

REGULATORY ESSENTIALS FOR E-HEALTH IN INDIA BY DR. MILIND ANTANI @MILINDANTANI



A doctor should not give any advice over electronic media that would ordinarily require the physical examination of the patient.

- » The Supreme Court has noted that prescriptions should generally not be given out without actual examination.
- » It has also stated that prescriptions should not be given over the telephone, except in case of emergency.

Ensure that your doctors/healthcare service providers are duly registered with the relevant state medical councils.

- » Keep in mind that certain states require the doctor to be registered in the relevant state where the advice is being provided/patient is situated.

Obtain informed consent from the patient before providing advice over telemedicine. Consent should have declarations that patient:

- » has attained the legal age of majority;
- » is voluntarily providing personal and medical information;
- » has read the privacy policy, terms of use and other documentation;
- » consents to the provider intimating public authorities about results and findings during the course of services, if required by law;
- » understands the inherent risks related to the provision of telemedicine and other related services;
- » is aware that s/he may withdraw consent at any time; and
- » can inspect and modify personal information provided at any time.

Make sure that the patient has read about the inherent limitations of telemedicine that arise due to absence of physical contact between the doctor and the patient.

- » Ensure that the patient is aware that the issuance of a prescription is not guaranteed.

Make it clear to the patient that telemedicine services are not for emergencies.

- » Build in disclaimers that state that telemedicine services should not be used in case of an emergency.
- » However, in case of one, please do not shy away from providing whatever assistance that you can.

Ensure that no one other than the doctor is privy to the consultation, as it may result in breach of the patient's privacy. Have a privacy policy in place. It should lay down:

- » whose personal information is being collected;
- » for what purpose;
- » until when; and
- » whether it will be disclosed/transferred to a third party or not.

Have a terms of use of service in place and clearly identify:

- » limitation of liability;
- » indemnity; and
- » the jurisdiction of courts.

Bear in mind that e-prescriptions require digital signature of the doctor.

- » A prescription carrying a picture of the doctor's signature may not be a valid prescription.
- » A scanned copy of a physical prescription may also not be considered valid.

Maintain records of the consultation to the extent possible.

- » The period of limitation for civil cases is 3 years. Maintaining records for this period at the minimum would help mitigate risk.
- » The government is contemplating making it mandatory to maintain records of OPD patients.

Always request patients to share contact information of a person who may be reached in case of an emergency during consultation. There are inherent limitations of operating a platform model versus a service model.

- » In the platform model, the service provider cannot monitor quality beyond a point, else it will lose the status of a platform provider.
- » In the service model, the quality can be monitored to a great extent.

However, there is a risk of litigation against the service provider for any deficiency in service rendered by the doctor.

Documentation is key! Make sure you have all the required documents in place to mitigate risk.

- » Proper documentation will help in clearly demarcating roles and responsibilities, which becomes essential in ascertaining liability.

What are the changes you envisage in the legal framework governing Telemedicine services in india?

Dr. Milind Antani: I would consider e-Health more relevant than Telemedicine as e-Health has broader scope of activities. India has been witnessing significant upward surge in e-Health recently. However, regulations have not evolved completely or not matching the pace.

However I am envisaging the following changes/new laws in near future

- Electronic Healthcare Data Privacy legislation
- E-Prescription guideline/ amendment to allow e-prescription
- Amendment to allow e-Pharmacy
- Telemedicine Act (may not happen in near future but required)
- Amendment in MCI Code to allow Audio Video consultation for doctors
- Central license by MCI to practice in every state of India