

JAPAN

Telehealth around the world: a global guide



Introduction

The COVID-19 pandemic has caused healthcare systems around the globe to rapidly, and in some cases, radically rethink the delivery of medical care. The global expansion of telehealth services is one way we have seen this transformation occur. This has resulted in significant opportunities in the field, as well as unprecedented regulatory change.

As a quickly evolving area, 'telehealth' can have different meanings in different contexts. In this Global Guide, telehealth refers to the delivery of healthcare services where patients and providers are separated by distance, using information and communications technology for the exchange of information for the diagnosis or treatment of diseases and injuries. We have adapted this definition from the World Health Organisation's definition of telehealth.

Telehealth is not a new concept – healthcare providers, academics and technology developers have been advocating for its use for decades. There are many benefits to the widespread adoption of telehealth, including improved access to healthcare services, risk mitigation, convenience and flexibility, and in many cases, a reduction in overhead costs. However, the use of telehealth is not without its challenges. For example, it is not suited to all forms of healthcare, its implementation and adoption can be time consuming and costly, and additional care must be taken in relation to the transfer of patient health information.

The restrictions of movement in many parts of the world due to COVID-19 has caused governments to recognise the potential of telehealth, and amend laws and regulations seemingly overnight to enable healthcare providers to deploy telehealth solutions. Many governments have adopted telehealth reforms in a matter of weeks, which may otherwise have taken years to be considered and introduced.

Although many of these reforms presently have an expiration date (dependent on the duration of the COVID-19 pandemic), there is likely to be continued growth in telehealth due to the advantages of such a service – even after the pandemic. There are enormous opportunities in the telehealth space for businesses already operating in this field, businesses considering expanding into telehealth, and start-ups.

This Global Guide provides an overview of the current state of telehealth regulations worldwide and assists readers to identify the opportunities, challenges and risks, on a country-by-country basis. As the field of telehealth, and the regulations underpinning it, remain highly dynamic and subject to change, this document is intended as a general guide and does not constitute legal advice. Should you wish to discuss any aspects of telehealth with a specialist lawyer, please contact us below.

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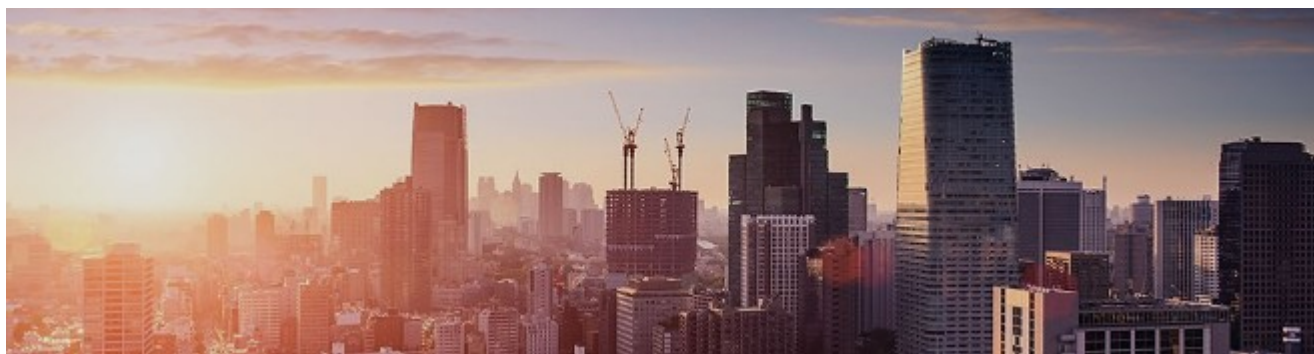
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Japan

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Is the use of telehealth permitted?

Yes, 'telehealth' is permitted in Japan. Medical institutions are allowed to decide whether to adopt telehealth systems.

How is telehealth regulated?

In Japan, telehealth is generally subject to the Medical Practitioners' Act (the "**Act**") and various guidelines issued by the Minister of Health, Labour and Welfare (the "**MHLW**") and other government agencies.

Under Article 20 of the Act, medical practitioners cannot provide medical care or issue a medical certificate or prescription without personally performing a "medical examination". Under the guideline issued by the MHLW ("**Guideline 1**"), telehealth is not considered a "medical examination" under the Act unless the relevant medical institutions, medical practitioner, patients, and any other relevant person comply with the following requirements:

- Each medical practitioner shall enter into an agreement regarding telehealth with each patient after providing sufficient information to the patient;
- The first examination of each patient is conducted face to face to collect accurate information from such patient;
- Medical institution / practitioner shall prepare and preserve the treatment plan of each patient;
- Confirmation of both parties' IDs at the beginning of each telehealth meeting, such as doctor's license and patient's driver license;
- Accurate management of the pharmaceutical drugs each patient has taken before or during the telehealth treatment;
- Setting up a system which allows medical practitioners to obtain the same information from the patient as in the case of face-to-face examination;
- Medical practitioner needs to provide telehealth services from a location so that he / she can obtain sufficient and accurate information about the patient's physical and mental condition, such as an isolation room in a hospital;
- Medical practitioners need to attend a training prescribed by MHLW before providing telehealth service;
- A patient receives telehealth services from a location so that his / her privacy is secured, such as his / her home; and
- Medical practitioners institutions, and any other relevant person need to set up security systems to protect patient's personal information and any other important information.

However, in response to the COVID-19 pandemic, the MHLW issued a new guideline ("**Guideline 2**"). Under Guideline 2, telehealth can be conducted for the first examination of a patient as long as the medical institutions, medical practitioners, patients, and any other relevant person comply with following extra requirements in addition to the requirements discussed above:

- The medical practitioner shall collect accurate information about the patient based on some documents such past medical reports of the patient;

- The medical practitioner shall not prescribe any high risk pharmaceutical drug such as narcotics and psychotropics; and
- The medical institution shall submit reports regarding the telehealth services they provide as requested by the MHLW to local authorities every month.

However, under Guideline 2, it is not necessary for medical practitioners (excluding dentists) to attend the training prescribed by the MHLW before providing telehealth service.

Are there specific fields of healthcare in relation to which telehealth services are currently available, and do they involve the use of proprietary technology or platforms?

All types of telehealth service, including dentistry, are generally available in Japan. Telehealth services are provided by videoconferencing / teleconferencing apps as specified by the relevant medical institutions. Remote medication instructions and electronic prescription systems are becoming more widespread.

Does the public health system include telehealth services, and if so, are such services free of charge, subsidised or reimbursed? Where the public health system does not include telehealth services, are such services covered by private health insurance?

Public health system does not cover telehealth except for the following special policies:

- Telehealth services of certain specific areas such as paediatrics and life-style related diseases covered by public health insurance.
- Some local governments such as the Saitama prefecture provide subsidies to encourage medical institutions to adopt telehealth systems.

Additionally, some insurance companies have announced that their insurance programs cover telehealth services.

Do specific privacy and/or data protection laws apply to the provision of telehealth services?

The Act on the Protection of Personal Information ("APPI") applies to the provision of telehealth in Japan. Under the APPI, before collecting any personal information from patients receiving telehealth services, the medical institutions / practitioners shall inform the patients the purpose of collecting personal information and obtain consent from the patients.

How should the cross-border transfer of personal information collected and processed in the course of telehealth services be carried out to ensure compliance with applicable privacy laws?

Under the APPI, before a medical institution can transfer telehealth data of patients, including patients' personal information, to another institution located in a foreign country (excluding affiliates located in several specified countries such as EU countries and affiliates that have established internal data protection system as required under the APPI), the medical institutions are required to obtain consent from the patients after notifying the patients that their data might be transferred overseas.

Moreover, medical institution needs to inform the patients about the personal information protection system of the countries and affiliates to which the patients' personal data might be transferred.

Are there any currently applicable codes of conduct on the use of telehealth systems and/or security of telehealth data in your jurisdiction?

Yes, the following guidelines are the main codes of conduct for telehealth service providers.

- Guideline 1: "診療適切実施関指針" issued by MHLW;

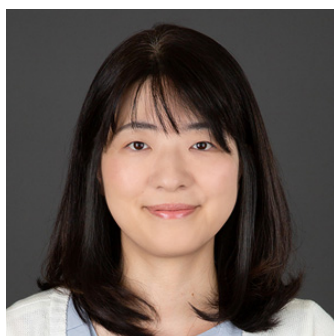
- Guideline 2: "新型コロナウイルス拡大際電話情報通信機器用診療等時限の特例の取扱" issued by MHLW. This guideline is issued by MHLW in response to the COVID-19 pandemic and the measures stated in this guideline are temporary; and
- Guideline 3: "医療情報取扱情報提供事業者安全管理" issued by the Ministry of Economy, Trade and Industry. This guideline is intended for service providers, and provides guidance regarding the storage of medical information and risk management process.

All the above-mentioned guidelines are only available in Japanese.

Are any specific laws, regulations, or self-regulatory instruments expected to be adopted in the near future?

Yes, depending on the development of the COVID-19 pandemic and other circumstances, it is expected that relevant government agencies may issue other guidelines regarding telehealth.

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