

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?
<p>In principle, telemedicine for patients is not permitted in South Korea, except under the limited exception of telemedicine among healthcare professionals.</p> <p>Article 34, paragraph 1 of the Medical Service Act defines ‘telemedicine’ and states that:</p> <p>‘Medical personnel (limited only to medical doctors, dentists or doctors of Korean medicine who engage in medical practices) may provide telemedicine services to furnish medical knowledge or technology to <i>medical personnel</i> in a remote area by using information communication technology, such as computers or video communications systems.’</p>
2. Please provide a high-level overview of the legal framework regarding telemedicine in your country.
<p>There are no separate laws regulating Telemedicine. Instead, existing laws including the Medical Services Act, Pharmaceutical Affairs Act, Medical Devices Act, and Personal Information Protection Act (for cases involving data) are applied to telemedicine.</p>
3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities.
<p>As mentioned above, because there are no separate laws regulating telemedicine, the Ministry responsible for relevant existing laws are the pertinent regulatory bodies. As a result, the Ministry of Health and Welfare (MOHW) is the regulatory body for matters that fall under the Medical Services Act; the Ministry of Food and Drug Safety (MFDS) is the regulatory body for matters falling under the Medical Devices Act and the Pharmaceutical Affairs Act; and the Ministry of Public Administration and Security is the regulatory body for matters involving data and the Personal Data Protection Act.</p>
4. Was telemedicine authorized during the Covid-19 pandemic?
<p>Due to the Covid-19 pandemic, consultation and prescription via telemedicine has been and continues to be temporarily allowed in accordance with Article 49-3 of the Infectious Disease Control and Prevention Act.</p> <p>Article 49-3 of the Infectious Disease Control and Prevention Act provides that:</p> <p>‘[w]hen a crisis alert of a serious level or higher is issued under Article 38(2) of the Framework Act on the Management of Disasters and Safety, [...] medical personnel [limited to medical doctors, dentists, and doctors of Korean medicine ...] engaged in medical services may continuously observe, diagnose, consult with, and prescribe medicines for, patients outside medical institutions with respect to their health and disease by using information and communications technologies such as wired, wireless, or image communications, and computers, within the scope determined by the Minister of Health and Welfare, where deemed necessary to protect patients, medical personnel, medical institutions, and others from the risk of infection.’</p>

5. Is there any possibility of the regulatory landscape being changed in the post-pandemic scenario? Or has there been already a change in the regulation in the post-pandemic scenario?
Although proposed changes in the law to allow telemedicine to be more widely used have been pending, even before the Covid-19 pandemic, no changes in law has been implemented due to strong objections from the medical community (see response to Question 26, below). However, during the pandemic a consensus among medical professionals and patients on the benefits of telemedicine has been developing. As such, proposed changes in the law to allow telemedicine to be more widely used is expected to receive greater support in future.
6. What types of teleservices are allowed? (e.g. second opinion, teleconsultation, telediagnosis, telesurgery, among others)
In principle, only medical professionals may provide telemedicine services to furnish medical knowledge or technology to other medical professionals in remote areas. (See response to Question 1, above).
However, due to the Covid-19 pandemic, temporary authorisation for the use of telemedicine has been granted that now allows medical professionals to provide telephone consultations and write patient prescriptions. (See response to Question 4, above).
7. Who can use telemedicine services? Please indicate if whether only doctor-doctor or also patient-doctor remote medical services are allowed.
See response to Question 6, above.
8. Please outline the funding model for telemedicine. Is it available in your jurisdiction public health system? Is telemedicine under mandatory insurance coverage? Please indicate what legislation applies.
In principle, telemedicine is not permitted in South Korea as mentioned above. Consequently, there is currently no separate funding model specifically for telemedicine.
However, costs for medical services and prescriptions under the current Covid-19 temporary authorisation that permits telemedicine are covered under Korea's current public health system.
9. Please indicate whether any insurance requirements applicable to telemedicine services providers.
In principle, telemedicine is not permitted in South Korea as mentioned above. Consequently, there are no separate insurance requirements specifically applicable to telemedicine.
REQUIREMENTS APPLICABLE TO HEALTHCARE PROFESSIONALS AND INSTITUTIONS
10. Who can practice telemedicine in your country? Please indicate whether other healthcare professionals are authorized to provide remote health services under the applicable rules (e.g. nurses, psychologists, nutritionists, alternative health therapies providers, etc.)
Only medical doctors, dentists or doctors of Korean medicine who engage in a medical practice are permitted to practice telemedicine under the exception provided in Article 34, paragraph 1 of the Medical Services Act and Article 49-3 of the Infectious Disease Control and Prevention Act. (See responses to questions 1 and 4, above).
11. Are there any specific education requirements or trainings that healthcare professionals need to meet or attend to provide telemedicine services?
There are no specific education or training requirements to provide telemedicine services other than the licence required of the healthcare professionals.
12. Is there any registration requirement applicable to physicians that provide telemedicine services?
There is no separate registration requirement to provide telemedicine services other than the general registrations required of the medical professionals.

13. Please indicate whether special licenses or authorizations are mandatory for institutional healthcare providers engaged in telemedicine services.
There are no such mandatory special licences or authorisations other than what is stated in our responses to questions 11 and 12, above.
REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES
14. Are there specific requirements applicable to the telemedicine platform?
There are no specific requirements applicable to a telemedicine platform.
15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?
There are no specific requirements regarding electronic equipment and internet speed for telemedicine services.
16. Does the legislation provide for specific rules concerning patients' medical records?
Personal information sharing is regulated by the Personal Information Protection Act. More specifically, medical information falls under the 'sensitive information' category that is more strictly regulated in comparison to other categories of personal information under the Personal Information Protection Act. Furthermore, a patient's medical information is even more strictly protected under the Medical Services Act and so in order for a medical professional to use such information for other purposes than the patient's treatment or to share such information to a third party, the patient's explicit consent must be obtained and specific procedures and requirements in using or sharing such information must be followed. Therefore, in order to collect, use, and provide such information, the requirements and procedures under the Personal Information Protection Act and Medical Services Act must be complied with thoroughly. Although the government has published <i>Guidelines for De-Identification of Personal Information</i> , there are limitations in that specific criteria for the use of medical data that are not provided in the guidelines.
17. Are there geographic location requirements applicable to the provision of telemedicine services?
In principle, administering telemedicine is not permitted in South Korea, as mentioned above. Therefore, there are no geographic location requirements for telemedicine.
18. Does the healthcare professional need to obtain patient's consent to engage in a telehealth?
In principle, administering telemedicine services to a patient is not permitted in South Korea, as mentioned above but there are limited exception under Article 49-3 of the Infectious Disease Control and Prevention Act (see response to Question 4, above). In the exceptional case of telemedicine services to a patient under Article 49-3 of the Infectious Disease Control and Prevention Act, the patient's explicit consent should be obtained.
19. Is there any other important requirement that should be highlighted?
The collection, use and transfer of a patient's personal information is strictly regulated under the Personal Information Protection Act and the Medical Services Act. (See responses to questions 16 and 22).
DATA PRIVACY ASPECTS
20. Are there data privacy issues should be considered for the exploitation of such market? If your answer is positive, please provide a short description.
Yes, see response to Question 16, above.
21. Does the applicable regulation provide for criteria and requirements for the security systems to protect the patient's information?

<p>Yes. The Personal Information Protection Act requires administrative, technical, and physical security measures are taken to protect personal information. Such measures include, but are not limited to the following.</p> <ol style="list-style-type: none"> 1. Administrative measures – establish and implement an internal data management plan; limit authority to access personal information. 2. Technical measures – implement an access control system; encryption for safely storing and transferring personal information; preserve and protect log files to monitor access records; install security programs and keep them up to date. 3. Physical measures – physically restricting access to sites, offices, and data rooms.
<p>22. Does the applicable regulation provide for requirements for the transfer of information abroad?</p>
<p>Yes. Under the Personal Information Protection Act, consent from the patient is, in principle, required after informing the patient of specific notification requirements. The notification requirements include: (1) items of personal information to be transferred; (2) the country to which such personal information is being transferred; (3) the name of the recipient; (4) the purpose for which the recipient makes use of the transferred personal information; (5) the period during which the transferred personal information will be used/retained by the recipient; and (6) (for overseas provision only) the right to refuse consent, along with any possible disadvantages resulting from such a refusal.</p> <p>In addition, certain safeguards including the procurement of security measures for the protection of personal information, the establishment of procedures for handling grievances and settling disputes, and other necessary measures to protect the patient's personal information may be required. Furthermore, if the personal information is processed by an online service provider operating in countries that restrict cross-border transfer of personal information, relevant Korean authorities may enforce restrictions to the extent equal to any such restrictions enforced by such countries (unless otherwise required under relevant treaties or international agreements).</p>
<p>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?</p>
<p>As a general rule, after a patient's personal information has been collected, when the patient's personal information thereafter becomes unnecessary, the personal information must be destroyed without delay in a manner that such personal information cannot be recovered and/or restored. Personal information is deemed unnecessary if, among other reasons: (1) the specified retention period pertaining to such personal information expires; or (2) the objective behind the collection of such personal information is fulfilled.</p> <p>Under specific circumstances, personal information may be required to be retained, rather than destroyed pursuant to certain laws and regulations. In such cases, the personal information, or any files pertaining to such personal information, must be stored and managed separately from other personal information.</p>
<p>LIABILITIES</p>
<p>24. Please provide a high-level overview of the liability of healthcare professionals and institutions involved in telemedicine practices.</p>
<p>A medical professional engaged in telemedicine shall be subject to a fine of less than KRW 5,000,000 (approx. US\$3,775) (Art 90 of the Medical Services Act), unless an exception applies.</p>
<p>TELEMEDICINE NUMBERS AND TRENDS</p>
<p>25. Is there any public disclosed information concerning the use and acceptance of telemedicine in your country?</p>
<p>There are many studies and articles on the need for allowing telemedicine to be more widely used that are publicly available. However, as telemedicine, in principle, is not permitted in South</p>

Korea, there are no publicly disclosed official reports or data on its use and acceptance that we are aware of.

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.

An amendment to the Medical Service Act which provides for implementation of telemedicine to those who live in islands or remote villages and have poor accessibility to medical institutions is currently pending at the National Assembly. The main contents of the proposed amendment are:

1. The expansion of the telemedicine targeted group

According to the current Medical Service Act, only telemedicine between healthcare professionals is permitted. The amendment will allow telemedicine to those who live in islands or remote villages, or the elderly or the disabled with reduced mobility.

2. Executive organ of telemedicine

The head of the medical institutions that wish to perform telemedicine must have certain facilities and equipment, and report to the mayor or governor of the relevant region.

3. Targeted patients of telemedicine and medical institutions

Targeted telemedicine patients should be mainly those with medical records of suffering from minor illnesses or for patients with chronic conditions such as high blood pressure, diabetes, etc. Residents in islands or remote villages, the elderly, the disabled, people with reduced mobility, and patients suffering from certain minor illnesses should also be allowed telemedicine consultations by medical institutions at clinic-level. In cases of continuous diagnosis/prescription for the same patient, this should be accompanied by a periodic face-to-face consultation in order to reduce the risks of solely relying on telemedicine.

In addition, with respect to patients who need continuous management such as checking on a medical device attached to their body after a medical operation, a prison inmate, or a patient with limited access to medical institutions, including military personnel, telemedicine may be provided by a medical institution at clinic-level in conjunction with that at hospital-level.