DIGITAL HEALTH IN INDIA – KEY TRENDS AND IMPACT OF REGULATION

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ABSTRACT

Technology has the potential to transform the healthcare sector in India. This revolutionary effect can be seen at all levels of service delivery, including telemedicine apps that allow patients in remote areas to consult with senior specialists in urban areas, the use of AI in treatment and diagnosis of diseases, and the prevalence of e-pharmacies that allow patients to purchase medicines from the comfort of their own homes. Proper regulation of these emerging technologies is essential to ensure that the patients are able to fully capitalize on these technological developments, without any danger to their health or safety.

This article explores the impact of existing and proposed legislation on key trends emerging in the digital health sector. Firstly, the article outlines how digital health can help boost healthcare service delivery and examines the prevalent business models and trends in the digital health sector. Secondly, the article provides a background on existing and proposed legislation which may have an impact on the digital health sector. Thirdly, the article examines the impact of existing and proposed regulation in the digital health sector. The article concludes by providing recommendations on how regulation should be framed to ensure sustainable growth of the digital health sector.

I. INTRODUCTION

The World Health Organisation defines digital health as *"a broad umbrella term encompassing eHealth, as well as emerging areas, such as the use of advanced computing sciences in 'big data', genomics and artificial intelligence"*.[1] Therefore, the expression Digital Health may be said to include the tools and services that use Information and Communication Technologies (ICT) for purposes connected to health. These purposes may include improving accuracy of diagnosis, monitoring chronic diseases more closely and improving treatment outcomes for patients.

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[1] *WHO Guideline on Recommendations on Digital Interventions for Health System Strengthening*, World Health Organization, 9, available at https://apps.who.int/iris/bitstream/handle/10665/311941/9789241550505-eng.pdf?ua=1, last seen on 14/01/2020.

Often, ICT tools that form part of digital health are considered to be futuristic technology which will come into existence years, maybe even decades from now. However, digital health technologies are no longer a thing of the future. In fact, the world's first world's first 'tele-surgery' took place in 2001, where Dr. Jacques Marescaux (located in New York) surgically removed the gall bladder of a 68-year-old woman (located in France) using dedicated Asynchronous Transfer Mode telecommunication technology, which provided minimum response time between the surgeon and the robot.[2]

Closer to home, the Manipal Group of Hospitals have tied up with IBM's Watson for Oncology, a data-driven artificial intelligence ("**AI**"), to assist the doctors to diagnose and treat seven types of cancer.[3] Watson reportedly applies natural language processing and machine learning to assist oncologists and their care team to analyse a patient's medical record, to help identify personalized treatment options using clinical evidence.[4] Though Watson has had its fair share of controversies ranging from whether Watson is merely a 'mechanical turk' i.e. a human driven engine masquerading as AI to whether treatment plans recommended by Watson are effective[5], the potential of AI in medicine is undeniable.

A more accessible and visible digital health tool is the e-pharmacy. E-pharmacies/online pharmacies are crucial in improving accessibility of medicines (especially medicines for uncommon or rare diseases) across India as currently, healthcare resources are heavily concentrated in urban areas.

Tele-surgeries, AI and e-pharmacies are only the tip of the digital health iceberg. ICT tools in the health sector have myriad applications ranging from the use of blockchain technology to digitize health records to collating data from these health records to chart out disease prevalence and frame policy to tackle public health issues. Separately, tools for

[2] J. Marescaux, J. Leroy, F. Rubino, M. Smith, M. Vix, M. Simone, and D. Mutter, *Transcontinental Robot-Assisted Remote Telesurgery: Feasibility and Potential Applications*, 235(4) Annals of Surgery 487, 487 (2002), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1422462/, last seen on 14/01/2020.

[3] *Artificial Intelligence in the Healthcare Industry in India*, Centre for Internet and Society, available at https://cis-india.org/internet-governance/files/ai-and-healtchare-report, last seen on 14/01/2020.

[4] *Manipal Hospitals is the First Healthcare Provider in India to Adopt Watson for Oncology for Upgradation of Cancer Care*, Manipal Hospitals, available at https://www.manipalhospitals.com/blog/manipal-hospitals-is-the-first-healthcare-provider-in-india-to-adopt-watson-for-oncology-for-upgradation-of-cancer-care, last seen on 14/01/2020.

[5] C. Doctorow, *Watson for Oncology isn't an AI that fights cancer, it's an unproven mechanical turk that represents the guesses of a small group of doctors*, Boing Boing, available at https://boingboing.net/2017/11/13/little-man-behind-the-curtain.html, last seen on 14/01/2020.

augmented and virtual reality, big data, drones and 3D printing also have applications in the digital health space. Correctly leveraging digital health tools can be the key component for both developing and developed nations, to maximize efficiency in providing healthcare services to their citizens as well as to significantly improve the quality of those services.

The purpose of this article is to understand how digital health in India is currently regulated and, in cases of business models which are currently not specifically regulated, to take positions which are yet to be tested, with the hope that it would set the tone for legal discussions in larger platforms. To this end, the article begins by analysing prevailing business models from a legal and regulatory compliance perspective. Subsequently, this article contextualizes these business models within the applicable regulation, to understand whether these business models are being regulated in the best way possible. Finally, the article concludes by suggesting changes to existing regulations, identifying gaps in regulation and providing recommendations for new regulation.

II. PREVAILING BUSINESS MODELS AND TRENDS

1. Telemedicine

Telemedicine is the use of telecommunications technology to provide healthcare. Currently, 75% of the country's healthcare infrastructure is concentrated in urban areas while more than 75% of the population lives in rural areas.[6] Telemedicine could be used to effectively bridge the gap between the patient and the doctor.

While telemedicine is not a separate specialty in itself, its standout is the use of various technologies in providing traditional healthcare services. It is a broad concept that covers various aspects such as tele-radiology, tele-consultation, tele-nursing, tele-ICU and tele-surgery. Each brings its own advantages and challenges and as a result, is regulated separately under law.

2. e-Pharmacies

An e-pharmacy or online pharmacy is a pharmacy that operates over the internet and sends the orders to customers through mail, courier or delivery persons. There are various models that have been adopted where some pharmacies operate as online-only pharmacies and some as physical

[6] A.V. Patil, K. V. Somasundaram and R. C. Goyal, *Current Health Scenario in Rural India*, 10 Aust. J. Rural Health 129, 134 (2002), available at http://www.sas.upenn.edu/~dludden/WaterborneDisease3.pdf, last seen on 15/01/2020.

pharmacies with an online presence. Online pharmacies allow pharmacists to cater to a larger group of patients as the geographical restrictions inherent in physical pharmacies are removed in the online model.

3. Self-Monitoring Healthcare Devices

Monitors and sensors are now being integrated into wearables, which allow it to detect various physiological changes in the body. These smart devices are capable of tracking weight, sleep patterns, posture, diet and exercise[7]. The raw data that is collected can be used to self-monitor by detecting various health symptoms and alert the user in case of potential issues.

4. Robot-Assisted Surgery

Robotic surgery, or robot-assisted surgery, allows doctors to perform many types of complex procedures with more precision, flexibility and control than is possible with conventional techniques.[8] Using the assistance of robots, doctors are able to perform surgical procedures more efficiently. Even in minimally invasive surgeries the assistance of robotics allows surgeons to maneuver more precisely and with smaller incisions[9]. This ultimately leads to reduced loss of blood, better pain management and quicker recovery for the patient.

With advancements in deep learning, robots would be able to observe and replicate procedures that are simple and repetitive, while the surgeon concentrates on more complex tasks.[10]

5. Electronic Health Records ("EHR")

An EHR is a digital version of a patient's health records. EHRs help eliminate the problems associated with physical records such as loss and lack of accessibility. EHRs can be stored centrally and accessed at any

[7] G. Appelboom, E. Camacho and M.E. Abraham, *Smart wearable body sensors for patient self-assessment and monitoring*, 72(1) Archives of Public Health, (2014), available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4166023/, last seen on 15/01/2020.

[8] *Robotic Surgery*, Mayo Clinic, available at https://www.mayoclinic.org/tests-procedures/robotic-surgery/about/pac-20394974, last seen on 15/01/2020.

[9] *Minimally Invasive Surgery*, Johns Hopkins Medicine, available at http://www.hopkinsmedicine.org/minimally_invasive_robotic_surgery/types.html, last seen on 15/01/2020.

[10] K. Claek and E. Strickland, *Robot Surgeons are Taking over the Operating Room*, IEEE Spectrum, available at http://spectrum.ieee.org/video/robotics/medical-robots/robot-surgeons-are-taking-over-the-operating-room, last seen on 15/01/2020.

time, irrespective of where or when the information was collected[11]. With EHRs, doctors are able to view their patients' complete medical history even if they are treating the patient for the first time. This helps reduce duplication of tests and facilitates the secure exchange of information, which in turn helps the patient and the healthcare facilities manage costs.

The data collected from EHRs and wearables can be put to use in different ways. This data set has multiple big data applications ranging from understanding the general state of public health to targeted advertising. Due to the potential for help and harm arising from big data, the regulation of EHRs (specifically privacy and data protection concerns) takes on even more importance.

6. Health Service Aggregation

Information asymmetry is one of the biggest challenges in healthcare. Patients are not privy to essential information which can help them pick the right doctor for their needs. Conversely, sometimes doctors are not able to reach out to a large number of patients due to a lack of visibility. A number of online platforms are springing up which attempt to solve this problem. These platforms list the names of doctors with their specialties, and allow for patients to search for and make an appointment with the right doctor to suit their specific needs. Patients are also able to rate and review the quality of the service provided by the doctor or institution, which serves as guidance for future patients to make an informed decision.

7. m-Health

Mobile health, or m-Health, is the provision of digital health services on a mobile platform. India is home to the 3rd largest smartphone market in the world, which makes m-Health a very lucrative option. The growth potential for m-Health in rural areas looks particularly promising due to the lack of access to traditional clinics coupled with the rapid increase in internet penetration in these areas.[12]

8. Artificial Intelligence

[11] L. Poissant, J. Pereira and R. Tamblyn, *The Impact of Electronic Health Records on Time Efficiency of Physicians and Nurses: A Systematic Review*, 12(5) Journal of the American Medical Informatics Association 505, 505 (2005), available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1205599/, last seen on 15/01/2020.
[12] N. Mathur, *India's internet base crosses 500 million mark, driven by Rural India*, Livemint (11/03/2019), available at https://www.livemint.com/industry/telecom/internet-users-exceed-500-million-rural-india-driving-growth-report-1552300847307.html, last seen on 15/01/2020.

Artificial Intelligence ("AI") is the use of complex algorithms and software to emulate human cognition in the analysis of data. In the health sector, AI can be used to analyse patient records and identify a personalized course of treatment. For instance, since many types of cancer have a genetic basis, human clinicians have found it increasingly complex to understand all genetic variants of cancer and their response to new drugs and protocols.[13] AI can help clinicians process this data to design effective treatment plans. An AI based medical device has already been approved by the drug regulator in Singapore.[14] See-Mode's Augmented Vascular Analysis (AVA) is intended to assist clinicians in interpreting and reporting vascular ultrasound studies which would otherwise require the clinician to review and analyse 50-150 individual images (including ultrasound images and doppler waveforms).[15]

III. IMPORTANT LAWS, REGULATIONS AND POLICIES GOVERNING DIGITAL HEALTH IN INDIA

Digital health in India is regulated under various laws, rules, and guidelines. While every digital health tool/business model is regulated separately, some regulations are applicable to digital health tools generally. We have provided an outline for some of these regulations below. Information Technology Act, 2000 ("IT Act"), The Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011 ("SPDI Rules"), and the Information Technology (Intermediaries Guidelines) Rules, 2011 ("Intermediary Guidelines")

The IT Act, SPDI Rules and the Intermediary Guidelines constitute the general data protection framework in India. The IT Act was enacted to provide legal recognition to online transactions and the exchange of electronic data generally. Broadly, the IT Act governs all forms of online activity including methods of authenticating digital signatures[16] and granting legal recognition to electronic records.[17] The IT Act also specifies penalties for damaging a computer system (hacking or denial of service attacks etc.) and lists out acts which amount to cybercrimes.

[13] T. Davenport and R. Kalakota, *The potential for artificial intelligence in healthcare*, 6(2) Future Healthcare Journal 94, (2019), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6616181/, last seen on 24/01/2020.
[14] Digital News Asia, Singapore *Approves Medical AI Software for Automated Analysis of Vascular Ultrasound*, Digital News Asia (12/12/2019), available at https://www.digitalnewsasia.com/digital-economy/singapore-approves-medical-ai-software-automated-analysis-vascular-ultrasound, last seen on 24/01/2020.
[15] Ibid.
[16] Chapter II, Information Technology Act, 2000.
[17] S. 4, Information Technology Act, 2000.

1. SPDI Rules

The SPDI Rules require all body corporates who collect, receive, possess, store, deal, or handle information of a provider of information to undertake measures to ensure that the provider of the data is informed about the manner in which the data would be used. These measures include publishing a privacy policy specifying, *inter alia,* the purpose of collection and usage of information and names of entities to which such information may be disclosed.[18] Additionally, it also mandates that the information collected be processed only in accordance with the terms of the consent provided by the provider of information[19] and places certain restrictions on the disclosure[20] and transfer[21] of sensitive personal information. Body corporates are also required to put in place reasonable security practices (prescribed under the SPDI Rules) to keep sensitive personal information secure.[22]

Most entities in the digital health space are required to comply with the SPDI rules as they would deal with physical, psychological or mental health conditions of persons and their medical records which are considered to be sensitive personal information under the SPDI Rules.[23]

2. Intermediary Guidelines

The Intermediary Guidelines specify the due diligence to be undertaken by an intermediary (persons processing information on behalf of other persons, such as telecom service providers, internet service providers and web-hosting service providers) so that they may avail the safe harbour provision under Section 79 of the IT Act. Section 79 of the IT Act states that intermediaries would not be held liable for third party information, data, or communication link made available or hosted by the intermediary provided the (i) function of the intermediary is limited to providing access to a communication system over which information made available by third parties is transmitted or temporarily stored or hosted, or (ii) intermediary does not initiate the transmission, select the receiver of the

[18] Rule 4, Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011.
[19] Rule5, Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011.
[20] Rule 6, Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011.
[21] Rule 7, Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011.
[22] Rule 8, Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011.
[23] Rule 3, Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011.

transmission, and select or modify the information contained in the transmission.

Broadly, the Intermediary Guidelines require the intermediary to publish rules and regulations, a privacy policy and a user agreement (which should contain information prescribed under the Intermediary Guidelines) as a pre-condition to access or use the intermediary's computer resource.[24] Additionally, in the event the intermediary is hosting content that is found to be in contravention of the IT Act and rules, the intermediary would be required to take down such infringing content on the receipt of a notice from a government authority to this effect.[25]

The safe harbour provision under the IT Act and Intermediary Guidelines is particularly useful for digital health services that merely facilitate the interaction between the patient and the service provider and are not directly involved in the provision of the services.

The IT Act along with the SPDI Rules and Intermediary Guidelines forms the bedrock over which any digital health business model is built.

3. Drugs and Cosmetics Act, 1940 ("D&C Act") and Drugs and Cosmetics Rules, 1945 ("D&C Rules")

The D&C Act along with the D&C Rules constitute the primary framework governing drugs in India. D&C Rules regulate the clinical trial, import, manufacture, and sale of drugs and biologics. The D&C Rules specify that certain drugs should be sold only on the basis of a prescription issued by a doctor licensed to practice in India and dispensed directly to the patient or their caretaker under the supervision of a registered pharmacist.[26] Drugs which can be sold only on prescription are stated in Schedules H, H1, and X of the D&C Rules. More generally, the D&C Act states that no person can sell any drug without a license issued by the licensing authority. The only exception in this respect are drugs specified in Schedule K of the D&C Rules which may be sold without obtaining a valid sale license from the drug regulator. These broadly include drugs not intended for medical use, quinine and other antimalarial drugs, magnesium sulphate, substances intended to be used for destruction of vermin or insects that cause disease in humans or animals and household remedies, among others.

The D&C Rules in their current form were not intended to govern e-pharmacy business models. Under the D&C Rules, a valid prescription is

[24] Rule 3, Information Technology (Intermediaries guidelines) Rules, 2011.
[25] Rule 3, Information Technology (Intermediaries guidelines) Rules, 2011.
[26] Rule 65, Drugs and Cosmetics Rules, 1945.

required to be in writing and bear the doctor's signature. However, scanned copies of signatures made by hand are not considered to be valid within the meaning of the IT Act. The Government is currently considering options on how e-pharmacies should be regulated and would hopefully take into account this difficulty faced by most e-pharmacies.

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

The MCI Act along with the MCI Code constitutes the regulatory framework regulating medical education and the practice of medicine in India. The MCI Act provides that only those persons who have a recognized degree in medicine and are registered with a state medical council have the right to practice medicine in India. The MCI Code lays down professional and ethical standards of interaction of doctors with patients, pharmaceutical companies and other doctors.

It is pertinent to note, however, that the MCI Act will soon be repealed by the National Medical Commission Act, 2019 ("**NMC Act**") and a new body i.e. the National Medical Commission will be constituted to replace the Medical Council of India as the apex body to regulate the practice of medicine in India.

5. Draft E-pharmacy Rules

The Ministry of Health and Family Welfare ("**Health Ministry**") released a set of draft rules to govern e-pharmacies ("**Draft E-pharmacy Rules**").[27] The Draft E-Pharmacy Rules will introduce a registration system[28] for e-pharmacies and permit them to function on par with traditional pharmacies by granting them legal recognition. It also imposes conditions on e-pharmacies, such as requiring them to maintain a confidential record of prescriptions as well as details of the drugs sold to patients.[29] E-pharmacies are also required to establish a 24/7 customer support and grievance redressal mechanism, in order to address consumer complaints.[30] Consumers are empowered to submit complaints with the drug regulator for violation of the D&C Rules (including with respect to the quality of drugs dispensed).[31] If the e-pharmacy is found to

[27] Draft E-Pharmacy Rules, 2018.
[28] Rule 67J, Draft E-Pharmacy Rules, 2018.
[29] Rule 67M, Draft E-Pharmacy Rules, 2018.
[30] Rule 67J, Draft E-Pharmacy Rules, 2018.
[31] Rule 67U, Draft E-Pharmacy Rules, 2018.

be in violation of the law, the regulator can cancel the license of the e-pharmacy in addition to other penalties prescribed.[32]

The Draft E-pharmacy Rules were released to specifically govern online pharmacies as the current regulatory framework does not account for the online sale of medicines. The D&C Rules require the pharmacist to dispense drugs directly to the patient or caretaker which is not convenient in the case of e-pharmacies.

The regularization of e-pharmacies has been a highly controversial subject for a few years now. After the Draft E-pharmacy Rules were published, the All India Organisation of Chemists and Druggists ("**AIOCD**") went on multiple strikes to protest against the government's decision to regularise e-pharmacies.[33] Subsequently, petitions were filed in the Madras High Court[34] and Delhi High Court.[35] Initially, both the Madras and Delhi High Court had passed orders banning online sale of medicines. However, the Madras High Court subsequently lifted the ban and directed the Government to notify the draft rules by January 31, 2019.[36] As of this writing, the Draft E-pharmacy Rules has still not been notified by the Central Government.

Subsequently, on November 28, 2019, the Drugs Controller General of India – India's apex drug regulator – issued an office letter requiring all drug controllers to enforce an order passed by the Delhi High Court in December 2018, which prohibited the online sales of medicines without a valid license.[37]

Currently, the online sale of medicines seems to be legal provided the online pharmacies are operating under a valid license that permits them to stock and sell medicines.

6. Draft Personal Data Protection Bill, 2019 ("PDP Bill")

[32] Rule 67U, Draft E-Pharmacy Rules, 2018.

[33] *Chemists declare strike against Centre's move to regularize e-pharmacies*, ET Retail (28/09/2019), available at https://retail.economictimes.indiatimes.com/news/health-and-beauty/pharmacy/chemists-declare-strike-against-centres-move-to-regularise-e-pharmacies/65994969, last seen on 15/01/2020.

[34] Tamil Nadu Chemists and Druggists Association v. The Union of India, W.P. No. 28716 of 2018 (Madras High Court, 17/12/2018).

[35] Zaheer Ahmed v. Union of India W.P.(C) 11711/2018 (Delhi High Court).

[36] S.R. Singh, *Two High Courts, two different views on online drugs sale,* The Hindu (21/01/2019), available at https://www.thehindu.com/news/cities/Delhi/two-high-courts-two-different-views-on-online-drugs-sale/article26045505.ece, last seen on 15/01/2020.

[37] S. Dey, *Online drugs sales may come to halt as licence made must*, Times of India (04/12/2019), available at https://timesofindia.indiatimes.com/business/india-business/e-pharmas-come-to-a-halt-as-regulator-makes-licence-must/articleshow/72357270.cms, last seen on 15/01/2020.

The PDP Bill has been introduced in the Lok Sabha and is intended to replace the IT Act as the primary data protection legislation in India. The PDP Bill is currently being examined by a Joint Parliamentary Committee. The PDP Bill, if enacted will apply to[38]:

i. The processing of all personal data which has been collected, disclosed, shared, or otherwise processed within the territory of India;

ii. The processing of personal data by the State (Central or State Government, public authority, government institution or any organisation performing a public function), any Indian company, any citizen of India or any person or body of persons incorporated or created under Indian law;

iii. The processing of personal data by data fiduciaries or data processors outside the Indian territory, provided such processing is in connection with any business carried on in India or any systematic activity of offering goods or services to data principals within India or in connection with any activity which involves profiling of data principals within the territory of India.

However, the PDP Bill would not apply to processing of anonymized data unless such data is being provided to the Central Government to better enable targeting of delivery of services or formulation of policies.[39] The PDP Bill, though sector agnostic, is more comprehensive compared to the IT Act when dealing with health data. Under the PDP Bill, the terms health data[40], biometric data[41] and genetic data[42] are defined clearly and have been categorized as sensitive personal information.

Additionally, the PDP Bill ensures that the data principal (natural person to whom the data relates) remains informed about the data that has been

[38] S. 2, Personal Data Protection Bill, 2019 (passed by Lok Sabha, 11/12/2019).
[39] Ibid.
[40] Section 3(21) of Personal Data Protection Bill, 2019 defines Health Data as the data related to the state of physical or mental health of the data principal and includes records regarding the past, present or future state of the health of such data principal, data collected in course of registration for, or provision of health services, data associating the data principal to the provision of specific health services.
[41] Section 3(7) of Personal Data Protection Bill, 2019 defines Biometric Data as facial images, fingerprints, iris scans, or any other similar personal data resulting from measurements or technical processing operations carried out on physical, physiological, or behavioural characteristics of a data principal, which allow or confirm the unique identification of that natural person.
[42] Section 3(19) of Personal Data Protection Bill, 2019 defines Genetic Data as personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the behavioural characteristics, physiology or health of that natural person and which result, in particular, from an analysis of a biological sample from that natural person in question.

collected and the manner in which it would be processed. Most of the compliances under the PDP Bill are required to be undertaken by the data fiduciary (entities who determine the purpose and means of processing data). The data fiduciary may engage a data processor to process the data on behalf of the fiduciary by way of a written agreement.

The PDP Bill places obligations on data fiduciaries to undertake certain compliances to process personal data as follows:

i. The data fiduciary is required to provide the data principal with a notice, inter alia, regarding the nature and categories of personal data collected, purposes for which it will be utilized, who it may be shared with[43];

ii. The data collected should be processed only for the purpose specified to the data principal and for an incidental purpose for which the data principal would reasonably expect the personal data to be used for;[44]

iii. The data should be retained only until the purpose for which the data was collected is completed; and;[45]

iv. Data fiduciaries are required to implement measures to provide information to data principals in the manner in which their data is being processed and provide notification on data breaches.[46]

In each case, the consent of the data principal should be obtained for processing personal data.[47] For processing sensitive personal data (such as health information), the following additional requirements should be fulfilled:[48]

i. Consent should be obtained after informing data principal the purpose of processing the sensitive personal information which is likely to cause significant harm to the data principal;

ii. Consent should be obtained in clear terms without recourse to inference from conduct in a context: and

iii. Consent should be obtained after giving the data principal the choice of separately consenting to the purposes of processing, or

[43] S. 7, Personal Data Protection Bill, 2019 (passed by Lok Sabha, 11/12/2019).
[44] S. 5, Personal Data Protection Bill, 2019 (passed by Lok Sabha, 11/12/2019).
[45] S. 9, Personal Data Protection Bill, 2019 (passed by Lok Sabha, 11/12/2019).
[46] S. 25, Personal Data Protection Bill, 2019 (passed by Lok Sabha, 11/12/2019).
[47] S. 11, Personal Data Protection Bill, 2019 (passed by Lok Sabha, 11/12/2019).
[48] S. 11(3), Personal Data Protection Bill, 2019 (passed by Lok Sabha, 11/12/2019).

the use of different categories of sensitive personal data relevant to the processing.

Separately, the PDP Bill also specifies an exhaustive list of situations in which the personal data/sensitive personal data may be processed without the consent of the data principal. Sensitive personal data may be processed without the consent of the data principal:[49]

i. to respond to any medical emergency involving a threat to the life or a severe threat to the health of the data principal or any other individual;

ii. to undertake any measure to provide medical treatment or health services to any individual during an epidemic, outbreak of disease or any other threat to public health; or

iii. to undertake any measure to ensure safety of, or provide assistance or services to, any individual during any disaster or any breakdown of public order.

The PDP Bill also requires data fiduciaries identified to be significant data fiduciaries by the Data Protection Authority of India (no data fiduciaries have been identified yet) to appoint a data protection officer.[50]

The PDP Bill also establishes the Data Protection Authority of India to administer and enforce the PDP Bill, respond to data or security breaches and protect the rights of data principals (natural persons to whom the data relates).[51]

7. Digital Information Security in Healthcare Act ("DISHA")

DISHA, currently in the draft stage, is sought to be enacted to standardise and regulate the process related to the collection, storage, transmission and use of digital health data. DISHA, if enacted, would increase interoperability of patient data across healthcare service providers (including hospitals, clinics, primary healthcare centres and emergency response services) by instituting a health information exchange.[52] This health information exchange would be facilitated by the National Electronic Health Authority of India[53] and the State Electronic

[49] Chapter III, Personal Data Protection Bill, 2019 (passed by Lok Sabha, 11/12/2019).
[50] S. 30, Personal Data Protection Bill, 2019 (passed by Lok Sabha, 11/12/2019).
[51] Chapter IX, Personal Data Protection Bill, 2019 (passed by Lok Sabha, 11/12/2019).
[52] S. 19, Digital Information Security in Healthcare Bill, 2018 (pending).
[53] S. 4, Digital Information Security in Healthcare Bill, 2018 (pending).

Health Authority of India[54] (to be established under DISHA) who will be responsible for coordinating data transfers between HCPs.

DISHA defines digital health data as *"an electronic record of health-related information about an individual…"*[55] Crucially, DISHA clearly identifies the patient as the owner of the digital health data[56] and outlines a comprehensive set of rights of the patient in respect of such data.[57] These rights include the right to privacy, confidentiality and security of their digital health data,[58] the right to refuse or withdraw consent,[59] the right to know the clinical establishments and entities that may access this data,[60] the right to be notified in the event their health data is accessed by a clinical establishment,[61] and the right to seek compensation for damages caused in case of breach of digital health data.[62]

DISHA also lays down the process of storage and transmission of digital health data and the circumstances in which the digital health data may be accessed. Notably, DISHA places restrictions on the commercial use of digital health including prohibiting pharmaceutical and insurance companies from accessing digital health data stored in the health information exchange in any circumstances.[63]

IV. EVALUATION OF RULES AND REGULATIONS AND IMPACT ON DIGITAL HEALTH SPACE

The digital health space is constantly evolving as new and existing technologies are used in the health sector. Below we have analysed some of the emerging trends in the digital health sector to see how they would be regulated under existing and proposed legislation and examined the policy challenges faced by stakeholders towards fully capitalizing on these technologies.

1. Tele-medicine and E-pharmacies

Apps and websites offering online or phone consultations with doctors as well as e-commerce websites engaged in the online sale of medicines are already operational in many parts of India. Currently, telemedicine and online pharmacies are not regulated under any specific law. However, the

[54] S. 7, Digital Information Security in Healthcare Bill, 2018 (pending).
[55] S. 3(e), Digital Information Security in Healthcare Bill, 2018 (pending).
[56] S. 3(j), Digital Information Security in Healthcare Bill, 2018 (pending).
[57] S. 28, Digital Information Security in Healthcare Bill, 2018 (pending).
[58] S. 28(1), Digital Information Security in Healthcare Bill, 2018 (pending).
[59] S. 28(3), Digital Information Security in Healthcare Bill, 2018 (pending).
[60] S. 28(6), Digital Information Security in Healthcare Bill, 2018 (pending).
[61] S. 28(6), Digital Information Security in Healthcare Bill, 2018 (pending).
[62] S. 28(8)(g), Digital Information Security in Healthcare Bill, 2018 (pending).
[63] S. 29(5), Digital Information Security in Healthcare Bill, 2018 (pending).

rules generally applicable to the practice of medicine (MCI Act and MCI Code) and pharmacies (D&C Act and D&C Rules) would apply to telemedicine and e-pharmacies as well.

2. Telemedicine

There seems to be some legal ambiguity in how telemedicine is regulated in India. The major gaps in regulation have been specified below.

Practice across State Boundaries

As discussed above, doctors are required to be registered with a state medical council (which operates under the overall supervision of the Medical Council of India) as a prerequisite to practicing medicine in India. The names registered with the state medical council also form part of a central register maintained by the Medical Council of India. An unresolved concern in this respect is whether a doctor registered with the state medical council of one state can practice medicine outside of that state. The MCI Act states that a person whose name is a part of the Indian Medical Register, which is a central register maintained by the MCI, is entitled to practice as a medical practitioner in any part of India, subject to any other conditions laid down under the MCI Act.[64] However, certain state medical council legislations expressly prohibit the practice of medicine within the state unless the medical practitioner is registered with the relevant state medical council.

One concern with cross-state practice would be to determine which state medical council would have jurisdiction to try a violation of the MCI Code in cases the violation occurs outside of the state in which the medical practitioner is registered.

The Supreme Court in the case of *Malay Ganguly v. Medical Council of India and Ors.*[65], had considered the question of liability when a medical practitioner commits an offence while practicing in an area that is outside of the jurisdiction of the relevant state from which he/she received registration. The question was sent to the MCI for deliberation, and in the meeting of the ethics committee held from 26th to 28th August, 2004, the matter was taken up for consideration. The ethics committee observed "*as such there is no necessity of registration in more than one State Medical Council because any doctor who is registered with any State Medical Council is automatically borne on the strength of the Indian Medical Register and also by virtue of Section 27 of the MCI Act, a person who is borne in the Indian Medical Register can practice anywhere in India*". The committee also laid down how

[64] S.27, Indian Medical Council Act, 1956.
[65] Malay Ganguly v. Medical Council of India and Ors., (2002) 10 SCC 93.

complaints against a medical practitioner were to be dealt with when the medical practitioner was registered with more than one state. Unfortunately, the ambiguity regarding registration was not conclusively put to rest.

Since the ambit of a telemedicine practice would be to provide medical services that are not restricted to the location of the patient, it is unclear whether a doctor registered with a state medical council would be permitted to provide medical services to patients residing in another state, and whether such doctors would be required to obtain multiple state registrations in order to be entitled to practice.

A solution may be to consider adopting some of the practices being followed by the USA in terms of special licensing for the purpose of telemedicine, which would bring some clarity and aid medical practitioners and healthcare institutions in being compliant with regulatory requirements.

Prescribing Medicines Online

Though not expressly forbidden, the Supreme Court has observed that prescriptions for drugs should not be given over the telephone, except in cases of emergencies.[66] Additionally, prescriptions given in apps providing telemedicine services (which tend to be scanned copies of prescriptions written and signed by hand) are usually not valid under law. The D&C Rules state that for a prescription to be valid, it must be in writing, signed and dated by the doctor issuing the prescription.[67] The prescription must also state the name and address of the person for whom it is given and the quantity to be supplied. Under the IT Act, a document in electronic format is considered validly signed if the information in the document is capable of being authenticated by means of electronic signature in a manner prescribed under the IT Act. Scanned copies of documents where a signature is made by hand are not considered a valid signature under the IT Act. Therefore, it is possible for pharmacists to deny supplying medicines on the basis of such prescription as a consequence for which ill patients may be left without the medicines they need.

Data Protection Requirements

Apps and websites offering telemedicine services process what is considered to be sensitive health information under the SPDI Rules. Therefore, the requirements of obtaining informed consent, publishing a privacy policy and putting in place adequate security measures are all

[66] Martin F. D'Souza v. Mohd. Ishfaq, (2009) 3 SCC 1.
[67] Rule 65, Drugs and Cosmetics Rules, 1945.

compliances the telemedicine service providers are required to undertake. It is pertinent to note that the SPDI Rules provide only a basic level of protection to patient data by ensuring that the person providing the data is informed about the manner in which the data will be used. However, a common problem with obtaining user consent for processing their digital data is the difficulty in explaining to the user in simple terms what data is being collected, how it is being processed and who it may be shared with. This problem is compounded in India due to low levels of digital literacy.

To resolve this, in addition to obtaining user consent for collecting and processing data, a robust regulatory framework on how health data can be used should be put in place.

3. E-pharmacies

The regulation of e-pharmacies has been hotly debated for a few years now, primarily because e-pharmacy business models can be manipulated by users to obtain drugs illegally. Under the current regulatory framework, there are multiple challenges to dispensing drugs online under the current framework.

Validity of Prescription

The converse of the issue faced by doctors when prescribing medicines online is applicable in the context of e-pharmacies. Generally, patients upload a scanned copy of a physical prescription provided to them by their doctor on the website or app of the e-pharmacy and the e-pharmacy supplies drugs to the patient on the basis of this prescription.

As discussed above, a valid prescription should be in writing and should be signed by the medical practitioner providing the prescription. Under the IT Act, a document that is required by law to be in writing would be deemed to be in compliance of such law if the same is made available in an electronic form and accessible in a way that it can be used for future references[68]. Hence a prescription uploaded online would fulfill the first requirement of a valid prescription under the D&C Rules. However, the IT Act further states that where a law requires for a document to be signed, it would be deemed to be in compliance only if such information or matter is authenticated by means of an electronic signature[69]. Affixing an electronic signature to any document thus becomes essential for it to fulfil a legal obligation mandating a regular signature. This would imply that uploading a scanned copy of a prescription may not be recognized as valid under law. The Draft E-pharmacy Rules also do not account for this

[68] S. 4, Information Technology Act, 2000.
[69] S. 5, Information Technology Act, 2000.

difficulty. Prescription, under the Draft E-pharmacy Rules is defined as *"an instruction from a Registered Medical Practitioner to a patient, written by hand or in any electronic mode duly signed, to dispense a drug and quantity of drug to a patient"*.[70] As the term 'duly signed' is used, the requirements under the IT Act with respect to an electronically signed document would continue to be applicable.

Separately, it would also be challenging to ensure that the drugs are not dispensed by two different pharmacies based on the same prescription. Currently, once a prescription has been fulfilled, the pharmacists will typically stamp the prescription and put their signature on it. However, there is no way to replicate this process online. Therefore, measures must also be put in place whereby a prescription drug is not dispensed more than once against the same prescription, something that has not been accounted for in the E-Pharmacy Rules.

Validity of License for E-pharmacies

In most e-pharmacy models, the e-pharmacy supplies drugs to the patients either from an inventory maintained by the e-pharmacy in a warehouse or by providing aggregator and logistics services where the order is fulfilled by a third party seller, but delivered to the customer by way of courier or a delivery boy (engaged by the e-pharmacy). The former is similar to an inventory-based e-commerce model (e.g. the H&M online clothing store) while the latter follows the market place model where sellers list their products on an e-pharmacy portal (e.g. Amazon website).

In its current form, the D&C Act requires that all drugs must be sold under a license.[71] Thus, general retailers in India cannot sell drugs, except for a limited class of medicines such as gripe water, which can be sold without a license.[72] Moreover, a drug can only be dispensed by a registered pharmacist to either the patient or his/her caretaker. Therefore, even though most e-pharmacies have obtained a valid license under the D&C Rules, special provisions are required to be put in place for e-pharmacies where it is not mandatory for a drug to be delivered to the patient/caretaker directly by the pharmacist. It should be noted that the Draft E-Pharmacy Rules currently do not account for this requirement.

4. Digitization of Health Records

Digitization of health records is possibly the biggest challenge faced both in India and in developing countries towards making digital health a

[70] Rule 67-I(d), Draft E-Pharmacy Rules, 2018.
[71] Part VI, Drugs and Cosmetics Rules, 1945.
[72] Rule 123, Drugs and Cosmetics Rules, 1945.

reality. Having a comprehensive and reliable set of health data for each patient is the basis to providing many other digital health services including AI (that can process data to identify patterns and trends), telemedicine (where doctors from different specialties can access the same patient data) and improving delivery of welfare schemes (by keeping a track of what services have been availed by whom). However, creating a single repository of all health records is a mammoth task from a policy perspective. This is because the path to digitizing health records is predicated on the following.

First, each healthcare provider including clinics of individual doctors in both urban and rural areas, primary healthcare centres, mobile healthcare providers and emergency response services would be required to have internet connectivity. *Secondly,* each of these healthcare providers would be required to follow a standardized format for capturing and storing data to ensure that the data format is compatible across different systems. *Thirdly,* it would require patients to be able to use smartphones to effectively access these services digitally. The Indian Government has already considered some legislative and policy initiative to gradually digitize health records and eventually move towards universal healthcare.

We have examined some of these policy initiatives below to understand the work that has already been done towards making EHRs a reality and the steps required to be taken moving forward.

National Health Policy, 2017 ("NHP")

The NHP serves as a guide on how to approach healthcare regulation in India by laying down long-term goals for policymakers to keep in mind.[73] The NHP has identified the attainment of universal healthcare and aims to gradually move towards it. The NHP states that:

> *"The policy envisages as its goal the attainment of the highest possible level of health and well-being for all at all ages, through a preventive and promotive health care orientation in all developmental policies, and universal access to good quality health care services without anyone having to face financial hardship as a consequence. This would be achieved through increasing access, improving quality and lowering the cost of healthcare delivery."*

The NHP also specifies the use of digital health to improve healthcare service delivery by setting up a federated National Health Information

[73] *National Health Policy, 2017*, Ministry of Health and Family Welfare, Government of India, 2017, available at https://mohfw.gov.in/sites/default/files/9147562941489753121.pdf, last seen on 14/01/2020.

Architecture ("**NHIA**") and the establishment of a National Digital Health Authority to regulate, develop and deploy digital health across the continuum of care.

*National Health Stack: Strategy and Approach released by the NITI Aayog (**"NHS"**)*

The NHS is a policy document laying down the framework for a nationally shared digital infrastructure usable by both the Central and State authorities across public and private sectors.[74] The NHS is designed to provide foundational components that will be required across Pradhan Mantri Jan Arogya Yojana (Aayushman Bharat Yojana) (**"**AB-PMJAY**"**) (India's centrally funded healthcare scheme provides healthcare coverage to over 100 million families) and other health programs in India. The key components of the NHS are:

i. National Health Electronic Registries to create a single source of truth to manage the master health data of the nation;

ii. Coverage and Claims Platform as building blocks to support large health protection schemes;

iii. A federated personal health records system accessible by patients as well as for medical research;

iv. A national health analytics platform to combine data from multiple health initiatives for making policy decisions; and

v. Horizontal components as required e.g. Digital Health ID, Health Data Dictionaries and Supply Chain Management for Drugs shared across all health platforms.

*National Digital Health Blueprint Report (**"NDHB Report"**)*

The NDHB Report aims to create a framework for the evolution of a National Digital Health Eco-System and establish a specialized organization called National Digital Health Mission to implement the National Digital Health Blueprint (**"**NDHB**"**).[75]

[74] *National Health Stack: Strategy and Approach*, NITI Aayog, 2018, available at https://niti.gov.in/writereaddata/files/document_publication/NHS-Strategy-and-Approach-Document-for-consultation.pdf, last seen on 14/01/2020.

[75] *National Digital Health Blueprint*, Ministry of Health and Family Welfare, Government of India, 2019, available at https://mohfw.gov.in/sites/default/files/National_Digital_Health_Blueprint_Report_comments_invited.pdf, last seen on 14/01/2020.

At its core, the NDHB contains a set of principles for digital health systems to provide guidance to the architecture of any proposed system dealing with health information. The NDHB also specifies key principles of privacy by design, confidentiality and the right to be forgotten that health systems should incorporate into their architecture. The NDHB, properly executed, should allow for interoperability of health systems at the patient, hospital and ancillary healthcare provider level (such as ambulance and emergency response services). Effectively, this would lead to a creation of a health system with an electronic health record of every Indian citizen.

The NDHB broadly envisions a health system composed of over 35 building blocks which are part of a federated architecture. The health system will store data at the national, state and local (facility) level. More detailed records such as the Electronic Medical Record will be stored at a local level while a repository of standards and data dictionaries will be maintained at a national level. Each level is composed of building blocks appropriate at that level. For instance, the building block of 'Common Application' would be at the national level to publish the code of a few most commonly used applications. On the other hand, the building blocks of 'Anonymization' and 'Consent Manager' should be at the point of care while the building blocks of 'anonymizer-as-a-service' and 'consent-management-as-a-service' would be at the state level to facilitate inter-facility transfers. The entire system would be supported by call centres, a health portal, social media (for emergency management, health awareness and community-based services) and a range of apps.

The NHP, NHS and NDHB combined form the current understanding of our approach to electronic records. Currently, India is still in the nascent stage of putting in place a digital health framework and has only signalled its intent to do so. However, what are conspicuously missing from the above-mentioned policy framework are the instances in which patient data may be used for purposes other than providing healthcare services to patients. Given the resistance to the AADHAR initiative (which aimed to give unique identification numbers to every citizen), it remains to be seen whether Indians are forthcoming in providing the government with their sensitive personal data.

5. Role of Digital Health in Welfare Schemes

Digital health tools can streamline service delivery in healthcare schemes and increase efficiency by preventing duplication of work. It is difficult to ensure proper service delivery of healthcare schemes in a large country like India where the population is highly fragmented, and many reside in heavily forested or hilly areas. Digital health in these situations can greatly

improve the accuracy and quality of service delivery to ensure the good health of every Indian.

Some of these digital health interventions include linking digital health records with census data to measure the degree of penetration of health schemes, providing medical services over the telephone or online, disseminating health information online for common questions such as vaccinations, pre-natal and post-natal care (as preventive care to reduce the need for medical intervention) as well as using self-monitoring devices to gather information and provide medical care at the right times.

The poster-child of the benefits of deploying digital health tools in welfare schemes is the AB-PMJAY. AB-PMJAY is a comprehensive healthcare scheme to provide health insurance to over 500 million citizens.[76] The AB-PMJAY was structured to implement the recommendations of the NHP and aims to provide cashless and paperless access to medical services for the beneficiary right at the point of service. The scheme aims to assist in reduction of hospitalization expenditures for citizens, specifically those who are below the poverty line. The scheme issues an insurance cover of up to INR 5, 00,000 per family each year, for secondary and tertiary care hospitalization.[77] AB-PMJAY also intends to set up 1, 50,000 health and wellness centres as part of the scheme, in order to increase healthcare access for the population. Over 9,000 private hospitals have already been empanelled as part of the scheme.[78] It is expected that the provision of services through the public and private sector under Ayushman Bharat will generate enormous amounts of health data, mostly in the digital space.[79]

The AB-PMJAY has an app that enables patients to access their medical records online, view a list of empanelled hospitals, and understand whether they are eligible for the scheme. The National Health Authority (**"**NHA**"**) set up under the AB-PMJAY has also tied up with Google to strengthen the digital presence of AB-PMJAY. As part of this

[76] *About Pradhan Mantri Jan Arogya Yojana (PM-JAY)*, Ayushman Bharat Pradhan Mantri Jan Arogya Yojana, available at https://pmjay.gov.in/about-pmjay, last seen on 15/01/2020.
[77] Ibid.
[78] *1 lakh benefitted under PMJAY in one month of its launch: Nadda*, ET Healthworld (22/10/2018), available at https://health.economictimes.indiatimes.com/news/policy/1-lakh-benefitted-under-pmjay-in-one-month-of-its-launch-nadda/66309902, last seen on 15/01/2020.
[79] Ministry of Health and Family Welfare, Government of India, *National Digital Health Blueprint Report*, available at https://mohfw.gov.in/newshighlights/final-report-national-digital-health-blueprint-ndhb, last seen on 15/01/2020.

partnership, Google will help train NHA staff and help to improve the efficiency of NHA's everyday applications.[80]

Fully implemented, the AB-PMJAY will lead to the vast majority of Indians having an EHR which can be accessed by any empaneled healthcare facility.

6. 3D Printing ("3DP")

'Three-dimensional printing', or 'additive manufacturing', refers to the process by which Computer Aided Design (**"**CAD**"**) files are transformed into physical articles. There are many different types of 3DP, each using slightly different materials. However, the overall procedure applies generally to all 3DP versions. The CAD file, an all-encompassing three-dimensional electronic 'blueprint' with the schematics of the article to be printed, is created manually using dedicated software or through three-dimensional scanning devices. The file is then uploaded to a 3DP which creates the physical object through a layering process, where layers of the relevant material are continually deposited and built up in the printer, slowly building the structure, until the final product emerges.[81]

The applications of 3D printing in the pharmaceutical and healthcare sector are limited only by one's imagination. 3D printing has the potential to revolutionize the rapidly growing Indian pharmaceutical industry. 3D printing drugs can resolve supply chain inefficiencies, allow healthcare practitioners to make drugs customized to their patients' needs and reduce waste by allowing pharmaceutical companies to manufacture exactly to demand.

3D printing could be the key catalyst to push further growth of the pharmaceutical industry in India, by localizing manufacture and distribution of drugs and medical devices thereby resolving the supply chain inefficiencies that currently plague the market. 3D printing can also make clinical testing of drugs and medical devices simpler and cheaper by allowing companies to make changes to drug composition or the specifications of medical devices just by changing the CAD file.

7. Regulation of 3D Printed Drugs and Devices

[80] R. Kumar, *Google power to Ayushman Bharat-PMJAY! NHA, tech giant joint hands to strengthen Modicare,* Financial Express (04/10/2019), available at https://www.financialexpress.com/lifestyle/health/google-ayushman-bharat-pmjay-nha-collaboration-details/1726888/, last seen on 15/01/2020.

[81] E. Malaty and G. Rostama, *3D Printing and IP Law*, WIPO Magazine (February 2017), available at http://www.wipo.int/wipo_magazine/en/2017/01/article_0006.html, last seen on 15/01/2020.

Under India's existing legal framework, 3D printing of drugs and medical devices is not prohibited, provided the manufacturer obtains the requisite approvals from the regulator for manufacture of the drug or medical device. Additionally, a manufacturer of drugs and medical devices is also required to comply with strict standards in respect of plant and machinery when manufacturing a drug.

With respect to drug manufacturing, 3D printing has the potential to decentralize manufacturing as sophisticated equipment is no longer necessary. However, the main reason that drug manufacturing cannot be localized for a 3D printed drug is that the key component of the drug is its Active Pharmaceutical Ingredient (**"**API**"**), also known as bulk drug in India, is produced only by the manufacturer. Therefore, the supply of "ink" for the printer is controlled by the manufacturer of the drug.

Commercially, it could be possible to sell the API as opposed to the finished drug and allowing the patient or their caretaker to manufacture the drug in their homes. Alternate distribution models involving licensed pharmacies and hospitals can also be considered. While this would drastically reduce the cost and consequently the price of the drug, the current regulatory framework in India does not permit manufacture of drugs without a license or in facilities that are not compliant with the Good Manufacturing Practices (**"**GMP**"**).[82] The definition of "manufacturing" under the D&C Act *"includes any process or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug or cosmetic with a view to its sale or distribution."*[83]

Patients, hospitals and pharmacies 3D printing the drug clearly fall under the first part of the definition as 3D printing the drugs is part of making the finished drug. However, as patients are manufacturing the drug for consumption and not for sale, the definition of manufacturing should not strictly apply to them. Regardless, pharmacies or hospitals which 3D print drugs and sell them to patients would be required to obtain permission in this regard from the drug controller and abide by the GMP. When 3D printed drugs are more common, special provisions can be introduced in the drug regulatory framework to ensure patients are able to fully benefit from this revolutionary technology.

8. Regulation of 3D Printed Organs

3D printed organs can ensure that no person loses their life due to organ shortages. Over half a million people die in India every year due to

[82] Schedule M, Drugs and Cosmetics Rules, 1945.
[83] S.3(f), Drugs and Cosmetics Act 1940.

paucity of a replacement organ.[84] 3D printed organs can possibly eliminate the need to source organs from live and deceased donors. In the present system, it is difficult for doctors to find a match and then to harvest, store and transport organs so that they remain viable throughout the transplantation process. Referred to as bio-printing, customized 3D printed organs can be created for patients; saving thousands of lives every year. In India, the Transplantation of Human Organs Act 1994 (**"**THOA**"**) governs the retrieval, storage and transplantation process for organs. Organ trade in India is heavily regulated and seeks to ensure that donors make fully informed decisions about donating organs as well as to prevent commercial trade in organs. Many other countries also have provisions in place that prevent organ trading. Sale of 3D printed organs could be considered as trade in human organs. Regardless, the ethical reasons that countries rely on to prohibit organ trade in status quo do not apply to 3D printed organs. Therefore, it may be likely that in future 3D printed organs will be regulated much like blood and plasma is regulated currently.

V. CONCLUSION

Digital Health is clearly the next milestone in healthcare. In the past, technology has helped advance medical science mainly through improving accuracy of diagnosis and assisting doctors with treatment procedures. However, the digital health revolution happening now is different than other technological advances that took place before. Rather than just advances in medical technology, digital health has the potential to change the healthcare sector as a whole, specifically with respect to service delivery. Digitization of health records increases interoperability between healthcare providers helping patients to find the best care for them. EHRs also save costs for patients as they need not duplicate tests already done. Telemedicine makes specialized and high-quality medical care available even in remote areas, thereby removing geographical barriers. Ultimately, digital health gives patients control of their health and makes for a healthier world.

India is adopting digital health tools to improve the quality of and access to healthcare in India at a rapid pace. However, the rapid growth of digital health is outpacing the regulation. Hence, the need of the hour is to have specific regulation for these tools and technologies to provide a level-playing ground for all stakeholders to provide services for the well-being of the Indian citizens.

[84] A. Ahuja, *Lack of Organ Donation in India: Here Is Why Half A Million People Die Annually in India Due to Unavailability of Organs*, NDTV (26/11/2017), available at https://sites.ndtv.com/moretogive/lack-organ-donation-india-half-million-people-die-annually-india-due-unavailability-organs-2107/, last seen on 15/01/2020.