

Digital Health in India

Legal, Regulatory and Tax
Overview

April 2020

Digital Health in India

Legal, Regulatory and Tax Overview

April 2020

ndaconnect@nishithdesai.com

DMS Code: 559936,I:

About NDA

We are an India Centric Global law firm (www.nishithdesai.com) with four offices in India and the only law firm with license to practice Indian law from our Munich, Singapore, Palo Alto and New York offices. We are a firm of specialists and the go-to firm for companies that want to conduct business in India, navigate its complex business regulations and grow. Over 70% of our clients are foreign multinationals and over 84.5% are repeat clients.

Our reputation is well regarded for handling complex high value transactions and cross border litigation; that prestige extends to engaging and mentoring the start-up community that we passionately support and encourage. We also enjoy global recognition for our research with an ability to anticipate and address challenges from a strategic, legal and tax perspective in an integrated way. In fact, the framework and standards for the Asset Management industry within India was pioneered by us in the early 1990s, and we continue to remain respected industry experts.

We are a research based law firm and have just set up a first-of-its kind IOT-driven Blue Sky Thinking & Research Campus named Imaginarium AliGunjan (near Mumbai, India), dedicated to exploring the future of law & society. We are consistently ranked at the top as Asia's most innovative law practice by Financial Times. NDA is renowned for its advanced predictive legal practice and constantly conducts original research into emerging areas of the law such as Blockchain, Artificial Intelligence, Designer Babies, Flying Cars, Autonomous vehicles, IOT, AI & Robotics, Medical Devices, Genetic Engineering amongst others and enjoy high credibility in respect of our independent research and assist number of ministries in their policy and regulatory work.

The safety and security of our client's information and confidentiality is of paramount importance to us. To this end, we are hugely invested in the latest security systems and technology of military grade. We are a socially conscious law firm and do extensive pro-bono and public policy work. We have significant diversity with female employees in the range of about 49% and many in leadership positions.

Accolades

A brief chronicle of our firm's global acclaim for its achievements and prowess through the years –

- **Legal500:** Tier 1 for Tax, Investment Funds, Labour & Employment, TMT and Corporate M&A
2020, 2019, 2018, 2017, 2016, 2015, 2014, 2013, 2012
- **Chambers and Partners Asia Pacific:** Band 1 for Employment, Lifesciences, Tax and TMT
2020, 2019, 2018, 2017, 2016, 2015
- **IFLR1000:** Tier 1 for Private Equity and Project Development: Telecommunications Networks.
2020, 2019, 2018, 2017, 2014
- **AsiaLaw Asia-Pacific Guide 2020:** Tier 1 (Outstanding) for TMT, Labour & Employment, Private Equity, Regulatory and Tax
- **FT Innovative Lawyers Asia Pacific 2019 Awards:** NDA ranked 2nd in the Most Innovative Law Firm category (Asia-Pacific Headquartered)
- **RSG-Financial Times:** India's Most Innovative Law Firm *2019, 2017, 2016, 2015, 2014*
- **Benchmark Litigation Asia-Pacific:** Tier 1 for Government & Regulatory and Tax *2019, 2018*
- **Who's Who Legal 2019:**
Nishith Desai, Corporate Tax and Private Funds – Thought Leader
Vikram Shroff, HR and Employment Law- Global Thought Leader
Vaibhav Parikh, Data Practices - Thought Leader (India)
Dr. Milind Antani, Pharma & Healthcare – only Indian Lawyer to be recognized for 'Life sciences-Regulatory,' for 5 years consecutively
- **Merger Market 2018:** Fastest growing M&A Law Firm in India
- **Asia Mena Counsel's In-House Community Firms Survey 2018:** The only Indian Firm recognized for Life Sciences
- **IDEX Legal Awards 2015:** Nishith Desai Associates won the "M&A Deal of the year", "Best Dispute Management lawyer", "Best Use of Innovation and Technology in a law firm" and "Best Dispute Management Firm"

Please see the last page of this paper for the most recent research papers by our experts.

Disclaimer

This report is a copy right of Nishith Desai Associates. No reader should act on the basis of any statement contained herein without seeking professional advice. The authors and the firm expressly disclaim all and any liability to any person who has read this report, or otherwise, in respect of anything, and of consequences of anything done, or omitted to be done by any such person in reliance upon the contents of this report.

Contact

For any help or assistance please email us on ndaconnect@nishithdesai.com or visit us at www.nishithdesai.com

Acknowledgements

Dr.Milind Antani

milind.antani@nishithdesai.com

Darren Punnen

darren.punnen@nishithdesai.com

Shreya Shenolikar

shreya.shenolikar@nishithdesai.com

Contents

1. INTRODUCTION	01
I. What is Digital Health?	01
II. What was the need to write this paper and what does it propose to do?	01
2. SOME PROMINENT EXAMPLES OF DIGITAL HEALTH	03
I. Telemedicine	03
II. Robot-Assisted Surgery	03
III. Self-Monitoring Healthcare Devices	03
IV. Electronic Health Records (“EHR”)	04
V. Health Service Aggregation	04
VI. m-Health	04
VII. Big Data in healthcare	04
VIII. Targeted advertising	04
IX. e-Pharmacies	05
X. e-Learning in the healthcare sector	05
3. INVESTMENT IN DIGITAL HEALTH	06
I. Foreign Direct Investment	06
II. Foreign Venture Capital Investment	06
4. LEGAL AND REGULATORY FRAMEWORK	08
I. The Information Technology Act, 2000 (“IT Act”), The Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011 (“Data Protection Rules”) and the Information Technology (Intermediaries Guidelines) Rules, 2011 (“Intermediary Guidelines”)	08
II. Other Service Providers Regulations under the New Telecom Policy 1999 (“OSP Regulations”)	09
III. The Drugs and Cosmetics Act, 1940 (“D&C Act”) and Drugs and Cosmetics Rules, 1945 (“D&C Rules”)	10
IV. The Indian Medical Council Act, 1956 (“MCI Act”) and The Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002 (“MCI Code”)	10
V. Telemedicine Practice Guidelines	11
VI. The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955 (“DMRA”)	11

VII. Telecom Commercial Communication Customer Preference Regulations, 2018 (“TCCP Regulations”)	12
VIII. The Clinical Establishments (Registration and Regulation) Act, 2010 (“Clinical Establishments Act”)	12
5. INTELLECTUAL PROPERTY	13
I. Patent	13
II. Copyright	13
III. Design	14
IV. Trademark	14
V. Trade Secrets	15
6. TAXATION REGIME	16
I. Indirect Taxes	16
II. Corporate Tax	16
III. Structuring investments	16
7. LIABILITY AND DISPUTE RESOLUTION	17
I. Suits before a Civil Court	17
II. Vicarious Liability	17
III. Liability under the Consumer Protection Act, 1986 (“CPA”)	17
IV. Disciplinary Action by the MCI	18
V. Criminal Liability	18
8. DIGITAL HEALTH IN FOREIGN JURISDICTIONS	20
I. United States of America	20
II. European Union (EU)	21
III. Australia	21
IV. China	22
9. CURRENT ISSUES AND CONSIDERATIONS	23
I. General Considerations	23
II. Model-specific Considerations	24
10. GOVERNMENT INITIATIVES	27
I. National Digital Health Authority (“NeHA”)	27
II. National Digital Health Blueprint	27
III. State Initiatives	27
IV. Proposed Legislation	28
V. National Intellectual Property Rights Policy (“NIPR”)	28

11. RECOMMENDATIONS	29
12. CONCLUSION	30
ANNEXURE - A	31
Telemedicine Scenarios	31

1. Introduction

“

“I think the biggest innovations of the twenty-first century will be the intersection of biology and technology” – Steve Jobs, as told to Walter Isaacson.

”

In 2001, Dr. Jacques Marescaux surgically removed the gall bladder of a 68 year old woman. While thousands of these procedures are done on a daily basis, the reason this particular surgery stands out is because the surgeon was in New York, while the patient was in France. Separated by a distance of thousands of miles, this robot-assisted ‘tele-surgery’ was made possible using dedicated Asynchronous Transfer Mode (“ATM”) telecommunication technology, which provided minimum response time between the surgeon and the robot.

At a time when such activities were not even anticipated, the United States Food and Drug Administration (“USFDA”) took a very conservative approach while granting approvals for the procedure. To minimize liabilities and ambiguities, the USFDA allowed the surgery to be performed by French surgeons on a French patient while the French government was to take all the responsibilities. The whole procedure cost a whopping \$11 million, but served the purpose of demonstrating to the world the potential of the amalgamation of healthcare and technology.

The world has come a long way since then, with the development of information technology culminating to a phase where such innovative procedures are steadily gaining acceptance. Healthcare technology is pushing boundaries, broadening its scope every day and with it, the opportunities. From heart rate monitors built into watches to glucose monitors integrated into contact lenses, the healthcare industry is heading into some interesting and revolutionary times.

I. What is Digital Health?

There is a popular tendency to group every technological advancement in healthcare under the umbrella of “Digital Health”. But what exactly is Digital Health?

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.

II. What was the need to write this paper and what does it propose to do?

“

“The hare of science and technology lurches ahead. The tortoise of the law ambles slowly behind”²

”

A patient survey predicts that 75% of all patients expect to use digital services in the future. With the healthcare sector expected to touch INR 8.6 trillion (US\$ 133.44 billion) by 2022, one should not harbor a doubt that Digital Health services would bite into a large portion of the pie.

1. WHO Guideline on Recommendations on Digital Interventions for Health System Strengthening, World Health Organisation, available at <https://apps.who.int/iris/bitstream/handle/10665/311941/9789241550505-eng.pdf?ua=1>.
2. Michael Kirby, Medical Technology and New Frontiers of Family Law, 1 AUSTL. J. FAM. L. 196, 212 (1987).

However, the current legal and regulatory landscape that governs Digital Health is scattered and ambiguous. To make matters worse, there is none or very little legal scholarship in the area of Digital Health in India. The scope of Digital Health is vast and covers various business models, which inherently makes it difficult to regulate as a whole.

This paper seeks to knit together existing laws and regulations into what may be called an

“ad-hoc” legal framework for Digital Health in India. It is being written for those who are already invested in Digital Health as workforce or capital contributors as well as those who are still testing the waters.

Since this is a research paper, it also seeks to raise questions and takes positions which are yet to be tested with the hope that it would set the tone for legal discussions in larger platforms.

2. Some Prominent Examples of Digital Health

I. Telemedicine

Telemedicine is the use of telecommunications technology to provide healthcare. 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 within its ambit various aspects such as tele-radiology, tele-consultation, tele-nursing, tele-ICU and tele-surgery. Telemedicine can be a particularly useful tool to improve treatment outcomes in India as over 75% of the country's healthcare infrastructure is concentrated in urban areas while more than 75% of the population lives in rural areas.³ Telemedicine could effectively bridge the gap between the patient and the doctor.

II. Robot-Assisted Surgery

Using the assistance of robots, doctors are able to perform surgical procedures more efficiently. Minimally invasive surgeries have been around for a while, but with the assistance of robotics, surgeons are able to maneuver more precisely and with smaller incisions.⁴ This ultimately leads to reduced loss of blood, better pain management and quicker recovery for the patient. Going forward we may also witness the use of microbots for diagnosis and treatment of diseases. One such procedure called capsule endoscopy, in which the patient swallows a tiny camera so that the healthcare provider can take pictures of the digestive tract, has already been approved by the United States Food and

Drugs Administration (the apex regulatory body governing drugs and medical devices in the United States of America).⁵ Other applications in the future may include removing plaque from arteries, taking tissue biopsies, attacking cancerous tumors directly and delivering targeted medication.

Microrobots are far less likely to cause tissue damage than conventional medical interventions, such as surgical incisions and catheter insertions. By aiming for specific destinations in the body, microrobots could drastically reduce the side effects of pharmaceuticals.⁶

Further, 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.⁷

III. 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.⁸ 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.

3. Ashok Vikhe Patil, K. V. Somasundaram and R. C. Goyal; Current Health Scenario In Rural India; available at <http://www.sas.upenn.edu/~dludden/WaterborneDisease3.pdf>

4. Johns Hopkins Medicine; Types of Minimally Invasive Surgery; available at http://www.hopkinsmedicine.org/minimally_invasive_robotic_surgery/types.html

5. The Growing Emergence of Robots in Healthcare: Key Opportunities & Benefits, available at: <https://hitconsultant.net/2019/12/05/the-growing-emergence-of-robots-in-health-care-key-opportunities-benefits/#.XpNgs8gzblIV>

6. Tumbling Microrobots for Future Medicine, available at: <https://www.americanscientist.org/article/tumbling-microrobots-for-future-medicine>.

7. IEEE Spectrum; Robot Surgeones are Taking over the Operating Room; available at <http://spectrum.ieee.org/video/robotics/medical-robots/robot-surgeones-are-taking-over-the-operating-room>

8. Geoff Appelboom, Elvis Camacho, Mickey E Abraham; Smart wearable body sensors for patient self-assessment and monitoring; available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4166023/>

IV. 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 time, irrespective of where or when the information was collected.⁹ With EHRs, doctors are able to view their patient’s complete medical history even if they are treating the patient for the first time. This would help reduce duplication of tests and facilitate the secure exchange of information, which in turn helps the patient and the healthcare facilities manage costs.

V. Health Service Aggregation

Information asymmetry is one of the biggest challenges in healthcare. Patients are not privy to information which is essential in aiding with their choice of doctors, and at times 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.

VI. m-Health

Mobile health, or m-Health, is the provision of Digital Health services on a mobile platform. India is home to the 2nd largest smartphone market in the world, which makes m-Health a very lucrative option.¹⁰ Providing access to

such applications on smartphones would also not be a big hurdle, with the country expecting to reach 664 million mobile internet users by 2023.¹¹ The convenience of Digital Health coupled with the mobility of m-Health opens the arena for a lot more players to actively take part in the revolution.

VII. Big Data in healthcare

Raw data is collected from the use of various Digital Health services. EHRs in itself generates a massive amount of information that can be put to use in different ways. 25 billion devices are expected to be connected through the Internet of Things (“IoT”),¹² and the data that these connected devices are expected to churn out have to be processed. The sheer volume of information generated requires solutions such as big data processing, which then can be put to use by various companies.

VIII. Targeted advertising

Wearables and information provided by users generate information related to the user’s medical history and health conditions. This information can be used by companies to provide targeted advertising of products to users who are more likely to purchase or use such products.¹³ For instance, glucose monitoring products could be advertised to diabetic patients based on the medical history provided by them. Targeted advertising however, throws up various legal and ethical questions where in some instances, where the correct approach may be difficult to ascertain.

9. Lise Poissant, Jennifer Pereira, Robyn Tamblyn; The Impact of Electronic Health Records on Time Efficiency of Physicians and Nurses: A Systematic Review; available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1205599/>

10. India is now the second largest smartphone market in the world, surpassing the U.S., available at: <https://mashable.com/article/india-smartphone-market/>

11. Number of internet users in India, available at <https://www.statista.com/statistics/255146/number-of-internet-users-in-india/>.

12. Guy Daniels; Internet of Things to Reach 25 Billion Devices within Five Years; available at <http://www.telecomtv.com/articles/iot/internet-of-things-to-reach-25-billion-devices-within-five-years-11931/>

13. Vinny La Barbera; Wearable Technology and Its Impact on Internet Marketing; available at <https://www.imforza.com/blog/wearable-technology-impact-on-internet-marketing/>

IX. e-Pharmacies

India is seeing a rise in e-pharmacies or online pharmacies in the last couple of years. 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 such as online-only pharmacies and physical pharmacies with an online presence. Online pharmacies allow pharmacists to cater to a larger group of patients as the inherent geographical restrictions on physical pharmacies are removed in the online model.

X. e-Learning in the healthcare sector

Continuous Medical Education (“CME”) is a mandatory requirement under the regulation governing doctors and is necessary so that doctors can keep in touch with the current trends and developments in the field of medicine. e-Learning is a more convenient platform for doctors to attend such programmes. E-Learning also saves on time and costs is accessible from anywhere.

3. Investment in Digital Health

The healthcare sector as an industry is expanding rapidly in India and has not been as severely impacted by the economic slowdown as some of the other industries.

India, one of the biggest emerging markets, is currently an important destination for Foreign Direct Investment (“**FDI**”).

A significantly low presence of doctors in rural and semi-urban areas has led to limited access to proper healthcare facilities for people living in these areas. Digital Health tools such as telemedicine and online pharmacies are considered to be some solutions to this lack of access. The growth of the IT sector in India (which plays a crucial role in telemedicine) has led to the emergence of this sector in India. Tele-radiology has emerged as a fast growing area with an increasing number of foreign hospitals active in this space. These hospitals consult Indian experts to provide opinions, i.e., on x-rays of patients in the hospital. Many hospitals have also adopted the public-private partnership route to render services through telemedicine.

Some investment options are discussed below:

I. Foreign Direct Investment

Foreign investment into India is governed by the Foreign Exchange Management Act, 1999 (“**FEMA**”), the rules and regulations made by the Reserve Bank of India (“**RBI**”), and the Industrial Policy and Procedures issued by the Ministry of Commerce and Industry through the Secretariat for Industrial Assistance, Department for Promotion of Industry and Internal Trade (“**DPIIT**”). The provisions pertaining to FDI are laid down in Regulation 16 of FEMA (Transfer or Issue of Security by a Person Resident outside India) Regulations, 2017.

While the DPIIT issues policy guidelines and press notes/releases from time to time regarding foreign investment into India, it also issues a consolidated policy on an annual basis (“**Consolidated FDI Policy**”). Currently, foreign investment is regulated by the Consolidated FDI Policy of 2017.¹⁴

100% FDI is permitted in most sectors under the automatic route, i.e., where prior approval of the government, is not required. Generally, there are no restrictions prescribed for Digital Health services, and therefore FDI up to 100% should be permitted without government approval. It may also be noted that FDI is permitted up to 100% under the automatic route in the hospital sector and in the manufacture of medical devices. In the pharmaceutical sector, FDI is permitted upto 100% in Greenfield projects and 74% in Brownfield projects under the automatic route and FDI beyond 74% in Brownfield projects requires Government approval.¹⁵ Green field projects are new projects that are coming up in India while Brownfield projects are existing projects in India.

II. Foreign Venture Capital Investment

Another vital means of investment is through venture capital investment by entities registered with the Securities Exchange Board of India (“**SEBI**”) as foreign venture capital investors. While it is not mandatory for a private equity investor to register as a Foreign Venture Capital Investor (“**FVCI**”) under the FVCI regulations,¹⁶ there are some significant advantages to be gained by registering as an FVCI. An FVCI is exempt from compliance with the pricing

14. Consolidated FDI Policy, Government of India, Ministry of Commerce & Industry, Department for Promotion of Industry and Internal Trade, available at https://dipp.gov.in/sites/default/files/CFPC_2017_FINAL_RELEASED_28.8.17.pdf

15. Press Note 5 of 2016, available at: http://dipp.nic.in/English/acts_rules/Press_Notes/pn5_2016.pdf

16. SEBI (Foreign Venture Capital Investor) Regulations, 2000.

guidelines under the Consolidated FDI Policy for the acquisition of securities at the time of entry as well as for the transfer/sale of securities at the time of exit. Secondly, in cases where the promoters of the company intend to buy-back the securities from an FVCI, they are exempted from making an open offer under the Takeover Code.¹⁷ It should be noted that SEBI has been granting approvals to FVCIs only for investments

in certain identified sectors, amongst them being research and development of new chemical entities in the pharmaceutical sector, and units of SEBI registered Venture Capital Funds (“VCFs”). Further, the Reserve Bank of India (“RBI”) has made recent amendments to the foreign exchange control regulations to permit FVCIs to invest in SEBI registered Alternate Investment Funds (“AIFs”).¹⁸

17. Regulation 10 of the Securities Exchange Board of India (Substantial Acquisition of Shares and Takeovers) Regulations, 2011.

18. SEBI introduced SEBI (Alternate Investment Funds) Regulations, 2012 to govern domestic pooling vehicles. RBI has issued Notification no. FEMA. 355/2015 that permits AIFs and other investment vehicles to accept foreign investments under the automatic route

4. Legal and Regulatory Framework

The laws that broadly cover Digital Health services are discussed below:

I. The Information Technology Act, 2000 (“IT Act”), The Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011 (“Data Protection Rules”) and the Information Technology (Intermediaries Guidelines) Rules, 2011 (“Intermediary Guidelines”)

Digital Health involves a constant exchange of information between the patient and the service provider. The patient’s personal information, such as medical history and physiological conditions, are considered Sensitive Personal Data or Information¹⁹ (“SPDI”) under the Data Protection Rules. When a body corporate²⁰ collects, stores, transfers or processes such information, certain requirements under the Data Protection Rules are triggered.

Consent is one of the major requirements under the Data Protection Rules. Before a doctor or an institution does anything with a patient’s data, they are required by law to obtain the recipient’s

consent in writing.²¹ The patient must be informed about the fact that the data is being collected, what it will be used for and whether it would be transferred to any third parties, along with the contact details of the agency collecting the information.²² There is also a requirement for body corporates to have a privacy policy in place and published on its website.²³ The patient’s consent for use/processing of their SPDI is usually obtained by having the patient accept the terms of the body corporate’s privacy policy, which contains the information required to be given the patient under the Data Protection Rules.

If the SPDI is planned to be disclosed to a third party, prior permission of the owner of the SPDI is to be obtained. In cases where the SPDI is being transferred, the body corporate transferring the SPDI must ensure that the receiver of the SPDI has adequate security practices in place in addition to obtaining the consent of the provider of information for such transfer.²⁴

The Data Protection Rules also mandate the implementation of reasonable security practices and procedures in order to keep the SPDI secure. This requirement is fulfilled if the body corporate conforms to the international standard IS/ISO/IEC 27001 on “Information Technology – Security Techniques – Information Security Management System – Requirements” or similar standards that are approved and notified by the Central Government. As on date, no such standards have been notified.

There is also a requirement to appoint a ‘Grievance Officer’,²⁵ whose contact details are to be published on the website. Apart from these, there are also other requirements such as allowing users to opt-out²⁶ or modify²⁷ their SPDI if required.

19. Rule 3 of the Data Protection Rules defines Sensitive personal data or information of a person to mean such personal information which consists of information relating to (i) password; (ii) financial information such as Bank account or credit card or debit card or other payment instrument details; (iii) physical, physiological and mental health condition; (iv) sexual orientation; (v) medical records and history; (vi) Biometric information

20. Section 43A of the IT Act defines “body corporate” means any company and includes a firm, sole proprietorship or other association of individuals engaged in commercial or professional activities

21. Rule 5(1) of the Data Protection Rules

22. Rule 5(3) of the Data Protection Rules

23. Rule 4(1) of the Data Protection Rules

24. Rule 7 of the Data Protection Rules

25. Rule 5(9) of the Data Protection Rules

26. Rule 5(7) of the Data Protection Rules

27. Rule 5(7) of the Data Protection Rules

In 2013, the Ministry of Communications and Information Technology came out with a clarification²⁸ which stated that body corporates that were collecting, storing, processing or transferring information out of a contractual obligation were not required to observe some of the requirements of the Data Protection Rules such as obtaining consent from the owner of the SPDI for collecting or disclosing the SPDI. The other requirements, however, must still be observed.

The applicability of the IT Act is slightly different for digital health services which have set ups that merely facilitate the interaction between the patient and the service provider and are not directly involved in the provision of the services e.g. website hosting services and search engines. In such cases, the service provider would be considered an intermediary²⁹ under the Intermediary Guidelines and the IT Act and certain relaxations are given to intermediaries with respect to liability for third party data or communication. Under the IT Act, an intermediary would not be responsible for third party content hosted by the intermediary provided the role of the intermediary is limited providing access to a communication system over which information over which the information is hosted or stored, and the intermediary has complied with the due diligence requirements prescribed under the IT Act.³⁰ These requirements are extensive, and include having a terms of use in place, removal of offending/unlawful³¹ material within 36 hours if called upon to do so by way of a court order, and appointing a grievance officer.

The constitutionality of the Intermediary Guidelines and section 79³² of the IT Act were challenged before the Supreme Court in the case of *Shreya Singhal v. Union of India*,³³ stating that these provisions were vague, broad and in violation of Article 19 of the Constitution of India, which provides for the fundamental right to the freedom of speech and expression.

It was argued that section 79 and the Intermediary Guidelines allow the intermediary the discretion to decide upon whether an unlawful/offending material is being published and that the restrictions under the Intermediary Rules go beyond the permitted restrictions under Article 19(2).

The Supreme Court read down the provisions of section 79 and the Intermediary Guidelines to mean that the intermediary must receive a court order or notification from a government agency requiring it to remove specific information. The court also stated that any such court order or notification must necessarily fall within the ambit of reasonable restrictions under Article 19(2), meaning that such removal must be in the interest of the sovereignty and integrity of India, the security of the State, friendly relations with foreign States, public order, decency or morality or in relation to contempt of court, defamation or incitement to an offence. The judgment was, however, silent on which administrative authority could pass such an order or notification.

II. Other Service Providers Regulations under the New Telecom Policy 1999 (“OSP Regulations”)

Service providers who render “Application Services” - which includes telemedicine services – using telecom resources provided by telecom service providers, are required to be registered

28. Clarification on The Information Technology (Intermediary Guidelines) Rules, 2011 under section 79 of the Information Technology Act, 2000 issued on 18th March, 2013; available at: http://meity.gov.in/sites/upload_files/dit/files/Clarification%2079rules_1.pdf

29. Intermediary under the IT Act is defined as any person who on behalf of another person receives, stores or transmits that record or provides any service with respect to that record and includes telecom service providers, network service providers, internet service providers, web hosting service providers, search engines, online payment sites, online-auction sites, online market places and cyber cafes.

30. Section 79 of the IT Act.

31. Rule 3(2) of the Intermediaries Guidelines

32. Section 79 of the IT Act provides intermediaries with exemption from liability if it meets the requirements laid down under the section

33. Writ Petition (Criminal) No.167 Of 2012

as an ‘Other Service Provider’ (“OSP”) with the Department of Telecommunications.

III. The Drugs and Cosmetics Act, 1940 (“D&C Act”) and Drugs and Cosmetics Rules, 1945 (“D&C Rules”)

The D&C Act and D&C Rules regulate the manufacture, sale, import and distribution of drugs in India. In many foreign jurisdictions, there is a clear distinction between a drug that must be sold under the supervision of a registered pharmacist on the production of a valid prescription (signed by a registered medical practitioner) and those that can be sold by general retailers over-the-counter (“OTC”). OTC drugs have a different meaning in the context of Indian laws. The D&C Act requires that all drugs must be sold under a license. The D&C Rules clearly lay down which drugs can be sold only on the production of a prescription issued by a registered doctor, which implies that there is a distinction between prescription and non-prescription drugs. Drugs which can be sold only on prescription are stated in Schedules H, H1, and X of the D&C Rules.

The D&C Act states that no person can sell any drug without a license issued by the licensing authority. However, it provides for certain drugs, namely those falling under schedule K of the D&C Rules, to be sold by persons who do not have such a license. Hence, OTC drugs in the Indian context would mean only those drugs that are specified under schedule K. These broadly include drugs not intended for medical use, quinine and other antimalarial drugs, magnesium sulfate, 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 also state that prescription drugs can only be dispensed on the production of a prescription which is in accordance with the provisions of the rules. For a prescription to be considered valid under the D&C Rules, it must be in writing, signed and dated by the doctor

issuing the prescription.³⁴ The prescription must also state the name and address of the person for whose treatment it is given and also the quantity to be supplied.³⁵

IV. 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, administered and enforced by the Medical Council of India, regulates the medical education and medical profession in India. The MCI Act provides that only those persons who have a recognized degree in medicine and are registered with one of state medical councils have the right to practice medicine in India. The MCI Code lays down professional and ethical standards to be followed by doctors in their interaction with patients, pharmaceutical companies and within the profession. The MCI Code also specifies that efforts are to be made to computerize medical records so that they can be retrieved quickly.³⁶ Doctors are bound by the MCI Code and are required to submit a declaration to that effect.³⁷

The MCI Act is currently in the process of being repealed and replaced by the National Medical Commission Act, 2019 (“NMC Act”). Provisions of the NMC Act establishing the National Medical Council (the apex regulatory body to replace the Medical Council of India) and other advisory councils have already come into force while remaining provisions are expected to come into force soon.

34. Rule 65(10)(a) of the D&C Rules

35. Rule 65(10)(a) of the D&C Rules

36. Regulation 1.3.4 of the MCI Code

37. Regulation 1.A of the MCI Code

V. Telemedicine Practice Guidelines

The Board of Governors instituted by the Central Government for regulating medical education and the medical profession in India (in supersession of the Medical Council of India), issued the Telemedicine Practice Guidelines in partnership with the NITI Aayog. These guidelines have been made part of the MCI Code and are therefore binding on medical practitioners practicing allopathic medicine. The Telemedicine Practice Guidelines enable medical practitioners to practice telemedicine in any part of the country, provide guidance on the nature of care that may be provided and the manner of providing such care. For instance, it provides guidance on which mode of communication (audio/video/text) to use for which types of consultation (emergency/non-emergency/medical practitioner to medical practitioner). The Guidelines also categorize medicines in List O, List A, List B and Prohibited List and specify which medicines can be prescribed in which situations. However, the Telemedicine Practice Guidelines are only a stop gap measure put in place due to the exigencies of the COVID-19 pandemic until a more comprehensive regulation can be put in place.

To properly regulate the practice of telemedicine the Indian Government may consider enacting a comprehensive legislation regulating telemedicine that is binding not only on the healthcare practitioner providing consultation by way of telemedicine but also on the platform providing telemedicine services and the patient. This legislation should account for the following:

- i. Specify system requirements that telemedicine platforms should adhere to;
- ii. The rights and obligations of the patient, telemedicine platform and the healthcare practitioner in relation to the others;
- iii. The nature of consultation that may be provided over a telemedicine platform and the manner of providing such consultation; and

- iv. Framing rules for telemedicine that are specific to practitioners of Ayurveda, Siddha and Unani systems of medicine e.g. how consultations should take place and what medicines may be prescribed.

VI. The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955 (“DMRA”)

The DMRA was enacted in 1954 to curb advertisements of drugs and remedies alleged to possess magic qualities. The DMRA prohibits persons from taking part in the publication of an advertisement referring to any drug in terms which suggest or are calculated to lead to the use of that drug for—

- i. the procurement of miscarriage in women or prevention of conception in women; or
- ii. the maintenance or improvement of the capacity of human beings for sexual pleasure; or
- iii. the correction of menstrual disorder in women; or
- iv. the diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in the schedule to the DMRA.

Advertisements are, however, permitted to be sent confidentially to registered medical practitioners and chemists, so long as such communication bears the words ‘For the use only of registered medical practitioners or a hospital or a laboratory’ at the top of the document in indelible ink and in a conspicuous manner.

The Ministry of Health and Family Welfare, on February 03, 2020, published a draft amendment to the DMRA to amend the definition of ‘advertisement’ under the DMRA to specifically include advertisements made over an online/

electronic medium, increase penalties for violation of the DMRA and expands the list of diseases, disorders or conditions in the schedule to the DMRA. However, the proposed amendment does not substantially alter the existing regulation as advertisements over electronic media were already within the purview of the DMRA.

VII. Telecom Commercial Communication Customer Preference Regulations, 2018 (“TCCP Regulations”)

Sending unsolicited commercial communications over voice or SMS are prohibited under the TCCP Regulations and TCCP Regulations. Promotional messages may only be sent to subscribers who have opted in for receiving such communications once registered with an access provider. However, there is no legal bar over sending transactional messages or voice calls. A transactional message is one which is triggered by a transaction performed by the receiver of the message provided the receiver is a customer of the sender and the message is sent within 30 minutes of the transaction

being performed and is directly related to it. For example, any information sent for OTP or purchase of goods and services would be identified as a transactional message. All other messages (even though directly connected with the delivery of goods) may only be sent as per a format registered with the access provider after obtaining the consent of the receiver.

VIII. The Clinical Establishments (Registration and Regulation) Act, 2010 (“Clinical Establishments Act”)

Establishments falling under the definition of a ‘clinical establishment’ under the Clinical Establishments Act would be required to register with the relevant authority and conform to the minimum standards as prescribed under the act. The Clinical Establishments Act is applicable in Arunachal Pradesh, Himachal Pradesh, Mizoram, Sikkim, Bihar, Rajasthan, Uttar Pradesh, Uttarakhand, Jharkhand, Assam, Haryana and all Union Territories except the NCT of Delhi. Certain states such as Maharashtra and Karnataka have their own state clinical establishment legislations.

5. Intellectual Property

The Digital Health space has seen a lot of innovative products being developed. Protection of these ideas and inventions becomes essential in this highly competitive market. India's Intellectual Property Rights (“IPR”) regime allows for such protection in various forms, notably patents, copyright, trademarks and designs.

In the context of Digital Health, development is concentrated in the areas of software applications (including mobile applications) and wearable devices. This section covers the various forms of IP protection available with such developments in mind.

I. Patent

The Patents Act, 1970 (“**Patent Act**”) provides for patent protection in India. The Patent Act is largely compliant with the Trade-Related Aspects of Intellectual Property Rights (“**TRIPS**”) and India, being a signatory, has been committed to fully adopting and implementing the provisions of the agreement.

In order for an innovative product to be considered an ‘invention’ under the Patent Act, it must fulfill three criteria – novelty, non-obviousness and utility. Apart from meeting these requirements, the inventions must also not be specifically excluded from being considered an ‘invention’ under sections 3 and 4 of the Patent Act. These exclusions include ‘a process for the medicinal or other treatment of human beings and animals’ and a ‘computer program per se’.

Behind every Digital Health application is the software that runs it, which is essentially a computer program. A computer program ‘per se’ is excluded from patentability under Section 3(k) of the Patent Act, 1970. The Indian Patent Office, however, in its ‘Guidelines for Examination of Computer Related Inventions (“**CRI**”)’ in 2017, states that while the CRI in itself is not patentable, it is possible for a CRI claimed in conjunction with a novel hardware to be patented, provided it meets the other requirements such as the three prong test laid

down under the guidelines. Patents for software programs have been issued in the past where it involves a hardware component as well. If the technology/software fulfills these requirements, it could file for a patent and receive protection if the same is granted.

A patent may not be granted if the device or program is determined to be ‘a process for the medicinal or other treatment of human beings and animals’ under section 3(i) of the Patent Act (section 3 deals with what are not considered inventions). However, the Patent examiner's observations in *Lalit Mahajan's* patent application³⁸ distinguished between a device and process, where ‘a device for detection of antibodies to HIV and p24 antigen of HIV in human serum or plasma’ was found to be outside of the scope of section 3(i).

II. Copyright

The Copyright Act, 1957 (“**Copyright Act**”) provides for copyright protection in India. Copyright can subsist in the form of original literary, dramatic, musical or artistic work, cinematograph films, and sound recordings. While registering a copyright is not essential since copyright in a work exists regardless of its registration, the registration serves as prima facie evidence as to the existence of the right.

Software would fall under the definition of “computer programme” under the Copyright Act and according to section 2(o), a literary work includes computer programmes. Hence the literal part, i.e., the source code, is protected under copyright law. The copyright, however, extends to the form and substance of the work, and not the idea itself. This would mean that the idea would have to be expressed in some form of medium before it can be protected.

Clinical guidelines and data could be protected under the Copyright Act, provided that it is

³⁸. Patent Application No. 693/KOL/2007 decided on 11.01.2010

expressed in some form of medium. A mere compilation of data without any further effort may not be protected by copyright law. This is derived from the ‘sweat of the brow’ doctrine, where even though there may not be any originality in content such as tables or databases, copyright would subsist only when a person undertakes an independent collection of the information. The person is then entitled to have his effort and expense protected.

III. Design

Industrial designs are protected under the Designs Act, 2000 (“**Designs Act**”). A ‘design’ has been defined to mean only features of shapes, configurations, patterns, ornaments or composition of lines or colors that are applied to an ‘article’.³⁹

In terms of Digital Health, the two major components that would require design protection would be the Graphical User Interface (“**GUI**”) of applications and the design of the devices.

GUI may be protected under the Designs Act, more specifically under Article 14-04 of the Design Rules, 2001, which covers ‘Screen Displays and Icons’. However, there have been applications by companies for registration of its GUI which were rejected. The reasoning of the authorities have been that a GUI cannot be registered as a design, as screen displays do not constitute an article, which is one of the requirements for design protection. However, some icons and user interfaces have been registered as a design under Article 14-99 (miscellaneous). A company could, therefore, apply for design protection of its GUI. The design of various devices could also be protected under the Designs Act. However, ‘design’ under this act excludes any mode or

principle of construction, or anything which is in substance a mere mechanical device. The design of the device can thus be protected provided it does not fall within the exceptions under the Designs Act.

Registration of a design under the Designs Act confers copyright protection upon the proprietor of the design. This would give the proprietor the exclusive right to apply the design to any article in any class in which the design is registered.

IV. Trademark

The Trade Marks Act, 1999 (“**TM Act**”) governs and protects trade marks in India. Apart from statutory protection, unregistered marks are also protected under common law. A ‘mark’ under the TM Act has been defined to include “a device, brand, heading, label, ticket, name, signature, word, letter, numeral, shape of goods, packaging or, combination of colors, or any combination thereof⁴⁰”. Any mark that is capable of being ‘graphically represented’ and indicative of a trade connection with the proprietor can be registered as a trademark. The rules formulated under the TM Act provide for the classification of trade marks. India follows the NICE Classification of Goods and Services,⁴¹ which has been incorporated in the schedule to the rules. One of the classes under which a trademark can be registered is class 9, which includes computer software and computer programs⁴².

The ‘mark’ of a Digital Health application or device could be registered as a trade mark under the TM Act, subject to certain exclusion criteria that form grounds for refusal of the trade mark, such as being devoid of distinctive character or marks or indications which have become customary in the current language or established practice of trade.⁴²

39. Section 2(a) of the Designs Act defines an ‘article’ to mean any article of manufacture and any substance, artificial, or partly artificial and partly natural and includes any part of an article capable of being made and sold separately

40. Section 2(m) of the TM Act

41. The Nice Classification, established by the Nice Agreement (1957), is an international classification of goods and services applied for the registration of marks

42. Section 9 of the TM Act

V. Trade Secrets

In a nascent industry such as Digital Health, ideas are everything. Business strategy and cutting-edge technology must be protected before they are disclosed, in order to prevent misuse. There are no exclusive legislations that deal with confidential information and trade secrets in India. However, judicial decisions have helped secure protection of such information, albeit with the necessity of agreements to the effect.

The first frontier of protection for any company would start right at the workplace. Confidential information that is shared with employees can be protected by means of contractual obligations tailored to protect the company's formulae, products, databases and strategic business plans.

One of the most effective forms of contractual protection would be to enter into Non-Disclosure Agreements with employees

which provide remedies in case of disclosure of sensitive business information. Companies can limit their exposure by disclosing sensitive information to employees on a need-to-know basis, providing only what is necessary for effective completion of tasks.

Non-compete clauses are another way in which companies can limit the unwanted disclosure of information. However, care must be taken while drafting such clauses as Indian courts have, in the past, treated unreasonable non-compete clauses as being unenforceable. A combination of confidentiality and non-compete clauses would add an essential layer of protection for companies, especially in the absence of legislation in this regard. Developing detailed protocols for handling confidential information would also go a long way in ensuring that such information stays within the company.

6. Taxation Regime

The power to levy direct and indirect taxes in India are distributed between the central and state governments. The Income Tax Act, 1961 (“**ITA**”), imposed by the central government, is the main source of direct tax, while the Goods and Services Tax Act 2017 (“**GST**”) is the primary legislation imposing indirect tax. Earlier, indirect taxes were split between multiple legislations at the central and state levels. The GST has subsumed, inter alia, the following taxes:

- a. Service tax,
- b. Additional Customs Duty commonly known as Countervailing Duty (CVD),
- c. Special Additional Duty of Customs (SAD),
- d. Central Sales Tax, and
- e. Value Added Tax.

Some direct and indirect taxes that may be applicable to Digital Health services are discussed below.

I. Indirect Taxes

The GST prescribes four tax slabs i.e. 5%, 12%, 18% and 28%.⁴³ However, health care services provided by a clinical establishment, an authorized medical practitioner or para-medics are exempt from GST.⁴⁴

“Health care services” have been defined as *“any service by way of diagnosis or treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognized system of medicines in India...”* However, health care services do not include hair transplant or cosmetic or plastic surgery unless it is undertaken to restore or reconstruct anatomy or functions of body functions affected due to congenital defects, developmental abnormalities, injury or trauma.

43. Central Board of Excise and Customs, GST Rates, available at: <https://cbic-gst.gov.in/gst-goods-services-rates.html>.

44. Department of Revenue, Ministry of Finance Notification No.12/2017- Central Tax (Rate) available at: http://cbic.gov.in/resources/htdocs-cbec/gst/Consolidated_notification_CGST_12.pdf;jsessionid=7E8EF98F76EAC9C0D2B46BC6A10BB90A.

II. Corporate Tax

Income tax in India is levied under the ITA. While residents are taxed on their worldwide income, non-residents are only taxed on income arising from sources in India. Under the current provisions of the ITA, the corporate tax rate for resident companies in India is 30%. However, domestic companies are taxable at the beneficial tax rate of 25%⁴⁵ if (i) their total turnover or gross receipts does not exceed INR 4 billion (USD 56 million approx.) during the financial year 2017-18;⁴⁶ or (ii) a company (engaged in the business of manufacture / production of any article or thing and research / distribution of such article or thing (“**Manufacturing Company (ies)**”) that has been set up and registered on or after March 1, 2016 opts for being taxed at such lower rate provided all the prescribed conditions are satisfied.⁴⁷ Tax rates for domestic manufacturing companies can be as low as 15% provided the conditions specified in the ITA are satisfied. Non-resident companies are taxed at 40%.

III. Structuring investments

Foreign enterprises could make investments into the Indian companies through an intermediate holding company set up in a tax friendly jurisdiction. India has a wide treaty network and the judicious use of an appropriate offshore jurisdiction could result in benefits for the foreign company, such as a reduced or nil-rate of tax on capital gains income, reduction in withholding tax rates, etc. The choice of an offshore entity would depend on the benefits available under the treaty between India and the offshore jurisdiction and the domestic tax laws of that jurisdiction. Additional concerns include economic stability, investment protection, corporate and legal system, availability of high quality administrative and legal support, banking facilities, reputation and costs, etc.

45. Exclusive of applicable surcharges and cess.

46. First Schedule, Finance Act 2019.

47. Section 115BA of the ITA.

7. Liability and Dispute Resolution

The liabilities that could arise for contraventions of the various legal requirements can be civil or criminal in nature, and different for doctors running the services and for service providers such as online platforms, institutions, etc.

I. Suits before a Civil Court

Civil suits could arise out of a breach of contractual obligations between the Digital Health service provider and the patient/user. It could also be instituted due to the commission of a tort such as negligence on the part of the service provider or its employees.

A breach in contractual obligations could lead to payment of damages that are either decided at the time of execution of the contract (liquidated damages) or based on the decision of the court (unliquidated damages).

Suits may also be brought before civil courts in cases of negligence, which has been explained by the Supreme Court has explained to mean a “breach of a duty caused by the omission to do something which a reasonable man, guided by those considerations which ordinarily regulate the conduct of human affairs would do, or doing something which a prudent and reasonable man would not do.”⁴⁸ To establish negligence in a civil suit, it must be proved that there was: (1) A legal duty to exercise due care; (2) a breach of that duty; and (3) consequential damage due to the breach.

In the context of a doctor-patient relationship, as would be the case in many Digital Health services, the Supreme Court has held that a “person who holds himself out ready to give medical advice and treatment impliedly undertakes that he is possessed of skill and knowledge for the purpose. Such a person when consulted by a patient owes him certain duties, viz., a duty of care in deciding whether to undertake the case, a duty of care in deciding what treatment to give or a duty of care in the

administration of that treatment. A breach of any of those, duties gives a right of action for negligence to, the patient.”⁴⁹ There is no limit to the amount that can be claimed as damages in such cases, provided the damages claimed are consequential in nature.

II. Vicarious Liability

In the provision of Digital Health services where there is an employer-employee relationship, the employer could also be proceeded against due to the principle of vicarious liability, where the employer is deemed to be vicariously liable for acts and omissions of the employee arising in course of his/her employment. This would not usually be the case in an employer-independent contractor relationship, where the service provider does not have much control or supervision over the acts of the independent contractor.

III. Liability under the Consumer Protection Act, 1986 (“CPA”)

The CPA was enacted with a view to allow for consumers to address their grievances rather than having to go to a civil court, which turns out to be a very expensive and time consuming affair. The CPA allows consumers to claim compensation from service providers in case there is a deficiency in the service that is provided. Apart from deficiency of services, consumers can also institute claims for defective products and unfair trade practices. Consumer forums have been set up at the district, state and national level in order to hear such matters.

Earlier, there was some ambiguity with regard to whether medical services provided by doctors, hospitals or other institutions were covered

48. Jacob Mathew v. State of Punjab & Anr. (2005) 6 SCC 1

49. Laxman Balkrishna Joshi v. Trimbak Babu Godbole and Anr. 1969 SCR (1) 206

under the ambit of the CPA. The Supreme Court in the case of *Indian Medical Association v. V. P. Shantha and Ors.*⁵⁰ clarified the position and held that medical services would fall within the ambit of the CPA, provided the patient is being charged for the service.

One of the essential elements to a claim is the payment for the services, as the CPA excludes services that are performed free of charge. However, a notable exception that was discussed in the *V. P. Shantha* case was in situations where the service rendered is usually chargeable, but waived in certain cases such as for persons who cannot afford it. In such cases, the person who received the services without charge would still be able to institute a claim under the CPA.

For claims raised with consumer forums, there is no limit to the amount of compensation that can be sought. While the quantum of compensation granted varies, the average compensation is between INR 2 Lakh to INR 6 Lakh. There have also been instances where compensations of up to INR 11 crore⁵¹ have been granted in medical negligence cases.

The Consumer Protection Act, 2019 (“**CPA 2019**”) has received Presidential Assent and is expected to come into force soon. The CPA 2019 sets up a Central Consumer Protection Authority as a regulator in the consumer law space. The CCPA is empowered to take up consumer cases on its own without the institution of a complaint by a consumer.

Currently, there is some ambiguity with respect to whether healthcare services are covered under the CPA 2019. An earlier version of the consumer protection bill passed by the Lok Sabha in 2018 (“**CP Bill 2018**”) explicitly included healthcare in the definition of service.⁵² However, the CPA 2019 does not mention healthcare explicitly in the definition

of services.⁵³ The ambiguity arises because even though healthcare is not explicitly included as a service under CPA 2019, it is also not explicitly excluded. The definition of services under CPA 2019 includes services not explicitly listed out in the definition.

IV. Disciplinary Action by the MCI

A consumer is entitled to raise a complaint with the relevant state medical council against a doctor for professional misconduct. If a complaint against a doctor has not been decided by the state medical council within six months from the date of receipt of the complaint, the MCI may, on its own or on the request of the consumer, impress on the relevant state medical council to decide on the complaint or refer the same to the Ethical Committee of the MCI for expeditious disposal.⁵⁴ Consumers who are aggrieved by the decision of the state medical council also has the right to appeal to the MCI within a period of 60 days from the date of the order passed by the state medical council.⁵⁵

Instances of professional misconduct are specified in the MCI Code, such as non-maintenance of medical records,⁵⁶ refusing treatment on religious grounds, performing operations without written consent,⁵⁷ etc. These are not exhaustive and complaints can be made for acts or omissions that are not covered under the MCI Code as well. If a complaint is found to be valid, the doctor faces the risk of suspension or cancelation of his/her medical license.

V. Criminal Liability

Criminal prosecution takes place before criminal courts for grounds such as the

50. AIR 1996 SC 550

51. INR 5.9 Crore plus interest; *Balram Prasad v. Kunal Saha;* (2014) 1 SCC 384

52. PRS Legislative Research, Consumer Protection Bill 2018 as passed in Lok Sabha, available at: <https://www.prsindia.org/billtrack/consumer-protection-bill-2018>

53. PRS Legislative Research, Consumer Protection Bill 2019, available at: <https://www.prsindia.org/billtrack/consumer-protection-bill-2019>.

54. Regulation 8.7 of the MCI Code

55. Regulation 8.8 of the MCI Code

56. Regulation 7.2 of the MCI Code

57. Regulation 7.16 of the MCI Code

commission of offences under any criminal statute, most notably the Indian Penal Code, 1860 (“**IPC**”).

In the case of Digital Health services, if a person is rash or negligent in rendering a service and the service results in bodily injury or death of the patient/user, the person may face criminal prosecution. The common charges faced by doctors and other providers of such services are causing death by negligence,⁵⁸ act endangering life or personal safety of others,⁵⁹ causing hurt by an act endangering life or personal safety of others⁶⁰ and causing grievous hurt by an act endangering the life or personal safety of others.⁶¹ In case a person is convicted under a criminal charge as described above, he/she may face imprisonment as well as fine.

Unlike criminal prosecution in ordinary cases, criminal prosecution in cases of medical negligence only takes place when the negligence is “gross” in nature. In fact, the Supreme Court has taken a sympathetic view towards criminal prosecution of doctors. In the words of the Supreme Court, “if the hands be trembling with the dangling fear of facing a criminal prosecution in the event of failure for whatever reason whether attributable to himself or not, neither a surgeon can successfully wield

his life-saving scalper to perform an essential surgery, nor can a physician successfully administer the life-saving dose of medicine.”⁶² A special exception has been carved out by the Supreme Court for initiation of prosecution in medical negligence cases. A criminal prosecution cannot be initiated unless there exists credible opinion of another doctor to support the charge of rashness or negligence on the part of the accused doctor.

Another special exception that has been carved out by the Supreme Court is in matters of the arrest of doctors. The Court has laid down that “a doctor accused of rashness or negligence, may not be arrested in a routine manner (simply because a charge has been levelled against him) unless his arrest is necessary for furthering the investigation or for collecting evidence or unless the investigation officer feels satisfied that the doctor proceeded against would not make himself available to face the prosecution unless arrested.”⁶³.

The principle of vicarious liability does not apply to criminal prosecutions. This would mean that the institutions/online platforms that provide the Digital Health services would not be criminally liable for the acts of its employees.

58. Section 304-A of the IPC

59. Section 336 of the IPC

60. Section 337 of the IPC

61. Section 338 of the IPC

62. Jacob Mathew v. State of Punjab and Anr. (2005) 6 SCC 1

63. Id.

8. Digital Health in Foreign Jurisdictions

In most jurisdictions around the world, regulators are still working on addressing Digital Health technology and services from a legal standpoint. One of the first questions that invariably arises is whether such technology should be fit into the current legal framework meant for conventional healthcare devices and services, or whether there is a need to address it with more individualized and comprehensive regulations. The progress and outlook of various countries towards Digital Health have been discussed below.

I. United States of America

Various states in the United States of America (“USA”) have passed telemedicine specific regulations.⁶⁴ The District of Columbia, for example, has dedicated telemedicine rules incorporated into its municipal regulations. The proposed rules place obligations on the physicians such as obtaining patient consent for the telemedicine services, archival and retrieval of patient records and implementing quality oversight mechanisms. The rules also propose to amend certain definitions in order to integrate and recognize telemedicine services into the municipal code.

Actions at the state level have addressed some concerns that arise from the practice of telemedicine. Some of these have been discussed below:

A. Cross-State Licensing

Licensing of medical practitioners in USA is state-bound, which requires a medical practitioner to apply for a separate license in order to practice in another state. This becomes an issue when the patient is located in one

state while the medical practitioner is located in another. In order to address this, some state medical boards such as Alabama have been permitted to issue ‘special purpose licenses’ to practice medicine across states and provide telemedicine services.⁶⁵ In certain other states, such as the District of Columbia, doctors are required to be licensed in the state where the patient is located, with limited exceptions for consultations. While representations for a better system have already been initiated, it may take some time before a system catering specifically to Digital Health services is set up.

B. Reimbursements

The American Telemedicine Association (“ATA”) - a leading not-for-profit organization helping to transform healthcare by improving the quality, equity and affordability of healthcare throughout the world – has been one of the biggest proponents of integrating telemedicine into the existing healthcare systems that are in place in USA. One of the major pushbacks that USA is dealing with currently for better adoption of the technology is the lack of coverage of such services in insurance policies. Certain policies go to the extent of specifically excluding Digital Health services such as telemedicine from its coverage. The ATA along with other organizations have been pushing for states in USA to pass parity laws that will allow for private insurance coverage of telemedicine.⁶⁶ More than 30 states have passed such enactments, while some other states have introduced bills for the same. This would go a long way in ensuring better adoption of Digital Health services, since insurance coverage is a major consideration in USA.

64. D.C. Mun. Regs. Tit. 17.

65. The Federation of State Medical Boards; Telemedicine Licensure; available at: www.fsmb.org/pdf/GRPOL_Telemedicine_Licensure.pdf

66. American Telemedicine Association; State Legislative & Regulatory Trackers; available at: <http://www.americantelemed.org/main/policy-page/state-policy-resource-center>

C. Patient privacy and confidentiality

In terms of patient privacy and confidentiality, sharing of information and other critical aspects have been covered under the Health Insurance Portability and Accountability Act and the Health Information Technology for Economic and Clinical Health Act. Amendments to federal privacy and security laws in 2013 now requires all subcontractors having access to protected health information must now be compliant with all applicable laws, which ensures that sensitive data is accorded the same level of protection regardless of where the data is transferred.

D. Online prescriptions

States have come up with regulations which either list the medicines that are permitted to be prescribed over telemedicine or list medicines that are prohibited from being prescribed over such platforms. Some states require prescriptions to be issued only after an actual physical examination is conducted on the patient. The state of Minnesota, for example, requires referring practitioners to have performed an in-person examination of the patient before a medicine can be prescribed.⁶⁷

E. m-Health

In the m-Health and telemedicine space, the USFDA has been playing an active role in addressing the new technology.⁶⁸ The USFDA has divided mobile applications into three categories - mobile applications that are considered medical devices and subject to USFDA regulations, mobile applications that may be considered medical devices, but which the FDA does not currently intend to regulate, and mobile applications that could be used in a health care environment, but are not considered medical devices.

USA still has some regulatory overlaps that it needs to iron out, but regulators have understood and acknowledged the importance of Digital Health and its potential, and are working towards adapting the current legal framework to fit these new requirements.

II. European Union (EU)

The EU has been studying Digital Health in its various forms from as early as 2008, with its European Patients Smart Open Services Project. It has been working towards improving citizens' health and increasing healthcare quality and access by making Digital Health part of the health policy and coordinating EU countries' political, financial and technical strategies.

Over the years, the EU has come out with multiple recommendations, guidelines and suggestions for cross border Digital Health services. Aspects such as insurance, data privacy, competition, electronic health records and integration of Digital Health services have been examined extensively. In 2014, a report was published with an overview of the national laws on electronic health records in the EU Member States and their interaction with the provision of cross-border Digital Health services.⁶⁹ The report contained recommendations such as the content to be included in health records, placing legal obligations on doctors to update health records, safeguards for accessing health data and the interoperability of health records.

III. Australia

The Australian government has a dedicated arm for digital health – the Australian Digital Health Agency (“ADHA”).⁷⁰ Standards Australia, a government-recognized standard setting organization in Australia, has laid

67. 2016 Minnesota statutes, Chapter 151, section 151.37; available at: <https://www.revisor.mn.gov/statutes/?id=151.37>

68. FDA, Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff, Sept. 25, 2013.

69. Overview of the national laws on electronic health records in the EU Member States and their interaction with the provision of cross-border eHealth services; available at: http://ec.europa.eu/health/ehealth/docs/laws_report_recommendations_en.pdf

70. Australian Digital Health Agency, Australian Government; more information available at: <http://www.digitalhealth.gov.au/>

down an exhaustive set of standards for various aspects of Digital Health, covering communications, data security, health concept representation, health record interoperability, patient administration messaging, prescription messaging and tele-health.⁷¹

The ADHA has set up a “My Health Record” System, with healthcare practitioners and organizations registering onto the platform in order to be placed into the Healthcare Identifiers Service and to obtain a Public Key Infrastructure Certificate to access the My Health Record System. My Health Record is a centralized, secure online summary of patient health information. Patients are able to control what goes into it, and who is allowed to access it by choosing to share health information with specific doctors, hospitals and other healthcare providers.⁷² While registration is not mandatory, organizations and doctors will not be able to have full access to the My Health Record System unless registered.

IV. China

The National Health and Family Planning Commission of the People’s Republic of China (“NHPC”) in 2014 came out with a set of interpretations and associated guidelines (titled “**Opinions of the National Health and Family Planning Commission Regarding Promoting Medical Institutions’ Telemedicine Services**”) related to telemedicine services in China. The guidelines actively promote the use and development of telemedicine services in China, while also covering essential points such as the need to ensure quality and efficiency as well as supervision and oversight in the performance of such services.

71. List of standards available at: <http://www.e-Healthstandards.org.au/Home/Publications.aspx>

72. My Health Record, Australian Digital Health Agency; more information available at: <https://myhealthrecord.gov.au/internet/mhr/publishing.nsf/content/home>

9. Current Issues and Considerations

I. General Considerations

A. Cross-State and Cross-Border Tele-Consultations

There seems to be some dichotomy with regard to the extent to which a license to practice medicine applies. 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. 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 that state medical councils may have would be in relation to which council would be required to try a violation by a medical practitioner – the state in which the practitioner is registered or the place in which the violation took place. However, the Supreme Court in the case of *Malay Ganguly v. Medical Council of India and Ors.*⁷³ 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 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.

However, the recently issued Telemedicine Practice Guidelines have clarified that a registered medical practitioner registered in the State Medical Register or the Indian Medical Register established under the MCI Act is entitled to practice telemedicine in all parts of the country. Therefore, it should be permissible for medical practitioners qualified to practice medicine under the MCI Act to provide teleconsultation services across the nation.

B. Prescribing Drugs

Doctors must exercise caution while prescribing drugs through a telemedicine platform. Apart from IT Act requirements relating to the validity of a prescription (discussed under the e-Pharmacies section), Indian courts have stated that prescriptions should not ordinarily be given to a patient without actual examination. They have also observed that the tendency to give prescriptions over the telephone should be avoided, except in cases of emergency.⁷⁴ However, as these judgements were delivered prior to the introduction of online pharmacies, courts may not take the same view if similar situation arose now.

Further, the prescription of drugs over telemedicine has also gained legitimacy under the Telemedicine Practice Guidelines. The guidelines categorize drugs into three lists – List O, List A, List B and a Prohibited List and specify the circumstances in which medicines specified in each category may be prescribed over telemedicine.

73. 2004 (1) SCC 305

74. *Martin F. D'Souza v. Mohd. Ishfaq*; (2009) 3 SCC 1

C. Delivery of drugs

Home delivery of medication may face challenges from a pharmacy regulation perspective. The Pharmacy Practice Regulations, 2015 (“**PPR Regulations**”) – which regulates the practice of pharmacy by registered pharmacists in India - state that prescription drugs are to be handed over to the patient or his caretaker directly by a registered pharmacist. Thus, it becomes practically challenging in an online set-up to have pharmacists deliver medication directly to patients. Nonetheless, the Ministry of Health and Family Welfare due the exigencies of the COVID-19 pandemic, issued a notification permitting the doorstep delivery of drugs directly to consumer (“**Doorstep Delivery Notification**”). The notification also prescribes additional record keeping requirements in the event prescription drugs are dispensed. It is unclear whether the Doorstep Delivery Notification will continue to remain in force once the COVID-19 pandemic has abated.

D. Jurisdictional issues

Since Digital Health services are not location-specific, service recipients are distributed around the country. This becomes an issue in the case of an untoward event which leads to a suit being filed in a civil, criminal or consumer court. The plaintiff – the aggrieved patient in this case – is entitled to institute a suit at a forum where he or she is situated, which requires the provider of the service to have to travel to the location in which the suit has been instituted. This also acts as a deterring factor for practitioners who are on the fence regarding the adoption of Digital Health services in their practice, as there is a constant risk of having to travel to any part of the country to appear before the relevant forum if a case is instituted.

II. Model-specific Considerations

Digital Health being a very broad concept, the legal considerations for each model are diverse. This paper focuses the legal and regulatory

framework of three major models that are picking up momentum in India – telemedicine, m-Health and e-Pharmacies.

A. Telemedicine

The most common form of telemedicine seen today is tele-consultation. Doctors sitting in one state are able to provide consultation to patients residing in the most remote locations. The barriers that once restricted access to quality healthcare have now been reduced significantly with the help of telemedicine services. While there are many services popping up around the country, care must be taken that the services provided are in compliance with the legal and regulatory requirements.

Annexure A provides a schematic representation of a few telemedicine scenarios. While not formally regulated so far, rules governing telemedicine are under development.

In a typical telemedicine setup, there would be exchange of patient information, interaction between a doctor and a patient and the involvement of an intermediary in certain cases. Each of these components have their own legal considerations under various legislations.

i. Informed Consent

Consent while handling SPDI is one of the most essential compliance requirements under Data Protection law. The SPDI of patients that is collected, stored, transferred or processed must be in accordance with the Data Protection Rules. Informed consent of the patient/user is an essential requirement before such data is collected or processed.

ii. Privacy Policy and Due Diligence Requirements

The service provider is also required to have a privacy policy in place in accordance with the Data Protection Rules. In case the service provider is an intermediary, there is also a requirement of a terms of use and compliance with certain due diligence requirements in order

to be protected from violations of the IT Act and its rules by users of the service.

iii. OSP Registration

Telemedicine services have specifically been covered under the OSP Regulations. While there are no express penalties for non-compliance with the regulations, there is still a legal requirement to register the service. Applications for registration under the OSP Regulations are to be made with the Department of Telecommunications.

B. m-Health

With the number of smartphone users on the rise, m-Health applications have a lot of potential. However, service providers utilizing this model must keep certain considerations in mind.

SPDI of users are collected on a real-time basis, which makes protection of such data a challenge. Users would also rely heavily on these applications and the information it provides, which makes accuracy an essential element. Service providers may face inevitable issues such as server downtime, inability to communicate with the device, etc. To protect both the user as well as the service provider, certain disclaimers must be put in place that informs the user of the accuracy of the information provided and the possibility of errors, mechanical or otherwise.

C. e-Pharmacies

Regulation of e-pharmacies has been hotly debated. There are multiple challenges to dispensing drugs online under the current framework. In its current form, the D&C Act requires that all drugs must be sold under a license. 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. Moreover, a drug can only be dispensed by a registered pharmacist to either the patient or his/her caretaker. The abovementioned requirements make it difficult for e-pharmacy retailers to deliver drugs to

patients. Additionally, the D&C Rules require a prescription to be in writing and signed by a registered medical practitioner. 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.⁷⁵ 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.⁷⁶ 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 Doorstep Delivery Notification provides temporary clarity on this subject. The notification states that drugs may be dispensed “*based on receipt of prescription physically or through e-mail*” thereby making it easier for online pharmacies to dispense drugs even if the prescription has not been digitally signed.

Other regulatory issues for e-Pharmacies would include having to satisfy the requirement of dispensing prescription medication only on the production of a valid prescription. Measures must also be put in place whereby a prescription drug is not dispensed more than once against the same prescription. For a prescription to be considered valid when it is transferred electronically - as in the case of uploading a prescription to an online pharmacy - it must comply with the provisions of the IT Act as well as the D&C Act and Rules.

In August 2018, the Ministry of Health and Family Welfare published draft rules to regulate e-pharmacies under the D&C Rules (“**Proposed Rules**”). The proposed amendment will introduce a licensing system for e-pharmacies

75. Section 4 of the IT Act

76. Section 5 of the IT Act

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. E-pharmacies are also required to establish a 24/7 customer support and grievance redressal mechanism, in order to address consumer complaints. Consumers are empowered to submit complaints with the regulator for violation of the license requirements (including with respect to the quality of drugs dispensed). The regulator can cancel the license of the e-pharmacy if a violation is found, in addition to other penalties prescribed.

After the release of the draft rules, both the Madras and Delhi High Court had passed orders banning online sale of medicines. However, the Madras High Court has since then lifted the ban and directed the Government to notify the draft rules expeditiously.

e-Pharmacies in India have not been received well by existing brick and mortar set ups. The All India Organisation of Chemists & Druggists (“**AIOCD**”), called for a nation-wide strike in protest against online pharmacies in order to “protect the general health of the public and interest of its members”⁷⁷. The strike saw 8.5 lakh chemists from all across India closing their shops for the entire day, demanding action from the government. The Maharashtra Food and Drug Administration had also raided 27 online pharmacies and filed a First Information Report against a popular e-commerce platform and its CEO.⁷⁸ The Madras High Court e-pharmacy case mentioned above was also instituted by the Tamil Nadu Chemists and Druggists Association to prevent e-pharmacies from functioning in the state.

77. ‘72,000 chemists in Maharashtra to shut shops on Oct 14 against e-pharmacy; FDA asks chemist assns to call off strike’; available at <http://www.pharmabiz.com/NewsDetails.aspx?aid=91092&sid=1>

78. ‘Online medicine sales: Are you aware?’; available at <http://www.pharmabiz.com/ArticleDetails.aspx?aid=90368&sid=9>

10. Government Initiatives

I. National Digital Health Authority (“NeHA”)

NeHA, which is the brainchild of the Ministry of Health and Family Welfare, is a proposed authority that is intended to be responsible for the development of an integrated health information system in India. It will be the nodal authority that will develop an integrated health information system along with the application of telemedicine and mobile health by collaborating with various stakeholders. Apart from this, it will also be responsible for enforcing the laws and regulations relating to the privacy and security of the patients’ health and information records.

NeHA is proposed to be a promotional, regulatory and standards setting organization to guide and support India’s journey in Digital Health and consequent realization of benefits of ICT intervention in the health sector in an orderly way. It also spells out the proposed functions and governance mechanism of NeHA.⁷⁹

II. National Digital Health Blueprint

In 2017, the Health Ministry released the National Health Policy (“NHP”) identifying the gradual attainment of universal healthcare as a long-term goal. To accomplish this, the NHP recommended establishing a federated health information architecture, health information exchanges and a National Health Information Network by 2025. The National Digital Health Blueprint Report was drafted to lay down the basic framework for future health systems (including information health exchanges). The 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”).

At its core, the NDHB contains a set of principles for digital health systems, which 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.

III. State Initiatives

The Gujarat government has started the initiative ‘E-Olakh’, which is developed for recording and registering births, deaths, and compilation of records. The primary aim is to maintain a database of birth and death records and issue birth and death certificates.⁸⁰

The Chhattisgarh government, with the help of the Indian Space Research Organisation (“ISRO”), has linked government medical colleges at Raipur and Bilaspur which have in turn been linked with premier hospitals across the country creating a statewide network.⁸¹ 30 such nodes have also been set up in Karnataka in collaboration with ISRO.

The ISRO is also deploying telemedicine nodes under the ‘gramsat scheme’. Along with various state governments, the ISRO has managed to establish a vast telemedicine network that consists of 225 hospitals that are connected to

79. NeHA concept note, available at <http://mohfw.nic.in/showfile.php?lid=3099>

80. http://www.nhp.gov.in/e-Health-initiatives-in-gujarat_pg

81. Central Bureau of Health Intelligence; Telemedicine Project, Chattisgarh; available at <http://www.cbhi-hsprod.nic.in/searum.asp?PNum=210>

40 super specialty hospitals. The Andaman and Nicobar Islands are also now linked through satellite connectivity.⁸²

IV. Proposed Legislation

The proposed Digital Information Security in Healthcare Act (“**DISHA**”) as well as the Personal Data Protection Bill, 2019 (“**PDP 2019**”) are the two major proposed legislation in the Digital Health space. DISHA is the legislation that seeks to formally establish NeHA and facilitate the online exchange of patient information with a view to prevent duplication of work and streamline resources.

The PDP Bill 2019 in its current form requires sensitive personal data e.g. medical records to be processed only with the explicit consent of the data principal or to respond to a medical emergency involving a threat to the life or a severe threat to the health of the data principal or any other individual. Moreover, it puts into place data localization requirements under which all Data Fiduciaries i.e. organizations such as government and corporations who determine how the data may be used, must store at least one copy of all personal data on a server/data centre located in India. Data designated as critical data by the Indian Government can only be stored in India. Currently, as the PDP 2019 has not been enacted, the Central Government has not notified any form of personal data as critical personal data. However, health data may be classified as critical personal data once the PDP 2019 is enacted. The report of a

committee set up by the Government under the chairmanship of Justice Srikrishna to frame policy on data protection has recommended that to protect national interests and prevent foreign surveillance, critical data such as Aadhaar number (a unique identification number provided to Indian citizens), genetic data, biometric data and health data should be stored and processed exclusively in India.

V. National Intellectual Property Rights Policy (“**NIPR**”)

The Department of Industrial Policy and Promotion (“**DIPP**”) released the NIPR on May 12 2016, after receiving approval from the cabinet ministry. The NIPR, themed ‘Creative India; Innovative India’, focuses on creating awareness on the importance of IPR as a marketable financial asset and economic tool and lays down seven broad objectives ranging from awareness creation to strengthening the enforcement and adjudication mechanisms for combating infringement.

The NIPR recognizes the potential for innovation that exists in new and emerging technologies like nano-technology, biotechnology, agri-biotech, life sciences, green technologies, telecommunications, new materials, space technologies, etc.⁸³ The policy also talks about developing novel technology platforms in order to ensure enhanced access to affordable medicines and other healthcare solutions.⁸⁴

82. Prof. S K Mishra; E health Initiatives in India; available at http://stbmi.ac.in/matter/international%20pub/35_e-%20Health%20Initiatives%20in%20India_skmishra.pdf

83. Objective 5 of the NIPR

84. Objective 5.8 of the NIPR

11. Recommendations

The uncertain environment in which Digital Health players are currently operating has made it difficult to effectively perform such services. At the same time, it also acts as a deterring factor for new entrants to venture into this field. It has become abundantly clear that the large scale adoption of Digital Health is the need of the hour in a country whose population is in need of better access to healthcare.

The need of the hour is for India to implement a nation-wide framework for the adoption of EHRs. Ancillary services such as telemedicine, e-pharmacies and even the use of big data in healthcare can be put in place once a robust EHR system is in place. Additionally, there is also a need for specific legislations to regulate telemedicine and online pharmacies. The Telemedicine Practice Guidelines are only binding on the healthcare providers practicing allopathic medicine while online pharmacies are operating in the gaps of the law, neither legal nor illegal. Regulating these spaces can encourage stakeholders to make full use of available technologies and ensure that the

maximum number of patients are able to benefit from them. The government could also engage in discussions with foreign jurisdictions to come up with a framework in which Indian qualified doctors can provide medical services to patients situated outside of India. In this way, India could help other countries that are currently in need of healthcare services, as well as allow for the provision of such services by foreign practitioners to patients situated in India.

Standards could also be laid down for e-Prescriptions and the manner in which such documents are required to be maintained in order for it to be considered valid. In certain countries, it has been found that the use of e-prescriptions have in fact reduced the misuse of prescriptions by patients, since there would be definitive records of dispensations against a prescription. These methods, while still in early stages of implementation, seem to have benefitted jurisdictions such as USA, and may be able to address some of the issues the Indian Digital Health industry is facing today.

12. Conclusion

The Digital Health market presents a lot of opportunities, but with every opportunity, there are bound to be risks involved. Innovation in this sector is yet to reach a saturation point, with new products frequently being introduced in the market. The legislative framework to protect and regulate such developments will remain one step behind, as it is yet to be seen how the industry will mature. Regardless, regulators have taken note of the restrictions and in many cases, the absence, of the law and are striving to formulate forward looking policies and legislations. The NIPR is only one such example.

In a country where access to affordable healthcare is still a looming issue, the public stands to gain immensely from the development of the Digital Health industry. With the public interest in the minds of both the regulators as well as the innovators, it remains to be seen if the developing legal and regulatory framework of the nation will impede or ignite its growth. While there is a long way to go, it is hoped that the overall positive outlook and support that the industry is receiving will continue and sustain itself in the future.

Annexure - A

Telemedicine Scenarios

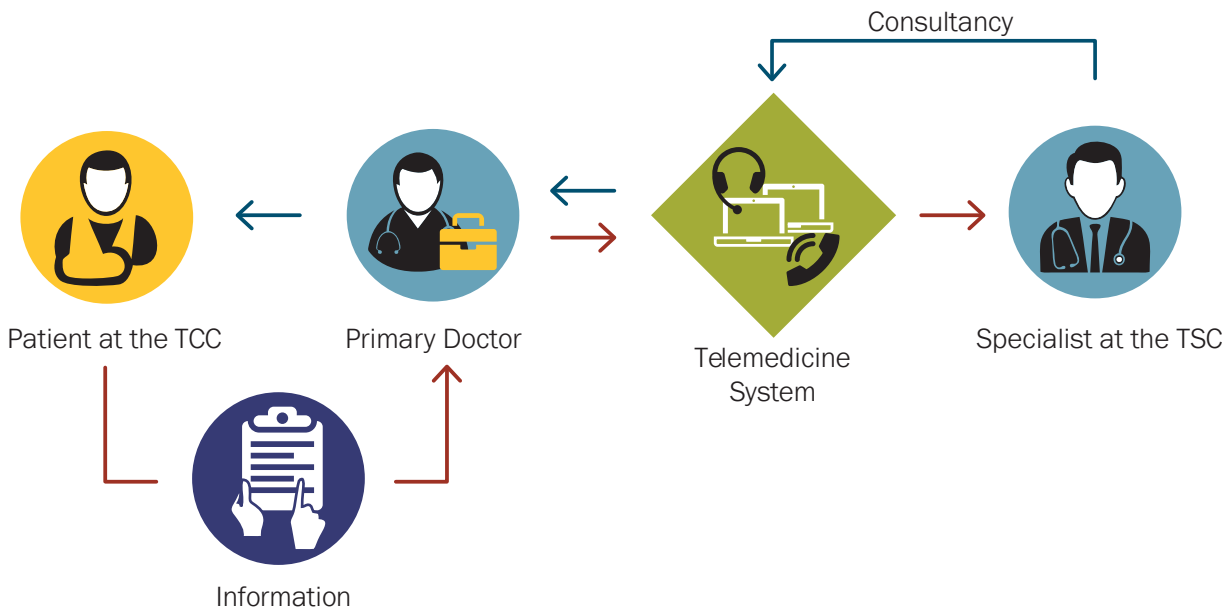
I. Important Components of the Process of Telemedicine

- a. **Patient:** The individual who requires Tele-consultation.
- b. **Primary Doctor:** The registered medical practitioner who has physical access to the Patient. The Primary Doctor will be available at the TCC (defined below).
- c. **Specialist:** The registered medical practitioner who provides medical consultation to the Patient from over a distance. A Specialist is located at Telemedicine Specialty Centre.
- d. **Telemedicine System:** The system / technology created in order to store, transmit and control all the information / data of the patient [(e.g. the Electronic Medical Record (“EMR”) from the Patient to the Specialist, via TCC and TSC (defined below)].
- e. **Telemedicine Consultancy Centre (“TCC”):** The medical facility where the patient is present. The TCC will be equipped with basic technology required for exchange of medical information and medical consultation.
- f. **Telemedicine Specialty Centre (“TSC”):** The medical facility where the Specialist is present. Like the Telemedicine Consultancy Center, this facility will be equipped with basic technology required for exchange of medical information and medical consultation. The specialist will provide Tele-consultancy from the TSC.
- g. **Tele-consultation:** The delivery of health care services using information and communication technology over a distance.

II. Scenarios

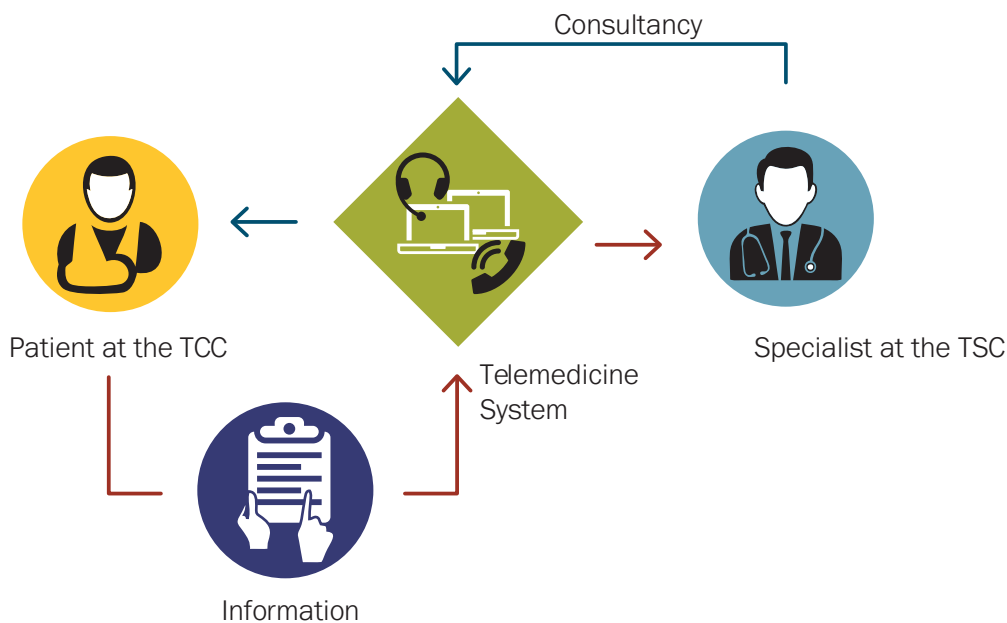
A. Telemedicine between Patient and Specialist via the Primary Doctor

- i. The patient goes to the TCC to receive expert advice of the Specialist who is located at the TSC.
- ii. The TCC houses a Primary Doctor who examines the Patient and sends report of his examination to the TSC.
- iii. The health information of the patient is shared real time (synchronously) or in a specific format (asynchronously, e.g. EMR), to the TSC via a Telemedicine System. The Telemedicine System permanently stores all health related information.
- iv. The specialist present at the TSC examines the health information and gives his or her expert consultation/advice.
- v. The expert advice is relayed real time (synchronously) or in a specific format (Doctor Opinion) to the TCC, via the Telemedicine System. In either event, it is stored permanently in the Telemedicine System.
- vi. The Primary Doctor at TCC receives the expert advice and treats the Patient accordingly.



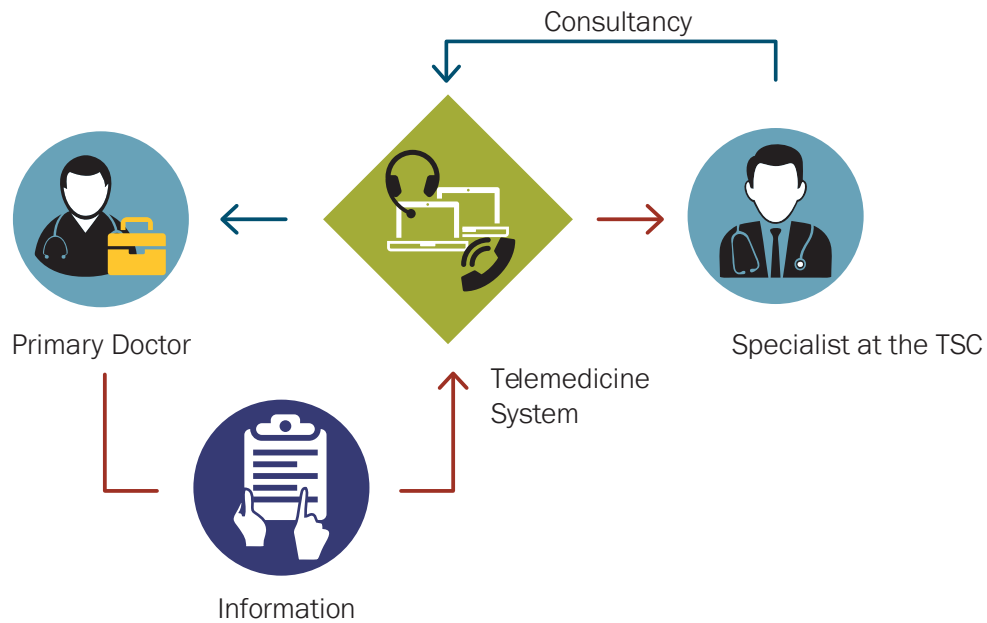
B. Telemedicine between Patient and Specialist without the Primary Doctor

- i. The patient goes to the TCC to receive expert advice of the Specialist who is located at the TSC.
- ii. The health information of the patient is shared real time (synchronously) or in a specific format (asynchronously, e.g. EMR), to the TSC via a Telemedicine System. The Telemedicine System permanently stores all health related information.
- iii. The specialist present at the TSC examines the health information and gives his or her expert consultation/advice.
- iv. The expert advice is relayed real time (synchronously) or in a specific format (Doctor Opinion) to the TCC, via the Telemedicine System. In either event, it is stored permanently at the Telemedicine System.
- v. The patient is directly treated by the Specialist.



C. Telemedicine between the Doctors

- i. The health information of the patient is shared in a specific format (asynchronously, e.g. EMR), to the TSC via a Telemedicine System. The Telemedicine System permanently stores all health related information.
- ii. The Specialist present at the TSC examines the health information and gives his or her expert consultation/advice.
- iii. The expert advice is relayed in a specific format (Doctor's Opinion) to the TCC, via the Telemedicine System. It is stored permanently at the Telemedicine System.



The following research papers and much more are available on our Knowledge Site: www.nishithdesai.com

 <p>Private Equity and Private Debt Investments in India</p> <p>May 2019</p>	 <p>International Commercial Arbitration: Law and Recent Developments in India</p> <p>May 2019</p>	 <p>Are we ready for Designer Babies?</p> <p>June 2019</p>
 <p>India Opens Skies for Drones</p> <p>August 2019</p>	 <p>Digital Health in India</p> <p>November 2019</p>	 <p>Impact Investing Simplified</p> <p>July 2019</p>
 <p>IP Centric Deals: Key legal, tax and structuring considerations from Indian law perspective</p> <p>February 2019</p>	 <p>Fund Formation: Attracting Global Investors</p> <p>February 2019</p>	 <p>Building a Successful Blockchain Ecosystem for India</p> <p>December 2018</p>

NDA Insights

TITLE	TYPE	DATE
Delhi Tribunal: Hitachi Singapore’s Liaison Office in India is a Permanent Establishment, Scope of Exclusion Under Singapore Treaty Restrictive	Tax	November 2019
CBDT issues clarification around availment of additional depreciation and MAT credit for companies availing lower rate of tax	Tax	October 2019
Bombay High Court quashes 197 order rejecting Mauritius tax treaty benefits	Tax	May 2019
Investment Arbitration & India – 2019 Year in review	Dispute	January 2020
Changing landscape of confidentiality in international arbitration	Dispute	January 2020
The Arbitration and Conciliation Amendment Act, 2019 – A new dawn or sinking into a morass?	Dispute	January 2020
Why, how, and to what extent AI could enter the decision-making boardroom?	TMT	January 2020
Privacy in India - Wheels in motion for an epic 2020	TMT	December 2019
Court orders Global Take Down of Content Uploaded from India	TMT	November 2019
Graveyard Shift in India: Employers in Bangalore / Karnataka Permitted to Engage Women Employees at Night in Factories	HR	December 2019
India’s Provident Fund law: proposed amendments and new circular helps employers see light at the tunnel’s end	HR	August 2019
Crèche Facility By Employers in India: Rules Notified for Bangalore	HR	August 2019
Pharma Year-End Wrap: Signs of exciting times ahead?	Pharma	December 2019
Medical Device Revamp: Regulatory Pathway or Regulatory Maze?	Pharma	November 2019
Prohibition of E-Cigarettes: End of ENDS?	Pharma	September 2019

Research @ NDA

Research is the DNA of NDA. In early 1980s, our firm emerged from an extensive, and then pioneering, research by Nishith M. Desai on the taxation of cross-border transactions. The research book written by him provided the foundation for our international tax practice. Since then, we have relied upon research to be the cornerstone of our practice development. Today, research is fully ingrained in the firm's culture.

Our dedication to research has been instrumental in creating thought leadership in various areas of law and public policy. Through research, we develop intellectual capital and leverage it actively for both our clients and the development of our associates. We use research to discover new thinking, approaches, skills and reflections on jurisprudence, and ultimately deliver superior value to our clients. Over time, we have embedded a culture and built processes of learning through research that give us a robust edge in providing best quality advices and services to our clients, to our fraternity and to the community at large.

Every member of the firm is required to participate in research activities. The seeds of research are typically sown in hour-long continuing education sessions conducted every day as the first thing in the morning. Free interactions in these sessions help associates identify new legal, regulatory, technological and business trends that require intellectual investigation from the legal and tax perspectives. Then, one or few associates take up an emerging trend or issue under the guidance of seniors and put it through our "Anticipate-Prepare-Deliver" research model.

As the first step, they would conduct a capsule research, which involves a quick analysis of readily available secondary data. Often such basic research provides valuable insights and creates broader understanding of the issue for the involved associates, who in turn would disseminate it to other associates through tacit and explicit knowledge exchange processes. For us, knowledge sharing is as important an attribute as knowledge acquisition.

When the issue requires further investigation, we develop an extensive research paper. Often we collect our own primary data when we feel the issue demands going deep to the root or when we find gaps in secondary data. In some cases, we have even taken up multi-year research projects to investigate every aspect of the topic and build unparalleled mastery. Our TMT practice, IP practice, Pharma & Healthcare/Med-Tech and Medical Device, practice and energy sector practice have emerged from such projects. Research in essence graduates to Knowledge, and finally to *Intellectual Property*.

Over the years, we have produced some outstanding research papers, articles, webinars and talks. Almost on daily basis, we analyze and offer our perspective on latest legal developments through our regular "Hotlines", which go out to our clients and fraternity. These Hotlines provide immediate awareness and quick reference, and have been eagerly received. We also provide expanded commentary on issues through detailed articles for publication in newspapers and periodicals for dissemination to wider audience. Our Lab Reports dissect and analyze a published, distinctive legal transaction using multiple lenses and offer various perspectives, including some even overlooked by the executors of the transaction. We regularly write extensive research articles and disseminate them through our website. Our research has also contributed to public policy discourse, helped state and central governments in drafting statutes, and provided regulators with much needed comparative research for rule making. Our discourses on Taxation of eCommerce, Arbitration, and Direct Tax Code have been widely acknowledged. Although we invest heavily in terms of time and expenses in our research activities, we are happy to provide unlimited access to our research to our clients and the community for greater good.

As we continue to grow through our research-based approach, we now have established an exclusive four-acre, state-of-the-art research center, just a 45-minute ferry ride from Mumbai but in the middle of verdant hills of reclusive Alibaug-Raigadh district. **Imaginarium AliGunjan** is a platform for creative thinking; an apolitical ecosystem that connects multi-disciplinary threads of ideas, innovation and imagination. Designed to inspire 'blue sky' thinking, research, exploration and synthesis, reflections and communication, it aims to bring in wholeness – that leads to answers to the biggest challenges of our time and beyond. It seeks to be a bridge that connects the futuristic advancements of diverse disciplines. It offers a space, both virtually and literally, for integration and synthesis of knowhow and innovation from various streams and serves as a dais to internationally renowned professionals to share their expertise and experience with our associates and select clients.

We would love to hear your suggestions on our research reports. Please feel free to contact us at research@nishithdesai.com

Nishith Desai Associates

LEGAL AND TAX COUNSELING WORLDWIDE

MUMBAI

93 B, Mittal Court, Nariman Point
Mumbai 400 021, India

tel +91 22 6669 5000
fax +91 22 6669 5001

SILICON VALLEY

220 California Avenue, Suite 201
Palo Alto, CA 94306-1636, USA

tel +1 650 325 7100
fax +1 650 325 7300

BANGALORE

Prestige Loka, G01, 7/1 Brunton Rd
Bangalore 560 025, India

tel +91 80 6693 5000
fax +91 80 6693 5001

SINGAPORE

Level 30, Six Battery Road
Singapore 049 909

tel +65 6550 9856

MUMBAI BKC

3, North Avenue, Maker Maxity
Bandra-Kurla Complex
Mumbai 400 051, India

tel +91 22 6159 5000
fax +91 22 6159 5001

NEW DELHI

C-5, Defence Colony
New Delhi 110 024, India

tel +91 11 4906 5000
fax +91 11 4906 5001

MUNICH

Maximilianstraße 13
80539 Munich, Germany

tel +49 89 203 006 268
fax +49 89 203 006 450

NEW YORK

1185 Avenue of the Americas,
Suite 326 New York, NY 10036, USA

tel +1 212 464 7050