



Institute of Medicine & Law
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National Consultation on
Legal & Regulatory Framework for Telehealth
– Issues in Data Privacy, Security & Confidentiality

Mumbai – September 27, 2020

Institute of Medicine & Law (IML) conducted a National Consultation on Legal & Regulatory Framework for Telehealth, which specifically dealt with issues in Data Privacy, Security & Confidentiality on September 27, 2020. This consultation addressed the specific issues raised in the 5th National Convention on Medicine & Law held on 05th July 2020.

The convention was conducted online and streamed live to viewers, in view of the current pandemic. It was well attended by an extremely distinguished panel comprising of Doctors, Techpreneurs, IT Experts, Patient groups and Legal luminaries.

This deliberation was chaired by **Hon'ble Justice Ravi Tripathi**, Chairman, Gujarat Human Rights Commission, and former member of Law Commission of India. **Mr. R. Sunder Rajan**, CEO of Institute of Medicine & Law moderated the event.

The various suggestions and recommendations of the esteemed panelists that require immediate attention and appropriate action are as follows:

General Recommendations

1. Follow global standards as laid down in the General Data Protection Regulation (GDPR) of the European Union.
2. Evolve concept of privacy in the Indian context.
3. Adopt a win-win approach instead of zero-sum approach.
4. Greater transparency is required in who uses the data, who has access to it, and who is its owner.
5. Address issues relating to third parties in telehealth who are not under the control or jurisdiction of the Government of India. Efforts are required to reduce dependency on non-Indian companies in this domain.
6. Use telehealth to build trust between doctors and patients.
7. Ensure that the use of telehealth becomes simpler and convenient and the legal framework comprehensible for both patients and doctors.
8. Self-discipline is needed.
9. Ensuring continuity in care in the current fragmented healthcare system.
10. Evolve a business model to finance data security as healthcare providers are not willing to pay for the same.
11. All actors involved in physical healthcare delivery as well as telehealth must be made aware and imparted training in data privacy keeping in mind that the Indian society is not very serious about data privacy, not only in digital but even in physical interactions. Socio, economic and cultural aspects of the Indian society must be taken into account.



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Policies / Legal Framework

12. Policy, law, legal framework, and defined mechanism on telehealth is required. A principal legislation, that is overarching and defines the substantive rights and liabilities of stakeholders is the need of the hour. Uncertainty is frightening and taking healthcare providers away from telehealth and they have to be reassured. A few specific areas where legal framework is immediately required are:
 - a. Data privacy
 - b. Data security
 - c. Interoperability of data
 - d. Using transactional data for analytics
 - e. Designs of telehealth platforms
13. Data Privacy Bill needs to be passed by the Parliament at the earliest. Activities in telehealth need to be disciplined and accountable in the intervening period.
14. Current EHR guidelines (2016) are outdated
 - a. Need to be updated
 - b. Need to be implemented properly otherwise healthcare providers get exposed to legal issues
 - c. Clarifications on certain aspects is required, especially on procedures for patients to get access to their own data
 - d. Uniform set of rules for EHR and technology companies is required.
15. Need for
 - a. A central body for verifying and certifying apps and digital platforms engaged in telehealth
 - b. Involving and mandating requirements like self as well as third party audit of the processes, including data security assessment tests
 - c. Standard Contracting / Grievance Redressal Mechanism.
16. More clarity required on
 - a. Consent in telehealth, especially on and about withdrawal of patients consent
 - b. Applicability of telehealth in homecare, e-prescriptions, and insurance
 - c. Contradictions in different laws relating to data storage and data ownership
 - d. Data breach while dispensing medicines on prescriptions
 - e. In cases, where patient is taking consultations from different pathies simultaneously.

Software

17. Privacy should be by default and not by design as mentioned in NDHM document.
18. Software must be designed in such a way that compliances, especially for data-security are built-in.

Protecting Healthcare Providers

19. Protect doctors and other healthcare providers as data is not in their control. They must be entrusted only with patients care. Doctors must be 'data collectors' rather than 'data fiduciary'.



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20. Treat data breach separately from medical errors, negligence, misconduct, and deficiency of service.
21. Address the issue relating to complications faced by doctors due to lack of access to complete medical records resulting in avoidable errors.

Protecting Patients

22. Need for a patient-friendly system, less-confusing to a layman.
23. Address the issue of illiterate patients / language barriers that exist in the country.



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THE ESTEEMED PANELISTS

1. **Dr. Srinivas Vuthoori** – Los Angeles, US
A seasoned healthcare executive / physician / serial entrepreneur with over 20-year history in the US practicing as a hospitalist / internist. He has an extensive career in the healthcare sector with a deep understanding of KPIs / metric requirements for providers, hospital systems and payors.
2. **Dr. Rohan Sequeira** - Founder & CEO, Queira Technologies LLP
Founder of a cloud based electronic health record and telemedicine platform for doctors and patients. He is a visiting Professor in Medicine, Harvard School of Medicine, Boston, and Ex-Hon. Major, United States Army Medical Corps, Battalion Surgeon & Unit in Command.
3. **Dr. Suraj Dhirwani**
A third-generation doctor and a second generation M.D. Homeopath. He is involved with two healthcare IT companies (TechnoMedix & Ekinwise technologies). He has led to many successful projects and EHR related apps, including one for MoHFW, Government of H.P.
4. **Dr. Rajeev Joshi** - Immediate Past President, Indian Association for Medical Informatics
He is a Health Data Interoperability Professional certified by HL7 and SNOMED-CT International; and was Chairman, eCommunication Cell, Indian Medical Association, Pune.
5. **Mr. Mayank Agrawal** – Founder, vCliniq
Founder of a mobile phone-based telemedicine solution for doctors and a technology entrepreneur with over 12 years of experience. He has filed for patents and authored research papers in diverse technologies.
6. **Mr. Sujeet Katiyar**
Entrepreneur and healthcare IT professional with over 20 years of domain expertise in digital healthcare (Telehealth & Telemedicine, mHealth, EHR, Health Information Technology, Healthcare Analytics).
7. **Dr. Ratna Devi**
She is the Chair of the International Alliance of Patient Organisations, a charity based out of UK; founder of Indian Alliance of Patient Groups; and the founder board member of NCD Alliance in India.
8. **Mr. Aniket Rane**
A legal professional with over 12 years' experience as an in-house counsel to different domestic and international corporates. He specialises in legal issues in data protection and data privacy and has many articles published on the subject to his credit.
9. **Dr. Suman Bhattacharya**
A healthcare informatics expert with more than 33 years of experience. His special areas of interest include telehealth, EHR standards, clinical data analytics, and applications of predictive analytics in treatment planning.
10. **Adv. Mahendra Bajpai** – Advocate, Supreme Court
He is Editor Emeritus, Medical Law Cases - For Doctors; and Hon. Director, Institute of Medicine & Law.
11. **Mr. R. Sunder Rajan** – CEO, Institute of Medicine & Law
A seasoned professional with vast experience in legal, technology, publishing and healthcare.