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## EDITORIAL

### The Significance of Regulatory Provisions in Achieving Universal Health Coverage (UHC)

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Universal Health Coverage (UHC) means ensuring that all individuals and communities receive the health services they need without suffering financial hardship. Delivery of healthcare services—virtual care, telehealth or telemedicine, and digital health—is enabled through electronic and digital communication technologies.

Achieving this ambitious goal UHC requires more than just funding and infrastructure—it demands strong, transparent, and enforceable regulatory provisions. These play a critical role in shaping quality, equity, efficiency, and accountability in health systems.

On August 11, 2023, India passed the Digital Personal Data Protection Act, 2023 (DPDP Act). This new law governs how personal data is handled in India.

Regulations aim to protect people's privacy while also establishing a framework for data accountability and governance.

#### The following objectives are central to safeguarding people's privacy

- i) Safeguarding Equity and Access,
- ii) Ensuring Quality and Patient Safety,
- iii) Financial Protection and Pricing Controls,
- iv) Regulation of Health Insurance Schemes,
- v) Controlling Commercialization and Overmedicalization,
- vi) Protecting Public Health and Pandemic Preparedness,
- vii) Enabling Health Workforce Regulation &
- viii) Building Trust and Accountability

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## Regulations for Secure Digital Healthcare

### ▪ ***Ayushman Bharat Digital Mission (ABDM)***

- Aims to establish nationwide digital health infrastructure (such as digital IDs, health records) to enhance accessibility and efficiency across the country. Extension of the ABDM aims to create a seamless online platform for all stakeholders in the healthcare industry, including hospitals, insurance companies and citizens, to interact.

### ▪ ***Data Security Council of India (DSCI) Privacy Guide for Healthcare, 2021***

- Identifies Personal Health Data or Information (“PHI”) via multiple channels of data collection and distribution. Aids in visualizing potential scenarios of data breaches and liability under the applicable laws.

### ▪ ***Telemedicine Guidelines, 2024***

- Released by the Ministry of Health and Family Welfare in collaboration with NITI Aayog, it provides a legal framework for remote healthcare services, especially helpful for rural areas. Cues increased the adoption of telemedicine services, thereby broadening the healthcare delivery landscape.

### ▪ ***Digital Personal Data Protection Act, 2023***

- The India Digital Personal Data Protection Act 2023 (DPDPA) is landmark legislation that aims to safeguard the privacy of individuals in the digital age. The Act came into effect on September 1, 2023, and it applies to all organizations that

process personal data about individuals in India.

### ▪ ***Clinical Establishments Act of 2010***

- This mandates all State Governments to create and maintain a digital State Register of Clinical Establishments. This register, following the format and including the details specified by the Central Government, will document all clinical establishments within each state.

### ▪ ***Health Data Management Policy, 2020***

- Introduces a consent framework for the collection, storage, processing and sharing of health data, ensuring users maintain control over their data.

### ▪ ***Consumer Protection Act, 2019 and Consumer Protection (E-commerce) Rules, 2020***

- To regulate the marketing, sale and purchase of goods and services online. It also incorporates requirements and other applicable laws for the sale of goods online. It also distinguishes between the responsibilities of the marketplace, inventory entities and sellers.

### ▪ ***Information Technology Act, 2000***

- Mandates implementation of reasonable security practices for Sensitive Personal Data or Information (“SPDI”) considered under the Information Technology Act or similar standards approved by the Central government.

### ▪ ***The National Medical Commission Act, 2019 & The Indian Medical Council***

- Regulations, 2002 Applicable to digital health applications involving

the delivery of healthcare by a physician to Indian patients.

### **Key Drivers of Digital Healthcare Growth in India**

- **Evolving customer preferences:** Digital health is driving a revolution, making care convenient, accessible, and tailored. It's a tech-powered shift fueled mostly by a younger, tech-savvy generation, and it's here to stay
- **Building strategic partnerships & collaborations:** To become dominant players in the healthcare landscape, Indian digital healthcare companies are forging strategic partnerships. These alliances enable them to offer a more comprehensive suite of services, enhancing their competitiveness and market penetration.
- **Supportive government policy framework:** Supportive policies like ABDM, telemedicine, etc. are paving the way for a booming digital healthcare industry, making efficient, accessible care a reality for all.
- **Data privacy and security – a paramount need:** Healthcare providers who invest in robust data management and systems might see initial bumps in cost, but they'll win big in the long run. Strong security builds trust, and trust fuels adoption. So, get ready for a healthcare revolution built on patient privacy.
- **Compliance consistency for digital healthcare:** India's digital healthcare landscape is characterized by a dynamic and rapidly evolving regulatory environment.

### **Driving Sustainable Growth by Anticipating Evolving Customer Expectations**

- Today's healthcare consumer is digitally savvy, increasingly relying on online platforms to make informed decisions. Growing awareness of digital tools and wearables, a surge in demand for mental health support and personalized wellness solutions, and an emphasis on inclusivity are reshaping the healthcare landscape. The outlook is promising—within India's digital health market, the Digital Fitness & Wellbeing segment is poised to take center stage.

### **Teleconsultation, Telemedicine Evolution**

- India's telemedicine market is on a rapid growth trajectory, projected to expand from USD 830 million in 2022 to USD 5.5 billion by 2025—an impressive annual growth rate of 31%. Telemedicine is not just gaining ground; it's becoming a cornerstone of India's digital healthcare revolution. This surge is fuelled by increased internet penetration, smartphone usage, expanding rural connectivity, and a regulatory push for digital healthcare delivery. Thus, telemedicine has become a scalable and cost-effective solution to bridge healthcare access gaps across the country.

### **Delivering Hybrid Customer Experiences that Blend Physical and Digital Touchpoints**

- Prioritising a high-quality “phygital” healthcare experience for users. This means seamless care, online and offline,

for a truly integrated healthcare journey. Online consumer feedback, particularly patient reviews and ratings, has become a critical factor influencing healthcare decisions. Numerous studies have highlighted the significance of patient reviews in healthcare decision-making.

### **International provisions in healthcare & medical data handling**

Patient data has become one of the most valuable assets—and one of the most vulnerable. With the increasing digitization of health records, cloud-based platforms, telemedicine, and health apps, the safeguarding of sensitive health information has never been more critical.

Two of the most well-known data privacy frameworks—the Health Insurance Portability and Accountability Act (HIPAA) in the United States and the General Data Protection Regulation (GDPR) in the European Union—have set foundational standards for data protection in healthcare.

### **The Importance of Medical Data Privacy**

In an interconnected global system, data privacy compliance extends beyond these regulations.

Medical data, also referred to as protected health information (PHI) or personal health data, includes a wide range of sensitive information such as:

- Medical histories
- Test results and diagnoses
- Prescriptions and treatment plans
- Genetic and biometric data
- Mental health records
- Insurance and billing details

- Unlike general personal data, health data is particularly sensitive because its exposure can lead to serious consequences, including discrimination, identity theft, emotional distress, and financial fraud.
- Moreover, patient trust is central to effective healthcare. A single data breach can damage a healthcare provider's reputation and compromise the patient-provider relationship.

### **HIPAA & GDPR status in India**

- India does not have a direct equivalent of HIPAA, but it is moving towards a comprehensive data protection law with the Digital Personal Data Protection Act, 2023 (DPDP Act). While the DPDP Act is not yet fully operational, it will regulate the processing of digital personal data within India and in some cases, outside India if it involves offering services in India. GDPR, on the other hand, applies to organizations processing data of EU residents, regardless of where the organization is located.