

Pharma & Healthcare Update

December 28, 2021

REGULATORY YEARLY WRAP 2021: DIGITAL HEALTH IN INDIA

INTRODUCTION

India has been gearing towards digital health since the launch of the flagship programme Digital India Campaign in 2015. The National Health Policy, 2017 identified the attainment of universal healthcare through the creation of a digital health ecosystem. In pursuance of this, the Government has steadily been releasing policy documents for a prospective nationwide digital health system. This year has seen even more progress with the announcement of pan-India implementation of National Digital Health Mission, which was originally launched in 2020.

In this update we have discussed the major developments in digital health in India in 2021. For understanding the various developments across the pharmaceutical and healthcare industry, refer to our updates on pharma, medical devices and healthcare respectively.

AYUSHMAN BHARAT DIGITAL MISSION LAUNCHED

The National Digital Health Mission ("NDHM") was introduced in August 2020 as a pilot initiative in six union territories. In implementation of the digital health ecosystem envisaged under the National Health Policy, 2017, NDHM aims at developing a unified digital health infrastructure based upon the establishment of three components – creation of Unique Health IDs for patients, Healthcare Professionals Registry, and Health Facility Registry. A year after its implementation, it has been renamed as Ayushman Bharat Digital Mission ("ABDM") and is now applicable nationwide.¹ The National Health Authority ("NHA") is the apex body responsible for the implementation of the ABDM. Effectively, all policies and guidelines issued under the NDHM is deemed to be under the ABDM and is applicable pan India.

Once the ABDM is fully functional, a Health ID will be issued to every citizen which will enable portability and interoperability of health data across the patient, practitioner and hospital levels. The creation of a unified health id enables the access to health data and medical records of any individual on one platform with greater opportunity to exchange all relevant data which enables portability of the same with ease.

In order to incentivise participation, the ABDM Sandbox² has also been devised. Enrolment in the ABDM Sandbox enables participating entities to test the product without a large-scale roll out and allows for experimentation of products on a wider range of consumers. However, it must be noted that this is not a legal waiver and the entity will continue to be liable to consumers for any violation of applicable regulations. Further, the Guidelines for Health Information Providers, Health Repository Providers, Health Information Users and Health Lockers³ has been issued to provide clarity to participating entities regarding their responsibilities.

Previously, the Health Data Management Policy ("HDM Policy")⁴ was introduced for secure storage and access of medical records under this digitised system. The HDM Policy lays down the framework for security by design for the digital health ecosystem under ABDM. As per the HDM, three separate Health IDs-for patients (Health ID), medical practitioners (Health Practitioner ID) and clinical establishments (Health Facility ID) will be created. 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 functional, the ABDM 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 is applicable to entities participating in the ABDM. It provides the framework for management of digital health data privacy of patients, registered healthcare professionals, and other participating entities under the ABDM.

With the announcement of ABDM, the existing policies and guidelines issued under the NDHM including the HDM Policy, Sandbox Guidelines and Guidelines for Health Information Providers, Health Repository Providers, Health Information Users and Health Lockers will be now be applicable pan India.

AYUSHMAN BHARAT DIGITAL MISSION - UHI INTERFACE CONSULTATION PAPER RELEASED

In July 2021, the NHA released a Consultation Paper on Unified Health Interface⁵ ("UHI") to invite comments on the design and functionality of the system under the NDHM. The consultation paper envisions an open network UHI system which will standardize the technology pathways of digital health services to create an efficient digital framework for patients and health service providers. It outlines the proposed design, scope and functions of UHI to provide for the interoperability of health services across the country.

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NDHM will manage the UHI Gateway which will enable all participating entities of the NDHM to connect and communicate using standard protocols. Through UHI, health service providers including hospitals, healthcare professionals, pharmacies, and patients will be able to connect for bookings, consultation, e-prescriptions (among others). The UHI Gateway will also facilitate the secure transfer of medical records. Some key services which the UHI seeks to automate include:

- Booking OPD appointments at hospitals / clinics
- Booking Tele-Consultation
- Discovering availability of critical care beds
- Discovery of lab and diagnostic services
- Booking of home visits for lab sample collections
- Booking an ambulance
- Discovery of nearby pharmacies⁶

A major aspect of the UHI is to execute a patient-centric healthcare service system. It intends to promote transparent pricing where health service providers such as telemedicine platforms, hospitals, healthcare practitioners etc. will be required to display prices for services including consultations, scans, tests etc. This is intended to help individuals make a more informed decision when availing these services through the online platform. Further, a feature will assist individuals to monitor drug stocks in pharmacies near their location and even place orders for home delivery with pharmacies which provide this facility. Additionally, UHI also intends to bring ambulance service providers under its ambit for quicker emergency response and care. Registered ambulance operators can receive patient requests through this interface.

CONCLUSION

The revamp of the NDHM to ABDM and its implementation pan-India creates new hope and revives the excitement for a digitised health ecosystem. It also holds tremendous potential for better collection and management of health data records of individuals in the country. The prospects of Digital Health ecosystem in India are also amplified by the COVID-19 pandemic. Therefore, the promotion of ABDM and surge in demand for remote health services is likely to construct India as one of the largest consumer markets for Digital Health interventions. While, the implementation of the policy and framework remains to be seen in the coming year, an improved health data management system and multitude of opportunities for the Digital Health industry is anticipated. We are eagerly looking forward to this tremendous growth.

– Varsha Rajesh, Tanya Kukade, Darren Punnen & Dr. Milind Antani

You can direct your queries or comments to the authors

¹ Anuska Jain, Indian Government Braces For A Nationwide Rollout, Medianama, available at: <https://www.medianama.com/2021/09/223-ndhm-roll-out-nationwide/>

² National Digital Health Mission Sandbox Enabling Framework dated August 18, 2020; available at: https://ndhm.gov.in/publications/sandbox_guidelines

³ National Digital Health Mission, Guidelines for Health Information Providers, Health Repository Providers, Health Information Users and Health Lockers, dated August, 2020; available at: https://ndhm.gov.in/publications/policies_regulations/hip_hiu_Policy

⁴ National Digital Health Mission, Health Data Management Policy, available at: https://ndhm.gov.in/publications/policies_regulations/health_data_management_policy

⁵ Consultation Paper on Unified Health Interface, available at: https://ndhm.gov.in/assets/uploads/consultation_papersDocs/UHI_Consultation_Paper.pdf

⁶ Para 3.2, Consultation Paper on Unified Health Interface, available at: https://ndhm.gov.in/assets/uploads/consultation_papersDocs/UHI_Consultation_Paper.pdf

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