

The Legal Regime of E-Health in India

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Abstract

E-health in layman's terms would mean any form of synergy which exists between internet and healthcare facilities. The World Health Organization (WHO) defines 'e-health' as the use of information and communication technologies for health and the same has been adopted by the National Health Authority in India. While these definitions indicate the realm under which the aforementioned topic lies, the dimensions of e-health takes a multi-nuanced approach. E-Health is transpiring into a paradigm of legal framework wherein not only technology is facilitating the better and easier access to health care but also is '*an emerging field of medical informatics, public health services and information delivered or enhanced through Internet and related technologies*'.¹

Coming to a country like India, where the resources are less in the face of a dense population who are even more backward and helpless when it comes to access to adequate healthcare facilities, especially the poor and those living in remote and rural areas. Hence 'E-health' as a mechanism acquires even a greater importance as it would supplement the better usage of not only the existing medical facilities but also would render better data management of various diseases and their cures, medical history of respective patients, people being armed with better knowledge so as to make informed choices when deciding the recourse to healthcare etc. However, the current legal background and regulatory mechanism in India with respect to 'e-health laws' is not only scattered but also very vague. This paper attempt to find a coherent link to all the existing laws within the scope of 'e-health' laws and draw a clear picture of the further needs, including those in terms of resources, medium, spread of awareness, training and education of workforce engaged in the medical field as well as training, workshops and awareness programmes of the common people, finance required and its relation to corporate governance etc.

¹ G Eyesenbach, Speech at UNESCO (Paris), June 2001, Conference of the International Council for Global Health Progress: Global Health Equity, Medical Progress and Quality of Life in 21st Century

Introduction

The immediate decade following the year 2000 witnessed the introduction of 'internet' into the lives of common people all over the world including India in various forms, some of which include e-mail which generates the quicker mode of communication and transfer of information amongst people, as e-commerce (the electronic network which allows the operation of business online²) etc.

In the same wake arose the concept of e-health which represented the promise of information and communication technologies to improve health and the health care system.³ Thus, e-health in layman's terms would mean any form of synergy which exists between internet and healthcare facilities. Another school of thought exists which considers that e-health is nothing but a part and component of e-commerce only, conducted as the 'health care's component of business over the Internet'⁴. However, an extensive research conducted by Centre for Global e-Health Innovation, University Health Network and Department of Health and Policy Management and Evaluation, University of Toronto, Canada and the consequent analysis of the same led to the conclusion that the definitions concentrated better on 'healthcare' as a process rather than health as an outcome.

The World Health Organization (WHO) defines 'e-health' as the use of information and communication technologies for health. However, the lack of consensus in the meaning of the term 'health' itself among important international agencies in the world, such as the narrow definition by the European Union 'converse of disease or infirmity or when disease or infirmity is absent'⁵ to the ever widened approach undertaken by the World Health Organisation where it defines health as 'a state of complete physical, mental, and social well being and not just the absence of disease or infirmity'⁶ creates a difficulty in ascertaining the exact and precise meaning of e-health as well.

While these definitions indicate the realm under which the aforementioned topic lies, the dimensions of e-health takes a multi-nuanced approach. E-Health is transpiring into a paradigm of legal framework wherein not only technology is facilitating the better and easier access to health care but also is '*an emerging field of medical informatics, public health services and information delivered or*

² What is 'Electronic Commerce - ecommerce', Investopedia, Topics, Available at <https://www.investopedia.com/terms/e/ecommerce.asp> [Last Accessed: May 6, 2018]

³ Alvarez RC. 'The promise of e-Health - a Canadian perspective.' *eHealth Int* 2002;1:4. [PMC] [Medline]

⁴ JP Morgan Partners. The Rise & Fall ?? Of e-Health. URL: http://www.upenn.edu/ldi/healthpolicyseminarjan26_Jan.%202022%20'01.ppt [Last accessed: May 5, 2018]

⁵ The Atlas of Canada - Health. URL: <http://atlas.gc.ca/site/english/maps/health/1> [accessed 2004 December 12]

⁶ Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948. URL: <http://www.who.int/about/definition/en/> [accessed 2004 July 5]

enhanced through Internet and related technologies'.⁷ G Eyesenbach, further goes on to elaborate the not-so-technological aspect e-health which, according to him, also includes a '*a state of mind, a way of thinking, an attitude, and a commitment for networked, global thinking*'.⁸

Thus, to a layman, e-health would mean nothing but any form of synergy which exists between internet and healthcare facilities. The inclusion of technology in the healthcare facilities has rendered seeking health advice for the general consumers feasible so much so that it is not only the sick and the infirm but also the healthy people who have the requisite information related to health and diseases at their easy disposal.

However, this leads to the problem of different forms of information available on the internet and the ones which could be relied upon rather than the fake ones.

E-HEALTH AND INDIA

In a country like India, where the resources are less in the face of a dense population who are even more backward and helpless when it comes to access to adequate healthcare facilities, especially the poor and those living in remote and rural areas, 'E-health' as a mechanism acquires even a greater importance as it would supplement the better usage of not only the existing medical facilities but also would render better data management of various diseases and their cures, medical history of respective patients, people being armed with better knowledge so as to make informed choices when deciding the recourse to healthcare etc. However, the current legal background and regulatory mechanism in India with respect to 'e-health laws' is not only scattered but also very vague. The definition as provided by the WHO mentioned above has been adopted by the National Health Authority in India. Thus, it becomes only obvious to find a coherent link to all the existing laws within the scope of 'e-health' laws and draw a clear picture of the further needs, including those in terms of resources, medium, spread of awareness, training and education of workforce engaged in the medical field as well as training, workshops and awareness programmes of the common people, finance required and its relation to corporate governance etc.

LEGAL FRAMEWORK AND GOVERNMENT'S INITIATIVES

The implementation of various e-health facilities such as telemedicine, maintenance of electronic health records, healthcare information systems, healthcare knowledge systems, usage of m-health to determine the information of a patient by the medical practitioners is nothing less than a challenge for the Government of any country, more so that of India. It not only requires the employment of staff

⁷ G Eyesenbach, Speech at UNESCO (Paris), June 2001, Conference of the International Council for Global Health Progress: Global Health Equity, Medical Progress and Quality of Life in 21st Century

⁸ *ibid*

which carries a sound knowledge of technology but also expression of such technology in a manner that can be understood and hence utilised by the general consumers all over the country, especially the people belonging to the poor and remote areas.

GOVERNMENT INITIATIVES

Digital India Initiative - Ministry of Health and Family Welfare

The initiative undertaken under the ambit of e-Gov initiative with respect to the healthcare sector in India, commonly known as the e-Health Division aims at utilising the already present and well-integrated IT system in the country so as to make the feasible provision of facilities to the population. The main aim of the initiative is to put life and blood into the online delivery of healthcare solutions to the consumers in the form of Online delivery of healthcare facilities by the professionals such as specially initiated programme by the Government include setting up of a tele-medicine facility for HIV infected patients on a pilot basis in the Center of Excellence, Maulana Azad Medical College, New Delhi under the aegis of partnership between the University of New Mexico, USA and National AIDS Control Organisation (NACO), Government of India.

The eHealth initiatives has a vision to delivery better health outcomes in terms of access, quality, affordability, lowering of disease burden and efficient monitoring of health entitlements to citizens.⁹

National eHealth Authority

The Ministry of Health and Family Welfare proposed setting up of a 'national e-health authority' to promote regulatory and standards setting mechanism in the sector of e-health in India. With an aim to create an e-health ecosystem such that better organization, management and provision of health care facilities take place, the following objectives were cited to be achieved under the said initiative¹⁰:-

- Formulation of "National eHealth Policy and Strategy" for coordinated eHealth adoption in the country.
- Orderly evolution of eHealth initiatives and guide adoption of eHealth at various levels and in different geographical and health system areas.
- Setting up of state health records repositories and health information exchanges (HIEs) to facilitate interoperability.
- Formulation and Management of all health informatics standards for India. (Electronic Health Exchanges)

⁹ e-Health in India, Available at https://www.nhp.gov.in/e-health-india_mty [Last Accessed: May 3, 2018]

¹⁰ National eHealth Authority (NeHA), Objectives and Functions Envisaged, Available at: https://www.nhp.gov.in/national_eHealth_authority_neha_mtl [Last Accessed: May 5, 2018]

- Enforcement of the laws and regulations relating to the privacy, confidentiality, and security of the patient's health information and records.

National Intellectual Property Rights Policy

This policy was released by the Department of Industrial Policy and Promotion in the year 2016 with the aim of identifying IPR (Intellectual Property Rights) and attributing the importance as a marketable financial asset and economic asset. In the context of e-health laws, this policy also promotes evolution of such technology platforms whereby people can be availed with affordable medicines and healthcare facilities as well as a better and easier access to such facilities.¹¹

LEGISLATIONS RELATED TO E-HEALTH

The absence of any particular legislation clearly prescribing the ambit and implementation of the e-health regime in India makes it imperative to take a look at the existing legislations whose provisions would govern the regime of e-health laws in India till the point the proposed legislation on e-health receives the assent of the Parliament.

The following legislations contain the relevant provisions which acquires importance when discussing the e-health law regime in India:-

1. The Information Technology Act, 2002

The most important aspect of e-health includes the transfer of information amongst various players in the whole medical paradigm. Be it the exchange of information with respect to a patient's data records amongst/between hospitals and medical experts or the storage of patient's personal information i.e., case history for better diagnosis by the doctor, all fall under the ambit of Sensitive Personal Data or Information.¹² These namely include bank account details, mental, physical, physiological and mental health condition, medical records and history, biometric information etc.

Collection of such data by a body necessitates the requirement of 'consent' by such providers be it the doctor or any other institution where such consent is informed as well as in a written form.¹³

Other important requisites for such data collection and sharing include the prior permission of the owner of such information before sharing the same with a third party, ensuring adequate security of the transferee by the body undertaking transferring¹⁴, appointment of Grievance Officer',²⁰

¹¹ Objective 5.8, NIPR

¹² Rule 3, The Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules 2012

¹³ Rule 5(1) of the Data Protection Rules

¹⁴ Rule 7 of the Data Protection Rule

whose contact details are to be published on the website¹⁵, options to exit or opt-out from such services or undertaking modification of information as per the will of the consumer¹⁶. However, it has been clearly provided by the Central Government that in case there exists those small companies which only perform the role of intermediary by facilitating the interaction between the patient and the doctor or the hospital rather than storing the details about either, would fall under the ambit of Intermediary Guidelines.¹⁷ Disputes arose with respect to the right of removal, communication, transmission or even selection and modification of such information by the intermediary. In the case of *Shreya Singhal v Union of India*¹⁸, after the discussions the SC finally ruled that for effecting the removal of any such information, it becomes incumbent on the intermediary to firstly receive either a court order or a notification from the Government directing the intermediary agency to do the same and such order or notification must comply under reasonable restrictions under Article 19(2) of the Indian Constitution.

2. Unsolicited Commercial Communications Regulations, 2007 and Telecom Commercial Communication Customer Preference Regulations, 2010-

Under the above mentioned regulations, unsolicited commercial communications to the patients by the corporate body or any other body which holds the personal information of such persons such as their contact details and other information, is prohibited. However, companies generally tend to send such messages under the guise of transactional messages over which there is no legal bar.

3. Other Service Providers Regulations, 1999

Under this act fall all those service providers who utilise the facilities such as telephone to render 'Application Services' such as the provision of telemedicine through telephone network. These service providers are known as 'Other Service Provider' and must be registered as one with the Department of Telecommunication, Government of India as per the New Telecom Policy of 1999.

4. The Indian Medical Council Act, 1956 and The Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002

While the IMC Act, 1956 provides pre-requisites such as a recognised degree in medicine registered with State Medical Council for enabling a practitioner to practice legally, one of the

¹⁵ Rule 5(9) of the Data Protection Rules

¹⁶ Rule 5(7) of the Data Protection Rules

¹⁷Section 2(1)(i)Information Technology (Intermediaries Guidelines) Rules, 2011; Section 2(1)(w) IT Act, 2002

¹⁸ Writ Petition (Criminal) No.167 Of 2012

important code of conduct under the Ethics Code 2002 include that it is the responsibility of the doctors to electronically record the medical records of the patient for easy retrieval of such records when the need be.¹⁹

LIABILITY REGIME UNDER E-HEALTH LAW

The liability regime for the violation of legal requirements under the e-health laws in India can be categorised into civil and criminal liability. While the former includes suits filed before the civil court, criminal liability exists for commission of offences under the e-health's boundaries.

a) CIVIL LIABILITY

Civil Liability include the following:-

- Breach of Contractual Obligations : This might take place between e-health service provider and the patient or when negligence is committed by such a service provider (organization or the medical practitioner). The damages might include both liquidated and unliquidated damages.
- Similar to the health law cases, vicarious liability can be attributed to the e-health service provider in case any negligence or breach has been committed by their employees such as supply of wrong telemedicine etc.
- It was in the case of *Indian Medical Association v V. P. Shantha and Or*²⁰ that the SC recognised that healthcare facilities fall within the ambit of services under the Consumer Protection Act, 1986 and hence the liability can be claimed from the service providers who fail to provide quality e-health care services in return of the price paid by the consumer or in comparison to the claims made by the service provider.
- Disciplinary Action can also be initiated by an application made to the Medical Council of India, both at the State and at the Central Level in case the service providers' actions lead to any misconduct such as refusal to provide certain services such as online counselling or treatment to persons living in remote areas etc.

b) CRIMINAL LIABILITY

Similar to the Penal Regime as in case of health laws, criminal prosecution can be initiated in case case of e-Health services, if a person is rash or negligent in rendering a service and the service results in bodily injury or death of the patient/user, the person may face criminal prosecution.

CONCLUSION

¹⁹ Regulation 1.3.4, MCI Code 2002

²⁰ AIR 1996 SC 550

All in all, one thing which stands out is the fact that e-health laws are a comparatively recent branch of 'healthcare facilities' which have emerged in the marketplace. Moreover, the difficulty in prescribing a clearly defined and compartmentalised system of laws for the e-health regime arises because of the pervasive nature of such laws which bring into its ambit not only the health sector, but also the other sectors of laws including Corporate Laws, Business Laws, Intellectual Property Rights Laws, Human Rights Laws etc. Moreover, an Indian analysis of such laws further highlight the hindrances that poverty and huge population in the background of disconnected remote areas lacking basic communication facilities which makes the introduction and implementation of such laws all the more chaotic. Hence, there is a need of a consolidated legislation which could realise all of the goals set up by the Government (Indian Context: National e-Health Authority etc.) thereby ensuring a correct implementation of e-health law regime.



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