

<b>TELEMEDICINE: A GLOBAL APPROACH TO TRENDS AND PRACTICES</b>
<b>Author: Kensuke Suzuki, Nagashima Ohno &amp; Tsunematsu</b> <b>Date of completion: 11 November 2022</b>
<b>LAWS AND REGULATIONS ON TELEMEDICINE</b>
<b>1. Is telemedicine allowed in your country? If so, how is it defined?</b>
Telemedicine is allowed in Japan pursuant to a guideline issued by the Japanese health authority, the Ministry of Health, Labour and Welfare (MHLW). Under the telemedicine guideline, telemedicine is defined as the act of performing medical care, such as communication of diagnosis and prescription, upon examining and diagnosing the patient, through the use of information communication equipment in real time between a physician and patient.
<b>2. Please provide a high-level overview of the legal framework regarding telemedicine in your country.</b>
As a general principle, the law (the Medical Practitioners' Act) essentially requires medical diagnosis to be performed by a physician through a face-to-face consultation with a patient. However, a guideline issued by the MHLW provides guidance on the permissible scope of telemedicine. This telemedicine guideline was revised and updated by the MHLW in January 2022. Among other revisions to the past rules, the revised guideline now allows for telemedicine to be conducted from the first patient visit, provided that, in general, the first patient contact is conducted by a primary care physician.
<b>3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities.</b>
The MHLW is the Japanese Government authority responsible for overseeing the medical care regulatory regime, including physician licensure and the national universal healthcare plan reimbursement system. The MHLW has issued the 'Guideline concerning Proper Implementation of Telemedicine', which provides guidance on the permissible scope of telemedicine.
<b>4. Was telemedicine authorised during the Covid-19 pandemic?</b>
Telemedicine was authorised before the Covid-19 pandemic, but was subject to more stringent limitations. The MHLW has taken special measures to facilitate the use of telemedicine in Japan during the period of the Covid-19 pandemic. Initial consultations between physicians and patients were generally not permitted to be conducted online prior to the pandemic, but under the special measures taken by the MHLW, this prohibition has been temporarily suspended, and telemedicine is currently broadly permitted from the initial consultation. Separate and aside from these temporary special measures, the MHLW has revised its telemedicine guideline to expand the scope of permissible telemedicine in order to facilitate the use of telemedicine, even after the expiration of the temporary pandemic measures.
<b>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?</b>
The telemedicine guideline was revised and updated by the MHLW in January 2022. The revised guideline allows for more flexibility in providing telemedicine in the post-pandemic scenario. For example, the revised guideline now allows for telemedicine to be conducted from the first patient visit, provided that, in general, the first patient contact is conducted by a

<p>primary care physician.</p>
<p><b>6. What types of teleservices are allowed (eg, second opinion, teleconsultation, teliagnosis and telesurgery)?</b></p>
<p>The telemedicine guideline allows for a wide variety of telemedicine to be provided by a physician to a patient, including second opinion, teleconsultation and teliagnosis. Telesurgery is also allowed under the telemedicine guideline, but will need to be performed in accordance with appropriate guidelines that are to be established by the Japanese medical society.</p>
<p><b>7. Who can use telemedicine services? Please indicate whether only doctor-doctor or also patient-doctor remote medical services are allowed.</b></p>
<p>Telemedicine performed pursuant to the telemedicine guideline is limited to those conducted between the physician and patient. This includes the scenario where the patient is physically together with another physician (ie, D to P with D) or a nurse (ie, D to P with N). Telemedicine is allowed in cases in which conducting a face-to-face consultation would be practically difficult or where the patient has a chronic, yet stable, condition. It is generally considered that patients with acute symptoms or emergency conditions are not eligible for telemedicine and must be treated in person.</p>
<p><b>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.</b></p>
<p>Japan has a universal healthcare system. Most legal residents are covered by the health insurance system. The costs for a substantial part of medical services provided and prescription drugs sold are covered by it. Reimbursement under the Japanese universal healthcare system is available for telemedicine that is provided pursuant to the telemedicine guideline.</p>
<p><b>9. Please indicate whether any insurance requirements are applicable to telemedicine service providers.</b></p>
<p>In addition to the requirements stipulated in the telemedicine guideline, there are specific requirements applicable to telemedicine in order to be eligible for reimbursement under the Japanese universal healthcare system. These reimbursement requirements include, for example, that the healthcare institution has established systems to enable it to provide face-to-face medical services to patients. The reimbursement price of telemedicine has been increasing, with an aim to promote the use of telemedicine; however, it is still lower than the reimbursement price for similar medical services provided in a face-to-face patient visit.</p>
<p><b>REQUIREMENTS APPLICABLE TO HEALTHCARE PROFESSIONALS AND INSTITUTIONS</b></p>
<p><b>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).</b></p>
<p>Telemedicine is defined as a medical practice in Japan, and therefore can only be provided to the patient by a physician licensed in Japan. A licensed physician can provide telemedicine to a patient who is physically together with a licensed nurse (ie, D to P with N), but a nurse cannot provide telemedicine to a patient.</p>
<p><b>11. Are there any specific education requirements or training that healthcare professionals need to meet or attend to provide telemedicine services?</b></p>
<p>Physicians performing telemedicine are required to receive training designated by the MHLW to ensure that the physicians have the required knowledge to properly perform telemedicine.</p>

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

There is no special registration requirement applicable to physicians that provide telemedicine pursuant to the telemedicine guideline. Physicians that perform telemedicine pursuant to the temporary special measures provided during the Covid-19 pandemic period are required to file a monthly report with the regulatory authority concerning telemedicine performed by those physicians.

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

There are no special licenses or authorisations that are mandatory for institutional healthcare providers engaged in telemedicine services pursuant to the telemedicine guideline. Healthcare institutions that provide telemedicine pursuant to the temporary special measures provided during the Covid-19 pandemic period are required to file a monthly report with the regulatory authority concerning the telemedicine performed by those healthcare institutions.

**REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES**

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

The telemedicine guideline sets forth various specific requirements applicable to the telemedicine platform, including, among other requirements, those concerning access control, security systems, access logs, encryption and software updates. The telemedicine platform must also comply with multiple other guidelines separately established by the Japanese Government authorities concerning security measures to be implemented for information systems handling medical information. The applicable requirements are technical in nature, and quite voluminous and detailed, and it is important, as a practical matter, for the system providers of the telemedicine platform to familiarise themselves with these technical requirements when constructing the system platform for providing telemedicine.

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

The telemedicine guideline sets forth various specific requirements applicable to the electronic equipment and internet connection environment used to provide telemedicine. The telemedicine guideline requires that the physician provide telemedicine in an environment with a stable and good network connection so that the physician is able to obtain sufficient information on the patient's physical and mental status, and properly perform telemedicine. Additional requirements are separately stipulated in multiple other guidelines separately established by the Japanese Government authorities concerning security measures to be implemented for information systems handling medical information, which must be complied with in performing telemedicine. Under these guidelines, bring your own device (BYOD) is generally not permitted and physicians are generally not allowed to use their own personal device to perform telemedicine.

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

The telemedicine guideline issued by the MHLW requires a medical care plan to be prepared before performing telemedicine, which sets out, among others, specific details of the medical care to be provided and the method of telemedicine. This medical care plan must be kept as a record for two years. The law also requires that a physician prepare and keep medical records for five years when he/she has provided medical care to a patient. These medical records are required regardless of whether medical care is performed in person or via telemedicine.

<b>17. Are there geographic location requirements applicable to the provision of telemedicine services?</b>
<p>A physician may perform telemedicine from within a medical institution, and may also perform telemedicine from a location other than a medical institution, provided that the environment can be considered comparable to a medical institution for the purposes of properly obtaining information concerning the patient's physical and mental status. Physicians are generally not allowed to perform telemedicine in public places. It is generally considered that telemedicine is permissible under Japanese law to the extent that the physician and patient are both physically located within Japan.</p>
<b>18. Does the healthcare professional need to obtain the patient's consent to engage in telehealth?</b>
<p>The telemedicine guideline requires that the physician provide a sufficient explanation to the patient and obtain the patient's consent prior to performing telemedicine to the patient. The explanation to be provided should cover, among others, details of the medical care to be provided, the method of telemedicine, security measures to be implemented and relevant security risks. The physician is also required to explain that the information that can be obtained through telemedicine is limited and so telemedicine will need to be performed in combination with in-person medical care. In obtaining the patient's consent, the physician is required to explicitly confirm that the patient wishes to be provided telemedicine.</p>
<b>19. Is there any other important requirement that should be highlighted?</b>
<p>The telemedicine guideline does not allow for telemedicine to be performed by telephone as it lacks visual information. However, telemedicine by telephone is currently temporarily allowed pursuant to the special temporary measures taken by the MHLW during the period of the Covid-19 pandemic. Telemedicine performed by only using a chat system with words, photographs and recorded videos is not allowed. Separate and aside from these restrictions, the telemedicine guideline also requires that proper know your customer (KYC) measures are implemented to verify the identity of the physician as well as the patient.</p>
<b>DATA PRIVACY ASPECTS</b>
<b>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.</b>
<p>The Japanese privacy law (the Act on the Protection of Personal Information) is applicable to patient data obtained through telemedicine conducted in Japan. The Japanese privacy law generally requires the patient's consent in order to transfer the patient's data to another person or use the patient's data for another purpose. These privacy law requirements are applicable on an entity-by-entity basis, so it is important, when assessing the Japanese privacy law implications, to identify the specific entities involved in each flow of patient data. Patient data obtained through telemedicine generally falls within the category of sensitive personal information, which is subject to more stringent restrictions under the Japanese privacy law regime. For example, the patient's consent is generally required in order to obtain the patient's sensitive personal information. This includes the case in which a person obtains such information from a third party, which means that the data recipient cannot obtain patient data from such a third party unless the patient (not the transferor third party) has consented to the data recipient obtaining such patient data.</p>
<b>21. Does the applicable regulation provide for criteria and requirements for security systems to protect the patient's information?</b>
<p>The Japanese privacy law provides for a general requirement that necessary and proper security measures must be implemented when handling personal data. Detailed</p>

requirements concerning security systems and security measures to be implemented for telemedicine are set forth in the telemedicine guideline issued by the MHLW, as well as the relevant guidelines issued by the Japanese Government authorities concerning security measures to be implemented for information systems handling medical information. The applicable requirements are technical in nature and quite voluminous and detailed, and it is important, as a practical matter, for system providers to familiarise themselves with these technical requirements when constructing the system platform for providing telemedicine.

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

Under the Japanese privacy law, the transfer of personal data to a person located outside Japan generally requires the consent of the data subject. When obtaining the data subject's consent, the Japanese privacy law now requires that certain prescribed information be provided to the data subject in advance, such as information on the privacy law regime in the destination foreign jurisdiction and the data protection measures to be taken by the foreign data recipient. There are certain prescribed exceptions to such consent requirements. For example, European Union Member States and the United Kingdom are designated as exempted countries, so the transfer of personal data from Japan to an EU Member State or UK will not be subject to this cross-border transfer consent requirement. In addition, this cross-border transfer consent is not required if a group policy is implemented or a contract is entered into with the foreign data recipient setting out data protection measures that are equivalent to the requirement under the Japanese privacy law.

**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 special registration requirement for databases used to provide telemedicine pursuant to the telemedicine guideline. The telemedicine guideline requires a medical care plan to be prepared by the physician before performing telemedicine, which sets out, among others, specific details of the medical care to be provided and the method of telemedicine. This medical care plan must be kept as a record for two years. The law also requires that a physician prepare and keep medical records for five years when he/she has provided medical care to a patient. These medical records are required regardless of whether medical care is performed in person or via telemedicine. To ensure privacy, the taping and recording of the telemedicine performed requires the consent of both the patient and the physician.

**LIABILITIES**

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

There is no special legislative measure established to cover liability issues involved in the performance of telemedicine. Liability claims relating to telemedicine under Japanese law will generally be based on tort principles and contract provisions. In tort cases, the claimant bears the burden of proving: (1) an intentional or negligent act (or omission) by the person committing the tort; (2) damage suffered by the claimant; and (3) a reasonable connection between the act and damage. For contractual claims, there needs to be a contractual relationship between the parties. The claimant bears the burden of proving: (1) the contractual counterparty's non-performance of contractual duties; (2) damage suffered by the claimant; and (3) a reasonable connection between the non-performance and damage. Unlike in a tort action, the burden of proof is placed on the claimee (contractual counterparty) to prove that it was not negligent in its actions. There is no established doctrine or court precedent on the allocation of liability among the physician, the medical institution and the system vendor in the case of an accident or incident occurring in the course of performance of telemedicine leading to damage incurred by a patient. Whether or not there is liability, who is liable and the actual scope of liability will ultimately be determined by the Japanese court

on a case-by-case basis, taking into consideration the specific factual circumstances of the case in question.

## TELEMEDICINE NUMBERS AND TRENDS

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

According to statistics published by the Ministry of Internal Affairs and Communications, the number of healthcare institutions that have reported that they are capable of performing telemedicine increased after the MHLW implemented the special temporary measures to relax telemedicine requirements during the period of the Covid-19 pandemic in April 2020. As of April 2021, those healthcare institutions comprise approximately 15 per cent of all healthcare institutions in Japan.

### 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.

It is generally considered that the number of healthcare institutions in Japan that provide telemedicine is still limited, despite the various measures implemented by the MHLW during the Covid-19 pandemic to facilitate the use of telemedicine, including relaxing its telemedicine regulations and increasing the reimbursement price for telemedicine. There are views that point to economic reasons as hindering the use of telemedicine by healthcare institutions in that healthcare institutions will need to incur costs to establish and maintain proper IT systems and securities measures in order to implement telemedicine, and the current reimbursement price for telemedicine is still lower than similar medical care provided face-to-face. As the MHLW has already implemented various measures to facilitate the use of telemedicine, it is difficult to foresee if the MHLW will take additional measures to further enhance the use of telemedicine in Japan.