DIGITALIZATION OF HEALTHCARE AND LEGAL REGULATIONS IN INDIA

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ABSTRACT

The present study demonstrates digital technologies uses in public-health response to COVID-19, including population monitoring, case identification, contact tracing, and assessment of treatments based on mobility data and public communication. Health care, which is inextricably related to life in general, has exhibited increasing reliance on advancing Technology, which has taken the lead in the name of a Digital Revolution in the health sector. The authors, through this chapter, seek to discuss the same and its link with Information Technology and Data Privacy guidelines in a descriptive manner. The digital revolution, or, to use a correct term, technological interruption, became a reality in the latest days, particularly in the wake of the COVID 19 pandemic simulation. Disruptive digital technologies have the potential to modify the fundamental concepts of any sector, such as the notion of public health, resource management and implementation, consumer society, and so on. It distinguishes by a convergence of technologies that blurs the distinctions between the physical and biotech domains. Digital disruption has begun to affect many elements of human existence, including lifestyle, work, democracy and government, resource management, health, and education, among others.

Thus, the paper gives an outline about the digitalization of healthcare and its regulations along with patient's fundamental rights which gives a framework how it goes during Covid-19 Pandemic.

Keywords: Constitutional Rights, clinical establishment rules, Intellectual Property, IMC Regulations, Covid-19.

1. INTRODUCTION

The digital revolution, or, to use a correct term, technological interruption, became a reality in the latest days, particularly in the wake of the COVID 19 pandemic simulation. Disruptive digital technologies have the potential to modify the fundamental concepts of any sector, such as the notion of public health, resource management and implementation, consumer society, and so on. It distinguishes by a convergence of technologies that blurs the distinctions between the physical and biotech domains. Digital disruption has begun to affect many elements of human existence, including lifestyle, work, democracy and government, resource management, health, and education, among others. The healthcare industry is no exception. Because of its benefits in assuring cheap healthcare, there is a significant push toward digitizing the healthcare industry, particularly in undeveloped countries.(Schwab, 2017)

The Digitalization of different healthcare services is a step toward achieving the program's aims of Universal Health Coverage. In May 2018, WHO(*Archived: WHO Timeline - COVID-19*, n.d.) member

countries voted to create a worldwide digital health strategy. Based on the resolution, “World Health Organization published the 'WHO Guidelines: Recommendations on Digital Intervention for Health System Strengthening in 2019 as the first implementation of technology health recommendations. These recommendations encourage the appropriate use of digital technologies such as e-Health and m-Health to accomplish” the aims of "Universal Health Coverage and other Sustainable Development Goals (SDGs) without compromising on patients' fundamental rights, such as privacy and confidentiality. India intends to use the latest technological systems in various service areas, especially health care delivery.

The Prime Minister launched the National Digital Health Mission (NDHM) on August 15, 2020, as part of the 74th Independence Day celebrations, intending to modernize different health care services. The government announced numerous e-Health/m-Health projects involving Telemedicine consultations as part of the 'Digital India' plans in 2015." Many current healthcare laws will alter as a result of digital health. The concepts of the doctor-patient relationship and ethical norms will also significantly change the digital environment. In this context, this chapter aims to analyze a few of India's evolving ethical and legal rules.

2. DIGITAL HEALTH ECOSYSTEM

The idea of digital health has since changed the entire healthcare environment, including medical devices infused with cutting-edge technology governing the health-related elements of patients and healthy individuals. The concept of digital health is "its use of Digitalization in support of health and health-related domains, including e-Health and m- Health, as well as emerging fields such as the use of advanced computing sciences in big data."(*Archived: WHO Timeline - COVID-19*, n.d.) With the essential innovations brought about by digital technology, healthcare institutions, both public and private, are spending substantially on Digitalization various health services to provide patient-centered healthcare services. Digital technologies mean to give more customized health care services instantaneously, even to very far away individuals. (*88% of Providers Investing in Remote Patient Monitoring Tech*, n.d.)

According to 'm-health Intelligence,' approximately 88 percent of health institutions in the United States are developing remote patient monitoring (RPM) systems in 2019. It enables them to provide medical services outside of traditional health care facilities and monitor patients' health issues, especially those in rural areas. The healthcare market is seeing a significant increase in next-generation medical devices. Which provides different health care services such as measuring blood, stress, sleep quality, weight, heart rate, glucose level, automatic ECG, etc., which clinics and hospitals previously offered. Big Data, A.I., m-Health, wearable devices, cloud computing, robots, 3-D printing, Blockchain, and augmented reality are necessary technologies that have significantly influenced the healthcare business in 2019. These health techniques have proven to provide 'predictive, preventive, individually tailored, and collaborative' health care services.(*88% of Providers Investing in Remote Patient Monitoring Tech*, n.d.) The COVID 19 pandemic has created a more favorable environment for introducing digital technology,(Das, n.d.) “rating digital health usage for half of the year exceeding the previous 14 years.” Technology advancements include genetics with next-generation sequencing,(*Scope of Artificial Intelligence in Medicine*, n.d.) intelligent sensors, and materials that can modify the functionality of medical equipment that focuses on ecological circumstances, including temperature, pH, and so on.(sule, 2017) Even though the healthcare sector has established a flawless digital health ecosystem with the help of digital technologies, stakeholders prepare to take advantage of the potential benefits of a digital healthcare system.(Moroncsik & Muresan, n.d.)

3. DIGITALIZATION OF HEALTHCARE IN INDIA

The Indian healthcare system, with its vast network of public and commercial facilities, is essential for protecting people's right to health in developing countries. Since independence, the Indian healthcare sector has been commercialized and incorporated. The third phase, the digitization of healthcare, has already begun. The digitization of healthcare in India is in its initial stages in both the private (*(PDF)*

Tracing Privatisation of Healthcare in India, n.d.) and public sectors.(*Technology Is Going to Play a Key Role in India's Roadmap for Health Infrastructure: ETILC Members - The Economic Times*, n.d.) In 2015, the government launched several digital health initiatives in the 'Digital India plan.' The goal of digital health initiatives is to provide individuals, particularly those living in rural regions, with healthcare access. (*Services | Digital India Programme | Ministry of Electronics & Information Technology(MeitY) Government of India*, n.d.)

India is one of the world's most significant digital marketplaces, with the electronic usage indices expected to increase by 90% between 2014 and 2017.(*World Health Organization et al. - 2016 - The Health Workforce in India.Pdf*, n.d.) According to the 'India Future Health Index 2019,' approximately(*Philips' 2019 Future Health Index Report: Digital Health Technology Ups the Game - IndiaMedToday*, n.d.) 76% of healthcare professionals require digital health records, and 46% utilize A.I. technology in their healthcare profession. As stated previously, the government is already imitating major electronic health systems under the auspices of the 'Digital India' campaign since 2015.(*Digital Healthcare Market in India 2020*, n.d.) The 'National Health Portal' creates in 2016 as a single point of access for verified health information and a project to integrate digital healthcare programs, including E-Hospital, EHR, Personal Health Records, m-Diabetes.(*National Health Portal of India, Gateway to Authentic Health Information*, n.d.)

4. DIGITALIZATION OF HEALTHCARE AND TRANSFORMATION OF ETHICAL AND LEGAL REGULATORY REGIME

The medical profession's ideals are essentially stated on trust and secrecy. It has been acknowledged as the foundation of the medical profession since the Hippocratic period. The dynamics of bio-ethical grew with the emergence of modern healthcare models.

In the present circumstances of healthcare Digitalization, we must upgrade such rules of medical ethics to establish a secure technology platform for the next generation of healthcare consumers and providers, referred to as digital natives.

"The Indian Medical Council (Professional Conduct, Etiquette, and Ethics) Regulations, 2002 (in the future referred to as IMC Regulation)" govern the ethical norms of medical practitioners in India and update in 2016.

Even though just modified, the legal sectors may alter rapidly in the future. Amid the COVID 19 pandemic, some substantial reforms have been enacted, including guidelines for Telemedicine consultations, E-Commerce regulations, and pharmaceutical doorstep delivery, which are all meant to alter India's health systems.(*Digital Natives and Digital Immigrants — How Are They Different | by Martina Čut | Digital Reflections | Medium*, n.d.)

As a result, the focus of this research study is on the emerging legal and ethical aspects of nine pertinent issues. All covered are the cross-border practice of medicine, organization license, online pharmacy, e-consent, electronic health records, e-medical consumer, confidentiality, and legal measures. ('Jio 5G Explained', 2020)

5. MEDICAL PRACTICES HAVE CROSS LICENSE

Telemedicine and Telehealth (*The Integration of MHealth Technologies in Telemedicine during the COVID-19 Era: A Cross-Sectional Study - PMC*, n.d.) have become considerably more efficient in the technological age, particularly during the COVID 19 outbreak. Telemedicine and Telehealth services are now accessible across several countries without territorial barriers in healthcare. A comprehensive search can provide several online consultation portals in India that offer various services such as

fundamental health care, online consultations, digital Pharma services, medical diagnosis, consultation, chronic illness treatment, etc. Other healthcare systems, such as Ayurveda, Homoeopathy, Sidha, and Unani,(*Top Telemedicine Companies in India - InnoHEALTH Magazine*, n.d.) have also begun to provide Telemedicine services. Though technology is at the forefront in fulfilling people's needs by providing a broad range of services that would otherwise offer in traditional healthcare institutions, India's legal system is ambiguous and unoccupied to a significant portion. Telemedicine services have been available in India since the 1980s. However, there have been no attempts to codify the regulations regulating Telemedicine services. The Telemedicine Practice Guidelines have recently been practical and included in "IMC Ethical Regulation 2002."

According to Telemedicine Regulations, only registered healthcare professionals can consult with patients through various modalities for internet devices (video, audio, or text). Such certified registered healthcare professionals must take an online course within three years of receiving information on the Guidelines to provide Telemedicine services. All such practitioners must adhere to the exact ethical requirements for in-person care throughout all Telemedicine sessions.(*Telemedicine.Pdf*, n.d.)

Each registered healthcare professional must include their registration number on prescriptions, digital communication, websites, receipts, etc. The Guidelines expressly prohibit consultations (*Telemedicine-Practice-Guidelines.Pdf*, n.d.) outside India's competence and technology for medical and intrusive treatments.

A combined assessment of IMC Policies and Telemedicine Guidelines (*Telemedicine Practice Guidelines of India, 2020: Implications and Challenges - PMC*, n.d.) reveals that such regulations do not address issues about cross-state Telemedicine services. A doctor who has a known medical qualification and registers with the "Medical Council of India (National Medical Commission under the National Medical Commission Act 2019)" or state medical councils are only entitled to conduct modern medicine or surgery, (*Telemedicine Supported Strengthening of Primary Care in WHO South East Asia Region: Lessons from the COVID-19 Pandemic Experiences | BMJ Innovations*, n.d.) according to the IMC Regulations. A health practitioner who has passed the National Exit Test and is now on the state or national Register is allowed to operate in India, according to "Sections 33 and 34 of the National Medical Commission Act 2019." Most State Medical Councils,(*Https://Www.Emedinexus.Com/Post/10650/Kerala:-Registration-with-Tcmc-Mandatory-for-Doctors*, n.d.) however, made state-specific licensing necessary.

Several countries, however, set state-specific limits on Telemedicine consultations as well. Even though there were no restrictions to the reverse in the IMC Regulations or the Telemedicine Standards for the countrywide healthcare profession, the state medical councils demand compulsory registration.(Covid, n.d.) It is a barrier to cross-state activity, particularly in healthcare service digitization. Health care services spanning from primary to tertiary level, including surgery, can be provided to a client in those other countries in the growing digital health domain. There is no worldwide policy to govern international internet medical services, which has become a significant source of worry for global legal interpretation.

Health care services extending from primary to advanced levels, involving surgeries, could be provided to a patient in some other countries in the growing digital health domain. There is no worldwide policy to govern international internet medical services, which has become a significant worry source for international law jurisprudence. In the absence of any worldwide legal guidelines for Telemedicine and Telehealth services, international network operators must adhere to the applicable local legislation of each jurisdiction. Because the digital health concept connects individuals and service providers in multiple jurisdictions, the new digital health platforms must deal with legal systems from numerous foreign countries. (Ferreira & Rosales, 2020)

A comprehensive examination of the Telemedicine Principles reveals that several internet-based healthcare service portals must simplify their capabilities to comply with the guidelines. Further

crucially, multinational Telemedicine websites that already have engaged physicians from outside India would maintain their services because they are not authorized to provide any medical services in India. According to the Telemedicine Guidelines, technological platforms must guarantee that customers consult with healthcare professionals. They must exercise caution while registering medical practitioners for Telemedicine consultations. Their services will violate the "Medical Commission Act, the IMC Regulations," and the Telemedicine Guidelines without a supportive regulatory framework.

To enable foreign internet platforms, the administration must develop the International Medical Practitioners Registration and acknowledge medical degrees for digital health care with much more clarity in accommodating the desire of global Telemedicine providers. Nevertheless, in the current scenario, the scarcity of Telemedicine service licenses and permits, regulatory authorities, and an approved list of foreign medical practitioners, institutions, and medical degrees will lead to electronic quackery rather than the cost-effective quality service envisioned by digital health programs.

6. CLINICAL ESTABLISHMENT ORGANIZATION LICENSE

As per the "Clinical Establishments (Registration and Regulation) Act 2010," only those clinical establishments, including hospitals, clinics, and dispensaries, help with diagnosis, treatment, or care for illness under any acknowledged system of medicine. It provides single doctor units registered with the State Councils of Clinical Establishments.(*The Clinical Establishments (Registration and Regulation) Act*, n.d.) The medical facility must meet the National Council's essential criteria for facilities, services, employees, and medical records to be eligible.

Medical professionals may examine patients through Telemedicine services, according to Telemedicine Guidelines. However, the Telemedicine Guidelines article does not mention certifying establishments that provide online health care services.

Furthermore, neither distinct registration procedure of Telemedicine platforms envisions under the CEA or other authority. The Consumer Protection (E-Commerce) Regulations (hereafter known as the E-Commerce Rules) went into effect on July 23, 2020. They apply to any products and services purchased or sold over electronic or digital networks. "According to the E-Commerce Guidelines, an e-commerce firm must be a company registered under the Companies Act. To enforce consistency with CPA and the Guidelines, this should establish a focal line of communication or an alternative senior designated functionary who is now a resident of India."

Though the E-Commerce Rules necessitate a registered office, there is no suitable legislation for institutional registration or maintaining Telemedicine service quality criteria. The IMC/State Medical Councils was not involved in overseeing digital platforms which provide online consultations because they are only permitted to supervise Health Care Professionals who have already qualified with the respective state medical councils in India. The CEA, which was created in India to oversee medical facilities, has no mention of Telemedicine services. With the increasing amount of Telemedicine platforms under medicinal and Indian systems of medicine, it is critical to design a plan for registering Telemedicine companies in India. The proposed NDHM intends to provide a beneficial environment by taking those factors into account. (*National Digital Health Mission Sandbox*, n.d.)

7. ONLINE PHARMACIES DURING PANDEMIC

Amid this same establishment of a separate Department of Pharmaceuticals within the Ministry of Chemicals and Fertilizers in 2008 and the introduction of the "Jan Aushadhi" Scheme, presently known as the "Pradhan Matri Bhartiya Janaushadhi Pariyojana (PMBJP),"(*Pharmaceuticals & Medical Devices Bureau of India*, n.d.) this same accessibility of medicines at an economical cost continues to be a challenge for India's pharmaceutical sector. Between 50 and 65 percent of individuals lacked access to personal medications.(*Making Markets Work for Affordable Healthcare - Policy Note | NovoJuris*, n.d.) The lack of an appropriate number of "Janaushadhi" retail pharmacies, consumer-

friendly service plans, and economic factors in e-commerce platforms, among other factors, helped pave the way for the significant expansion of online pharmacies or e-pharmacies in India. Even though e-pharmacies had an immediate good reaction again from targeted consumers, there have been no relevant laws to determine whether it satisfies specified requirements as traditional pharmacies. The rapid expansion of e-pharmacies was currently at a confluence due to a slew of significant legal decisions, an absence of appropriate regulatory frameworks, and considerable resistance by traditional pharmacy groups. (*E-Pharmacies in India: Can They Improve the Pharmaceutical Service Delivery? - PMC*, n.d.)

The Legal System involves the sale of the medicinal product involves the "Drugs and Cosmetics Act of 1940, the Drugs and Cosmetics Rules of 1945, the Narcotic Drugs and Psychotropic Substances Act of 1985 (in the future referred to as the NDPSA), the Pharmacy Act of 1948, and the Pharmacy Practice Regulation of 2015." Because established few of these laws were in the 1950s, fundamental concerns with e-pharmacies also were not addressed in such laws. The recently launched "Pharmacy Regulations 2015" describe prescription as "prescription in writing or electronic form," but it does not refer to internet pharmacies. Thus, regulating e-pharmacies is essential to ensuring patient safety and public health. In 2018, the Madras and Delhi High Courts issued orders prohibiting online pharmacies just infringing the safeguards of the "D & C Act, the Pharmacy Act, and the absence of appropriate regulations for online pharmacies."

The attempt to regulate e-pharmacies commenced in 2015 when the "Central Drugs Standard Control Organization (CDSCO)" published a notification instructing all State Governments and Union Territories should prohibit e-pharmacies until they adopted rules for e-sales of medicines.(*Regulatory Guidelines For E-Pharmacy Start-Ups - Food and Drugs Law - India*, n.d.) It also states that e-pharmacies must never process Schedule X pharmaceuticals or other habit-forming drugs under the D&C Rules. Pharmacists are responsible for ensuring the safe distribution of medicines with appropriate instructions, and they must permanently preserve patient confidentiality. Along with these guidelines, the Code mandates the establishment of a commission to resolve customers' concerns. In 2018,(*The Tamil Nadu Chemists And ... vs The Union Of India on 17 December, 2018*, n.d.) “the Ministry of Health and Family Welfare recommended a regulatory framework for e-pharmacies by revising the D & C Rules.” (*Dr. Zaheer Ahmed vs The Union Of India & Ors on 8 January, 2019*, n.d.)

The proposed laws include mandatory registration of e-pharmacies, prescription downstream processes, regular e-pharmacy reviews, etc. However, the Guidelines have not ratified by the government. During the final approval of the Rules, the Pharmaceuticals Controller General of India instructed all State Governments and Union Territories to prevent the selling of drugs through e-pharmacies in November 2019. It also is interesting to note that, amid COVID 19 outbreak, the government stated pharmaceutical deliveries to people's homes. The notifications permitted people possessing a valid "D & C Rules license to sell medications through retailing, excluding narcotics, psychotropic, and controlled substances as defined in the NDPS and drugs classified in Schedule H1 & Schedule X to the D & C Rules."

It must follow the essential regulations to enable doorstep delivery:

1. A licensee must provide an e-mail I.D. for registration with the relevant local authorities if prescriptions are to be received by e-mail.

2. It must deliver the medicines to the patients' residences if they are in the same revenue district as the licensee.

3. It must give the prescriptions for chronic conditions to the licensee within 30 days.

4. In crises, must submit the prescription within seven days after its issuance.

5. They shall give an Invoice or cash memo to the patient, and the licensees should keep records of all such transactions.

One such update has evaluated the problem in the operations of online pharmaceuticals because it does not vindicate e-pharmacies. It, therefore, does not consider the current strategy used by pharmaceutical companies. Many e-pharmacies depend on a marketing strategy that acts as an intermediate.(*Ficci-Press-Nov21-e-Pharmacy.Pdf*, n.d.)

As a result, e-pharmacies obtain and make medicine available to patients from authorized drug dealers relying on the prescriptions submitted by the patients. Any manufacturing industry must support E-pharmacy initiatives to conduct properly in the market through correct legislation and regulations. Relevant authorities will strictly watch their actions to prevent troublemakers from abusing technology's advantages. The current registration should be a final solution to fulfilling the demands of patients throughout a lockdown situation. As a result, thorough regulation, which considers contemporary technological Pharma trends, public interest, and safety, must be created as soon as possible.

8. ELECTRONIC PRESCRIPTIONS IN ONLINE DURING PANDEMIC

Electronic prescriptions are referred to as medical prescriptions (*2011-04-21_eHI_Clinicians-Guide-to-EPrescribing--2011_Update.Pdf*, n.d.) generated, transmitted, and filled using a technology. Which can classify as using a computer, hand-held device, or even other equipment with an application that enables prescribers to:

a) Obtain the patient's prescribed medications,

b) Automated transfer of the prescription to a pharmacy,

c) Request a rejuvenation from the dispensary if a patient is out of medications

d) Supervise the complete medical management process. (*2011-04-21_eHI_Clinicians-Guide-to-EPrescribing--2011_Update.Pdf*, n.d.)

According to various surveys conducted by the "Institute of Medicine (IOM) in the United States in 1999, approximately 98000 individuals died due to medical errors. Adverse medication reactions are among the most common causes of medical malpractices."

According to the "second report, issued in 2006, at least 1.5 million Americans injures due to medication errors, the majority of which causes by prescription errors. Introducing the innovation of electronic prescription may diminish medical problems inflicted through prescription inaccuracies or unsuccessful treatment responses."

The general practitioner can use the electronic drugs to get Medicinal Decision Support (MDS), such as recommended dose, grammatical error, and treatment options. Clinical Decision Support (CDS) includes information on drug interactions with other medications, food intolerance, and health conditions. In India, relevant research is absent. Unfortunately, throughout rare instances, erroneous prescriptions have arisen.

Due to the slow adoption of innovative technologies, particularly in the health sector, the principle of e-prescription is still to realize in India. Prescription specifies as "an instruction from a Registered Medical Practitioner to a patient, written by hand or in any automated method properly verified, to dispense a drug and amount of the medicine to the patient" in the approved "Drugs & Cosmetics (Amendment) Rules, 2018." Prescriptions can be in paper or electronic format, whereas the definition is constrained to the mode of electronic prescription issuance. The recommended D & C Rules do not

include the rest of the steps of e-prescription, including checking unsuccessful treatment responses, transfer to pharmacies, and so on.

The Telemedicine Guidelines advise Health Care Professionals to maintain this level of professionalism that they do in regular consultations. Protocol states that it may dispense drugs if an online consultation establishes a proper diagnosis. Prescription of medication without the need for an accurate diagnosis is unlawful & constitutes medical negligence. "The Guidelines allow Health Care Professionals to prescribe painkillers from Lists O, A, and B. It expressly forbids the prescription of medicines specified in Schedule X of the D & C Rules and every Narcotic and Psychotropic Substance mentioned in the NDPS Act of 1985." The medication should be correct and issued following MCI requirements, including a registration number and signature. (Institute of Medicine (US) Committee on Quality of Health Care in America, 2000)

Electronic prescriptions may ultimately be replacing traditional paper-based medical medicines. E-prescriptions would be widely accessible to various service providers, law enforcement agencies, insurance companies, patients, third-party administrators, and the emergence of electronic health data. Consequently, it is essential to develop a highly secure health infrastructure that does not hinder patients' “constitutional rights, such as the right to privacy and confidentiality.” Even though the Telemedicine Guidelines permit physicians to treat digitally, the incumbent regulatory regime is insufficient to overcome patients' data privacy in a digitized medical environment.

9. ELECTRONIC MEDICAL RECORDS IN DIGITAL MEDICAL ERA

Medical record maintenance is an age-old implementation intervention by the medical profession, and Hippocrates founded it.(*The Edinburgh Companion to the Critical Medical Humanities*, n.d.) However, a codified form of medical documentation did not begin until the nineteenth century. Electronic health records replace patient records with the advancement of technology. However, due to rising interest in possessing and managing medical information and patient privacy concerns, healthcare institutions worldwide are transitioning into personal health information. "For Digitalization health records, various terminology is already in use, such as Automated Health Record (PHR), Computer-based Patient Records (CPR), Electronic Medical Records (EMR), Electronic Health Records (EHR), Patient Health Records (PHR), and so on." (n.d.)

Electronic medical records are created digitally by doctors and kept and regulated by doctors and other health care professionals. The electronic health record (EHR) is a much more complete version of the medical record that includes demographic, financial, medical history, immunizations, laboratory, and diagnostic results.(Seymour et al., 2012) EHR, like EMR, is maintained and managed by physicians or other health care practitioners. On the other hand, PHR is a thorough, lifetime health record of patients owned and controlled by the patients themselves. Though first used electronic medical records were in the 1960s, they became increasingly widespread throughout the 1990s as information technology advanced.

According to a "WHO international assessment on e-health, almost half of high-income and upper-middle-income nations have implemented EHR systems. EMR/ EHR/ PHR technologies have only been recently unveiled in India. The Electronic Health Record Guidelines (in the future referred to as EHR standards) were approved by India in 2013 and modified in 2016." The EHR standards were introduced to facilitate interoperability, minimize implementation costs, and guarantee the involvement of stakeholders. However, the rate of implementation of EHR guidelines by health care establishments in India is substantially better than average. Looking at the "legal regime of health records in India, the IMC Rules encourage medical professionals to maintain medical records for three years from the start of treatment and attempt to digitalize medical records."

Furthermore, according to an Official Notification dated by the “Directorate of Health and Family Welfare,” should electronically maintain medical files of in-patients from the previous ten years. In the

future, we must retain all I.P. patients' health data on a consistent and continuing baseline for developing access. Moreover, Rule 9(iv) of the Clinical Establishments (Central Government) Rules 2012, implemented under the CEA, states that clinical establishments must maintain EMR/ EHR following the prescribed international specifications. Department of health and human clinical facilities are also needed to maintain EMR/EHR.

A detailed focus analysis reveals no consistent guideline sets for the country, and its implementation is chaotic. The Telemedicine recommendations could be the first step in the proper process since they require Healthcare professionals who will provide Telemedicine consultations to preserve the following record-keeping for the period stipulated.

a) Telemedicine interaction log or record.

b) The health care Professionals should keep all patient records, reports, documents, imaging, tests, data, and other materials used throughout the Telemedicine consultation (digital or non-digital).

c) In specifically, if a medication provides to the patient, the health care professionals are expected to keep the prescribed records as needed for in-person visits.

It will be essential to implementing EHR initiatives before even providing a safe and secure environment for a sustainable digital ecosystem. The most severe issues about EHR programs are data protection and cybersecurity. Even though the state proposed legislation, the "Digital Information Security in Healthcare Act 2018 (subsequently referred to as DISHA) and the Personal Information Protection Bill 2019 (subsequently referred to as PDP Bill), both are still outstanding in legislative bodies." Consequently, in the absence of a specific legal framework to assure the safety and security of electronic health information, a more cautious approach to deploying EHR programs in India is required.

10. E-PATIENT DURING PANDEMIC ARENA

Dr. Tom Ferguson stated that E-patient is those individuals who have an involvement in medical decisions. Health issues, efficiency, and the effectiveness of health services are well for e-consumers. (*E-Patients, Cyberchondriacs, and Why We Should Stop Calling Names | Pew Research Center*, n.d.) Individuals engage in the treatment, are self-focused, anticipate on-demand medical treatment and clarity in all healthcare services, we are willing to keep their health information, and are active members of online patient networks. All digital healthcare systems should inherently plan for the rise of enabled patients and implement strategies to increase the free flow of information in health care services. With the introduction of current online systems and the Digitalization of healthcare systems, the doctor-patient conversation has evolved from doctor-dominated moralism to a more equal and transparent collaboration based on mutual respect and autonomy.

India has become the furthermore adoption of Digitalization since the launch of the 'Digital India' campaign, with over a billion internet users and 350 million Smartphone users. The impact of digital technology and simple access to health information will result in shared decision-making and the democratization of medical treatment. With the implementation of the consumer protection law, medical practice has shifted to a defensive approach, and consumerism places enormous strain on the doctor-patient relationship in India. The number of medical negligence lawsuits is rising, and it has significantly increased in the previous decade. Increased health consciousness, simple access to second views, the availability of medical literature, information technology, and other factors have prepared the path for changing people's attitudes and perceptions of doctors and healthcare systems. As a result, a more effective patient management system will implement to meet the demands of the 21st century's smart customers.

One of the most challenging problems for Indian lawmakers is meeting the requirements of rising e-consumers and developing a legislative framework to resolve their problems in the digital health age. Though the recently passed "Consumer Protection Act, 2019", omitted medical services from its scope, the term of service is broad enough to include medical treatments. Even though the "CPA 2019" does not cover healthcare, the critical decision in **Indian Medical Association v. V.P. Shantha & Ors** (*Indian Medical Association vs V.P. Shantha & Ors on 13 November, 1995*, n.d.) entire blame helps bring services provided to a patient by a medical professional by appointment, diagnostic test, and therapeutic interventions. Under the ambit of consumer protection law. Officials have established that the new "CPA, 2019", encompasses health services for all intensive reasons. (*Dipak-K-Dash: Read Latest News from Dipak-K-Dash - Times of India*, n.d.)

The E-Commerce Rules require establishing a grievance addressed procedure with a grievance officer for online health consumers to facilitate quick restitution of consumer complaints. The grievance officer must acknowledge a complaint within 48 hours of receiving it and resolve the case within one month.

a) The legal name of the e-commerce business,

b) A primary geographic address of its headquarters and all branches,

c) Its name and details of its website, and

d) Customer support and grievances office contact details.

Furthermore, the Telemedicine Guidelines protect against online medical malpractice. Also, it urges technological solutions to provide an appropriate system for addressing patient symptoms. In addition to such safeguards, patients can contact medical councils in the event of unprofessional conduct or may request the authority of civil or criminal courts in the event of medical negligence. All treatments prescribed to people online or through traditional healthcare facilities must meet the quality of treatment needed for hospital facilities under common law and the IPC. Apart from such regulatory requirements that protect the interests of enabled medical consumers, must modify the medical education curriculum should sensitize students. Also, it requires meeting the demands of e-patients and establishing a healthcare system based on autonomy, mutual respect, and shared decision-making processes.

11. RIGHT TO PRIVACY AND CONFIDENTIALITY DURING PANDEMIC

The foundation of all doctor-patient relationships involves trust and secrecy. According to the IMC Regulation, "doctors shall keep confidence regarding the independent or residential living endowed to a physician, and must never reveal defects in the temperament or personality of patients observed during healthcare attendees except (*Jacob Mathew vs State Of Punjab & Anr on 5 August, 2005*, n.d.)

a) In a court of law under the orders of a presiding judge,

b) In circumstances where there is a serious risk to a specific person or community, and

c) Communicable/notifiable diseases."

The "United Nations Human rights Commission's Charter of Patients" Rights stipulates that it shall not violate patients' right to privacy and confidentiality unless it benefits others or public health. It also requires that any data about a patient be kept private and protected against data theft and leaks. Even though it has been applied in the circumstances with no strictly secret connection, the tort of fraudulent misrepresentation has dominated the doctor-patient relationship for centuries. In a digital health care system, the tort of breach of confidentiality is insufficient to address all data privacy problems. The

core concept of digital health policies worldwide is to make patients than in healthy people's health available at numerous levels, including healthcare providers, insurance companies, third-party administrators, patients, government authorities, administrators, etc. It also requires that any data about a patient be kept private and protected against data theft and leaks. Even though it has been applied in the circumstances with no strictly secret connection, the tort of fraudulent misrepresentation has dominated the doctor-patient relationship for centuries. In a digital health care system, the tort of breach of confidentiality is insufficient to address all data privacy problems.(*Charter_patient_rights_by_NHRC_2019.Pdf*, n.d.) The core concept of digital health policies worldwide is to make patients' than in healthy people's medical content accessible at numerous levels, including healthcare providers, insurance companies, third-party administrators, patients, government authorities, administrators, etc.

The main concept of digital health policies throughout the world is to make patients' than in healthy personal health information available at numerous levels, including healthcare providers, insurance companies, third-party administrators, patients, government authorities, administrators, etc. As a result, there is a growing need to create suitable safeguards to maintain patients' sensitive health information safety and confidentiality. “The right to protect the security of personal data is also part of the right to privacy. In India, the Supreme Court decision in **Justice K.S. Puttaswamy v. Union of India** (*Justice K.S.Puttaswamy(Retd) ... vs Union Of India And Ors. on 24 August, 2017*, n.d.) cleared the path for the right to privacy to be acknowledged as a fundamental right.”

They are considering significant digital technology usage and the decision in the K.S. Puttaswamy case as either a background, policymakers-initiated conversations with all stakeholders, culminating in preparing two Bills primarily intended to safeguard data privacy and security called the DISHA and the PDP Bill. Both these Bills call for the development of national and state-level authorities to protect data privacy and confidentiality. According to DISHA, patients/individuals have ownership of their health data. The storage, transmission, and sharing of personal health data must follow the standards outlined in the Bill to protect the information owner's privacy and confidentiality.

But on the other hand, the “Data Protection Bill, 2019” specifies a general data protection foundation where data ownership is uncertain and criteria for processing and sending personal data of the data owner by the data fiduciary.

Since “DISHA and the Data Protection Bill are now in the projects, the current legal structure determines patients' right to privacy through the Information Technology Act, 2000” and the “Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011. Medical records categorize as sensitive personal data or information of a person within Rule 3 of the I.T. Rules 2011.”(*Section 43A in The Information Technology Act, 2000*, n.d.)

According to Rules, anyone body-corporate that has communicates with and manages each sensitive personal data or information needs to use reasonable security methods to avoid the unjust loss or gain to any individual. If the public company fails to adopt appropriate security requirements, it may be held accountable under Section 43A. The Electronic Health Records Requirements 2016 give a full overview of technological standards for protecting patients' privacy and confidentiality. However, because they are not mandated, all healthcare facilities do not follow these guidelines. The recently established Telemedicine Guidelines also charge Healthcare Professionals to protect patient's privacy and confidentiality.

It further states that if a patient's privacy or confidentiality is violated due to a technological breach or by someone other than Healthcare Professionals, Healthcare Professionals would not be held liable. Since India is a rapidly developing digital health economy, separate legislation is essential to safeguard patients' data security, privacy, and confidentiality.

12. THE ELECTRONIC-APPROVAL MODE IN PANDEMIC

Informed consent involves healthcare providers getting the patient's agreement before undergoing medical treatments or surgery. It entails proper communication between the physician and his patient on the patient's physical and mental status. It also involves informing the patient about possible choices and natural remedies, recognizing their intellectual and emotional maturity, and assuring that their decision is not swayed by coercion or undue influence. Informed consent dates to 1949, when the Nuremberg Code was enacted, and has since been an essential aspect of medical and biomedical standards of morality. (Institute of Medicine (US) Committee on Regional Health Data Networks, 1994)

It establishes a legal connection between a doctor and his patient, replacing the self- rule or paternalistic paradigm of medical care with shared decision-making. Different structures of informed consent are used in other countries, ranging from non-disclosure to full disclosure. The IMC Guidelines are limited in their application, directing that "before operating, the physician should obtain in writing the consent from the husband or wife, parent or guardian in the case of a minor, or the patient himself, as the case may be." If the surgery might lead to sterility, both the husband and wife must consent.'

The Supreme Court of India examined the subject of informed consent in **Samira Kohli v. Dr. Prabha Manchanda and Others**, (*Samira Kohli vs Dr. Prabha Manchanda & Anr on 16 January, 2008*, n.d.) stating that a doctor must provide enough knowledge about the intended therapy, including pros and cons, alternatives, and the repercussions of refusing treatment, and so on. Informed consent concerns will get more challenging in the digital health sector as treatments are delivered through digital technology, and patients provide assent online. Because of the IoMT, many medical services that were previously only available in the clinical environment are now available using wearable devices and mobile applications. The mechanics of voluntary participation are becoming increasingly essential. Aside from that, patients' health information might be collected, kept, and processed without their knowledge.

In the digital health era, informed consent involves more than just an agreement for medical intervention or surgery. The creation, ownership, use, and transmission of health data of patients/users requires the understanding of the relevant patient/user, and the requirement must acquire permission has evolved from a simply ethical component of the healthcare profession to the legal responsibility of service providers.

According to the Telemedicine Guidelines, informed permission is required for all Telemedicine consultations in India. Before beginning online consultations, must disclose Health care Professionals' and patients' identities at the first level. Healthcare Professionals should authenticate and validate the patient's identification by name, age, cell phone number, e-mail I.D., etc. (Jacob, 2014) There should be a mechanism for patients to check their Healthcare Professionals' credentials and contact information. The Guidelines allowed for both explicit and inferred consent. The 2019 Digital Health Blue Print also outlines the electronic consent management strategy for acquiring and accessing personal health records.

On the contrary, there is no mention of computerized authorization in the 2016 EHR standards. Despite these Guidelines/ Standards for online consultations, India lacks proper legal regulation to address the issues of informed consent for electronic health interventions and the generation and transmission of health data/information via online consultations and wearable medical devices and mobile apps. Thus, with the help of legislative rules, would develop a suitable atmosphere for capturing the e-consent of patients/users in India.

13. INDIA'S POSITION IN BIG DATA IN CURRENT HEALTHCARE CHALLENGES

One of the primary problems for all nations now dealing with the COVID-19 outbreak involves balancing patient privacy law and political health assessments, which is being accomplished through numerous technologies like Aarogya Setu in India and is necessary for the broader interest of the nation. However well, public health surveillance systems must respect people's privacy. In the "Puttaswamy decision, the Supreme Court of India acknowledged the right to privacy as part of the right to life under Article 21 of the Indian Constitution.

The advancement and implementation of innovative technologies put customers' "electronic health records (hereafter 'EHR') in jeopardy. It is possible that the digital health data (hereafter 'DHD'), including patients' protected health information, is exposed to significant privacy and security threats. Usage of DHD" seemed promising enough to overhaul India's healthcare system, online monitoring is on the cusp of using it even without customers' informed consent.

Personal health data protection is a primary concern owing to the porous interaction between the right to privacy and the necessity for healthcare. A patient's personal health information is input and saved electronically just at the source of treatment to cure the patient's existence, from his initial admittance to the hospital to his final diagnostic procedures. The database is readily accessible to all healthcare providers responsible for the patient, but the scope and nature of gathering data are unprecedented. Not even to mention the risks that may occur when this information is combined with source information, such as pharmaceutical companies, resulting in deceitful sales promotion, privacy violations, exclusionary segmentation, and then re-selling of sensitive data in favor of website commercial transactions.

Administrative and physical safeguard norms arise for industries handling medical and personal patient records. However, as technological advances continue, predefined discrepancies spring up, and it becomes critical that confidentiality norms collaborate intimately to craft necessary measures and protections.

A significant concern is the usage of health-monitoring technologies, such as bands, smartwatches, activity trackers, and other wearable ECG monitors. The emerging interest in wearable fitness technology focuses on how to protect a user's privacy effectively. "The Ministry of Health and Family Welfare (hence 'MoHFW') issued a memorandum in 2015 creating the National e-Health Authority (in the future 'NEHA') to oversee the maintenance and growth of India's e-health ecosystem."

Acting on the same vision and objective, the "Ministry publicly revealed the proposal of the "Digital Information Security in Healthcare Act" (hence 'DISHA') in March 2018." "DISHA was established to develop NEHA and other health exchanges of information, including the State e-health authority (hereafter 'SEHA'), standardized the method of DHD collecting, and provided the highly required safety and confidentiality of DHD."

The existing legislative strategy in India toward this dilemma is to develop its privacy laws, known as the Data Protection Bill. The much-anticipated measure that began with turmoil was initially supposed to be adopted by the end of 2019. As one could remark, India's first attempt to comprehensively enact a potential framework for data protection appears to have failed. The rules in India governing security and privacy are highly uneven. It is a considerable concern when protecting healthcare data of around 1.3 billion of people.

14. LEGISLATION FOR HEALTHCARE DATA PROTECTION IN INDIA

The Indian healthcare profession is evolving and proliferating. Medical facilities have accessibility to the patient's healthcare records. The “National Health Policy 2017” proposed establishing a digital health technology ecosystem that would involve significant health data gathering, management, and exchange. Health data refers to information about the data principal's health & contains documentation about the information principal's past, present, or

future health status, collected information during enrolment for or provision of health services, and relevant data linking the information principally to the providing of specialized healthcare.

The first step toward the environment was done in 2012 when the administration mandated that hospitals “keep electronic health records on their patients under Clinical Establishment Rules. With this shifting landscape, the first thing that comes up is protecting from sensitive and essential medical data leakage. The issue now is how to strike the right balance between security, privacy, and development.”

There is presently “no legislation in India that explicitly safeguards health information. In March 2018, the Ministry of Health, and Family Welfare” proposed “'DISHA' ('Digital Information Security in Healthcare Act). DISHA expects an enactment focused on data protection, confidentiality, and security.”

“DISHA's mission is to educate administration professionals at the state and national levels to implement all the rights and duties specified in the Act.” The development of the “National Electronic Health Body (hereafter 'NEHA')” at the national level is envisaged, which is the ultimate authority in charge of rules & regulations, providing recommendations, and supervising the collecting, organization, and transmission of health data. The “State Electronic Health Authority (hereafter 'SEHA')” would be liable at the state level for ensuring that institutions fulfil “DISHA” needs. DISHA uses a consent-based approach, providing considerable privileges to the data owner, allowing him to determine what else should and can be done with his data.

Another proposal suggested was the “Personal Data Protection Bill 2019”, which might establish India's first cross-sectoral legislative platform for data protection. This legislation primarily addresses the safety of a patient's private information. This legislation is involved many different types of data, especially health information. Health information falls under the category of "sensitive personal data." As the term implies, must manage this sensitive data with utmost care and attention. Under this system, the governments have a role in safeguarding the data, and the primary agent does have the ability to information, remove, and update personal health information.

Both bills were proposed to protect personal healthcare data; however, these laws have yet to be enacted. The reason was the growing awareness about security as a privacy concept; such a concept has been established over the last few years. According to the Supreme Court, "the right to privacy is safeguarded integral aspect of the right to life and personal liberty under Article 21." Furthermore, informational privacy is a subset of it.

The existing legal regulations surrounding such protection specify when a corporate entity possesses or preserves any confidential personal data and is incompetent in ensuring stability to secure such information and data. Individuals receive a wrongful gain or loss. But such a corporation will be obliged to pay damages at that time. An essential issue is that it only addresses "corporate bodies," which is inadequate to encompass the digital realm.

Due to the current emergence of a new coronavirus (hence referred to as 'COVID-19,' the measured outcomes the “Arogya Setu” App, which offers health information about other individuals. Through this, the question of privacy enters the picture. Some individuals argue that this infringes the patient's privacy, while on the other hand, the administration is just prioritizing public interest above personal

benefit. According to the “Epidemic Diseases Act, the government can take the appropriate means to combat disease spread,” which might also include infringing on the right to privacy. Furthermore, the information privacy statute states that in the case of illness, may waive sensitive data even without the consent of the individual concerned. Finally, we must emphasize the importance of health-related data, notably the right to privacy granted under Article 21 of the Indian Constitution. It is a leisure activity to pass the “Digital Data Security in Healthcare Act (DISHA),” which will ensure that a person's electronic healthcare information is entirely secure and confidential.

15. OTHER LEGISLATION RELATED TO HEALTHCARE

Data Protection Bill 2021

A personal data protection law is currently being drafted. In December 2021, the Joint Parliamentary Committee submitted its report on the “Personal Data Protection Bill, 2019 ("PDP Bill") in Parliament.” The study suggests several modifications to the PDP Bill, including amending it to the Data Protection Bill, 2021 ("DPB"). The DPB was meant to become a comprehensive data protection law. It intends to govern personal and non-personal data collection and dissemination (including anonymize and de-identified data). When operational, the DPB would enhance India's privacy safeguards by managing the country's acquisition, preservation, use, and transfer of personal data. It applies to the government, local and international entities, and individuals.

Organizations about specific data are divided into "obligations imposed" and "data processors," with the "data principal" being the private individual to which the inhabitant estimates. Data fiduciaries have a greater responsibility than data processors, which includes informing the data principal, ensuring that data is not kept for an extended than required, and so on. In general, the responsibility of an information fiduciary is still far more than a data processor.

An autonomous Data Protection Authority ("DPA") (*A Guide To The Data Protection Bill, 2021 - Privacy Protection - India*, n.d.) would oversee the DPB. The DPB mandates that all information fiduciaries and processors adopt privacy by design. It does not refer to these criteria; instead, it should take appropriate measures to maintain sensitive information's integrity to demonstrate compliance.

It included conducting a Data Protection Impact Assessment ("DPIA"), adopting measures such as encrypting and De-identification, and adherence to any new security requirements specified by the DPA.

Personal information, including confidentiality, is classified by the DPB. There is also a third category containing sensitive information called essential private information, which includes specified types of sensitive information. According to the latest draft of the DPB, healthcare information is sensitive personal data and involves those data related to the data principal's health, including record-keeping information about the data principal's past, present, or future state of health, data collected while signing up for or providing health services, and data affiliating the data principal to the healthcare services.

So therefore, in the world of globalization transmissions data localization, data must be stored in India, and only a copy may be transmitted outside the country. Such a transfer is only lawful if the data fiduciary has given a signed agreement and the DPA has authorized it. Furthermore, there are various compliance standards for processing children's personal and sensitive personal data. The approval of the parent or guardian is needed for this.

Policy for Health Data Management in 2020

The HDM Policy applies to all entities involved in the ABDM. It is the method for implementing the confidentiality of electronic health data of consumers who grant a Health ID, authorized health professionals, and ABDM participating businesses. It provides the necessary standards for data privacy

protection to guarantee conformance and appropriate legislation, rules, and regulations. Its HDM Policies are based on the same ideas as the DPB. Information fiduciaries can indeed acquire or handle private or confidential private information with the consent of the data principal and for the purpose whereby obtaining the permission. Visibility, openness, and appropriate security standards and procedures are required. A data fiduciary must also sign confidentiality and non-disclosure agreements with data controllers that address data protection and privacy duties. Data subjects grant rights to their data, including confirmation and access, rectification, and deletion, including access to data.

Profound privacy personal information sharing is permissible in two circumstances. First, may share personal data processed by a data fiduciary with a Health Information User ("HIU") only upon the HIU's request and the data principal's approval. Second, information financial advisors could end up making accumulated anonymized or de-identified information available to support research and patient research, researchers, archiving, statistics, policy formulation, the protection and advancement of diagnostic solutions, and such other objectives the National Health Authority may specify.

Privacy Guide for Healthcare, Data Security Council of India, 2021

The Data Security Council of India ("DSCI") is a non-profit industrial group in India established by NASSCOM India. The DSCI Sectoral Privacy Project will develop sector- specific advice material to help businesses understand and implement privacy measures. DSCI has developed the DSCI Privacy Guide for Healthcare ("DSCI Guidance") as part of this endeavor. Although the Guidance is not legally obligatory, adopting it can help the organization better position itself to acquire new business opportunities and comply with authorities.

The DSCI Guidance defines Personal Health Data or Information as demographic data, administrative data, health risk information, and health status. PHI may be gathered using standard healthcare delivery or supplemental methods, including financial and economic care systems, remote health services, and routine tasks.

All healthcare service providers, including healthcare practitioners, institutions, insurers, pharmaceutical firms, and third-party aggregators, have been defined as entities subject to health data privacy regulations. There are recommendations for implementing regulatory requirements such as proportionate data collection, consent management, the use and sharing of health data, security measures, and personal data anonymity. The DSCI Guidance assists in conceptualizing probable scenarios of data breaches and liabilities under the relevant legislation and DPB inside the framework of Digital Health, where there are several routes of data production and dissemination.

16. INTELLECTUAL PROPERTY LAWS IN HEALTHCARE

Patent

In India, patent protection provides under the Patents Act, 1970 ("Patent Act"). The Patent Act is substantially consistent with the Agreement on "TRIPS", and India, as a signatory, has agreed to recognize and enforce the agreement's provisions fully. Every Digital Health application is powered by software, basically a software application. A software program "per se" is not patentable under Section 3(k) of the Patent Act of 1970. The Indian Patent Office, on the other hand, goes on to state in its 2017 “Guidelines for Evaluation of Computer Related Inventions ("CRI")” that if the CRI is not patentable.

A CRI claimed in combination with unique equipment may be patented if the other conditions, such as the three-prong test outlined in the rules, are met. Patents for software applications containing a hardware component were already issued. If the technology/software fits these requirements, it may be eligible for patent protection if a patent is awarded.

Copyright

The “Copyright Act, 1957 ("Copyright Act") protects copyright in India. Original literary, dramatic, musical, or creative work, cinematograph films, and sound recordings are all examples of copyright.” While registering a copyright is not required since copyright in work exists regardless of registration, the enrolment serves as prima facie proof of the right's existence. While copyright registration is not required because copyright in work exists irrespective of registration, enrolment serves as prima facie proof of the right's existence.

Section 2 (O) of the Copyright Act specifies software as a "computer program," and a literary work comprises computer software. As a result, copyright law protects the literal component, i.e., the source code. However, copyright only relates to the work's form and substance, not the notion itself. It would also suggest that ideas must be transmitted in some form before they can be protected. If clinical suggestions and information are represented in such media, they may be protected by the Copyright Act. Without additional effort, copyright protection may not cover an essential collection of material. It is also based on the sweat of the brow concept, which claims that copyright exists when a person collects information independently even if there is no originality in content such as tables or databases. The person is then allowed to have their time and money protected.

Trademark

In India, trademarks were governed and protected under the Trade Marks Act, 1999 ("TM Act"). Unauthorized trademarks are indeed safeguarded under common law, and protection is given. A mark is defined as "a device, brand, heading, label, ticket, name, signature, word, letter, numerical, form of products, packaging, or colors, or any combination thereof" under the TM Act. Trademarks can be registered for any mark that can be "graphically expressed" and indicates a commercial relationship with the holder. The regulations established by the TM Act govern trademark categorization. India adopts the NICE Classification of Goods and Services, including the rules' schedule. Class 9, consisting covers software applications and computer programs, is one of the classifications whereby can register a trademark." Under the Trade Marks Act, the mark of a Digital Health application or device could be made commercially, subject to exclusion criteria that create grounds for trademark denial.

17. CONCLUSION AND SUGGESTIONS

The analysis of the entire research conducted on Big Data in healthcare indicates the innovative method in Digitalization of healthcare services and the cybersecurity issues related to patient health records and their rights to protect it. Owing to Covid-19 when the whole world transforms all their sectors in digital platform patients are not connect with the technology easily as they prefer traditional mode of visiting the doctors for their health issues. As all the patients are helpless because of deadly Corona virus several conventions and legislations appear in order to safeguard patient rights like Information Technology Act, Intellectual Property, clinical establishment Act, IMC Regulation 2002, Drugs and Cosmetics Act of 1940, Pharmacy Act 1948 etc. These entire regulations are there to ensure the availability and accessibility of healthcare services during the COVID 19 pandemic scenario, and it has necessitated a serious approach towards the Digitalization of health care services.

Suggestions

1. The country needs comprehensive legal protection for the privacy rights for the patients with respect to medical records.

2. The country needs a comprehensive adoption of a Charter of patients’ rights valid across the nation. Patients’ rights must be adequately outlined, in order to be effective. Long lists

stipulating rights which lack order and clarity, causes ambiguity among the patients and health care providers.

3. There needs to be a consideration of moving public health into the concurrent list so that hospitals and clinics can be regulated uniformly across the nation. Also, considering the importance of protection of patient rights and its uniformity across states, a law regarding the protection of patients' rights can be made applicable across the nation, giving it much more effectiveness and comprehension. This seems to be important considering the enforcement of patients' rights because most of the patients' rights have got strong legal backing from various legal instruments and therefore, it is pertinent for the enforcement of the said rights uniformly across nation. The central and state/UTs govt. should consider the notion of immediate remedy or rectification for the patients in case of any violation of their rights.

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