

LEGAL AND TAX COUNSELING WORLDWIDE

MUMBAI

SILICON VALLEY

BENGALURU

SINGAPORE

NEW DELHI

NEW YORK GIFT CITY

Research

# Telemedicine in India

# **The Future of Medical Practice**

February 2025

Research

# Telemedicine in India

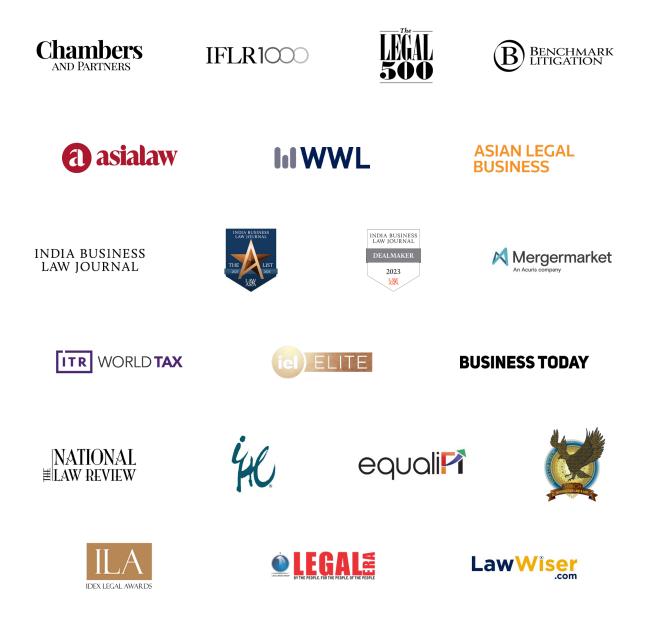
# **The Future of Medical Practice**

February 2025

DMS Code: 30666.1



Ranked as the 'Most Innovative Indian Law Firm' in the prestigious FT Innovative Lawyers Asia Pacific Awards for multiple years. Also ranked amongst the 'Most Innovative Asia Pacific Law Firm' in these elite Financial Times Innovation rankings.



## Disclaimer

This report is a copyright 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 **concierge@nishithdesai.com** or visit us at **www.nishithdesai.com**.

## Acknowledgements

Tanya Kukade tanya.kukade@nishithdesai.com

Varsha Rajesh varsha.rajesh@nishithdesai.com

Eshika Phadke Eshika.phadke@nishithdesai.com

**Dr. Milind Antani** Milind.antani@nishithdesai.com

1

3

6

10

19

# Contents

### Introduction

#### **Business Models**

- A. Consultation over Telemedicine Platform
- B. Consultation over a Messaging Platform
- C. Physician to Physician consultations
- D. Cross-Border Consultations

## **Regulatory Framework Governing Telemedicine**

- A. National Medical Commission Act, 2019 ("NMC ACT")
- B. Telemedicine Practice Guidelines ("TPG") Issued under the MCI Code
- C. Drugs and Cosmetics Act, 1940 ("D&C Act") and Drugs Rules, 1945 ('Drugs Rules")
- D. The Information Technology Act, 2000 ("IT Act"), the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or information) Rules, 2011 (together the "Data Protection Rules") and the Information Technology (Intermediaries Guidelines) Rules, 2011 ("Intermediaries Rules")
- E. Government Policies Regulating Health Data
- F. Telecom Commercial Communication Customer Preference Regulations, 2018 ("TCCP Regulations")

## **Telemedicine Practice Guidelines**

- A. Provides Legal Recognition to the Practice of Telemedicine
- B. Specifically Excludes Non-Teleconsultation Aspects of Telemedicine
- C. Types of Telemedicine Consultation
- D. Situations where Telemedicine is Permitted
- E. Identification of Patient and RMP Prior to Consultation
- F. Consultation to Minors
- G. Patient Consent
- H. Prescribing Medicines
- I. Liability of Telemedicine Platforms

## **Telemedicine Going Forward**

- A. Limited Applicability
- B. Patient Consent and Data Privacy
- C. Protection to Minors
- D. Restrictions on Prescribing Medicines
- E. Lack of Integration of Records Lack of Sufficient Data for Care Continuity
- F. Creating Service Awareness

# Conclusion Annexure A

List of Medicines

### **Annexure B**

Sample Prescription Format

27

24

25

# Introduction

Telemedicine is the use of information and communication technologies to improve patient outcomes by increasing access to healthcare and medical information. It is considered to be the tool of remote diagnosis and treatment of patients by the use of technology. The Indian Government has adopted the definition of telemedicine provided by the World Health Organization **("WHO")**, as follows.

"The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities"

In the Indian context, telemedicine has the potential to increase access to quality healthcare for all Indians, given that India suffers from a low doctor to patient ratio with only one doctor for every 1,445 Indians.<sup>1</sup> This hampers the equitable distribution of healthcare services which has remained to be a major goal in public health management for years. The disparity is even more pronounced in the rural areas as many doctors prefer to practice in the cities. According to a study conducted by the WHO, 59.2% of all health workers are located in urban areas, where 27.8% of the population resides, and 40.8% of all health workers were in rural areas, where 72.2% of the population resides.<sup>2</sup> Telemedicine can help smoothen over these inequalities by enabling doctors in urban areas to consult the rural population, including providing specialized care as necessary.

The COVID-19 pandemic served as a fillip for the legitimisation and development of telemedicine in India. The Telemedicine Practice Guidelines, which were released in 2020, brought about clarity on the legal status of telemedicine in India. The Indian government has since actively incorporate telemedicine into the public health delivery system through the eSanjeevani programmes.

In this paper, we have outlined the legal and regulatory framework regulating telemedicine and provided our inputs on how we see this space evolving. The paper focuses exclusively on the practice of telemedicine by allopathic practitioners and does not deal with the regulations applicable to practitioners of traditional medicine such as Ayurveda, Homoeopathy, Unani and Siddha forms of medicine. We hope this paper serves as a primer for existing stakeholders in the telemedicine space (such as patients, HCPs, telemedicine platforms and investors) as well as those who are testing the waters.

<sup>1</sup> Availableat:https://health.economictimes.indiatimes.com/news/industry/doctor-patient-ratio-in-india-less-than-who-prescribed-orm-of-11000-govt/72135237, (Last accessed on January 28, 2023).

<sup>2</sup> Available at: https://www.who.int/hrh/resources/16058health\_workforce\_India.pdf, (Last accessed on January 28, 2023).

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 Centre, 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.

# **Business Models**

The following business models are prevalent in the telemedicine sector.

## A. Consultation over Telemedicine Platform

Many telemedicine platforms have been launched in the past few years. These platforms are usually set up in the form of website or mobile applications. The platform connects patients with HCPs where consultation takes place over an app-integrated messaging or calling service. The platform may either provide patients with a list of doctors available on the platform and let the patient choose the HCP with whom to consult or directly connect the patient with the specific HCP. At the end of the consultation, the HCP may send a prescription online over the telemedicine platform on the basis of which the patient may purchase the required medicines. Alternatively, the HCP may also ask the patient to get certain tests done to be able to properly diagnose the underlying medical condition.

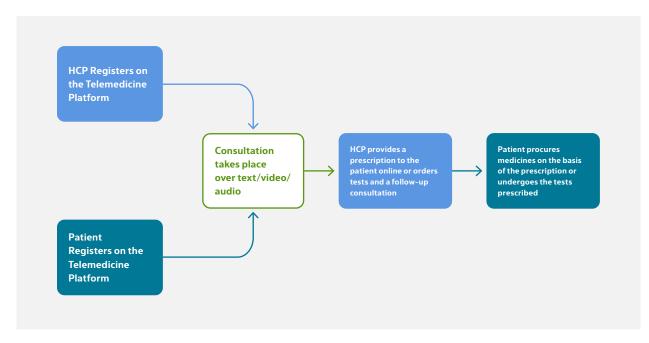


Chart 1: Consultation Over a Telemedicine Platform

## **B.** Consultation over a Messaging Platform

Patients and HCPs often consult informally over general messaging platforms. The messaging apps are distinct from telemedicine platforms as they are not specifically geared towards providing medical consultation or the collection or processing of health information.

The consultation may be initiated by a patient by reaching out to the HCP and may take place over text messaging, call or video facilities provided by the messaging app. At the end of the consultation, the HCP may send a prescription online over the messaging app on the basis of which the patient may purchase the required medicines. Alternatively, the HCP may also ask the patient to get certain tests done to be able to properly diagnose the underlying medical condition.

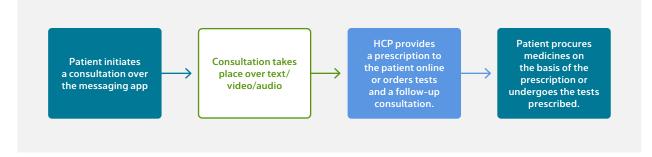


Chart 2: Consultation Over a Messaging Platform

## C. Physician to Physician consultations

As the name suggests, these consultations take place between two physicians when one physician (treating physician/referring physician) consults a specialist regarding a patient under the care of the treating physician. These consultations typically take place informally where the treating physician discloses patient information to the specialist to obtain the specialist's inputs on the diagnosis or the course of treatment. The specialist typically does not interact with the patient themselves and any advice provided by the specialist is conveyed to the patient by the treating physician.

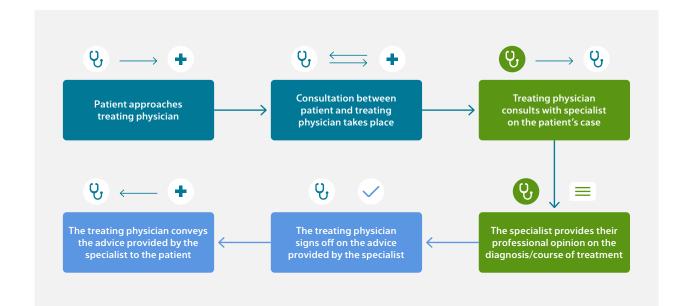


Chart 3: Physician to Physician Consultations

## **D. Cross-Border Consultations**

Cross-border consultations are a sub-set of physician-to-physician consultations. Cross-border consultations may take place in two ways:

- a. A physician licensed to practice in India reviews medical information of a patient located abroad based on a referral made by a foreign physician. In this case, the foreign physician is the referring/ treating physician while the Indian physician is the specialist. The specialist provides medical advice to either to the patient directly (depending on whether the laws in the patient's country permit this) or provides their professional opinion to the treating physician who ultimately signs off on the patient's treatment plan.
- b. A physician licensed to practice in India consults a foreign physician on a specific case. In this case, the Indian physician is the referring/treating physician and the foreign physician is the specialist. The foreign physician reviews the medical information provided and recommends a course of action. The Indian physician ultimately signs off on this course of action as the treating physician.

# Regulatory Framework Governing Telemedicine

The following Regulations regulate the practice of telemedicine in India.

## A. National Medical Commission Act, 2019 ("NMC ACT")

The Ministry of Health and Family Welfare **("Health Ministry")** notified the NMC Act in September 2020 as the primary legislation to regulate medical education and the medical profession in India. The NMC Act provides that only those persons who have a recognized degree in medicine and are registered with a state medical council have the right to practice medicine in India.

The NMC Act replaced the Indian Medical Council Act, 1956 **("IMC Act")** which regulated the medical profession prior to September 2020. The NMC Act contains transition provisions stating that rules and regulations published under the IMC Act continue to remain in force and operate till new standards or requirements are specified under the NMC Act.<sup>1</sup>

The rules and regulations are deemed to have been issued under the relevant provisions of the NMC Act itself.<sup>2</sup> One such regulation framed under the IMC Act is the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 **("MCI Code")** which 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 continues to remain in force and will be deemed to have been issued under the NMC Act unless a separate regulation on medical ethics is issued under the NMC Act.

In August 2023, the NMC issued the Registered Medical Practitioner (Professional Conduct) Regulations, 2023 ("NMC Code") in supersession of the MCI Code. The NMC Code also included the 'Guidelines for Practice of Telemedicine in India', which would replace the 2020 version of the Telemedicine Practice Guidelines. However, the NMC Code was subsequently put in abeyance and, pending its re-notification, the MCI Code prevails.

### B. Telemedicine Practice Guidelines ("TPG") Issued under the MCI Code

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 guidelines will remain binding and be deemed to have been issued under the NMC Act unless a new set of rules on this subject is issued under the NMC Act.

<sup>1</sup> Section 61(2) of NMC Act.

<sup>2</sup> Proviso to Section 61(2) of NMC Act.

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 TPG also categorizes medicines in List O, List A, List B and Prohibited List and specify which medicines can be prescribed in specific situations (covered in detail in Section IV sub-heading 8).

The Draft RMP Regulations contain Guidelines for Practice of Telemedicine (**"Proposed Guidelines"**) in India which will replace the existing TPG. The features of the Proposed Guidelines are discussed below.

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

The D&C Act and Drugs 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 Drugs 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, HI, and X of the Drugs 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 Drugs 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 sulphate, substances intended to be used for destruction of vermin or insects that cause disease in humans or animals and household remedies, among others. In May 2022, a draft amendment to the Drugs Rules was released for public consultation which specified sixteen drugs that may be sold without a prescription. The drugs include antifungals (clotrimazole), antiseptic and disinfectant (povidone iodine), mouthwash (chlorhexidine), analgesic (diclofenac), antipyretics (paracetamol), laxatives (lactulose), anti-dandruff shampoo (ketoconazole), nasal decongestants (sodium chloride) and antihistamine (diphenhydramine).<sup>3</sup>The Drugs 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<sup>4</sup> to be considered valid under the Drugs Rules, it must be in writing, signed and dated by the doctor issuing the prescription. 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.<sup>5</sup>

<sup>3</sup> Available at: https://egazette.nic.in/WriteReadData/2022/236010.pdf.

<sup>4</sup> Rule 65(10(a) of the Drugs Rules.

<sup>5</sup> Rule 65(10)(b), (c) of the Drugs Rules.

### D. The Information Technology Act, 2000 ("IT Act"), the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or information) Rules, 2011 (together the "Data Protection Rules") and the Information Technology (Intermediaries Guidelines) Rules, 2011 ("Intermediaries Rules")

Telemedicine involves a constant exchange of information between the patient and the service provider. At present, the patient's personal information, such as medical history and physiological conditions, are considered Sensitive Personal Data or Information6 **("SPDI")** under the Data Protection Rules. When a body corporate<sup>6</sup> collects, stores, transfers or processes such information, certain requirements under the Data Protection Rules are triggered.

The data protection framework is in the process of transformation given that the Digital Personal Data Protection Act, 2023 ("DPDPA") was passed by the legislature in August 2023 and is proposed to be brought into force in a phased manned followed by the specific rules for the purpose of implementation of the DPDPA. Once the provisions under the DPDPA are brought in force, it will replace the Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011. Our detailed analysis of the DPDPA is accessible here.

Broadly, the DPDPA provides specific compliance requirements to be undertaken by any entity processing digital personal data pertaining to an individual. Consent is one of the major requirements under the DPDPA. 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 upon providing a notice in compliance with the conditions prescribed under the DPDPA in this regard.<sup>7</sup> The rules are likely to provide further clarity on the form and manner of obtaining such consent in compliance with the DPDPA.

Further, if a body corporate is collecting, storing and processing personal data on behalf of another entity then it may avail the safe harbour provision provided under Section 79 of the IT Act. In order to avail this, it must follow the extensive requirements provided for under the Information Technology (Intermediary Guidelines and Digital Media Ethics Code) Rules, 2021 **("Intermediaries Rules")**. These requirements include having a grievance redressal mechanism,<sup>8</sup> displaying privacy policy and usage of personal data,<sup>9</sup> removal of unethical<sup>10</sup> and obscene information,<sup>11</sup> monthly compliance report,<sup>12</sup>implement reasonable security practices<sup>13</sup> etc.

- 10 Rule 3(1)(d), Intermediaries Rules.
- 11 Rule 3(2)(b), Intermediaries Rules.
- 12 Rule 3(1)(d), Intermediaries Rules.

<sup>6</sup> Section 43A of the IT Act defines "body corporate" to mean any company and includes a firm, sole proprietorship or other association of individuals engaged in commercial or professional activities.

<sup>7</sup> Section 5 and 6 of DPDPA.

<sup>8</sup> Rule 3(2), Intermediaries Rules.

<sup>9</sup> Rule 3(1)(a), Intermediaries Rules.

<sup>13</sup> Rule 3(1)(i), Intermediaries Rules.

#### E. Government Policies Regulating Health Data

The Indian Government is currently in the process of establishing a national health system with the ultimate aim of storing the medical records of every Indian electronically. The process commenced with the release of the National Health Policy, 2017 which identified the attainment of universal healthcare and the establishment of a National Digital Health Ecosystem **("NDHE")** as one of its goals. Subsequently, the NITI Aayog (the Indian Government's think tank) and the Health Ministry have released various policies towards setting up the NDHE.

These policies include the National Health Stack and the National Digital Health Blueprint Report which lay down the basic infrastructure and framework for the NDHE. On August 15, 2020, the Indian Government launched the National Digital Health Mission **("NDHM")** – a major digital health initiative which aims to provide a Health ID to every person in the country.<sup>14</sup> The NDHM was initiated as a pilot project in six union territories. Recently, the NDHM has been revamped as Ayushman Bharath Digital Mission **("ABDM")** and is now operational across the Country.

The establishment of the ABDM infrastructure is currently in the early stages of development. Once fully operational, HCPs providing teleconsultation would have the option of accessing their patient's electronic data with ease. It should be noted, however, that both HCPs and telemedicine platforms may be required to undertake certain compliances to ensure that they handle patient data in compliance with the policies framed under the NDHE.

Pursuant to this the Health Ministry also released the Health Data Management Policy ("HDM Policy") which covers the data protection and privacy aspect of the health data, which entities participating in the ABDM must comply with. It outlines the rights and obligations of all stakeholders involved in the collection and processing of digital health data i.e. patients, HCPs, clinical establishments, pharmaceutical companies, insurance providers etc.

#### F. Telecom Commercial Communication Customer Preference Regulations, 2018 ("TCCP Regulations")

Telemedicine platforms may be required to send SMS to patients and users on the platform. Sending unsolicited commercial communications over voice or SMS are prohibited under the 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.

<sup>14</sup> Hindustan Times, What is the National Digital Health Mission, available at: https://www.hindustantimes.com/india-news/explained-what-isnational-digital-health-mission-and-how-itwill-benefit-people/story-qOKIv3rbkrvB0aR9ZQyvdK.html), (Last accessed on January 28, 2023).

# **Telemedicine Practice Guidelines**

The TPG were issued in March 2020 to provide guidance to HCPs on the practice of telemedicine in light of the COVID-19 pandemic. Prior to the issuance of the TPG, the practice of telemedicine was governed in an ad-hoc fashion under applicable provisions of the IMC Act, MCI Code and the IT Act as covered above in the 'Regulatory Framework' section of this paper. While these legislations continue to apply, the TPG has plugged in the gaps in the erstwhile regulation and provided clarifications where necessary.

The stated purpose of the guidelines is to "assist the medical practitioner in pursuing a sound course of action to provide effective and safe medical care founded on current information, available resources and patient needs to ensure patient and provider safety". Accordingly, the TPG provides a wide berth of discretion to the HCP to determine the correct course of action when consulting patients over telemedicine.

At the moment, the TPG are only binding on a registered medical practitioner **("RMP")** i.e. a person registered to practice with a state medical council as per the provisions of the NMC Act. The TPG will continue to be binding on RMPs unless fresh regulations on this subject are issued under the NMC Act.

The TPG do not apply to dentists or practitioners of traditional medicine e.g. Ayurveda, Unani, Siddha and Homeopathy. It may be noted that the Central Council of Indian Medicine (the body responsible for regulating practitioners of Ayurveda, Unani and Siddha) has released a separate set of guidelines regulating the practice of telemedicine for Ayurveda, Siddha and Unani practitioners. Separately, the Central Council of Homeopathy has released Telemedicine Practice Guidelines applicable to homeopathic practitioners.

As the TPG is binding only on RMPs, other stakeholders of telemedicine such as patients, telemedicine platforms, messaging apps, insurance providers etc. are not bound by these guidelines. Nonetheless, we expect telemedicine platforms to comply with these guidelines as it should encourage more RMPs to register on a telemedicine platform that is compliant with the TPG than one that is not.

We have covered the salient features of the TPG below.

### A. Provides Legal Recognition to the Practice of Telemedicine

The TPG explicitly states that an RMP is entitled to provide telemedicine consultations from any part of India.

The formal legal recognition helps lay to rest legal ambiguities on whether RMPs are permitted to provide medical consultation over the telephone. Notably, a 2018 judgement by the Bombay High Court in the case of *Deepa Sanjeev Pawaskar and Anr v. The State of Maharashtra*<sup>1</sup> ("DSP Case") had created uncertainty in the minds of RMPs on whether it was permissible for them to provide medical advice over the telephone. In the DSP Case, the Bombay High Court had rejected the anticipatory bail application filed by the applicant who apprehended arrest under Section 304 (culpable homicide) of the Indian Penal Code, 1860. While the decision of the Bombay High Court was reversed in appeal by the Supreme Court, many RMPs in India continued to remain apprehensive about providing medical advice over the phone.

<sup>1</sup> Order dated July 25, 2018 in Criminal Anticipatory Bail Application No. 513 of 2018 passed by Justice Sadhana S. Jadhav of the Bombay High Court.

In the DSP Case, Dr.Deepa, a gynaecologist admitted Dnyanada to her clinic shortly after her initial discharge following a caesarean operation performed by Dr.Deepa, she did not consult with the patient in-person as she was not present in the hospital but prescribed medicines over the telephone after discussions with the hospital staff. Over time, the condition of the patient deteriorated and eventually Dnyanada passed away. The Bombay High Court held that Dr.Deepa had prescribed medicines without arriving at a diagnosis which amounts to a case of culpable negligence. While the facts of the case do not deal with the legality of telemedicine specifically (the Bombay High Court at no point stated that it was not permissible for Dr.Deepa to prescribe medicines over the telephone), the observations of the court had nonetheless created confusion on whether telemedicine was permissible in India.

Prior to the DSP Case, the Supreme Court, in the case of *Martin F. D'Souza v. Mohd. Ishfaq*<sup>2</sup> had observed 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.

Separately, there was also some ambiguity on whether an RMP registered with one state medical council would be entitled to practice in other Indian states. 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. The TPG have clarified that an RMP registered in any part of the country is entitled to practice nation-wide.

#### **B.** Specifically Excludes Non-Teleconsultation Aspects of Telemedicine

The TPG specifically excludes the following from its ambit.

- i. Specifications for hardware or software, infrastructure building and maintenance;
- ii. Data management systems involved, including standards and interoperability of such systems;
- iii. Use of digital technologies to conduct surgical or invasive procedures remotely;
- iv. Other aspects of telehealth such as research and evaluation and continuing education of healthcare workers; and
- v. Consultations outside the jurisdiction of India.

To understand why the above has been excluded from the ambit of the TPG, one should keep in mind the circumstances under which the TPG was enacted. While the NITI Aayog and the Board of Governors have been working on regulating telemedicine for some time now, the release of the TPG was expedited in light of the COVID-19 pandemic.<sup>3</sup>The guidelines are geared primarily towards providing guidance on the process of consulting remotely rather than the regulation of the consulting platforms themselves.

<sup>2 (2009) 3</sup>SCC 1.

<sup>3</sup> Sanchita Sharma, Telemedicine set to transform healthcare in a post COVID-19 world, Hindustan Times, available at:

www.hindustantimes.com/cities/telemedicine-set-to-transformhealthcare-in-a-post-covid-world/story-j79r1yEDFxYaE4nlcFNL31.html.

Nonetheless, the exclusions listed above are a key component of the broader concept of telehealth.<sup>4</sup> The regulation of hardware or software specifications for telemedicine platform, standards for data management systems and the regulation of equipment used to conduct surgeries remotely is essential for the protection of patient health. Further, given the general inclination of the Indian Government to regulate digital health technologies, it is only a matter of time before specific tele-health technologies are also regulated.

#### C. Types of Telemedicine Consultation

The TPG classifies telemedicine consultations into the different types on the basis of mode of consultation, timing of information transmitted, the purposes of consultation and the person to whom advice is provided (patient, caretaker or RMP). Each type of teleconsultation is further sub-divided in the following categories:

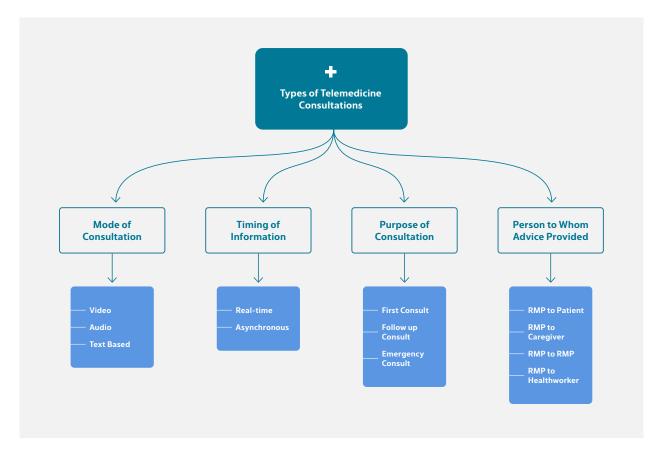


Chart 4: Types of Telemedicine

The TPG does not prescribe any type of telemedicine consultation. Rather, the TPG provides an overview of the advantages and disadvantages of each type of telemedicine consultation and gives discretion to the RMP on the type of teleconsultations best suited for achieving the intended purpose of the consultation.

<sup>4</sup> Tele-health has been defined under the TPG as "the delivery and facilitation of health and health-related services including medical care, provider and patient education, health information services and self-care via telecommunications and digital communications technologies.

#### D. Situations where Telemedicine is Permitted

The TPG states that the RMP should exercise their professional judgement to decide whether telemedicine is an appropriate method for providing consultation. The decision to consult by way of telemedicine should be made keeping in mind the following considerations:

- i. The mode/technology for consultation available i.e. if the RMP requires visual examination to arrive at a diagnosis (psoriasis or other skin conditions) and the only mode of consultation the patient/RMP has access to is through a phone call or text messaging, then the RMP should not arrive at a diagnosis or prescribe a course of treatment without physical examination.
- ii. The complexity of the patient's condition. At the start of the consultation, the RMP should inquire regarding the patient's medical history, past test reports or other information necessary. If the RMP believes that additional information or further tests are required for arriving at the diagnosis/treatment plan, the RMP should refrain from diagnosing the patient over telemedicine until such additional information/tests results have been obtained.
- iii. In emergency situations, the RMP may provide tele-consultation if this is the only means of providing timely care. In such situations, the RMP should provide consultation to their best judgement. If there are alternative methods available e.g. in-person care, the teleconsultation should be limited to first aid, life saving measure, counselling and advice on referral. The patient should be advised for an in-person consultation as soon as possible. In all cases where advice is provided by way of telemedicine, the standard of care is the same as in-person care keeping in mind the intrinsic limits of telemedicine. Therefore, RMPs should ensure that they keep in mind the MCI Code even when providing advice by way of telemedicine.

#### E. Identification of Patient and RMP Prior to Consultation

The TPG prohibits anonymous consultation on part of both the patient and the RMP. Each person should provide the following details at the start of the consultation.

Patient

- i. Name
- ii. Age
- iii. Address
- iv. Email ID
- v. Phone Number
- vi. Registered ID

#### **RMP**

- i. Name
- ii. Qualifications
- iii. Registration Number granted under the NMC Act (earlier IMC Act)

#### F. Consultation to Minors

As stated above, the RMP is required to identify the age of the patient at the start of the teleconsultation. In the event the patient is a minor, consultation should be done in the presence of an adult whose identity should be verified in accordance with the parameters stated above.

#### **G. Patient Consent**

The manner of obtaining patient consent depends on whether the teleconsultation was initiated by the patient, caregiver or by the RMP. In the event the teleconsultation is initiated by the patient, the consent is implied. In the event the teleconsultation is initiated by the caregiver, health worker or an RMP, the explicit consent of the patient should be recorded. The record may be maintained in the form of an email, text, audio/video message.

Additionally, the Proposed Guidelines requires that informed consent be obtained from the patient for the teleconsultation itself. According to the Proposed Guidelines, the patient must be informed of the distinctive features of telemedicine including how it works, how to schedule appointments, privacy concerns, the possibility of technological failures including confidentiality breaches, protocols for contact during virtual visits, prescribing policies and coordinating care with other health professionals in a clear and understandable manner, without influencing the patient's choices.<sup>5</sup>

#### **H. Prescribing Medicines**

The TPG contains detailed provisions on which medicines may be prescribed in specific circumstances as captured below.

#### **Outcome of Telemedicine Consultations**

In the event the RMP believes that the medical condition can be properly managed over telemedicine, the RMP may proceed with any (or all) of the below.

i. **Provide Health Education:** The RMP may impart health promotion and disease prevention messages e.g. advice on diet, physical activity, prevention of contagious infections, immunizations, exercises, hygiene practices, mosquito control etc.

<sup>5</sup> Para 1.1.4. of the Proposed Guidelines.

- ii. **Counselling:** This is advice specific to a patients' condition e.g. food restrictions, proper use of a hearing aid, home physiotherapy, etc. to mitigate the underlying condition. This may also include advice for new investigations that need to be carried out before the next consult.
- iii. **Prescribing Medicines:** The RMP may prescribe medicines over telemedicine if the RMP is satisfied that the RMP has gathered sufficient information regarding the patient's medical condition to arrive at a diagnosis and the prescribed medicines are in the best interest of the patient.

#### Manner of Prescribing Medicines

The TPG places limitations on the prescription of certain medicines depending upon the facts and circumstances of each case. Broadly, the TPG divides medicines into the following lists.

- i. **List O:** Medicines which are safe to be prescribed over any mode of teleconsultation. These include medicines for common conditions which are generally available 'over-the-counter' e.g. paracetamol, cough lozenges, ORS solution etc. or medicines necessary for public health emergencies.
- ii. List A: Medicines which may be prescribed over a first consult only in cases where the first consult is over video or as refills in a follow-up consultation. These include relatively safe medicines with low potential for abuse.
- iii. List B: Medicines which may only be prescribed refills during follow-up consultations provided the first consult where medicines were prescribed for the condition took place in person. The medicine may either be a re-fill or a new medicine for the same medical condition.
- iv. **Prohibited List:** Medicines which an RMP is prohibited from prescribing over telemedicine. This includes drugs specified in Schedule X of the D&C Act or listed in the Narcotic Drugs and Psychotropic Substances, Act, 1985 (India's anti-drug legislation).

The categories of medicines that may be prescribed over telemedicine would be notified by the government from time to time. As no list has been notified as of this writing, the general guidance provided by the lists would be applicable. The TPG provides an illustrative list of the medicines in each category above which has been provided in this paper as **Annexure A**.

The Proposed Guidelines have done away with the mode-wise restrictions on categories of drugs that may be prescribed through teleconsultations, and enables doctors to exercise professional judgment and discretion to prescribe drugs as they deem fit.

The terms — first consult and follow-up consult are defined under the TPG as follows:

- i. First Consult means that the patient is consulting with the RMP for the first time or the patient has consulted with the RMP earlier, but six months have passed since the first consultation or the patient has consulted with the RMP earlier but for a different condition.
- ii. Follow Up Consult means that the patient is consulting with the RMP within 6 months of their previous in-person consultation, and this consultation is for continuation of care of the same health condition. However, a consultation would not be considered to be a follow up consultation if there are new symptoms not in the spectrum of the health condition for which the first consult took place or the RMP does not recall the context of the previous treatment and advice. The Proposed Guidelines also permit follow-up consultations with a different doctor, if he/she is comfortable in comprehending the patient's condition after reviewing the information and reports provided by the patient.

#### **Format of Prescription**

The prescription issued by the RMP should be as per the requirements of the Drugs Rules as well as the MCI Code. The prescription should specify the registration number granted to the RMP under the MCI Act.

The TPG have significantly streamlined the process of granting digital prescriptions. The TPG stipulate that a photo, scan or other digital copy of a signed prescription or an e-prescription issued to a patient over a messaging platform would be considered to be valid.

Prior to the release of the TPG, there was considerable ambiguity on the legitimacy of e-prescriptions. The Drugs 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. 6 Hence a prescription uploaded online would fulfil the first requirement of a valid prescription under the Drugs Rules. However, the IT Act further states that where a law requires for a document to be signed (the law being the Drugs Rules in this case), it would be deemed to be in compliance only if such information or matter is authenticated by means of an electronic signature. 7 Affixing an electronic signature to any document thus became essential for it to fulfil a legal obligation mandating a regular signature. Therefore, prior to the clarification provided by the TPG, uploading a scanned copy of a prescription may not have been recognized as valid under law.

The TPG also provides for a model prescription format provided below in Annexure B.

#### **Misconduct in the Telemedicine Context**

The MCI Code provides some guidance on actions that constitute misconduct in general. For misconduct in the telemedicine context, one must turn to the TPG. The TPG states that the below actions would be considered to be misconduct. In the event an RMP is held guilty of misconduct, penalties prescribed under the MCI Act and the MCI Code would be applicable. The following activities are restricted:

- i. Prescribing Medicines without an appropriate diagnosis/provisional diagnosis.
- ii. Failure to uphold patient privacy and confidentiality as required under the MCI Act.
- iii. Failure to comply with the MCI Act, MCI Code or other data privacy laws (such as the IT Act or the DP Bill if enacted) for handling and transfer of medical information.
- iv. RMP insisting on telemedicine, when the patient is willing to travel to a facility and/or requests an in-person consultation.
- v. RMP misusing patient images and data, especially private and sensitive in nature (e.g. RMP uploads an explicit picture of patient on social media)
- vi. RMP who prescribes medicines from the specific restricted list over telemedicine e.g. prescribing medicines from the prohibited list or prescribing medicines from List B during a first consult.
- vii. Soliciting patients for telemedicine through advertisements or inducements.

<sup>6</sup> Section 4 of the IT Act.

<sup>7</sup> Section 4 of the IT Act.

The TPG do not prescribe any specific penalty in the event of misconduct but rather refer to the MCI Code for the same. The MCI Code authorizes state medical councils to decide complaints against RMPs. In the event the RMP is found guilty of misconduct, the state medical council may award punishment as the respective medical council deems fit. This may also include removal of the RMP's from the medical council register name (for a specified period of time or altogether) in effect barring the RMP from practicing medicine.

Separately, an action may be brought against an RMP by the aggrieved patient or their legal heirs before a court of law. Such cases may be civil or criminal in nature. Civil cases are typically filed by patients under India's consumer protection laws while criminal cases are initiated by filing a first information report (FIR) with the police.

#### **Maintenance of Records**

It is mandatory for the RMP to maintain the following records for teleconsultation:

- i. Log or record of telemedicine interaction e.g. phone logs, email records, chat/ text record, video interaction logs etc.
- ii. Patient records, reports, documents, images, diagnostics, data etc. (digital or non-digital) utilized in the telemedicine consultation.
- iii. In case a prescription is shared with the patient, the RMP is required to maintain the prescription records as required for in-person consultations.

#### I. Liability of Telemedicine Platforms

The TPG prescribe certain guidelines for telemedicine platforms. However, as the TPG has been issued as part of the MCI Code (and are therefore binding only on RMPs and not on telemedicine platforms), it is unclear how these guidelines would be enforced, or their violation penalized.

- i. Telemedicine platforms should ensure that patients are consulting with RMPs duly registered with MCI or respective state medical council.
- ii. Telemedicine platforms should provide the name, qualification, registration number granted under the MCI Act and contact details of every RMP listed on the platform.
- iii. In the event some non-compliance is noted, the telemedicine platform is required to report the same to the NMC so that the NMC may take appropriate action.
- iv. Telemedicine platforms based on Artificial Intelligence/Machine Learning are not permitted to counsel patients or prescribe any medicines to a patient. However, technologies such as Artificial Intelligence, Internet of Things and advanced data science-based decision support systems may be used to assist and support the clinical decisions of the RMP. In all cases, the final prescription or counselling has to be directly delivered by the RMP
- v. Telemedicine platforms are required to ensure that there is a proper mechanism in place to address any queries or grievances that the patients may have.

Where any specific technology platform is found in violation, the NMC may blacklist the platform thereby discouraging RMPs from using that platform to provide telemedicine. However, no specific penalty has been prescribed for RMPs who continue to provide telemedicine services on a blacklisted platform.

#### **Vicarious liability**

The principles of vicarious liability and intermediary liability, though derived from different laws, are closely linked and are both paramount factors for telemedicine platforms to take into consideration while structuring their business and governance policies. Vicarious liability arises when the platform had the right, ability or duty to control the activities of the violator i.e., the doctor. Intermediary liability, on the other hand, arises because the platform facilitates the violator's actions, and would cover violations by both the doctors and patients who use the platform. While vicarious liability is dealt with by the Consumer Protection Act, 2019, intermediary liability is derived from the IT Act and the rules issued thereunder.

It is an argument of the telemedicine platforms that they merely facilitate the interactions, and are not rendering medical advice themselves, so there is no doctor-patient relationship between the platform and patient, and the platform cannot be held liable for any deficiencies in service or negligence by the doctor several platforms are structured as marketplaces, where anyone (subject to their credentials) can list themselves on the platform and offer their services. There is no blanket exemption that has been provided to the telemedicine platforms but there are safeguards that can be put in place to minimise the risk of prosecution.<sup>8</sup>

#### Intermediary liability

Implementing quality control measures to mitigate risk is essential for telemedicine platforms to mitigate risk of being held vicariously liable for negligence and deficiencies in services on the platform. The law recognises that an intermediary does not control what third-parties do on the platform and they cannot reasonably be expected to monitor every single transaction. Thus, provided that the intermediary complies with certain requirements, they are exempted from liability for wrongdoings done by third parties on the platform without their knowledge.

In order to be eligible for the protection, the intermediary must follow the due diligence requirements stipulated in the Information Technology (Intermediary Guidelines and Digital Media Ethics Code) Rules, 2021 (**"Intermediaries Rules"**), which include publishing and complying with privacy policy and terms of service which specifies the types of content and activities that is prohibited on the website and/or mobile application, taking action against violators upon receiving knowledge of non-compliance with the guidelines, cooperating with governmental authorities, etc, as well as certain compliances under the Consumer Protection (E-Commerce) Rules, 2020 such as executing an undertaking with service providers to ensure that the descriptions and other contents pertaining to the services offered through the platform is accurate.<sup>9</sup>

Thus, telemedicine platforms are expected to undertake an organised approach to avail the protection conferred under Section 79 of the IT Act, upon losing the status they would be required to proactively monitor all transactions taking place on the platform which may become a logistical challenge.

<sup>8</sup> Available at:https://arogyalegal.com/2021/article/the-liability-conundrum-for-telemedicine-platforms-in-india-striking-a-balance-between-vicarious-and-intermediary-liability/, (Last accessed on January 18, 2022).

<sup>9</sup> Id.

# **Telemedicine Going Forward**

Telemedicine is a relatively new concept in its nascent stages of application. The rapid advancement in technologies pertaining to telecommunication make the evaluation of efficacy of telemedicine a difficult process which requires a constant upgrading of the key hardware and software.

Most telemedicine applications depend on technical and human infrastructures that are complex, incomplete, and sometimes unwieldy. Until those infrastructures become more ubiquitous and user-friendly (e.g., flexible, easy-to-use work-stations located where clinicians work), evaluations of costs and acceptability will often prove disappointing to proponents of the programs and applications that depend on this common infrastructure.<sup>1</sup>

Providing or supporting medical care at a distance may require an unusual level of cooperation among institutions and individuals not bound by common organizational affiliation and governance structure.

The TPG provide a robust foundation on which to more comprehensively regulate telemedicine in the future. The TPG were issued to bring clarity to the process of telemedicine in light of the COVID19 pandemic and have done an admirable job of clarifying some of the legal ambiguities regarding the status of telemedicine and providing a format for how teleconsultations should be conducted. That being said, there is room to expand the ambit of the TPG and to bring in changes to further consolidate the regulations governing telemedicine in India.

Below are a few recommendations for ensuring compliance with TPG and applicable laws as well as some considerations which can be taken into account for shaping future regulations on telemedicine:

### A. Limited Applicability

**Issue:** The TPG are applicable only to healthcare practitioners registered in accordance with the MCI Act and does not extend to dentists or other entities involved in providing telemedicine services.

**Background:** As a result, the TPG apply only to RMPs. This definition excludes dentists or other health professionals e.g. dentists, nurses and community health professionals who may also provide medical advice over a telemedicine platform. Separately, the TPG also do not apply to other entities involved in providing telemedicine services i.e. telemedicine platforms which connect RMPs with patients and hospitals (in cases where the telemedicine platform is maintained by a hospital for its RMPs/patients) (collectively referred to as **"Telemedicine Service Providers"**).

**Recommendation:** To ensure that all aspects of the practice of telemedicine are regulated, the TPG (with the appropriate modifications) should be enacted in the form of an act **("Telemedicine Act")**. The Telemedicine Act should specifically regulate the following

<sup>1</sup> Available at:https://www.ncbi.nlm.nih.gov/books/NBK45443/, (Last accessed on January 28, 2023).

- i. The type of care that each healthcare practitioner (which term should include nurses, healthcare workers, community health professionals etc.) is permitted to deliver over a telemedicine platform e.g. distinction between the medical advice that may be provided by an RMP as opposed to a community health worker.
- ii. Regulation of practices in addition to telemedicine consultations which are part of the telemedicine umbrella e.g. tele-ICU, tele-nursing, tele-radiology.
- iii. Software and security standards to be followed by Telemedicine Service Providers.
- iv. Regulation of data provided over a telemedicine platform including specific measures to protect the privacy of patients (explained below).
- v. Restrictions on providing care over platforms who are not equipped to ensure patient privacy.
- vi. Division of liability in the event harm is caused to the patient during or due to a teleconsultation.
- vii. Regulation of Artificial Intelligence (AI) and Machine Learning (ML) platforms as the TPG is not applicable to telemedicine platforms that use AI/ ML to consult patients.

#### **B.** Patient Consent and Data Privacy

**Issue:** The TPG do not contain adequate guidance on obtaining informed consent from patients nor do they contain provisions on how the patient data may be used.

**Background:** The TPG consider patient consent as implied in instances where the patient initiates the telemedicine consultation and require the RMP to obtain explicit consent from the patient in cases the RMP has initiated the telemedicine consultation. However, the TPG do not account for the following when obtaining patient consent.

- i. The patient is not informed regarding the limits of teleconsultation prior to commencing the consultation unless such consultation is taking place in the presence of a health worker.
- ii. The patient is not informed regarding how the data they provide may be used. Generally, this information
  is contained in the terms of use and privacy policy of the telemedicine platform or of the messaging app.
  However, patients may not be familiar with or even capable of understanding the privacy policy and
  therefore may not be in a position to give informed consent.
- iii. The patient may, when initiating a consultation over text, provide unsolicited information regarding their health. Currently, India's information technology and data privacy regulation does not provide guidance on the manner/level of protection this data would be granted as there is no privacy policy/ terms of use regulating this data.
- iv. For patients consulting with an individual RMPs over informal messaging apps, it would be responsibility of the RMP to safeguard patient data as per India's data protection regulation. However, India's data protection regulation is not binding on individuals (and only on body corporates or sole proprietorships) due to which patient data provided to individual RMPs is virtually unprotected.

**Recommendation:** The IT Act along with the DPDPA (once the provisions of the DPDPA are brought into force) would govern the storage, transmission and processing of online information.

In the event a body corporate collecting personal data is found to be negligent in implementing and maintaining reasonable security practices and procedures prescribed under the data protection laws, thereby causing wrongful loss or gain to any person, it may be liable to provide monetary compensation to any affected person.

The following steps may be taken to remedy the issues highlighted above.

- i. The RMP should be required to specifically inform the patient with a notice regarding the process of the teleconsultation and the limits to telemedicine prior to initiating the consult. This would ensure that the patient has made an informed decision to obtain medical advice over telemedicine.
- ii. The RMP should be required to provide a brief on how patient data would be processed prior to obtaining any health data as part of the process for obtaining consent the duration and purpose of collection of the health data must also be informed to the data provider.
- iii. To provide further protection, there should be specific provisions in the TPG ensuring a baseline level of data protection to personal data (including health data) provided during a teleconsultation. This would also ensure that in the event any unsolicited health information is provided by the patient, such information would also be granted adequate protection.

#### C. Protection to Minors

**Issue and Background:** The RMP is bound to consult minors only in the presence of an adult. However, this may create issues for minors who wish to talk about sensitive subjects e.g. mental health/reproductive health consultations and are not comfortable discussing these issues in front of a parent/guardian.

**Recommendation:** Minors above a certain age should have the option of initiating teleconsultations without the presence of a parent/guardian if they so choose. Consent of minors may be taken in compliance with the DPDPA. Ideally, the parent/guardian would give consent to the teleconsultation and to the privacy policy but would not be present when the teleconsultation takes place.

#### **D. Restrictions on Prescribing Medicines**

**Issue:** Medicines in List B can only be prescribed during a telemedicine consultation provided these medicines were first prescribed during an in-person consultation with the same RMP. However, there is no provision for an instance where the medicine was first prescribed during an in-person consultation with a different RMP than the one being consulted via telemedicine.

**Background:** Under the TPG a first consult means a consultation on a specific condition with an RMP for the first time or if more than six months have lapsed since an in-person consultation even though there were teleconsultations in the interim. A follow-up consultation is a consultation within six months of a first consultation. Some patients may have consulted an RMP on a particular condition prior to the COVID-19 lockdown in India but may not be able to consult the same RMP over telemedicine if the RMP is not available for teleconsultation. In other cases, six months may have elapsed between the last in-person consultation with an RMP due to the COVID-19 lockdown consequently changing the status of future consults from follow-up consults to first consults under the TPG. In all of these cases, patients may not be able to obtain treatment for their conditions or prescriptions for the drugs they require in the event those drugs are specified under List B of the TPG.

**Recommendation:** The definition of follow-up consultations should be modified to include first conditions in respect of a condition provided by any RMP and not the specific RMP sought to be consulted over telemedicine provided the RMP who was consulted in-person has already arrived at a diagnosis of the condition and had previously prescribed a drug listed in List B of the TPG.

Further, the six-month time limit between in-person consultations should be removed keeping in mind the exigencies of COVID-19.

#### E. Lack of Integration of Records – Lack of Sufficient Data for Care Continuity

**Issue:** With telemedicine consultations, there are two problems associated with record keeping. First, there is a higher likelihood of lack of maintenance of records of telemedicine consultations in a standardised interoperable format by the RMP. Second, there is lack of sufficient data easily accessible and available for continuity of care of the patient. Instead, the RMP has to rely on the patient's past history and any information/ medical records which the patient provides without any means to verify the authenticity of past diagnosis and chronology of the medical condition from the time of discovery.

**Background:** Under the TPG, the RMP has the duty to document all consultations and maintain digital records of the advice rendered and the prescription. There is a format for the prescription provided in the TPG (provided below in Annexure B). However, no guidance has been provided for manner of maintenance of records.

With respect to reliance on patient records and medical history, the TPG prescribes that the RMP is required to exercise professional discretion and proper clinical judgement to gather such information from the patient. Such information must be supplemented through a conversation between the RMP and patient over the digital platform. If the RMP feels that the information received is inadequate, then he/she can request for additional information from the patient. If a If a physical examination is critical information for consultation, RMP should not proceed until a physical examination can be arranged through an in-person consult.

**Recommendation:** A system with respect to maintenance of Electronic Health Records ("EHR') must be formulated. This must not be restricted for the purposes of TPG only, but a universal system of EHRs which incorporates aspects of security and interoperability must be designed. The HDM Policy under the ABDM is a stepping-stone to the creation of this interface, however, it has been formulated for the limited purpose of the participating entities in the ABDM only and lacks legislative backing. Hence, a universal EHR system will be mutually beneficial for RMPs and patients to maintain a reliable record of medical information.

#### F. Creating Service Awareness

**Issue:** Announcement of commencement of tele-consultation services by hospitals or RMPs and marketing of new telemedicine platforms may be perceived as advertising of medical services.

**Background:** Self- promotion by RMPs is strictly forbidden under the MCI Code. Any form or manner of advertising or publicity through any mode either alone or in conjunction with others which is of such a invites attention to them or professional position, skill, qualification, achievements, attainments, specialities, appointments, associations, affiliations or honours and/or of such character as would ordinarily result in self-promotion will be considered to be advertising. Only formal announcements with respect to starting practice and type of practice is permitted.

**Recommendation:** Raising awareness amongst existing and potential patients with respect to telemedicine platforms must be taken into account. Unlike traditional medical practice where patients may locate and access healthcare facilities physically, in the context of telemedicine services consumers need to be informed about the availability of such services online. Lack of promotion would make telemedicine inconspicuous, therefore disabling the general public from being aware of and seeking medical services remotely. Formal announcements are insufficient to create widespread awareness of the existence of teleconsultation services. Therefore, in the interest of the public, guidance must be prescribed to enable reasonable promotion of the commencement of such services.

# Conclusion

The release of the TPG is a watershed moment not only for the practice of telemedicine in India but for digital health ecosystem as a whole. Telemedicine is one of the simplest applications of digital health with widespread acceptance, therefore making it crucial for transition towards digital health. One of the biggest obstacles to the adoption of digital health tools including telemedicine, is the lack of specific regulations which address the unconventional issues posed by adoption of technology and internet in healthcare. There has also been a lag in regulatory focus when it comes to this industry. For instance, the Health Ministry has been in the process of regulating e-pharmacies for over two years now without much progress.

On the data privacy front, the data protection laws which address issues pertaining to collection and processing of personal data is being notified and are being reconsidered and discussed at the parliamentary level. While the pandemic has delayed the passage of a comprehensive data protection law which was expected to provide more information and greater control to Indians over how their data may be used, the passage of the TPG combined with the increased enthusiasm of the government in streamlining the storage and processing of health data, India appears to be at the cusp of the digital health revolution. For some applications of telemedicine, more rigorous evaluations will support claims about their value and will encourage their more widespread use.

Given the purpose of introduction of Telemedicine in our country, greater access to healthcare for remote areas and patients is a step in the right direction and the burden on the local and tertiary hospitals will be distributed. The potential in the health care delivery mechanism is on the rise and continues to attract foreign investments. With the restructuring of the digital health care delivery system in India, Telemedicine may be the next intervention.

# **Annexure A**

## **List of Medicines**

#### List O

#### Common over – the counter Medications such as

- Antipyretics: Paracetamol
- Cough Supplements: Lozenges
- Cough/ Common-cold medications (such as combinations of Acetylcysteine, Ammonium Chloride, Guaifensen, Ambroxol, Bromhexene, Dextromethorphan)
- ORS Packets
- Syrup Zinc
- Supplements: Iron & Folic Acid tablets, Vitamin D, Calcium supplements
- Etc
- Medications notified by Government of India in case from time to time an Emergency bases
  - Such as Chloroquine for Malaria control for a specific endemic region, when notified by Government

#### List A

- First Consult Medications (Diagnosis done on video mode of consultation) such as
  - Ointment/Lotion for skin ailments: Ointments Clotrimazole, Mupricin, Calamine Lotion, Benzyl Benzonate Lotion etc.
  - Local Opthalmological drops such as: Ciproflaxacilin for Conjunctivitis, etc
  - Local Ear Drops such as: Clotrimazole ear drops, drops for ear wax etc
  - Follow-up consults for above medications
- Follow-up medications for chronic illnesses for 're-fill' (on any mode of consultation) such as medications for
  - Hypertension: Enalapril, Atenolol etc
  - Diabetes: Metformin, Glibenclamide etc
  - Asthma: Salmetrol inhaler etc
  - Etc

#### List **B**

- On follow-up, medications prescribed as 'Add-on' to ongoing chronic medications to optimize management such as for hypertension: Eg, add-on of Thiazide diuretic with Atenolol
  - Diabetes: Addition of sitaglipin to Metformin
  - = Etc

# **Annexure B**

# Sample Prescription Format

REGISTRATION NUMBER ADDRESS CONTACT DETAILS (EMAIL AN	ND PHONE NUMBER)
Date Of Consultation	Age Gender Height Heigh
CHEF COMPLAINTS	DIAGNOSIS OR PROVISIONAL DIAGNOSIS
EXAMINATION / LAB FINDINGS	<ul> <li>NAME OF MEDICINE (in capital letters only withgeneric name) drug form, strength, frequency of administration &amp; duration</li> <li>NAME OF MEDICINE (in capital letters only withgeneric name) drug form, strength, frequency of administration &amp; duration.</li> </ul>
SUGGESTED INVESTIGATIONS	<ol> <li>NAME OF MEDICINE (in capital letters only withgeneric name) drug form, strength, frequency of administration &amp; duration.</li> </ol>

# **About NDA**

At Nishith Desai Associates, we have earned the reputation of being Asia's most Innovative Law Firm — and the go-to specialists for companies around the world, looking to conduct businesses in India and for Indian companies considering business expansion abroad. In fact, we have conceptualized and created a state-of-the-art Blue Sky Thinking and Research Campus, Imaginarium Aligunjan, an international institution dedicated to designing a premeditated future with an embedded strategic foresight capability.

We are a research and strategy driven international firm with offices in Mumbai, Palo Alto (Silicon Valley), Bengaluru, Singapore, New Delhi, Munich, and New York. Our team comprises of specialists who provide strategic advice on legal, regulatory, and tax related matters in an integrated manner basis key insights carefully culled from the allied industries.

As an active participant in shaping India's regulatory environment, we at NDA, have the expertise and more importantly — the VISION — to navigate its complexities. Our ongoing endeavors in conducting and facilitating original research in emerging areas of law has helped us develop unparalleled proficiency to anticipate legal obstacles, mitigate potential risks and identify new opportunities for our clients on a global scale. Simply put, for conglomerates looking to conduct business in the subcontinent, NDA takes the uncertainty out of new frontiers.

As a firm of doyens, we pride ourselves in working with select clients within select verticals on complex matters. Our forte lies in providing innovative and strategic advice in futuristic areas of law such as those relating to Blockchain and virtual currencies, Internet of Things (IOT), Aviation, Artificial Intelligence, Privatization of Outer Space, Drones, Robotics, Virtual Reality, Ed-Tech, Med-Tech and Medical Devices and Nanotechnology with our key clientele comprising of marquee Fortune 500 corporations.

The firm has been consistently ranked as one of the Most Innovative Law Firms, across the globe. In fact, NDA has been the proud recipient of the Financial Times–RSG award 4 times in a row, (2014-2017) as the Most Innovative Indian Law Firm.

We are a trust based, non-hierarchical, democratic organization that leverages research and knowledge to deliver extraordinary value to our clients. Datum, our unique employer proposition has been developed into a global case study, aptly titled 'Management by Trust in a Democratic Enterprise,' published by John Wiley & Sons, USA.

# 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.

Over the years, we have produced some outstanding research papers, reports and articles. Almost on a daily basis, we analyze and offer our perspective on latest legal developments through our "Hotlines". 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 NDA Labs 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 papers and disseminate them through our website. Our ThinkTank discourses on Taxation of eCommerce, Arbitration, and Direct Tax Code have been widely acknowledged.

As we continue to grow through our research-based approach, we now have established an exclusive fouracre, 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 from you about any suggestions you may have on our research publications. Please feel free to contact us at **research@nishithdesai.com**.

## **Recent Research Papers**

Extensive knowledge gained through our original research is a source of our expertise.



June 2024 Opportunities in GIFT City Fund Formation



June 2024 From Capital to Impact: Role of Blended Finance

Legal and Regulatory Framework



April 2024 **Third-Party Funding for Dispute Resolution in India** Exploring Recent Developments and the Legal Landscape



February 2024 Tracking NFTs from Code to Court Legal Considerations and Disputes



December 2023 Prevention of Sexual Harassment at the Workplace (POSH)

India Legal & HR Considerations



December 2023 **The Indian Defence Industry** Redefining Frontiers

For more research papers click here.



#### MUMBAI

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

Tel +912266695000

#### SILICON VALLEY

220 S California Ave., Suite 201 Palo Alto, California 94306, USA

Tel +1 650 325 7100

#### SINGAPORE

Level 24, CapitaGreen 138 Market St Singapore 048 946

Tel +65 6550 9855

#### **NEW YORK**

1185 6th Avenue, Suite 326 New York, NY 10036, USA

Tel +1 212 464 7050

#### MUMBAI BKC

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

Tel +91 22 6159 5000

#### GIFT CITY

408, 4th Floor, Pragya Towers GIFT City, Gandhinagar Gujarat 382 355, India

#### BENGALURU

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

Tel +91 80 6693 5000

#### **NEW DELHI**

13-H, Hansalaya Building, 15 Barakhamba Road, Connaught Place New Delhi 110 001, India

Tel +91 11 4906 5000

**Telemedicine in India** The Future of Medical Practice