

TELEMEDICINE: A GLOBAL APPROACH TO TRENDS AND PRACTICES
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LAWS AND REGULATIONS ON TELEMEDICINE
1. Is telemedicine allowed in your country? If so, how is it defined?
Telehealth is not regulated by any specific legislation at this point in time. However, the Telemedicine Act 1997, which, although not enforced, provides a suggested definition that telemedicine encompasses any method of practising medicine using audio, visual and data communications.
2. Please provide a high-level overview of the legal framework regarding telemedicine in your country.
<p>The practice of medicine in Malaysia is regulated by the Medical Act 1971, as well as the Malaysian Medical Council's Code of Professional Conduct. There is also the Telemedicine Act 1997, which was promulgated in 1977, but has not come into force.</p> <p>While the Telemedicine Act 1997 has not yet come into force, the Malaysian Medical Council (MMC) has advised that doctors can only have virtual consultation with persons who are already their patients, which is seen as a continuation of care.</p> <p>Furthermore, digital healthcare products or medical devices are governed primarily by the Malaysian Medical Device Act, 2012. Under this legislation, the definition of a 'medical device' is very wide, and therefore, electronic equipment that can be used to diagnose patients in telemedicine could also fall within the ambit of the Malaysian Medical Device Act.</p>
3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities.
The MMC is the main body responsible for regulating medical services and medical practitioners, and lays down general guidelines and regulations to be followed in practice.
4. Was telemedicine authorised during the Covid-19 pandemic?
<p>During the Covid-19 pandemic, the MMC issued an Advisory on Virtual Consultations, which was expressed as being applicable only during the Covid-19 pandemic.</p> <p>Telephone communications were also utilised to check in and follow up with Covid-19 patients who self-reported to government agencies to determine which patients should be admitted to hospital for further care.</p> <p>The Telemedicine Act 1997 was not enforced during and after the Covid-19 pandemic; however, multiple private hospitals and healthcare providers have embraced telemedicine by providing prescriptions online. However, the available legislation, such as the Medical Act 1971, does not make clear provisions for telemedicine, and accompanying regulations, such as the Code of Professional Conduct, also state that a physical examination is ethically mandatory, which increases the difficulty of implementing telemedicine in Malaysia.</p>
5. Is there any possibility of the regulatory landscape being changed in the post-pandemic scenario or has there already been a change in regulation in the post-pandemic scenario?
The pandemic has revealed that the Telemedicine Act 1997 needs to be updated and

<p>refreshed in order to effectively regulate telemedicine in Malaysia.</p> <p>The increase in popularity of telemedicine has caused the emergence of ancillary legal issues that relate to the governance and accountability of digital platforms, such as the prescription of certain medicines and the promotion of medical services.</p>
6. What types of teleservices are allowed (eg, second opinion, teleconsultation, tediagnosis and telesurgery)?
<p>Currently, telemedicine in Malaysia is largely limited to follow-up treatments and for the simple prescription of medicine that can be completed without a physical examination. However, the public healthcare system has not embraced telemedicine and continues to operate in a purely physical setting.</p>
7. Who can use telemedicine services? Please indicate whether only doctor-doctor or also patient-doctor remote medical services are allowed.
<p>Patient-doctor remote medical services have been on the rise in Malaysia in the private sector, which expanded quickly during the Covid-19 pandemic. However, neither patient-doctor or doctor-doctor remote medical services are expressly regulated by any particular legislation or regulation at this time.</p>
8. Please outline the funding model for telemedicine. Is it available in your jurisdiction's public health system? Is telemedicine under mandatory insurance coverage? Please indicate what legislation applies.
<p>Telemedicine is not generally available in the Malaysian public health system at this time.</p>
9. Please indicate whether any insurance requirements are applicable to telemedicine service providers.
<p>There are no mandatory insurance requirements imposed on telemedicine service providers at this time.</p>
REQUIREMENTS APPLICABLE TO HEALTHCARE PROFESSIONALS AND INSTITUTIONS
10. Who can practise telemedicine in your country? Please indicate whether other healthcare professionals are authorised to provide remote health services under the applicable rules (eg, nurses, psychologists, nutritionists and alternative health therapy providers).
<p>As there is no specific law in force to regulate telemedicine, there is no definitive regulation on this matter. However, the unenforced Telemedicine Act suggests that registered and accredited doctors and nurses are able to provide remote health services.</p>
11. Are there any specific education requirements or training that healthcare professionals need to meet or attend to provide telemedicine services?
<p>Healthcare professionals should be fully registered medical practitioners holding a valid practising certificate. Foreign doctors must hold a certificate to practise telemedicine issued by the MMC or practise telemedicine through a fully registered medical practitioner with a valid practising certificate.</p>
12. Is there any registration requirement applicable to physicians that provide telemedicine services?
<p>There is no specific requirement for registration at this time.</p>
13. Please indicate whether special licenses or authorisations are mandatory for institutional healthcare providers engaged in telemedicine services.
<p>No. Other than the requirement that healthcare professionals should be fully registered</p>

<p>medical practitioners with a valid practising certificate, there are currently no special licenses or authorisation required for healthcare providers engaged in telemedicine services.</p>
<p>REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES</p>
<p>14. Are there specific requirements applicable to the telemedicine platform?</p>
<p>There are no specific requirements in place to regulate telemedicine platforms in Malaysia. However, where the provider of the telemedicine service is a body corporate which is governed under the Personal Data Protection Act 2010 (the 'PDPA'), they must ensure that the platform is built securely in such a way to ensure adequate protection of patient's personal data as required under the PDPA.</p>
<p>15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?</p>
<p>There are no hard requirements in place to regulate the standard of equipment at this time.</p>
<p>16. Does legislation provide for specific rules concerning patients' medical records?</p>
<p>Generally, patients' medical records are governed by the Good Medical Guidelines 2019 and the first principle in the Confidentiality Guidelines published by the MMC, which states that: 'Patients have the right to expect that there will be no disclosure of any personal information, which is obtained during the course of a practitioner's professional duties, unless they give consent'.</p> <p>Furthermore, personal data in Malaysia is also subject to the PDPA, which regulates data use and data sharing in Malaysia.</p>
<p>17. Are there geographic location requirements applicable to the provision of telemedicine services?</p>
<p>There are no specific requirements in terms of geographic locations at this time.</p>
<p>18. Does the healthcare professional need to obtain the patient's consent to engage in telehealth?</p>
<p>The Good Medical Guidelines 2019 outline that a patient has a right to choice of care, adequate information and consent. Therefore, it can be inferred that a patient's consent is necessary to engage in telehealth.</p>
<p>19. Is there any other important requirement that should be highlighted?</p>
<p>While there is no single act regulating telehealth or telemedicine in Malaysia, care should be taken to ensure that one is in compliance with legislation and accompanying regulations such as the Medical Act 1971, Dental Act 1971, Sale of Drugs Act 1952 and Medical Device Act 2012, as well as the Private Healthcare Facilities and Services Act 1998 Act 1988.</p>
<p>DATA PRIVACY ASPECTS</p>
<p>20. Are there data privacy issues that should be considered for the exploitation of such a market? If your answer is yes, please provide a short description.</p>
<p>Yes. When personal data is collected for the purpose of exploiting a market, the provisions of the PDPA would apply if the data collected can be used to identify the connected individual in some shape or form. Therefore, it is important to ensure that the data collected is anonymised and ensure de-identification of individuals to remove the data collected from the purview of the PDPA.</p>

<p>Where this is not possible, extra care must be taken to ensure that the data is handled, stored and treated in compliance with the requirements imposed by the PDPA.</p>
21. Does the applicable regulation provide for criteria and requirements for security systems to protect the patient's information?
<p>The PDPA requires data users to take practical steps to protect personal data, and to develop and implement security policies to ensure that the patient's personal data is protected.</p>
22. Does the applicable regulation provide for requirements for the transfer of information abroad?
<p>The PDPA allows for personal data to be transferred outside Malaysia, given that the data user has taken all reasonable precautions and has exercised all due diligence to ensure that the personal data will not be processed in a manner that would be in contravention of the PDPA outside Malaysia.</p>
23. Is there any registration of databases requirement that companies must observe? Are there requirements regarding the recording of data in the patient's medical records?
<p>There is no requirement for companies to register themselves in a database in order to practise telehealth at this time.</p>
LIABILITIES
24. Please provide a high-level overview of the liability of healthcare professionals and institutions involved in telemedicine practices.
<p>Prior to the advent of telemedicine, liability in patient care would be determined in civil suits premised on medical negligence, with healthcare practitioners, healthcare providers and their employees as the primary defendants.</p> <p>The influx of new technology such as data analytics, artificial intelligence (AI) and machine learning, may impose liability on various parties, in addition to those mentioned above, although the determination of liability is likely to be heavily dependent on the cause of the injury suffered, reasonableness of the conduct and use of medical devices, and the sufficiency of training given in the use of such technology.</p> <p>However, exposure to liability in this context has yet to be tested in the Malaysian courts.</p>
TELEMEDICINE NUMBERS AND TRENDS
25. Is there any public disclosed information concerning the use and acceptance of telemedicine in your country?
<p>The Economic Planning Unit of the Prime Minister's Department in Malaysia published the Malaysia Digital Economy Blueprint, which sets out a national initiative to develop a framework for the rapid-growth adoption of technology for healthcare-related products and the acceleration of usage of the Malaysia Health Data Warehouse, with the inclusion of blockchain.</p> <p>Private healthcare providers in Malaysia have expanded and grown greatly with telemedicine, especially during the Covid-19 pandemic, with several new telemedicine providers entering the scene.</p>
26. What are the perspectives and trends in relation to the matter for the next few years? Please outline any unresolved issues, proposed changes or trends for the

telemedicine sector and briefly indicate how these may foreseeably affect medical practice in the near future.

The most important trends expected for the Malaysian market are:

- the rapid growth and specialisation of the telemedicine market;
- AI and predictive healthcare is expected to grow in the near future, with an increase in wearable devices with tracking functions; and
- increase in the use of telemedicine in the private and public sector for simple matters or for follow-up treatments.