Pharma & Healthcare Update

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REGULATORY YEARLY WRAP 2020: DIGITAL HEALTH IN INDIA

INTRODUCTION

Digital health is the inevitable next step in the healthcare space. Since the release of the National Health Policy, 2017 which identified the attainment of universal healthcare through the setting up of a digital health ecosystem, the Government has steadily been releasing policy documents on what India's national health system should look like. This year has seen even more progress in the adoption of digital health technologies due to the COVID-19 pandemic, as people were hesitant to venture outside of their homes.

In this update, we captured the key developments in the digital health space.

GUIDELINES ISSUED TO REGULATE THE PRACTICE OF TELEMEDICINE IN INDIA

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 ("**TPG**") in partnership with the NITI Aayog.[1] The TPG were issued as part of 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 – and is therefore binding on registered medical practitioners.

Subsequently, the parent legislation under which the MCI Code was enacted i.e. the Indian Medical Council Act, 1956 was repealed and the National Medical Commission Act, 2019 ("**NMC Act**") was brought in force as the primary legislation regulating the medical profession in India. Nonetheless, the TPG remains binding on medical practitioners (in accordance with the transitory provisions under the NMC Act) and is deemed to have been issued under the NMC Act until a new set of rules on this subject is issued under the NMC Act.[2]

The TPG provide legal recognition to the practice of telemedicine, enables medical practitioners to practice telemedicine in any part of the country, provides 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 categorize medicines in List O, List A, List B and Prohibited List (based on the risk for drug abuse) and specify which medicines can be prescribed in which situations.

The release of the TPG was expedited in light of the COVID-19 pandemic as both patients and medical practitioners were unwilling to enter hospitals and clinics unless absolutely required to do so. The TPG provides much needed clarity and guidance on how to provide medical advice remotely and was welcomed by medical practitioners nationwide.

INDIAN GOVERNMENT ANNOUNCES THE LAUNCH OF THE NATIONAL DIGITAL HEALTH MISSION

On August 15, 2020, the Indian Government announced the launch of the National Digital Health Mission ("**NDHM**") – a major digital health initiative which aims to digitize India's healthcare ecosystem and provide a Health ID to every person in the country. Pursuant to this Ministry of Health and Family Welfare has also recently finalized the Health Data Management Policy ("**HDM Policy**") under the NDHM for comments from the public.[3]

The HDM Policy provides the framework for the creation of three separate Health IDs for patients (Health ID), medical practitioners (Health Practitioner ID) and clinical establishments (Health Facility ID). Each ID comes with its sets of data access rights and privileges. The HDM Policy also gives the patient complete ownership over the health data and lays down a framework for how this data may be utilized.

Once fully operational, the NDHM will link all patient data with a single Health ID making it easier for both patients and healthcare practitioners to access their medical history when making clinical decisions. The data may also be utilized in an anonymized form to better understand trends in public health and assist the government in making data-driven policy decisions in the healthcare space.

The HDM Policy, while a welcome step on part of the Government does not provide sufficient guidance on some essential privacy-related areas such as government access to the data, maintaining logs of access (so that patients are aware if any entity has unauthorized access to the data) or how health data may be accessed in emergency situations if the patient is unconscious and family members cannot be reached.

CONCLUSION

The release of the TPG is a watershed moment for the practice of telemedicine in India while the HDM Policy is significant in being the first major policy document dealing with health data privacy and security.

One of the biggest obstacles to the adoption of digital health tools (such as artificial intelligence or cloud storage) is the lack of specific regulation for these technologies, and the TPG and HDM Policy are significant steps in

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addressing these regulatory gaps. It also appears that these are only the first of many steps the Indian Government plans to take to make digital health a reality in India.

For 2021, one thing is clear – the future is digital.

– Shreya Shenolikar, Darren Punnen & Dr.Milind Antani
You can direct your queries or comments to the authors

[1] TPG, available at: https://www.mohfw.gov.in/pdf/Telemedicine.pdf
[2] Section 62 of the NMC Act.
[3] HDM Policy, available at: https://ndhm.gov.in/assets/uploads/NDHM%20Health%20Data%20anagement%20Policy.pdf

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