

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?

Yes, telemedicine is allowed in Singapore.

As telemedicine is currently not yet regulated under any legislation (please refer to our response under item 2 for upcoming changes to the legal framework in Singapore affecting telemedicine), there is no statutory definition for it. However, pursuant to the Ministry of Health's (MOH's) 2015 National Telemedicine Guidelines (NTG) (which are non-legally binding guidelines), the term 'telemedicine' refers to the systematic provision of healthcare services over physically separate environments via information and communications technology (ICT), and distinguishes between four main dimensions/domains of telemedicine as follows:

Tele-collaboration

This refers to interactions between (facility-based or mobile) on-site and remote healthcare professionals for clinical purposes, for example, referral, co-diagnosis, supervision or case review. The distinguishing feature is that healthcare professionals are involved at both ends of the interaction and a patient may or may not be involved in the same telemedicine interaction, for example, radiologist-clinician, as well as consultant-junior-with patient situations. Tele-collaboration is used in many forms of remote specialty consultations, for example, tele-radiology and tele-pathology in current practice.

Tele-treatment

This refers to interactions between remote healthcare professionals and patients/caregivers for the purposes of direct clinical care, for example, triage, history, examination, diagnosis and treatment including robotic surgery from a remote location. The distinguishing feature is that a patient or caregiver is involved directly at one end of the interaction and this creates (or presupposes the existence of) a professional-patient relationship. Tele-treatment is used in the remote delivery of primary care and many forms of specialty care, for example, tele-geriatrics, tele-psychiatry, tele-neurology and tele-dermatology.

Tele-monitoring

This refers to biomedical and other forms of data collection directly from patients (or through caregivers) by remote systems, which are used by healthcare professionals for clinical purposes, such as vital sign monitoring and home nursing. Tele-monitoring is used in remote chronic disease management, for example, management of hypertension (blood pressure), diabetes (blood glucose) and coronary heart disease (weight and electrocardiogram (ECG)). The distinguishing feature is that a healthcare professional or organisation is engaged at one end, that is, it excludes self-monitoring, where the patient or the caregiver collects health data but does not have a healthcare provider involved at the other end as part of an organised arrangement. Another feature of tele-monitoring is that it need not create (or presuppose the

existence of) a professional-patient relationship, even though the healthcare organisation as a whole might owe a duty of care to the patient.

Tele-support

This refers to the use of online services for non-clinical (ie, educational and administrative) purposes to support the patient and caregiver. Examples include health education, care administration and the use of treatment prompts in chronic disease management. Tele-support is generally not addressed in these guidelines, which focuses on key activities that are (or ought to be) regulated for patient safety reasons, that is, that fall within scope of the first three domains.

2. Please provide a high-level overview of the legal framework regarding telemedicine in your country.

There is currently no legislation under which telemedicine in Singapore is regulated. However, the new Healthcare Services Act 2020 of Singapore (the 'HCSA') is gradually being implemented in Singapore, the regulatory scope of which includes that of telemedicine. Please refer to the following for more detail:

Currently, telemedicine services are not licensable per se under the Private Hospitals and Medical Clinics Act 1980 (the 'PHMCA'), which adopts a premises-based regulatory framework, and all registered medical practitioners may provide telemedicine services. However, telemedicine services are regulated under the NTG, as well as the Singapore Medical Council's (SMC's) Ethical Code and 2016 Handbook on Medical Ethics. The NTG provides guidance to healthcare providers on clinical standards and outcomes, human resources, organisational issues, and technology and equipment. The SMC Ethical Code, to which all registered medical practitioners are required to adhere, sets out how such services are to be provided responsibly. For instance, it provides that doctors engaging in telemedicine must endeavour to provide the same quality and standard of care as in-person medical care; otherwise, they must state the limitations of their opinion.

Although private hospitals and medical clinics were previously regulated under the PHMCA, the PHMCA has been gradually replaced by the HCSA. The HCSA adopts a services-based regulatory framework in contrast to the premises-based regulatory framework under the PHMCA, and also has a broader regulatory scope, which includes non-premises-based services (eg, telemedicine).

The phased implementation of the HCSA has commenced. Phase 1 of the implementation, which encompasses clinical support services (with the exception of human tissue banking services, nuclear medicine services and preventive health services), commenced on 3 January 2022. Phases 2 and 3 of the implementation, which encompass inpatient, outpatient and the remaining clinical support services, will commence in June and the end of 2023, respectively.

The MOH has also announced proposed amendments to the HCSA that will make the following licensable: specified services and non-premises-based modes of service delivery (eg, virtual medical consultations and home medical care). These amendments are expected to be effective in June 2023.

In relation to the scope of telemedicine that will be covered under the HCSA, it should be noted that, although there are several forms of telemedicine (eg, tele-collaboration and tele-support), under the HCSA, the MOH will be adopting a risk-based regulatory approach to healthcare services and will focus on licensing direct doctor and/or dentist-led teleconsultations, that is, the assessment of health, diagnosis, treatment, intervention or care where the service is provided exclusively over a distance through the use of ICT by a medical practitioner or dentist. At the time of writing, the MOH will not be licensing indirect telemedicine providers, that is, those who do not provide direct medical care, and only offer technology support for telemedicine, such as platforms offering software-as-a-service for teleconsultation, directory listings and payment solutions.

3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities.

The MOH is the main licensing body for and oversees the regulation of healthcare in Singapore. There are various statutory boards established under the oversight of the MOH, including the Health Sciences Authority (HSA) (established by the Health Sciences Authority Act 2001 of Singapore) and the Health Promotion Board (established by the Health Promotion Board Act 2001 of Singapore).

The HSA was formed on 1 April 2001 and integrated five highly specialised agencies, namely the Centre for Drug Evaluation, Institute of Science and Forensic Medicine, National Pharmaceutical Administration, Product Regulation Department and Singapore Blood Transfusion Service. The HSA has been designated as the authority responsible for the administration of Singapore's health laws and regulations, such as the Health Products Act 2007, Medicines Act 1975, Tobacco (Control of Advertisements and Sale) Act 1993 and Poisons Act 1938.

The SMC, a statutory board under the MOH, is responsible for the regulation of the conduct of medical practitioners in Singapore.

4. Was telemedicine authorised during the Covid-19 pandemic?

No, telemedicine was not authorised only during the Covid-19 pandemic. Prior to the Covid-19 pandemic, video consultations and telemedicine pilots had already begun at six public health institutions as early as 2017. Video consultations, however, rose throughout 2020 amid the Covid-19 pandemic – only 1,947 patients had used the service between 2017 and the start of 2020, but by January 2021, 36,000 patients had sought medical help via video consultations.

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?
Please refer to our response under item 2. The gradual implementation of the HCSA is already underway.
6. What types of teleservices are allowed (eg, second opinion, teleconsultation, telediagnosis and telesurgery)?
The four main dimensions/domains of telemedicine expounded on above in our response under item 1 are allowed: tele-collaboration, tele-treatment, tele-monitoring and tele-support.
7. Who can use telemedicine services? Please indicate whether only doctor-doctor or also patient-doctor remote medical services are allowed.
Both doctor-doctor and patient-doctor remote medical services are allowed. Please refer to our response under item 1 above.
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>In relation to telemedicine services, there are some subsidies in Singapore for patients, and small and medium-sized healthcare providers.</p> <p>In October 2020, the MOH announced that patients entitled to the Community Health Assist Scheme (CHAS) will be able to follow-up with their doctors via video consultation on all 20 chronic conditions covered by the subsidy scheme. Eligible patients will also be able to pay for such video consultations using their MediSave (ie, a national medical savings scheme). Prior to this announcement and from April 2020, such video consultation was only allowed for seven conditions to support safe distancing measures imposed to fight Covid-19.</p> <p>Similarly, in May 2020, the Infocomm Media Development Authority of Singapore and Enterprise Singapore expanded the range of pre-approved teleconsultation digital solutions (to include three teleconsultation solutions), and also announced grants and subsidies to encourage small and medium-sized healthcare providers to adopt these solutions.</p> <p>Telemedicine is not under mandatory insurance coverage, and there is currently no legislation in Singapore governing insurance coverage for telemedicine.</p>
9. Please indicate whether any insurance requirements are applicable to telemedicine service providers.
To the best of our knowledge, there are no specific insurance requirements applicable to telemedicine service providers.
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).

Healthcare providers may practise telehealth in Singapore. Healthcare providers include healthcare organisations and professionals, that is, audiologists, clinical psychologists, dietitians, occupational therapists, physiotherapists, podiatrists, prosthetists/orthotists, radiation therapists, radiographers, speech-language therapists and others.

11. Are there any specific education requirements or training that healthcare professionals need to meet or attend to provide telemedicine services?

The NTG stipulates that the following principles are to be considered in relation to the relevant education, training and orientation for healthcare providers involved in telemedicine:

- Healthcare professionals providing telemedicine services should have the necessary education, training/orientation and ongoing professional development needed for the safe provision of quality health services. The formality and degree of training provided should be commensurate with the complexity of the telemedicine service to be provided.
- Healthcare organisations should have in place orientation and structured on-the-job training programmes as required to ensure that staff involved in telemedicine possess the necessary skills and competencies for the safe provision of quality health services. Training records should be properly maintained for audit purposes.
- Organisations providing telemedicine services should link training and job performance evaluation, and encourage feedback on telemedicine training sessions.

The NTG also stipulates that the healthcare professional should be trained in the use of technology and equipment, and if the technical and environmental limitations affect the quality of a telemedicine consultation such that minimum standards cannot be met, an in-person session must be arranged.

Further, for a direct telemedicine service provider to be listed on the MOH's direct telemedicine service providers list, a service provider must complete the MOH's e-training.

12. Is there any registration requirement applicable to physicians that provide telemedicine services?

There are no such registration requirements.

13. Please indicate whether special licenses or authorisations are mandatory for institutional healthcare providers engaged in telemedicine services.

There are currently no such licensing requirements.

However, as mentioned in our response under item 2, direct doctor and/or dentist-led teleconsultations, that is, the assessment of health, diagnosis, treatment, intervention or care

where the service is provided exclusively over a distance through the use of ICT by a medical practitioner or dentist, will be licensed under the HCSA when it is fully implemented.

REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES

14. Are there specific requirements applicable to the telemedicine platform?

Depending on the intended use of the telemedicine platform, a telemedicine platform (eg, a digital health app) may fall under the definition of 'medical devices' under the Health Product Act 2007 (the 'HPA') and the Health Products (Medical Devices) Regulations 2010 (the 'Medical Devices Regulations'), if it is software that is 'intended by its manufacturer to be used, whether alone or in combination, by humans, for one or more of the specific purposes of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment or alleviation of, or compensation for, an injury;
- investigation, replacement, modification or support of the anatomy or of a physiological process, for medical purposes;
- supporting or sustaining life;
- control of conception;
- disinfection of medical devices; or
- providing information by means of in vitro examination of specimens derived from the human body, for medical or diagnostic purposes,

and which does not achieve its primary intended action, in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means'.

The intended use of a telemedicine platform will depend on, and be reflected in, the specifications, instructions and information provided by the product owner of the platform. If the telemedicine platform is intended to be used for investigation, detection, diagnosis, monitoring, treatment or management of any medical condition, disease, anatomy or physiological process such that it will be deemed to fall under the definition of 'medical devices' above, it is likely to be considered a telehealth medical device. Telehealth medical devices will be subject to HSA's regulatory control, and will have to comply with the applicable key regulations in Singapore, including but not limited to, the HSA, Medical Devices Regulations, and NTG and HSA's Regulatory Guidelines for Telehealth Products (April 2019).

Telehealth medical devices may also, where applicable, be subject to the following medical device regulatory controls:

- product registration;
- dealer's licence requirements; and
- post-market obligations.

15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?

Please refer to our response under item 14 in relation to electronic equipment for telemedicine

services.

There are no requirements regarding internet speed for telemedicine services.

16. Does legislation provide for specific rules concerning patients' medical records?

The Personal Data Protection Act 2012 of Singapore (the 'PDPA') and its related subsidiary legislation and guidance will apply to any processing of personal data (which includes patients' medical records, if such records constitute data that, whether true or not, allows an individual to be identified from that data, or from that data and other information to which the organisation has or is likely to have access to).

In particular, the Personal Data Protection Commission (PDPC) has, in collaboration with the MOH, specifically issued Advisory Guidelines for the Healthcare Sector (issued on 11 September 2014 and revised on 28 March 2017), elaborating on: (1) the application of data protection provisions to scenarios faced in the healthcare sector; and (2) application of the do not call provisions to scenarios faced in the healthcare sector.

The NTG has also specified that healthcare organisations must ensure that patient information and records are protected by having a confidentiality policy in place, and that healthcare providers must comply with the applicable existing legislation and regulations (eg, the PDPA, SMC Ethical Code and Ethical Guidelines) to ensure that the patient's healthcare information is protected.

17. Are there geographic location requirements applicable to the provision of telemedicine services?

The NTG stipulates that:

- A licensed healthcare provider in Singapore providing telemedicine services to patients residing in another country or who supervises, directs or collaborates with an overseas healthcare provider to provide telemedicine services to patients residing in Singapore, must adhere to the same standards that they are held to when treating a resident in Singapore.
- A licensed healthcare provider in Singapore intending to provide telemedicine services to patients residing in another country should adhere to and meet licensing requirements imposed by the country that the patient is residing in. Preferably the provision of such telemedicine services should be done in collaboration with a healthcare provider licensed in the patient's country.

18. Does the healthcare professional need to obtain the patient's consent to engage in telehealth?

The NTG states that a patient must be given the freedom to make informed decisions, and it is therefore essential that the patient, as in a traditional face-to-face consultation, be given all the

necessary details regarding his/her care and that informed consent is obtained in accordance with applicable laws and regulations. The NTG further states that the following principles are to be considered:

- Healthcare providers should obtain informed consent (which may be implied or expressed) before starting any service or intervention following principles and processes similar to standard practice for the particular healthcare service.
- Explicit consent should be obtained from the patient for medical acts that would normally require explicit consent in the traditional healthcare setting (eg, video or audio recording of sessions, and use of data for research or educational purposes).
- Healthcare providers should share relevant information with the patient and caregiver, as appropriate, before the beginning of any telemedicine interaction. This information includes informing the patient of the objective of the telemedicine interaction, the role and responsibility of the provider and the patient during the telemedicine interaction, other people participating in the interaction, care documentation requirements, risks and benefits, and that he/she has the choice to decline to participate in the telemedicine interaction.
- Patients and caregivers should be informed of any cost of using telemedicine in their care, including charges for specific services (eg, whether reimbursable through Medisave compared with other claimable alternative modes of care delivery).
- As far as possible, the consent process should be integrated with existing routine care processes.

19. Is there any other important requirement that should be highlighted?

Should medicine delivery be involved, Singapore has launched the first national standard, Singapore Standard 644 ('SS 644') for the supply and delivery of medication to patients. SS 644 provides guidance for healthcare and logistics service providers on the storage, security, traceability and safety of medication during the delivery process, and compliance with legal and professional requirements.

DATA PRIVACY ASPECTS

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.

Apart from our response under item 16, there are no other specific data privacy issues to be considered.

21. Does the applicable regulation provide for criteria and requirements for security systems to protect the patient's information?

Please refer to our response under item 16.

22. Does the applicable regulation provide for requirements for the transfer of information abroad?

Yes. Under the PDPA, if personal data is transferred to a recipient in a country or territory outside Singapore, the recipient shall be bound by legally enforceable obligations to provide a standard of protection to the personal data transferred that is comparable to that under the PDPA.

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?

There is no registration of database requirements that companies must observe.

Regarding the recording of data in the patient's medical records, the PDPA and its related subsidiary legislation and guidance will apply where such data constitutes personal data under the PDPA (ie data that, whether true or not, allows an individual to be identified from that data, or from that data and other information to which the organisation has or is likely to have access). Further, the NTG stipulates that organisations should take ongoing responsibility for their activities and actions, including but not limited to, the documentation and storage of patient records. In this respect, the NTG states that there should be policies and procedures for documentation, storage and retrieval of patient records that respect the confidentiality of the information.

LIABILITIES

24. Please provide a high-level overview of the liability of healthcare professionals and institutions involved in telemedicine practices.

The general standard of care or liability of healthcare professionals and institutions is not limited or affected in the context of the provision of healthcare services via telemedicine practices, and healthcare professionals and institutions are still expected to comply with all of their duties and responsibilities under the various applicable legislation and regulations, including but not limited to the Medical Registration Act 1997 of Singapore, SMC Ethical Code, 2016 Handbook on Medical Ethics, Allied Health Professions Act 2011 and PHMCA.

The NTG indicates that the overall standard of care in the context of telemedicine services must not be less than that provided in conventional services. The NTG also indicates that the healthcare provider must be satisfied that the patient is suitable for a telemedicine interaction and that the standard of care delivered via telemedicine is reasonable, considering the specific context. The healthcare professional should be trained in the use of technology and equipment, and if technical and environmental limitations affect the quality of a telemedicine consultation such that minimum standards cannot be met, an in-person session must be arranged.

Lastly, the standard of care or liability of a healthcare professional and institution will not be

limited or transferred to the producer of a digital health app or platform that is used for or in connection with the provision of healthcare services via telemedicine practices.

TELEMEDICINE NUMBERS AND TRENDS

25. Is there any public disclosed information concerning the use and acceptance of telemedicine in your country?

Please refer to our response under item 4 above.

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.

Given the huge rise in the number of video consultations that occurred over the course of the Covid-19 pandemic (please refer to our response under item 4) and therefore the greater prevalence of healthcare professionals and institutions that offer such telemedicine services, as well as patients' increased reception to such services, we expect to see a steady increase and growth in the area of telemedicine in Singapore.

However, the growth in the number of healthcare professionals and institutions that wish to offer direct doctor and/or dentist-led teleconsultations could be dampened or even reversed by amendments to the HCSA (in particular, the licensing regime regarding such teleconsultations), which will be coming into effect shortly.