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Telemedicine before, during and after COVID-19: Key Considerations and Issues

Introduction

The acceleration in the use of telemedicine is expected to be one of the lasting changes to lifestyles as a result of the COVID-19 pandemic. As defined by the Ministry of Health (Singapore) ("**MOH**"), telemedicine refers to the provision of healthcare services over physically separate environments via information technology, and it includes the exchange of information for clinical purposes between healthcare providers and patients through text messaging, web or mobile applications.

We shall discuss broadly below the regulatory framework in respect of telemedicine in Singapore and highlight some issues that healthcare providers, employers and patients should note in the implementation of telemedicine.

Regulatory Environment

At present, there is no single regulatory framework for telemedicine in Singapore. The regulatory environment for telemedicine includes the following guidelines and regulations set out below.

National Telemedicine Guidelines

The National Telemedicine Guidelines ("**NTG**") were developed with guidance from the National Telemedicine Advisory Committee and issued by the MOH in 2015. Broadly, the NTG sets out best practices that assist healthcare providers in implementing telemedicine solutions, in areas including clinical standards and outcomes, human resources, organisation, technology and equipment. One notable guideline in the NTG is that telemedicine services must be provided as part of a structured system and the overall standard of care must not be less than what is provided in conventional services. The doctor must also 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.

However, do note that the NTG is intended to only be a guide to the industry and has no force of law. It remains to be seen whether the MOH would sanction a healthcare provider or organisation that does not comply with the NTG.

Contribution Note: *This Client Update was written with contributions from Mildred Kwok, Senior Associate, and Serene Chung, Associate.*



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Singapore Medical Council Ethical Code and Ethical Guidelines

Registered doctors providing telemedicine services are required to comply with the Singapore Medical Council's ("**SMC**") Ethical Code and Ethical Guidelines ("**ECEG**"). The ECEG encapsulates the ethical and professional standards expected of medical doctors. In particular, Section A6 of the ECEG sets out the guidelines on the use of telemedicine. One of the requirements under the ECEG is that doctors performing remotely-guided medical procedures must have the necessary expertise to provide the remote guidance. Doctors must also take reasonable care to ensure the confidentiality of medical information shared through technology and ensure compliance with the relevant laws on personal data.

Failure to comply with the ECEG may lead to disciplinary proceedings by the SMC.

Licensing Experimentation and Adaptation Programme

The Licensing Experimentation and Adaptation Programme ("**LEAP**") is a regulatory sandbox initiative launched by the MOH in 2018 to develop innovative medical services and refine them in a safe and controlled environment. Providers participating in the regulatory sandbox will be able to introduce new healthcare models, with early visibility over the eventual regulatory environment. By working alongside providers participating in the sandbox, the MOH can develop more timely, appropriate and effective regulations that support new services. Telemedicine is the first service to come under LEAP. The MOH has been working with providers to ensure a safe telemedicine environment and intends to eventually regulate telemedicine as a licensed healthcare service after successful completion of the regulatory sandbox.

Regulatory Guideline for Telehealth Products

In 2019, the Health Sciences Authority of Singapore ("**HSA**") published a Regulatory Guideline for Telehealth Products which classifies telehealth products that are intended for a medical purpose as medical devices. A "medical purpose" includes the investigation, detection, diagnosis, monitoring, treatment or management of any medical condition, disease, anatomy or physiological process. Such telehealth medical devices are regulated by the HSA under the Health Products Act (Chapter 122D) of Singapore and its subsidiary legislation. For instance, controls in relation to product registration, dealer's licence requirements and post-market obligations which apply to medical devices in general will apply similarly to telehealth medical devices.

IMDA Pre-Approved Digital Solutions

In May 2020, the Infocomm Media Development Authority of Singapore ("**IMDA**") and Enterprise Singapore ("**ESG**") expanded the range of pre-approved digital solutions to assist Small and Medium-sized Enterprises ("**SMEs**") in the healthcare sector to manage the impact of COVID-19. IMDA and ESG worked with the MOH to pre-approve three teleconsultation solutions (offered by Doctor Anywhere, Doctor World and MyDoc) which will enable healthcare providers to deliver their services remotely for greater convenience and safety. All eligible healthcare providers will be able to receive subsidies to

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adopt these digital solutions. The aim is to employ digitalisation as an enabler for healthcare businesses even after COVID-19 and to support them in finding new ways of serving their patients.

New Regulatory Framework under Healthcare Services Act

Currently, the licensing regime for healthcare establishments is the Private Hospitals and Medical Clinics Act (Chapter 248) of Singapore ("**PHMCA**"). The existing regulatory framework is premise-based, without specific licensing requirements for the provision of telemedicine services. However, in recent years, because of the significant changes to the healthcare landscape giving rise to new healthcare services, the MOH intends to replace the PHMCA with the new Healthcare Services Act ("**HCSA**") to update the regulatory framework and requirements. The HCSA is expected to be implemented in phases from 2021 to 2022.

Pursuant to the HCSA, healthcare providers will be licensed based on the type of services they provide, instead of being licensed on the basis of physical premises. Telemedicine is expected to be licensed as a healthcare service under the HCSA. The standards required for each licensable healthcare service will be stipulated in their respective regulations.

Other regulatory regimes

Healthcare providers should note the specific regulations that may be applicable in their respective fields. These include regulations and guidelines relating to health products (regulated by the HSA) and telepharmacy (guidance issued by the Pharmaceutical Society of Singapore as well as the Health Products (Licensing of Retail Pharmacies) Regulations 2016). For example, retail pharmacies in Singapore would need the requisite approval from the HSA if they wish to provide other modes of services at or from their retail pharmacy, including telepharmacy service to dispense pharmacy-only medicine and prescription-only medicine.

Data Protection and Cybersecurity

The convenience and accessibility of telemedicine also brings about increased risks relating to data protection and cybersecurity. Care should be taken by healthcare and telemedicine solution providers to ensure that the collection and storage of personal data of patients is adequately safeguarded and that they are compliant with the Personal Data Protection Act 2012 (No. 26 of 2012) of Singapore. In addition, patients and employers using telemedicine should be aware of the data protection and use policies of telemedicine providers, to ensure that their personal data is adequately safeguarded and not being used for ancillary purposes.

Limitations of Telemedicine

Notwithstanding the benefits of telemedicine in terms of greater convenience and accessibility, we should be cognisant of the limitations of such services. Healthcare providers should consider the

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suitability of telemedicine in various circumstances, as part of the requirement to comply with the ECEG. While telemedicine provides convenience and accessibility to both patients or their caregivers and healthcare providers, issues involving the accurate diagnosis of patients and adequate understanding of the patient's medical history are certain to arise. Healthcare providers should be aware of the limitations of telemedicine, such as the inability to conduct physical examination, and the potential complications and difficulties arising from consultations with less tech-savvy patients.

Conclusion

Even pre-COVID-19, telemedicine had already been gaining traction in Singapore. We expect to see an accelerated development in this field given the current COVID-19 situation. With the implementation by the MOH of a new regulatory framework for telemedicine come 2022, we look forward to more innovative telemedicine solutions and products being developed and refined within a clear regulatory framework, coupled with a greater focus on safeguarding the safety and welfare of patients who utilise such services and products.

Visit our [COVID-19 Resource Centre](#) for views from our lawyers across the region on common issues and legal implications brought about by COVID-19. For specific inquiries, please reach out to your relationship partner or send an email to our [COVID-19 Legal Team](#).

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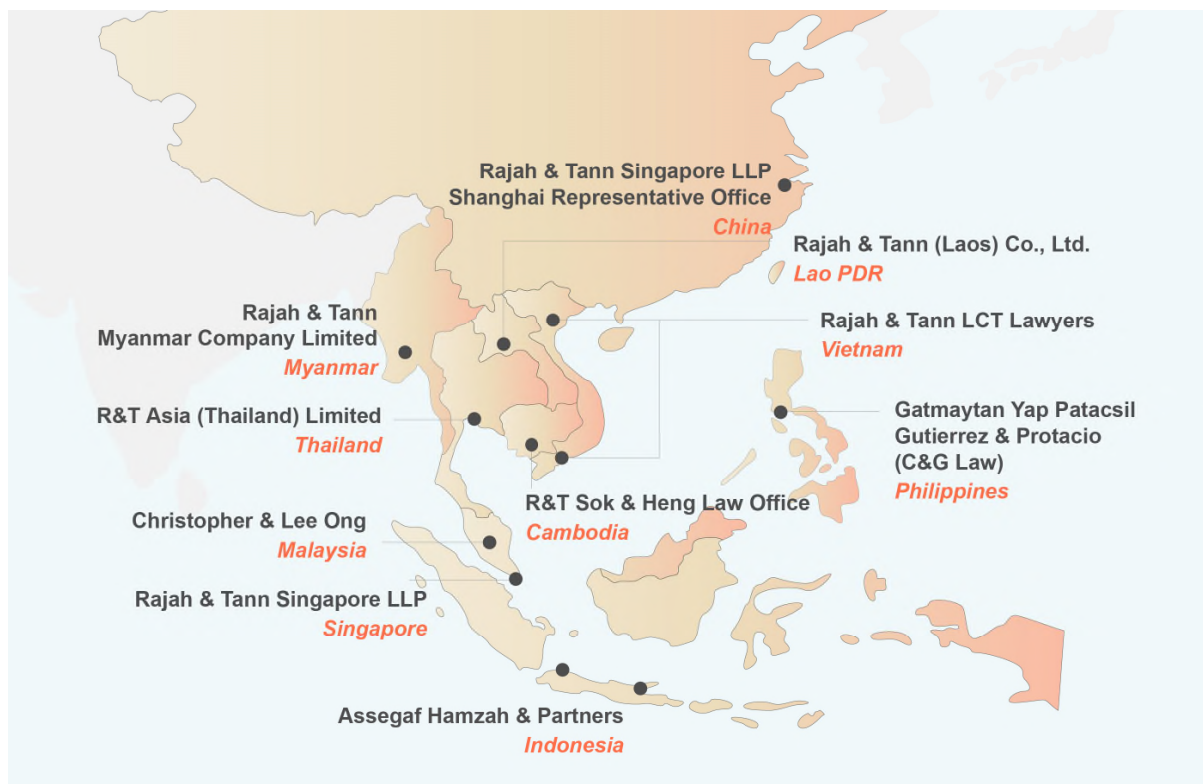
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