Impact of Legal Regime on Healthcare Services in India: 
A Critical Analysis

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Abstract
Right to healthcare has been interpreted in India through judicial activism under Article 21 of the Indian Constitution. The jerk lying underneath is easy and there is equitable access and regulation of healthcare services. The healthcare has emerged as a vast sector and the stakeholders are providers, medical professionals, and the patients. The duty to protect and improve public health is casted on the state and the rights and duties come into the question. The overlapping duties and interests of patients and professionals are a key point to solve the issue and law must play a vital role by regulating the service providers and defining the duties and rights for all. At the same time, a proper mechanism must be in place to handle this vast sector. Unfortunately, in India, the legal regime on healthcare is far behind the developed countries and it needs to be synchronized with a goal to provide easily accessible and affordable access to all; and at the same time, the healthcare professionals and providers need to be protected. This paper focuses on the impact factors caused by legal regime on all the stakeholders along with the concurrent challenges and various global factors that are spurring at different levels.

Keywords: Healthcare, right, law, access, State’s liability

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INTRODUCTION
Healthcare is the cornerstone of the socialist state. It is the crown jewel of the Welfare State. - Monica Crowley [1] Right to health has been construed as a Fundamental Right under the very right to life and liberty under Article 21 of the Indian Constitution. Right to healthcare is indeed deeply rooted into the very right to health and it is the obligation of the State to provide for adequate healthcare to all its citizens; this includes access to healthcare services, medicines, etc. The access is provided through hospitals and medical institutions in the form of services. They are either run by State or licensed by State and operated by private entities. Post-independence India has evolved a complex and lengthy legal regime to regulate various aspects of healthcare services, but the fact is that these services have remained highly unregulated in terms of administration, providing adequate and easy access to healthcare and medicines. The subject of public health, provisions of healthcare facilities finds its place in State list whereas, other concurrent issues such as hospitals are under Union List and the medical profession finds its place in Concurrent List, so there is overlapping of jurisdiction resulting into multiple regulations for different States leading to no uniform system of healthcare services. Even after 75 years of independence, India is not able to streamline healthcare services in one uniform code and mechanism which is responsible for poor health statistics of India; lately there has been an attempt in the form of Clinical Establishments Act, 2010 by central government to regulate the quality of healthcare services, but it is not a wholesome act, and yet left to the State’s will to enforce or not. Along with it, there are several factors which have remained either unaddressed or poorly addressed, they are: complexity of regulations, multiple regulators, lack of comprehensive legislation and poor participation by public sector, maximum reliance on private hospitals, competition, accreditation etc. These factors are leading to many unethical practices ranging from medical malpractices to uncontrolled treatment prices.
affecting the common man’s economy and right to healthcare severely. In the given context, it is challenging to achieve healthcare for all, how it can be achieved, what is the obligation of healthcare providers, to what extent they are obliged to fulfill the responsibility, what are the legal issues and challenges and what should be the role of law in protecting the right to healthcare of individuals and to provide for easy and adequate access to healthcare with quality healthcare services.

Over a hundred years ago Rudolf Virchow, physician and reformer wrote, ‘Medicine is a social science and politics is nothing but a medicine on large scale [2]’. The poor health status is a result of controllable factors as a matter of facts. And to improve the health index, political will is equally important. Health closely relates to every aspect of life including food to finances; efforts to assure good health and effective medical care must be broader in perspective.

HEALTHCARE IN INDIA: AN OVERVIEW

Given the fact of Indian social, economic and political conditions, Indian healthcare is unique and is one of the biggest service industries at present. Healthcare service has undergone change over the period.

In India, 1/3 of the total healthcare services are provided by Government run hospitals, whereas the 60% (average, based on few surveys) of bed occupancy is observed in private health care institutes, and government run hospitals have less response from the patients of course with several reasons being responsible for it. Impact of advanced technology has made the diagnosis and treatment easier. But with over commercialization and competition in the field, many unethical elements have entered leading to exorbitant fees, cut practices, unnecessary investigations, unnecessary procedures and ultimately, exploitation of the patients.

Time has changed when the patients are no more looking at the doctors as the element of God. They are gradually becoming more and more aware about their rights as consumers. With a little sense of exploitation, they avail right to information and do not hesitate to attack the doctors. In such a situation, the doctors have started adopting defensive practices. They blame the situation saying that they are now unable to concentrate on rendering of services.

Judicial Activism and Healthcare

The Indian judicial trend has shown many ups and downs in application of certain principles relating to the basic health care. This leads to confusion and one must be updated about the changing judicial trends.

India has construed health as a Fundamental Right, and health care, access is made a State’s obligation. However different the provisions in different countries, the literature survey reveals that right to health and health care is not always codified in domestic law and there is lot of scope for its effective implementation and adjudication.

India opened doors to most of the social rights under Article 21; it has now come to be invoked almost as a residuary right. A positive thrust is given to the nature and content of this right by the Apex Court imposing a positive obligation upon the State to take effective steps for ensuring to the individual, a better enjoyment of his life. The Supreme Court has held that the right to live with human dignity enshrined in Article 21 derives its life and breath from the Directive Principles of State Policy particularly Article 39(e) and (f), 41 and 42 and would therefore include protection of health as envisaged in the directives. The instances of realization of health as Fundamental Right of an individual can be seen through, CESC Ltd. vs. Subash Chandra Bose [3], which held that right to health is a fundamental human right to workmen; then in Mahendra Pratap Singh vs. Orissa State [4], it was stated that, people are entitled to adequate health care, further in CERC vs. Union of India, it was elaborated that health and health care of workers is an essential component of right to life. In State of Punjab vs. Mohinder Singh Chawla [5], right to health care of government employees is integral to right to life. In Virender Gaur vs. State of Haryana [6], the Supreme Court held that
environmental, ecological, air and water pollution, etc., should be regarded as amounting to violation of right to health guaranteed by Article 21 of the Constitution. There has been number of cases through which different aspects of healthcare and access to healthcare have been regarded as fundamental under the umbrella of Article 21.

The term “right” has different connotations, what the law is, what it is likely to be, and what it should be. However, health as a human right does not mean the right to be healthy nor does it assert an unlimited right to be treated for every medical condition. The right based approach to health incorporates both curative perspective focusing on healthcare and healthcare services, and public health and preventive perspective focusing on the social determinants of the health like water, sanitation, and nutrition and health education [7].

Healthcare Services and Regulations
In India, the health care sector must deal with almost more than 200 laws, regulations, guidelines etc. as laid down by the central and State legislatures, local governments, delegated legislation by the statutory regulators etc.

The history of legislation for healthcare dates to pre-independence, the Coroner’s Act enacted by colonial government in 1871 was applicable to presidency towns of Bombay and Calcutta which defined role of medical professionals in conducting autopsy and inquests. It took long time to enact the laws to create indigenous medical councils, meanwhile, the epidemic diseases act was enacted in 1807 and it is still applicable with amendments.

The first record of a regulatory law we found is draft which may be called as Bombay Medical Act which was a result of adoption of a resolution passed by committee of Grant College Medical Society, the act was based on UK medical Act, which dealt with the medical education and registration of death, regulation of medical practice in certain aspects, etc. However, the draft law did not touch the subject of medical ethics and self-regulations.

After a long wait, finally, the Bombay medical Act was enacted in 1880 by the presidency. On similar lines, Bengal Medical Act and Madras Medical Registration Act were enacted in 1914. They were more elaborate and contained provisions relation to code of medical ethics which is very similar to one presently used by various medical councils. The provincial acts were soon followed by the Indian Medical Degrees Act passed by Indian Legislative Council in 1916. During the later decade, the similar acts were enacted for regulation and registration of nurses and midwives.

Gradually, the Indian Medical Councils Act was enacted in 1933 and The Indian Medical Council, a national statutory body for the Doctor of Modern Medicine was constituted. The Bombay Medical Practitioners Act was enacted in 1938 which recognized the registration of Indian system of medicines.

Thus, post-independence era and the recent times have witnessed enactment of various laws and regulations to govern the healthcare profession and practice. However, in India, there is not any omnibus legislation covering all the aspects of medical profession and practice particularly. They are distributed among various rules and regulations that can be categorically classified as laws governing: 1) Medical Education, 2) entitlement to medical practice and limitations,3) Control over medical practices which includes local authorities and by-laws, 4) obligation of doctors and medical ethics, 5) medical malpractice laws,6) drug dispensing and drug laws, and 7) control over hospitals and nursing homes.

Of which the 3rd and 7th entries are widely elaborative and include numerous factors ranging from infrastructure, staff, services, safety, quality, access and equity. Right from commissioning stage of the hospital till its successful running at various stages, the laws come into picture, but at the same time, the regulations are scattered. The health care professionals (including medical officers, para-medical staffs, hospital management) find it difficult to tackle all these laws while facing challenges in rendering services. Unfortunately, in India, the health care
professionals are not much aware about the nuances of legal regime. In such a situation, many legal issues arise, and it is the need that the legal professionals should come forward to help them out.

The numerous statutory mandates at various levels under different heads can be mentioned in brief as follows:

- Infrastructure, management, administration;
- Professional ethics, code of conduct;
- Drugs storage and safety;
- Biomedical research;
- Doctor patient relationship;
- Medico-legal aspects;
- Employment and labor welfare;
- Safety issues: patients, staff, public;
- Environment protection; Green hospitals;
- Contractual relations;
- Ambulatory and non-ambulatory services;
- Diagnostic and therapeutic services; and
- Support and utility services, basic specialty services, super specialty services.

It is very difficult to enlist all the regulations here, but indeed it is necessary to see what impacts this legal regime has made on the stakeholders of healthcare i.e. healthcare providers, healthcare professional, and at the receiving end, the beneficiaries of healthcare i.e., patients. The author has restricted the scope to core medical services and has excluded the food and drugs laws and issues correlated as it is a separate entry and needs detailed connotations.

Access to Healthcare and Role of State
The Indian Constitution eminently indicates that India is a welfare state. As said by Pt. Jawaharlal Nehru, “political freedom is only a means to an end, the end being a raising of the people to higher levels and hence, the general advance mint of humanity” [8]. This philosophy is reflected in the Indian Constitution through various schedules and provisions in different parts. Health, as a separate sector does not find place under the Constitution but many of the provisions have indirect and continual reflections on health of the people and role of the state in the development and upliftment of the health of its citizens. If we start from the preamble; it refers to justice: social, economic and political and equality of status and of opportunity. The challenges to access to healthcare facilities can be well brought under the spectrum of social justice and the principle of equality in access to these facilities. The practice of medical profession and access to medical education can also be taken to refer to principle of equality of status and of opportunity.

Taking the line forward, the doctrine of equality can be well related to the health and healthcare services in terms of easy and equitable access to healthcare services [9], employment in the state run medical institutions [10] and freedom of practice of medical profession [11].

This thread is knitted well through the provisions of Directive Principles of State Policy and Articles 38, 39, 41 entrench the State’s liability to secure social order and public welfare through various measures enlisted therein. Under Article 47, particularly, State is under a duty to raise the level of nutrition and the standard of living of its citizens and improvement of public health.

This indeed is a clear-cut articulation of parental duty of the state in protecting the health of its citizens according to the Constitution of India, thereby making it desirable that State should provide equal access to healthcare to all its citizens.

Under the federal set up, again public health as a subject of legislation has been entrusted under the State list, though Centre has power to legislate upon certain matters such as medical education and hospitals, food and drugs safety, etc.

The health as a right gives some entitlements one of which is access to healthcare and medicines. State is thereby bound to provide an easy, equitable and affordable access to healthcare. There have been many theories of rights which cast this burden on the State to protect the right of healthcare of its citizens.

Public health is a subject for the States to legislate. However, very few States in India
have constructed public health legislations. At the national level, the archaic 112-year-old Epidemic Diseases Act, 1897 is an example of the nature of laws dealing with public health emergencies.

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Under the Indian Constitution particularly, as we have discussed earlier the Directive Principles of State Policy provide different measures to protect public health and improve the same in the process of time. The Supreme Court of India has drawn a link between obligations of State to provide health care under the public health mandate by making DPSP enforceable which can be seen through various landmark decisions like, in the first of kind Francis Coralie’s [12] case and subsequently the Bandhua Mukti Morcha [13], the supreme court interpreted Article 21, to include right to health. Thus, furthering the responsibility to protect this right in, Vincent Panikulangarav’s, Union of India [14], the court stipulated by citing Article 25 of UDHR and Article 21: ‘a healthy body is a very foundation for all the human activities, in a welfare State, therefore, it is the obligation of the State to ensure the creation and the sustaining conditions congenial to good health’. The same thread was taken further through Parmanand Katara vs. Union of India [15] which held, no medical authority could refuse immediate medical attention to a patient in need, Paschim Bangal Khet Mazdoor Samities, State of West Bengal [16], states to undertake measures to ensure the provision of minimal primary health facilities. Gian Kaur vs. The State of Punjab [17], court defined life with dignity, and expressed that, it is difficult to imagine life with dignity when basic healthcare is refused.

Thus, derived from right to life, it was expected that the scope of the right to health would be restricted to life saving emergency care, but this case of State of Punjab vs. Mohinder Singh Chawla [18], has broadly extended this right. In recent times, besides these cases, protection to right to healthcare is also recognized for rape victims, pollution control, working conditions of workers, mentally ill persons etc., so it can be said as healthcare as a matter of right in India has developed under the shed of State’s obligation to maintain and protect public health under DPSP and fundamental rights.

There is a debate whether right to healthcare is an absolute right or it should be treated as right to basic minimal healthcare. Herein the role of State is very crucial as right to health has been defined as ‘the right to highest attainable standards of health [19]’. Under the general comment 14 of ICESCR, the ECOSOC [20] committee stated that, right to health requires availability, accessibility, acceptability and quality about healthcare as well as preconditions to health. It interprets the right as inclusive of timely and appropriate healthcare and it also extends to underlying determinants of health, such as access to safe and potable water, adequate sanitation, adequate supply of safe food, nutrition and housing, healthy occupational and environmental conditions, and access to health-related education and information, including sexual and reproductive health. Health is thus influenced by varied factors. The State’s intervention in providing healthcare even at a minimal level is conducted through healthcare services, if it lacks, the private service providers are to be trusted and it will thus violate the principle of equality in providing right to healthcare, and for minimal protection approach, we must rationalize a theoretical basis for enforcement of right to health care.

The State is already heavily involved in healthcare through entitlement programs and direct payments to providers, government run hospitals and clinics, licensure of health care personnel and provider institutions, tax exemptions, health insurance, regulations, etc. thus, to make right to healthcare a reality, the suggested mechanism should be expansion of this existing role of State in health.
CONCLUSION AND SUGGESTIONS
The impact factor is to be determined keeping in mind the stakeholders and their rights and interests. Considering the same, it is very apt that due consideration be given at this juncture.

The healthcare providers: The proper administration of healthcare services in the given set up is a challenging task, and there always remains apprehension of non-compliances and risk of noncompliance which may lead to cancellation of licenses and imposing hefty fines. There are multiple number of regulators and number of compliances and so, it is very essential to keep track of compliances.

Maintaining proper records is again a giant task and the local inspection authority can at times ask the hospital for the same. There are not many legal experts who can save the healthcare providers in adverse situations and thus they end up in multiple numbers of litigations.

The major problem with the hospitals and healthcare institutes is lack of infrastructure and work force, social determinants of the health, compliance with government schemes, health promotion programs and poor governance can lead to malpractices’ conditions.

The small clinics and nursing homes are at the receiving end of all this as there are not many rules as to the number of staff, infrastructural requirements at these places, which leads to chaos.

As far as the medical professionals are concerned, theirs is no different story, from educational qualification to self-regulation, from local municipal registration to PC-PNDT compliance, from self-regulation to increasing number to vandalism against doctors, everything falls under the legal spectrum.

The range of negligence and malpractice laws is so vast that there is plethora of judgment on the issues. The application of tort law, penal provisions and scope of consumer laws, have made healthcare professionals to take defensive when it comes to standard of care and duty.

Thus, in a country like India, where doctor was once considered God’s messenger, is receiving the apathy of people. Increasing access to technology, unnecessary investigation, changing patient culture, increasing number of corporate hospitals etc. further mar the conditions of healthcare professionals and with unending competition, some unwanted elements like malpractices also find their way in the profession.

The accreditation processes, maintaining standard of services, quality of healthcare, and safety of patients are again some feudal issues which need the continuous surveillance and good governance practices. To all of these and above-mentioned issues, sound legal foundation is very much necessary. Lately, efforts have been made in the form of Clinical Establishments Act, 2010, a central legislation for registration and regulations of healthcare services but there remains the issue of implementation as overlapping jurisdiction between State and Centre and many States have chosen to keep with their existing State nursing homes acts, e.g. Maharashtra, Bombay nursing Homes Act and Delhi Nursing Homes Act.

The National Medical Council Bill, for regulation of education and ethics is receiving backlash by the medical fraternity. The aspirant health policies and government funding are not mostly in coordination and many of the desired goals remain underachieved.

The insurance coverage and its extent are very less in India as compared to other countries, and this is need of time that there should exist a vast coverage which can sustain the health needs of larger population, but given the socio-economic set up in India, it is difficult to achieve same without a strong political will and social movement.

Lastly, the patient as the main beneficiary of the healthcare services, his rights remains under the grey shade. The easy and affordable access, safety and quality for many people relying on public healthcare services, remains to be an unachieved goal. Those who can rely on the private sector have different issues lined
up ranging from safety, confidentiality, to over diagnosis and over charging at times.

Time and again it is necessary for a country like India to have a comprehensive legislation in place applicable to all uniformly and which can address the needs of healthcare and give the right to health and healthcare a wholesome meaning that is sought under the very Constitution of India by its makers and making the benevolent principles of social justice and equality a reality. The State’s liability to protect and provide healthcare is something which cannot be achieved without a proper mechanism, legal framework, resources and adequate economic provisions. One of the most basic of human rights is right to good health care. In recent years, we have come to understand that health care is not merely a technical problem for medical specialists, it is a vital concern for all who help shape the economic, social, and political process of our communities and nations [21].

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