

Legal Status of Telemedicine, Non-face-to-face Treatment, and Digital Healthcare in the Republic of Korea

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Abstract: Owing to the COVID-19 pandemic, the Republic of Korea and the rest of the world are experiencing a non-face-to-face era in most industries, including the medical field. The country's status as an aging society has led to its search for "digital healthcare," which helps manage health to improve length and quality of life. Telemedicine, non-face-to-face treatment, and digital healthcare are expected to continue evolving even after the COVID-19 pandemic. Hence, clarifying the legal status of each of the above concepts is necessary. This study examines the contents of the system addressed in current legislation and precedents. This study also conducts a comparative review on the contents of the system newly emerging in the bill. Regulating each type of telemedicine can lead to confusion in the legal system. Hence, the concept and scope of telemedicine under the Medical Service Act and non-face-to-face treatment under the Infectious Disease Prevention and Control Act should be established for the future. Meanwhile, in this process, in principle, face-to-face treatment should be given priority. Telemedicine or non-face-to-face treatment should be performed only under special circumstances where face-to-face treatment is considerably problematic.

Keywords: Digital healthcare, Health Management, Non-face-to-face treatment, Telemedicine

1. Introduction

In the Republic of Korea, before the spread of the coronavirus disease, the only telemedicine allowed was remote consultation under the Medical Service Act. By revising the Infectious Disease Control and Prevention Act on December 05, 2020, new regulations allowing non-face-to-face treatment were established temporarily when the infectious disease crisis alert was at the "severe" level or higher. During the COVID-19 pandemic, the most frequently used non-face-to-face treatment was telephone counseling and prescriptions and smartphone applications. Wearable devices were also utilized[1].

The Republic of Korea's transition into an aging society has led to the search for "digital healthcare," which, along with traditional healthcare, aims to effectively manage health and satisfy the desire for a healthy and long life[2]. Therefore, telemedicine, non-face-to-face treatment, and digital healthcare will evolve even after the COVID-19 pandemic. As the scope of telemedicine expands in the future, if related terms are used interchangeably, social confusion may arise. Therefore, since the health care system can be established only when the legislative amendment is made for these terms, this study is intended to examine this.

Received: November 28, 2022; 1st Review Result: January 11, 2023; 2nd Review Result: February 11, 2023
Accepted: February 28, 2023

2. Research Method

2.1 Research Design and Data Gathering Procedures

As a research method, this paper examines the contents of the system in the current legislation and precedents and compares and reviews the contents of the system newly emerging in the bill. We used data from current laws including the “Medical Service Act” and “Infectious Disease Control and Prevention Act.” Relevant legislative proposals include “Bill of Act on Fostering and Supporting the Digital Healthcare Industry.” Additionally, the governmental guideline, “Non-medical health care service guidelines and casebook” was also used. The relevant decisions were “Supreme Court 2020. 11. 12. Decision 2016 Do309” and “Supreme Court 2013. 4. 11. Decision 2010 Do1388.”

2.2 Data Analysis

This study classifies and compares how each concept is defined in the current laws and legislation and how the types and legal status are grasped as follows. This study also identifies how the Supreme Court grasps the applicability of each type of reality.

[Table 1] Data Analysis Procedure

Definition	<ul style="list-style-type: none"> - Telemedicine of Medical Service Act article 34 - Non-face-to-face treatment and Digital healthcare of Infectious Disease Control and Prevention Act article 49-3 - Health Management Service of Non-medical health care service guidelines and casebook - Digital Healthcare of Bill of Act on Fostering and Supporting the Digital Healthcare Industry(2022)
Type / Legal Status	<ul style="list-style-type: none"> - Teleconsultation / Remote medical treatment between patient and doctor including Home Monitoring / Teleeducation - Normal / Temporary
Applicability	<ul style="list-style-type: none"> - In particular, the Supreme Court's judgment on whether remote medical treatment between doctors and patients using the telephone is acceptable is problematic.

3. Comparison and Data Analysis

3.1 Telemedicine, Non-face-to-face Treatment, and Digital healthcare

3.1.1 Telemedicine or Telehealth

The WHO Guidelines define telemedicine as “The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities[3].”

Meanwhile, AMA uses the concept of telehealth in addition to telemedicine. According to the AMA,

telemedicine and telehealth are distinguished as follows: “Telehealth, telemedicine and related terms generally refer to the exchange of medical information from one site to another through electronic communication. While telemedicine has historically referred to remote clinical services, telehealth can refer to broader services including[4].”

Therefore, WHO lists the following objectives of telemedicine. First, it aims to provide clinical support. Second, it aims to overcome geographical barriers, connecting users who are not in the same physical location. Third, it uses various types of ICT. Fourth, it aims to improve health outcomes[5].

Telemedicine includes three main types. Teleconsultation discusses the direction of the patient’s treatment between doctor and patient. Ubiquitous Health or Home Monitoring involves the patient transmitting monitoring results using information and communication technology and digital devices to their doctors, with the doctor remotely conducting medical treatment. Teleeducation provides medical information and education to medical personnel and patients[1][6].

3.1.2 Non-face-to-face Treatment

Non-face-to-face treatment is a comprehensive term that refers to cases wherein a doctor performs medical practice without face-to-face interaction with a patient. Additionally, it also includes digital therapy to prevent, diagnose, manage, and treat diseases using digital technologies (e.g., artificial intelligence (AI), smartphone applications, or augmented reality)[7].

3.1.3 Digital Healthcare

Digital healthcare is a subcategory of healthcare referring to the use of digital technology and devices. Among them, those based on mobile are further subdivided into mobile healthcare[2].

“Bill of Act on Fostering and Supporting the Digital Healthcare Industry(2022)” defines digital health as using digital technology to collect and analyze personal health-related information and providing customized health management services.

3.2 Republic of Korea’s Current Regulations Related to Telemedicine, Non-face-to-face Treatment, and Digital Health

3.2.1 Medical Service Act Article 34

Article 34 of the Medical Service Act stipulates the following under the title of 'Remote Medical Treatment':

“(1) Medical persons (limited only to physicians, dentists or oriental medical doctors who engage in medical service) may, notwithstanding Article 33 (1), give remote medical treatment (hereinafter referred to as "remote medical treatment") to furnish medical knowledge or technology to medical personnel in a remote area by using information communication technology, such as computers or visual communication systems.

(2) A person who intends to give or take remote medical treatment shall have the facilities and equipment prescribed by Ordinance of the Ministry of Health and Welfare.

(3) A person who gives remote medical treatment (hereinafter referred to as "remote doctor") shall have the same responsibility as when he or she gives direct medical treatment to a patient.

(4) If any of medical personnel, who has performed medical practice following a remote doctor's remote medical treatment, is a physician, dentist or an oriental medical doctor (hereinafter referred to as "local doctor"), and if there is no obvious ground to believe that the remote doctor is negligent in performing his or her medical practice, the local doctor shall be responsible for a patient, notwithstanding paragraph (3).”[8]

Current legal provisions state that the Republic of Korea only allows “remote consultation”—which

supports medical knowledge or technology between remote doctors and local medical personnel—among the types of telemedicine discussed above[9][10][11].

3.2.2 Infectious Disease Control and Prevention Act Article 49-3

Article 49-3(Temporary Non-Face-to-Face Diagnosis to Protect Medical Personnel, Patients, and Medical Institutions) of the Infectious Disease Control and Prevention Act stipulates the circumstances and scope of non-face-to-face treatment as follows.:

“(1) When 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, notwithstanding Article 33 (1) of the Medical Service Act, medical personnel (limited to medical doctors, dentists, and oriental medical doctors among medical personnel defined in Article 2 of the Medical Service Act; hereafter in this Article, the same shall apply) engaged in medical service may continuously observe, diagnose, consult with, and prescribe medicines for patients outside medical institutions concerning 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.

(2)The Minister of Health and Welfare shall determine the scope, such as areas and period of temporary non-face-to-face diagnosis under paragraph (1), subject to deliberation by the Committee.” [12]

Under the Infectious Disease Control And Prevention Act, temporary non-face-to-face medical treatment is characterized by allowing telemedicine—including types of telemedicine beyond medical treatment and prescription using the telephone—to prevent infection of patients and medical personnel and protect medical institutions in serious infectious disease outbreaks[13]. However, during the COVID-19 crisis, the Ministry of Health and Welfare did not allow non-face-to-face treatment through text message to maintain the quality of treatment. This is because confirming the identity of the patient himself by text message is impossible. Moreover, they attempted to expand the diagnosis method by listening to the patient’s condition through video or voice.

[Table 2] Temporary non-face-to-face medical treatment during the COVID-19 crisis[14]

Contents	Telephone counseling and prescription if safety is determined according to the doctor's medical judgment
Coverage	Counseling and prescriptions using wired/wireless phone calls and video communication, however, treatment using only text messages and messengers is not allowed to ensure the quality of treatment
Issuing a prescription	Send prescriptions to the pharmacy designated by the patient by fax or e-mail, including the phone number of the patient treated by the doctor at the medical institution
Other things	Face-to-face treatment procedures such as identity verification and treatment records are applied

3.2.3 Health Management Service of the Korean Government

The Ministry of Health and Welfare defines the Health Management Service as counseling, education,

training, practice programs, and related services involving the judgment of providers for improving unhealthy lifestyles and inducing correct health management to maintain and promote health and prevent disease deterioration. Categories of health management service include face-to-face services between user and provider, non-face-to-face services using apps, service based on automated app algorithms [15].

3.2.4 Bill of Act on Fostering and Supporting the Digital Healthcare Industry (2022)

The Bill was proposed for the following reasons. The digital healthcare industry, which combines digital technology and healthcare, is attracting attention as a key driving force that will determine the survival and development of companies and national industrial competitiveness. Apart from the current treatment-oriented healthcare support system, focusing support for industrial revitalization and competitiveness by creating a foundation for the prevention-, management-, and monitoring-oriented digital healthcare industry is necessary. Although the basis for supporting the digital healthcare industry is explained in numerous laws and guidelines, the above legislation defines the concept of digital healthcare, nurtures and supports the digital healthcare industry, and promotes digital healthcare through innovation in regulation. This was intended for resolving the legal uncertainty of companies.

3.2.5 Legal status of various terms in the legal system of the Republic of Korea

In the legal system of the Republic of Korea, the legal status of what is used in various terms and forms is as follows.

[Table 3] Analysis of various terms

Legislation	Definition	Type	Legal Status/ Applicability
Telemedicine of Medical Service Act article 34	Medical persons may give remote medical treatment to furnish medical knowledge or technology to medical personnel in a remote area by using information communication technology, such as computers or visual communication systems.	remote consultation between medical personnel	Telemedicine/ Normal times
Non-face-to-face treatment of Infectious Disease Control and Prevention Act article 49-3	When a crisis alert of a serious level or higher is issued, medical personnel engaged in medical service may continuously observe, diagnose, consult with, and prescribe medicines for patients outside medical institutions concerning their health and disease by using information and communications technologies such as wired, wireless, or image communications, and computers.	remote monitoring and telemedicine between medical personnel and patients	non-face-to-face treatment/ Temporary times (Outbreak)
Health Management Service of Non-medical health care service guidelines and casebook	Counseling, education, training, practice programs and related services that involve the judgment of providers are provided to improve unhealthy lifestyles and induce correct health management for the purpose of maintaining and promoting health and preventing disease deterioration in advance. And the categories of Health management service non-face-to-face service using App, service based on automated algorithm of App are all available	remote education	Teleducation/ Non-medical/ Normal times

Digital Healthcare of Bill of Act on Fostering and Supporting the Digital Healthcare Industry(2022)	It combines digital technology and health care.	remote consultation home monitoring remote education	Digital Healthcare/ Medical or Non-medical/ Normal times
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3.3 Judgment of the Supreme Court

The Supreme Court has made several judgments about whether consultation and issuance of prescriptions by phone are forms of telemedicine as prescribed in the Medical Service Act. The Supreme Court’s judgments and reviews on major cases are as follows.

3.3.1 Supreme Court 2020. 11. 12. Decision 2016Do309

3.3.1.1 Summary of the Prosecution and Definition of Medical Practice

The defendant is an oriental medical doctor who runs an oriental medical clinic, and medical personnel must perform medical work within the medical institution, except in certain cases. Regardless, on April 07, 2014, the defendant was prosecuted for performing medical activities. These include conducting medical examinations over the phone without visiting a hospital for some patients and prescribing and delivering diet herbal medicines on April 09, 2014.

“Medical practice is the act of preventing or treating a disease by conducting a diagnosis, optometry, prescription, medication, or surgical procedure based on experience, skills, and medical expertise and other health and sanitation hazards if not performed by medical personnel. Medical examination involves listening to and observing the patient’s condition to identify and determine the condition and name of the disease. Diagnostic methods may include medical examination, inspection, auscultation, percussion palpation, and other various scientific methods.”

3.3.1.2 Interpretation of Article 33 Paragraph 1 and Article 34 Paragraph 1 of the Medical Service Act

Article 33 Paragraph 1 of the Medical Service Act stipulates that medical personnel cannot engage in medical business without opening a medical institution and must conduct medical business within the medical institution, except in court cases.

The Supreme Court stated that the purpose of the article is that “the medical law stipulates that medical personnel run medical business within medical institutions as above. This is considered in accordance with the need for health and medical policy to prevent infections as these pose serious health risks to the health and sanitation of medical personnel. Moreover, Article 34, Paragraph 1 of the Medical Service Act is an exception to Article 33, Paragraph 1 of the Medical Service Act.

3.3.1.3 Limitations of Medical Treatment Using Telephone and its Acceptability

On telemedicine via phone, the Supreme Court said, “Considering the current level of medical technology, when a medical practitioner performs medical treatment on a patient in a remote location through a phone call, expecting the same level of medical service as face-to-face medical practice is considerably problematic. Owing to a lack of patient information and restrictions on how facilities or equipment may be used in medical institutions, inappropriate medical practices may be performed. Hence, the possibility of causing a serious risk to public health cannot be eliminated. Combining these circumstances, medical acts conducted by medical personnel to patients in remote locations using information and communication technology beyond the medical personnel to medical personnel

behavior may violate Article 33 Paragraph 1 of the Medical Service Act unless there are special circumstances.”

The Supreme Court highlighted limitations of medical treatment over the phone and simultaneously explained that medical treatment using telephones could be allowed under “special circumstances”[13].

3.3.1.4 Applicability

Based on the above legal principle, the Supreme Court found the defendant guilty of the prosecution in this case as they had performed medical activities such as conducting only interviews over the phone, prescribing herbal medicines, and delivering them.

3.3.2 Supreme Court 2013. 4. 11. Decision 2010 Do1388

The Supreme Court said, “Even within the Medical Service Act, direct medical examination and face-to-face medical examination are distinguished and used, and Articles 33 and 34 of the Medical Service Act stipulate the scope of telemedicine permitted. Regulating whether it corresponds to permissible telemedicine can be seen as more in accordance to the system of Medical Service Act to regulate the above clause. Additionally, the Medical Service Act aimed to protect and promote the health of the people by prescribing the methods necessary for national medical care so that people can receive high-quality medical benefits (Article 1). There is no reason to prohibit the operation of the system in the interest of promoting convenience. Moreover, abuse of non-face-to-face treatment can be prevented by allowing non-face-to-face treatment only within a limited scope through the operation of the National Health Insurance System or by adjusting insurance fees. Furthermore, considering the fact that there are means to do so is also necessary, as countries around the world are currently moving in the direction of expanding the scope of telemedicine due to the development of advanced technology.”

In this case, the principle of face-to-face treatment was indirectly discussed relative to Article 34 of the Medical Act related to telemedicine. Whether the act of a doctor examining a patient over the phone constitutes a form of telemedicine was not confirmed by The Supreme Court. However, the Supreme Court stated that it is a separate issue that is permissible as telemedicine[16].

4. Results

4.1 Establishing the Relationship Between Telemedicine and Non-face-to-face Treatment Under the Medical Service Act and Infectious Disease Prevention and Control Act, Respectively

Article 34 of the Medical Service Act regulates the form of remote consultation between medical personnel in telemedicine. Article 49-3 of the Infectious Disease Prevention and Control Act regulates the form of remote monitoring and telemedicine between medical personnel and patients.

As each policy regulating the different types of telemedicine can lead to confusion in the legal system, the work of establishing the concept and scope of telemedicine under the Medical Service Act and non-face-to-face treatment under the Infectious Disease Prevention and Control Act should be followed in the future.

4.2 Telemedicine Between Doctors and Patients Through “Special Circumstances” as defined by the Supreme Court

Under the current medical law in the Republic of Korea, for telemedicine to become accepted as a “special circumstance,” the possibility of a misdiagnosis should be minimized as certain patients give up face-to-face treatment in view of the common sense of society and common sense. Only unavoidable circumstance must be considered for requesting medical treatment and prescription even over the phone

while taking the risk.

In the early stages of the COVID-19 crisis, telephone treatment and prescription between doctors and patients were temporarily accredited to prevent infection between medical personnel and patients. This is similar to the case of visiting nursing services for the disabled or the elderly with limited mobility, wherein a remote doctor provides telephone treatment and prescription through a medical professional (e.g., a visiting nurse)[17].

4.3 Expansion of Types of Telemedicine Under the Medical Service Act

The Medical Service Act currently only recognizes remote consultations between medical personnel (Teleconsultation). - The Infectious Disease Prevention and Control Act does not allow for non-face-to-face treatment between doctors and patients, unless the infectious disease crisis of a serious level or higher level. If the disease crisis level is lowered, non-face-to-face treatment between medical personnel and patients will be considered illegal.

However, during COVID-19 pandemic, telephone treatment and prescriptions in non-face-to-face situations became possible owing to the development of digital technology. In a situation wherein the public has recognized and experienced such convenience, recognizing telemedicine only as a form of teleconsultation under the Medical Service Act does not coincide with the societal development[18].

Therefore, examining the possibility of accepting telephone treatment and prescription in society is necessary. The future speed of development of medical technology and science technology, realistic necessity for telephone treatment and prescription, and medical safety must also be considered.

The government enacted partial amendments to the Medical Service Act in 2010 (18th National Assembly), 2014 (19th National Assembly) and 2016 (20th National Assembly) to allow telemedicine between doctors and patients to help address medical blind spots and development of the medical service industry. Additionally, as a member of the National Assembly, the 2007 Representative Proposition of Chun-sook Park, the 2013 Representative Proposition of Jae-cheol Shim, and the 2018 Representative Proposition of Ki-jun Yoo have been submitted. The above amendments to the Medical Act generally telemedicine scope from teleconsultation to telemedicine but limit patients eligible for telemedicine and permitted diseases. Conversely, in the 2021 Representative Proposition by Byung-won Kang, remote monitoring is allowed for patients with recurrent diseases as defined by the Ministry of Health and Welfare including hypertension, diabetes, arrhythmia. In the 2021 Representative Proposition by Hye-young Choi, only non-face-to-face treatment is accepted for patients in medical blind spot areas with poor accessibility.

Meanwhile, in this process, in principle, face-to-face treatment should be given priority. Telemedicine or non-face-to-face treatment should be performed under exceptional circumstances where face-to-face treatment is considerably problematic.

5. Conclusion

The terms related to telemedicine appearing in the current laws of Korea and the proposals of the National Assembly are summarized as follows. First, Article 34 of the Medical Service Act stipulates that Telemedicine for remote consultation among medical personnel and is applied in normal times. Second, as defined in Article 49-3 of the Infectious Disease Control and Prevention Act, non-face-to-face treatment refers to remote medical treatment between medical personnel and patients. This type of treatment is temporarily applied in outbreaks caused by infectious diseases. Third, the Health Management Service proposed through the government can be applied in normal times as part of distance education between non-medical personnel and patients. Fourth, digital healthcare proposed through the Bill of Act on Fostering and Supporting the Digital Healthcare Industry is between medical

or non-medical personnel and patients and can be applied to all types of telemedicine even in normal times.

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