy Act 1948/Indian Medical Degrees Act 1916</td>
<td>Create minimum and uniform quality standards</td>
<td>Various Councils (Medical, Nursing, Pharmacy, Dental, Indian Systems); Give recognition to institutions that train medical personnel; maintain uniform standards; maintain registry; define a professional code of conduct for doctors; take doctors off the rolls for violation of code of ethics</td>
<td>May prescribe standard curricula for training of medical personnel; conditions for admission; examination standards</td>
<td>Indian Medical association; Medical Nursing/Pharmacy Councils of India and respective State Councils</td>
</tr>
</tbody>
</table>

Sources: Sunil Nandraj (personal communication); Aggarwal and Chaudhri (1998); Government of India (various).
Table 2: Selected List of Legislation/Rules Linked to Consumer Protection in India

<table>
<thead>
<tr>
<th>Legislation</th>
<th>Objective</th>
<th>Powers/Functions/Procedure</th>
<th>Monitoring/Implementing Authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumer Protection Act, 1986</td>
<td>To protect consumer rights such as: 1. Protection from marketing of services hazardous to life 2. Right to be informed about quality, quantity, standard, price and purity for protection against unfair trade practices 3. Seek redressal against Unfair trade practices or Exploitation of consumers</td>
<td>A complaint under the Act can be made when there is a deficiency in services – any fault, shortcoming, inadequacy in quality of medical or insurance services, or if an excessively high price is being charged. To observe principles of natural justice and to award appropriately, compensation to consumers.</td>
<td>Central and State Consumer Councils ‘promote’ various objectives related to consumer rights. District, State and National Consumer Commissions function as quasi-judicial forums to address consumer complaints. Orders of the National Commission can be appealed only in the Supreme Court.</td>
</tr>
<tr>
<td>MRTP Act, 1969</td>
<td>Prevention of concentration of economic power, control of monopolies and prohibition of monopolistic and restrictive trade practices</td>
<td>Conduct inquiries into monopolistic and restrictive trade practices based on complaints by the government, own information, or a consumer, or an association of consumers or traders. Can award compensation for any loss or damage resulting from unfair trade practice.</td>
<td>Monopolies and Restrictive Trade Practices Commission.</td>
</tr>
<tr>
<td>Employees’ State Insurance Act, 1948 (Section)</td>
<td>Address consumer (and other complaints)</td>
<td>Complaints about treatment received; benefits not received; eligibility, etc.</td>
<td>Medical Benefit Council Medical Appeal Tribunal Employees’ Insurance Court</td>
</tr>
<tr>
<td>CGHS Rules</td>
<td>Address consumer (and other complaints)</td>
<td>Complaints about treatment received; benefits not received; eligibility, etc.</td>
<td>Internal dispute resolution mechanism</td>
</tr>
<tr>
<td>Arbitration and Conciliation Act, 1996</td>
<td>Address Consumer (and other complaints) generally, but also</td>
<td>All complaints and demands for compensation</td>
<td>Arbitration Tribunal</td>
</tr>
<tr>
<td>GIC specifically</td>
<td></td>
<td></td>
<td>Judicial system/Courts</td>
</tr>
<tr>
<td>Indian Contract Act 1872; Code of Civil (Criminal Procedure)</td>
<td>Consumer complaints</td>
<td>For breach of contract, deficiency in services, damages, dispute of facts, negligence and so on</td>
<td>Judicial system/Courts</td>
</tr>
<tr>
<td>Drugs (Control) Act, 1950</td>
<td>Control over sale and price of drugs</td>
<td>Fix maximum prices and maximum quantities that may be sold General limitations on the quantity that may be possessed at any one time</td>
<td>Chief Commissioner Drug Controller of India</td>
</tr>
<tr>
<td>Indian Medical Council Act, 1956</td>
<td>Defining a professional code of conduct</td>
<td>Taking doctors’ off the registry roles for violation of rules of conduct</td>
<td>State medical councils Medical council of India</td>
</tr>
</tbody>
</table>

Sources: Aggarwal and Chaudhri (1998); Reddy (1997); Government of India (1999c); Bhat (1996).