ALLEN & GLEDHILL

KNOWLEDGESHARE ALERT

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Dear Clients & Friends

Covid-19 and issues facing the healthcare community: How can telemedicine help?

1. Introduction

The measures prescribed under the Covid-19 (Temporary Measures) (Control Order) Regulations 2020 ("**Control Order Regulations**") which came into effect on 7 April 2020 have curtailed the provision of "non-essential" healthcare services. The Ministry of Health ("**MOH**") has expressed that where possible, services that are suitable for tele-consultation should be delivered remotely. Guidance on the type of healthcare services which are regarded as essential and non-essential services was provided by MOH on 6 April 2020 to licensees of general practitioner clinics and specialist medical clinics.

In the face of the prohibitions in place, telemedicine has emerged as an important tool in delivering care to patients with healthcare needs. In this article, we address three issues of relevance to healthcare providers in the provision of telemedicine services in Singapore, namely: (1) an overview of the regulatory regime governing the provision of telemedicine in Singapore; (2) best practices to maximise quality of care; and (3) the use of general video platforms in the delivery of telemedicine.

2. The regulatory framework for telemedicine

"Telemedicine" is generally understood as the systematic provision of healthcare services over physically separate environments via information and communications technology.

The current licensing regime for healthcare establishments under the Private Hospitals and Medical Clinics Act ("**PHMCA**") is premise-based, without specific licensing requirements for the provision of telemedicine services. Nevertheless, the following regulations and guidelines apply to the provision of telemedicine services.

- The Health Sciences Authority's ("**HSA**") Regulatory Guideline for Telehealth Products (April 2019) classifies telehealth products (i.e., instruments, apparatus, machines or software that are involved in the provision of healthcare services over physically separate environments via infocomm technologies) that are intended for a medical purpose as medical devices. A "medical purpose" would include the investigation, detection, diagnosis, monitoring, treatment or management of any medical condition, disease, anatomy or physiological process. Telehealth products classified as medical devices are regulated under the Health Products Act and relevant subsidiary legislation, under the supervision of the HSA.

- Retail pharmacies are licensed under the Health Products (Licensing of Retail Pharmacies) Regulations, and are required to obtain prior approval from the HSA if they wish to provide tele-pharmacy services.

- Pursuant to the Private Hospitals and Medical Clinics Regulations, healthcare establishments under the PHMCA are required to comply with the National Telemedicine Guidelines (30 January 2015) ("**NTG**") published by MOH.

- Breach of professional codes and guidelines issued by the regulatory body of a healthcare professional can result in disciplinary action. For medical practitioners, Guideline A6 of the Singapore Medical Council's ("**SMC**") Ethical Code and Ethical Guidelines ("**ECEG**") and the accompanying SMC Handbook on Medical Ethics ("**HME**") set out the ethical guidelines applicable to telemedicine. The MOH-SMC Joint Circular on Telemedicine and Issuance of Online Medical Certificates (18 April 2018) is also a useful resource that highlights key guidelines from the NTG and ECEG which medical practitioners should note.

- MOH currently runs a Licensing Experimentation and Adaptation Programme, to promote engagement between MOH and businesses involved in the provision of telemedicine. This regulatory sandbox initiative creates room for dialogue between telemedicine providers and the regulators, whilst MOH continues to develop and refine the regulatory framework. In this regard, MOH has stated its intention for the third implementation phase of the Healthcare Services Act 2020 (not yet in force) to include a licensing framework for telemedicine services.

3. Maximising quality of care (and minimising the risk of liability)

Drawing guidance from the NTG and ECEG, healthcare providers using telemedicine are generally expected to endeavour to provide the same quality and standard of care as in-person medical care. This is an onerous requirement, given the inevitable limitations of a tele-consultation, in contrast to an in-person consultation. To help healthcare providers maximise the quality of care offered (and minimise their risk of liability), we have identified a list of considerations relevant to the healthcare professional in the delivery of telemedicine:

- The healthcare professional is expected to be adequately trained in operating the telemedicine platform. However, a patient may not be suitable to receive care via telemedicine if he/she is unable to operate the platform or telehealth product appropriately. Elderly patients, for example, may have greater difficulties operating virtual platforms.

- If a diagnosis or treatment plan has to be made which hinges significantly on observations made via tele-consultation, consider whether the quality of the information acquired during the tele-consultation (whether by audio call, text messages and/or video call) is sufficient to support reasonable confidence in the diagnosis or treatment plan.

- In considering the limitations of diagnosis and treatment via telemedicine, it useful to take note of the Singapore Medical Association Telemedicine Workgroup's advisory on Leveraging on Telemedicine during an Infectious Disease Outbreak (12 February 2020). This identifies the potential limitations of telemedicine to include: (1) the inability of a doctor to perform a physical examination; (2) the lack of visual and other cues of the patient's condition when compared to an in-person consultation; and (3) technological limitations (e.g. image quality, transmission lag, potential for data breach). For example, a tele-consultation typically excludes physical examination by auscultation or palpation, and image / sound delays may hamper the ability to read visual cues, assess physical symptoms or make auditory assessments.

- Where the limitations of telemedicine are relevant and material for the patient to know, it is important to communicate these limitations to the patient, and ensure that they understand the risks and are nonetheless willing to accept care via telemedicine.

- As with in-person consultations, documentation remains important to record the care given and ensure high quality continuity of care. In particular, advice given regarding the limitations and risks associated with the use of telemedicine, and the patient's consent, should be documented in the medical records.

- Ultimately, if the healthcare professional is not comfortable with the sufficiency of the tele-consultation, and there is concern that the patient continues to require care urgently or within the "circuit breaker" period, steps should be taken to make appropriate alternative arrangements. These may include referring the patient to an appropriate alternative healthcare facility such as the Emergency Department of a hospital, or exploring the prevailing avenues to seek a time-limited exemption from the Control Order Regulations to review/treat the patient in person.

- Modern technology has meant that even in in-person consultations, healthcare professionals should be alive to the possibility of patients recording consultations without the healthcare professionals' knowledge or consent. The risk of surreptitious patient recordings is even more acute in the case of a tele-consultation, for example, through screen recording functions in a mobile device, or recording devices set up off-camera. Whilst many healthcare professionals understandably hold a dim view of such surreptitious recordings, these recordings may be admissible as evidence (subject to evidentiary rules and the weight to be given to such recordings) in civil claims or disciplinary proceedings against the healthcare professional. As such, it is prudent for healthcare professionals to always conduct themselves on the assumption that the consultation is being recorded.

- Healthcare providers seeking to incorporate telemedicine into their practice for the first time should also check that practising via telemedicine is covered by their relevant indemnity/ insurance.

4. Risks of utilising non-telemedicine-specific video platforms for tele-consultations

For convenience, some patients may request to use non-telemedicine-specific video platforms, such as Zoom or FaceTime for a consultation. Healthcare establishments who do not envision providing telemedicine services beyond the duration of the "circuit breaker" may also find it more financially prudent to conduct consultations via such platforms, rather than investing in developing a telemedicine-specific platform, or paying a fee to use an existing one.

Apart from concerns over the quality of video and sound transmissions explored above, due care must be taken to protect patient confidentiality and data security.

As regards the protection of patient data, healthcare providers are required by the Personal Data Protection Act 2012 to make reasonable security arrangements to protect such data from unauthorised access, collection, use, disclosure, copying, modification, disposal or similar risks ("**Protection Obligation**"). Therefore, whilst a non-telemedicine-specific platform may be convenient and inexpensive, healthcare providers owe a duty to consciously evaluate the chosen platform to satisfy themselves that it offers sufficient security for the protection of patient data. The Personal Data Protection Commission's decision in *Singapore Health Services Pte Ltd & Ors* [2019] SGPDPC 3 highlights the factors that are taken into account in assessing the reasonableness of security arrangements to include: the nature of the personal data, the form in which the personal data has been collected (e.g. physical or electronic), and the possible impact to the individual concerned if an unauthorised person obtained, modified or disposed of the personal data. In this regard, it is recognised that medical data is of a sensitive nature, and should be accorded a higher standard of protection.

Nevertheless, what is reasonable in each case depends heavily on its unique facts and circumstances, so there is room for the exercise of judgment. In the event that a patient urgently requires care via tele-consultation in circumstances where no other assistance or better secured platform is available, the urgency of the situation may dictate that the most accessible platform be used. In such situations, the consultation should be limited to the urgent and immediate purpose, often as a triage with a view to establishing if a patient needs to be seen urgently in person. If a healthcare establishment (or a healthcare professional) chooses to routinely use a non-telemedicine-specific platform to offer tele-consultations, it (or he/she) must be prepared to account for the reasonable steps taken to comply with the Protection Obligation.

5. Conclusion

Telemedicine has assumed a new significance in delivery of care to patients unable to or unwilling to leave the house for medical treatment. However, as with all technology, it must be properly understood and used safely - both for the protection of the patient and the healthcare provider. It is hoped that by highlighting the need for mindfulness of the regulatory framework and limitations of practising medicine remotely, this article will assist healthcare providers in the safe and effective implementation of telemedicine, for the benefit of our community.

Further information

Allen & Gledhill has a Covid-19 Resource Centre on our website www.allenandgledhill.com that contains knowhow and materials on legal and regulatory aspects of the Covid-19 crisis. In addition, we have a cross-disciplinary Covid-19 Legal Task Force consisting of Partners across various practice areas to provide rapid assistance.

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