



# Healthcare Services in India– Need for Better Regulations

By Hilal Ahmad Lone

## Abstract

India traditionally has a bureaucratic approach to regulate its health services. Research suggests that this approach has failed to protect the interests of poor and vulnerable groups, and has not gained the trust of providers or the public. So, are there any other ways to make India's health system more accountable?

A recent World Bank report suggests that Private Healthcare providers are heavily against any kind of legislation that might make them accountable to a Government regulatory body. Because most (up to 80%) of medical expenses come from personal funds, it becomes increasingly important that proper regulations are implemented to safeguard the interests of the consumers.

Researchers from John Hopkins Bloomberg School of Public Health in the US and the Indian Institute of Technology in Chennai, review alternative approaches to regulating health services in India. The bureaucratic approach, with the Ministry of Health focusing on its role as inspectorate and provider, has not worked, despite the presence of rules and procedures. Public safety in the health sector is not assured, service delivery and financing are not transparent or accountable and the delivery of healthcare favours the better-off over the poor.

However, greater accountability will only happen if governments improve access to information about health sector performance. The Government does not need to measure, analyse or disclose the information itself; it needs to create an environment where such information is seen as necessary by providers as well as service users.

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**Introduction** For better or worse, recently health care sector has seen a lot of changes globally. This has driven the need for functional and operational transparency in order to achieve higher performance efficiency. Indian healthcare sector is no stranger to this change and is witnessing an increased need for regulatory and compliance framework. Indian healthcare has recently been plagued with multiple crises. The lapse in safety procedures at the AMRI private hospital in Kolkata, India, which led to the death of 94 patients and staffs in a major fire in early December, 2011, has again highlighted the need for tighter and better regulations of healthcare services sector in India. Across the country, the healthcare system works on a traditional model where regulations and compliance are usually not the priority. Indian Healthcare is dominated by the Private Service providers. These institutions are reluctant to adopt any regulations that might bring more transparency in their activities. A recent World Bank report suggests that Private Healthcare providers are heavily against any kind of legislation that might make them accountable to a Government regulatory body. Because most (up to 80%) of the medical expenses come from personal funds, it becomes increasingly important that proper regulations are implemented to safeguard the interests of the consumers. The domestic healthcare system is soft on compliance and regulations, which can be verified by looking at various safety and control mechanisms established at the hospitals and clinics across the country. A huge number of patients that are treated at various hospitals and clinics across the country dwarf the medical staff available at these places. According to a World Bank survey, the patient/staff ratio stands at 8:1000, which is enormously smaller than world average. This could potentially impact the conformance to compliances due to heavy workload and fatigue. To avoid these problems, it is essential for Indian healthcare industry to develop and adopt a well-designed regulation and compliance framework. Data breaches, Unauthorized disclosure of healthcare data are more common than any other industry.

On the other hand, India is also not able to take full advantage of Medical Tourism (Discussed in detail in section under Medical Tourism). While alternative medical procedures such as Ayurveda continue to flourish, the conventional medical services have seen a significant drop; according to the survey conducted by Medical Tourism Journal (Medical Tourism Journal Survey 2010). The challenges that were identified in promoting Medical Tourism in India were lack of standards and quality procedures, Lack of regulation and compliance, and lack of controls in Insurance and Liability issues. Medical tourism is growing at 30% rate annually (FICCI, E&Y 2008). Lack of compliance and regulations required by acts such as Health Insurance Portability and Accountability Act (HIPAA) for coverage of Medical Insurance could result in massive loss in the Healthcare Industry in India. Not only do we need regulatory framework for Indian domestic healthcare services but also for patients who travel to India for medical facilities. To make medical tourism successful and to make it reach its potential, the regulatory and compliance framework needs to be implemented on emergency levels.

The absence of a regulatory and compliance framework for Healthcare Services in India fails to establish itself as a mature industry at par with International standards. It is often seen as poor alternative to facilities in Europe and Southeast Asia (Heena Jhingan, 2011). Vague and poorly defined compliance requirements do not encourage adoption of permanent and secure storage of patient's information and also results in poorly defined Safety and Security controls at facilities. Few hospitals in India conform to Joint Commission International (JCI) standards or other International standards; the standards which the Indian healthcare services try to emulate in the absence of framework. Due to the standard guidelines, many healthcare service providers fail to meet these requirements and hence do not have any alternative. This leads to lack of transparency and regulation in their operations in the absence of a regulatory and compliance framework for Healthcare sector in India.

## Research Methodology

### Primary Research:

Interviews over the phone and in person were conducted with Government and Private Sector Hospitals in Bangalore city area. The Clinics and smaller hospitals were

not contacted. A Sample size of 15 was selected that included the doctors and the administrators of the various hospitals.

#### Secondary Research:

Secondary research sources included internet, journals and periodicals. Sources included Analytics and research work done by KPMG, E&Y, Deloitte etc.

## Overview of Regulations and Compliance in Healthcare

**HIPAA and Directive 95/46/EC remain the two most popular healthcare regulation and compliance frameworks.**

Healthcare sector is one business area where compliance is not optional. World over, a lot of focus has been made on introducing healthcare regulations which can improve the quality of healthcare services and ensure confidence in patients are secured against unauthorised medical record disclosures and other malpractices. United States has traditionally had a broad set of regulations and compliance requirements for healthcare service providers. European compliance and regulations framework for healthcare services has also been a prominent subject in their legislative framework. American and European regulatory frameworks are explained briefly in passages below.

Health Insurance Portability and Accountability Act (HIPAA) is probably the most well-known compliance framework for healthcare service providers. This act has been effective in United States since August 21, 1996. This act has two parts or titles; the 1st title deals with protecting health insurance coverage for workers and their families in case they lose their jobs. The second title of this act deals with the administrative specifications (AS), such as addressing the security and privacy of health data and requirement of the establishment of national standards for electronic health care transactions, and national identifiers for providers, health Insurance plans and employers. This act has become extremely popular in US and is being emulated across the world in different shapes.

In European countries, universal healthcare through public funding is common. The countries that form the European Union Block, the compliance and regulations are taken care of by the Directive 95/46/EC (the "EU Data Directive") on the protection of individuals with regard to the processing of personal data and on the free movement of such data which is regulated under European Commission's Directorate-General for Health and Consumer Protection. The Directive protects a broad spectrum of information, including medical information and other types of "personal data," such as bank statements, credit card numbers, address, criminal records, employment and virtually any type of information that can be linked to an identified person. There are local compliance frameworks in individual countries such as in France and UK where national commission for health is responsible for all the healthcare related compliance and regulation frameworks.

## Why should we care about Regulations in Healthcare?

India offers its own unique version of universal healthcare system. Although, the public hospitals, clinics and other medical centres offer free-of-charge outpatient treatment, the indoor patient treatment charges are based on the financial condition of the patient. However, the government-run health service is understaffed and underfinanced, which makes patients prefer the private sector healthcare service providers. Private healthcare in India is significantly higher than the government run institutions. With the advent of privatised healthcare, this situation has changed. And with the economic prosperity, India has started institutionalising healthcare insurance. Many people, particularly the people who work in private sector and public sector, opt for medical insurance schemes

for themselves and their families. India is now one of the most sought-after destinations for Medical Tourism.

In India, the healthcare compliance and regulations are surprisingly unknown entities even at the high-end private healthcare institutions. While healthcare industry standards are given a lot of attention and are valued highly, the compliance and regulatory areas remain neglected almost universally across both private and public sector healthcare facilities. The doctors and Medical Administrators I talked to in Bangalore medical institutions (Table 1) were either not familiar with compliance requirements or were not sure if they had a compliance personnel. Although, many institutions have employed compliance officers, they lacked a compliance program or an Electronic Health record maintenance program. A high number of institutions were certified for ISO 9001, which gives an optimistic picture of the quality standards that these institutions maintain. Majority of the institutions were maintaining Electronic Medical Records (EMR), but not many were familiar with the security and confidentiality requirements for these records. It has been made mandatory by the Medical Council of India (MCI) that Healthcare institutions should electronically maintain medical records for a minimum of three years. Increasing usage of Technology and improvements in technology has also necessitated the need to have a strong compliance and regulatory framework in India and the improvements in technology usage in healthcare services sector.

The privacy and confidentiality of these records does not seem to be a priority; hence it becomes extremely important for Indian healthcare services sector to have a regulatory and compliance framework in place.

**Table: 1 Compliance Study in Urban Bangalore**

Hospitals and Clinics Covered in Bangalore - 15			
Requirement	Yes	No	Don't Know
Do you Have a Compliance Officer?	8	6	1
Do you have a Compliance Program?	3	9	3
Are you ISO 9001 Certified?	10	4	1
Do you use Electronic Medical Records?	11	3*	1
Do you have a Compliance Training Program?	2	13	0

**Majority of the Medical institutions in India use Electronic Medical Records without a compliance program.**

Acute need for more medical staffs and facilities is being experienced in India today. India is expected to require an additional 3.1 Million beds by 2018 (Ernst & Young 2008). This is a mammoth challenge for health services sector in India. 3.1 Million Beds mean that India will need considerable investment in health services. Along with the public sector health services expansion, the private sector players will also need to expand to meet this demand. This demand and subsequent funding requirements will make patients opt for major insurance covers and private fundings. This will lead to massive amount of information collection and record keeping for Insurance providers, Healthcare providers and other facility managers. In the absence of a regulatory framework, this is a recipe for disaster.

The expected expansion needs a solid regulatory framework to govern the inevitable changes that are going to happen in healthcare sector in India. Regulatory framework can also specify and can make it mandatory for healthcare providers to seek training on compliance. The Medical tourism which is going to be a huge business in coming years will also prompt the healthcare providers to have stricter privacy and confidentiality controls in their operations. The transitioning from a traditional to a more coordinated healthcare system will need to be made according to a specific regulatory framework given the scope of expansion in healthcare services. The landscape for Indian healthcare sector is changing at a very fast rate and if the expansion is not handled properly it could result in lack of governance, exploitation of patients and a messy transition. The Indian

constitution does not have Healthcare as a part of the concurrent list. As of today, every regional government formulates its own healthcare policies, which might not be suitable in the event of fast expansion of healthcare sector in India.

Less than 2% of India's GDP is being spent on healthcare services. This is substantially low when compared to global average of 10.2%. This is going to change in coming years due to the demand created for more staffing, financing and facilities in medical services in India. The health Insurance coverage, which stands at 20% today, also will see an exponential growth in the future. To accomplish the goals that have been set for Indian healthcare sector, India needs to develop a strong and effective Regulatory and Compliance framework.

**Table 2: Survey by FICCI-Ernst & Young 2008**

Additional Requirements	2008	2018	2028
Additional Beds required	1.1 million	3.1 million	2 million
Beds/1000 population	0.7 - 1.7	4	5
Additional Floor Space @ 800 sq feet/bed	880 million sq feet	2480	1600
Additional Land Area (FSI 1:1)	20,000 acres	56,400	36,400

*Explosive Growth expected in Healthcare Industry in India. Survey by FICCI- Ernst & Young 2008*

## Medical Tourism in India – Impact on Global Insurance Regulations

India today, stands as one of the major medical tourism destinations of the world. A report commissioned by the Medical Tourism Journal<sup>1</sup> points to India as one of the top four destinations for Medical tourism alongside Malaysia, Hungary and Turkey. According to ASSOCHAM, Indian medical tourism is expected to touch \$2 Billion by 2015. As medical treatments costs in the developed world balloon - with the United States leading the way - more and more Westerners are finding the prospect of international travel for medical care increasingly appealing. A rough estimate suggests that 150,000 of these patients travel to India for low-priced healthcare procedures every year. The recession in the world economy has had many victims, which includes the healthcare system of many countries. Whenever there is a slowdown in the economy, healthcare benefits become the first casualty. Recent events have had a significant impact on healthcare budgets of many developed nations and this has opened healthcare industry to many challenges and opportunities. This scenario also makes it a perfect case for seeking treatment in less costly destinations. India offers medical treatments at far less price than its counterparts America and Europe. The insurance companies are demanding that patients travelling abroad need to ensure that the place where they seek treatment meets necessary compliance requirements. This is a potential problem for India where majority of the medical institutions do not have a compliance program.

Economic issues apart, there are several major reasons for patients to seek treatment in places like India. For example, there are over 50 million people in the US who do not have an insurance cover and approximately 250 million people are underinsured. Cost of Healthcare in the US is 10 times more than that of India and is similarly up to seven times that of Europe or Middle East. There is a long waiting period for patients to undergo a procedure and many developed nations lack skilled staffs to do different specialised medical procedures. This makes India very attractive for medical tourism.

To take full advantage of the medical tourism, Indian health sector needs to improve

on many aspects, which includes Infrastructure development, meeting compliance, regulatory requirements and training staffs on medical tourism issues. Also, for India to take better advantage of the medical treatment, it needs to increase the limit of FDI in healthcare sector from 27% to much more reasonable level, so that it can attract necessary investments required to improve the medical facilities and infrastructure.

## Opportunities and Challenges

There is optimism regarding the Indian Healthcare sector. The projected expansion of the Healthcare services in India is going to benefit the Indian healthcare sector in a big way. However, there are still challenges in Indian Medical scene which need to be resolved before we can make the healthcare system more effective and more functional.

### Opportunities:

Indian healthcare sector is set to become a major industry and with the improvements in infrastructure it has the potential to be a global leader in the healthcare services. Based on the global standards, a new legislation can be drafted, which can make the healthcare sector more cohesive and dynamic. At the same time, the boom in economy can only affect the Healthcare sector in a positive way. The spending in healthcare on an individual level and at the national level is increasing constantly. The medical tourism industry is growing at 30% annually. This can be used as a catalyst to build a strong compliance framework, which will inevitably lead to a more organised and effective healthcare system in India.

### Challenges

Healthcare providers in India have a traditional mindset and in absence of regulations, as long as the patient is willing to pay, they will continue to operate. They are resistant to any legislation that might affect their immediate operational level. These institutions are reluctant to adopt any regulation that might bring more transparency in their activities. A recent World Bank report suggests that Private Healthcare providers are heavily against any kind of legislation that might make them accountable to a Government regulatory body. The unreasonable dependency of technology and its heavy usage contributes to the lack of proper regulations, particularly when the technology influx is complex and hard to understand. IRDA, which regulates the Insurance companies, has its hands full because of a rapidly growing economy in which increasing number of people are purchasing medical insurance. The bureaucratic approach, with the Ministry of Health focusing on its role as inspectorate and provider, has not worked, despite the presence of rules and procedures. Public safety in the health sector is not assured; service delivery and financing are not transparent or accountable and the delivery of healthcare favours the better-off over the poor.

### Emerging Trends in Healthcare

Indian healthcare has adopted a lot of practices and processes, which enables it to align itself to its global counterparts. Following are the major observations for emerging trends in Indian Healthcare services:

1. Use of Electronic Medical records is gaining prominence.
2. Technology plays an important part in the operations of the healthcare service providers.
3. There is an increased awareness about healthcare standards in India.
4. 14 healthcare institutes in India have been accredited by JCI, USA.

5. Tele-medicine and Remote medical consultations are being introduced in India.
6. Corporate and Institution sponsored medical care is being offered as compensation in India.
7. New Delivery channels such as online consultations are being offered, particularly in nutrition and fitness medical area.
8. Globalisation of Healthcare facilities is gaining ground and India stands as a primary beneficiary.
9. Research areas in Biotech and other related fields are also making rapid progress in India.
10. Traditional healthcare methods are being replaced by predictive and preventive healthcare models.

## Conclusion

Proactive action from the government and cooperation with medical service providers is the key to successful implementation of regulation and compliance framework. There is alarming absence of awareness about regulations and compliance in Indian Healthcare services sector in India. In order to Indian healthcare services sector to flourish and prosper, compliance and regulatory framework is mandatory. India has lagged behind the global players in healthcare, in forming legislations and laws pertaining to privacy and confidentiality of healthcare records, transactions and disclosures. To attract foreign healthcare business, Indian healthcare sector needs to improve its functions and processes by implementing a compliance and regulatory framework.

There is a strong case for developing, designing and implementing a regulations and compliance framework in India. Almost all the future trends point towards expansion of healthcare sector in India and to make the best use of it, India needs to get a framework in place.

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