

## Conference Paper

# Legal Protection of Patients in Telemedicine Services: Implementation and Challenges

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**Abstract.**

The increasingly widespread Covid-19 pandemic has an impact on the disruption of health services in hospitals, including patients who intend to consult or treat other diseases as most of the hospitals are used to treat Covid-19 patients. This situation encourages a group of health service providers to use telemedicine as an alternative for the community to continue receiving health services from medical personnel without having to go to the hospital. This study focuses more on the information services and medical consultations offered by service providers, hence it is necessary to know how the legal protection of patients in telemedicine services is being implemented and their challenges. This paper is a prescriptive normative research using secondary data in the form of regulations and policies as well as interviews with several sources in related fields. Regulations and policies by the government are still temporary (fluctuating) and have not comprehensively regulated transactions for telemedicine services, for example, when an incident occurs that results in patient loss, a strong legal basis is needed to restore patient rights so that in the end a legal certainty is created for the society.

**Keywords:** legal protection, patients, telemedicine

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## 1. INTRODUCTION

The development of transactions through digital and pandemics in almost all countries has encouraged both users and providers of health services to take advantage of telemedicine-telehealth services. The need for remote health services is needed especially during the pandemic and after, because people have started to get used to making transactions via digital to meet the needs of goods and/or services.

Telemedicine services are proven to bring benefits to the user community, although sometimes incidents occur which are experienced by patients as users of this service. Incidents experienced by patients are usually caused by two services, namely consulting services by doctors and health application user services. Incidents experienced by patients, among others, were due to inaccurate diagnoses made by doctors because there was no physical meeting between the patient and the doctor, resulting in a

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misdiagnosed that led to medication errors. [1] As for health application services, it is related to the confidentiality of patient data which is used by parties who intend to obtain economic benefits from obtaining the patient data. [2]

The incidents experienced by consumers are seen as potentially recurring because until now there are no rules that have a deterrent effect for actors in the field of telemedicine services, even though people need it more given the ease of carrying out activities compared to having to go to a health service center which can be at risk of contracting the disease. another patient who came in the same place. Therefore, a brief study is needed to find out and analyze what legal provisions are needed to anticipate the increasing incidents experienced by patients both in health services and the use of digital applications as the main means of connecting patients and their doctors.

Previous research revealed the legal relationship between the three legal subjects, namely between patients and application companies, application companies and doctors, and patients and doctors, as well as the responsibility of doctors as providers of health services. [3] There is also research in the scope of consumer protection that focuses on the legal relationship between consumers and business actors related to telemedicine services. [4] In addition, there are studies that compare telemedicine services with the United States [5] and several countries in Southeast Asia, especially telemedicine settings. [6]

This study focuses more on the protection of patients as consumers of health and the role of telemedicine service authorities who have the responsibility to supervise these services. The intended supervision is both in terms of health services by doctors and the use of health applications and the challenges, so that: it can be anticipated that preventive measures will increase in violation of the applicable legal provisions. Therefore, this study focuses on the problem of how to implement patient legal protection and the form of supervision of consumer protection authorities in the field of telemedicine services and the challenges ahead.

## 2. METHODOLOGY/ MATERIALS

The paper is a normative research, namely conducting research by explaining the data obtained based on concepts, legal norms, and rules that are relevant to the object. [7] The legal protection, consumers, and telemedicine services are the concept that used by this paper. Prescriptive is the nature of this research, namely research that purpose to get advice on what to do to resolve certain problems. [8] The secondary

data that used by this study obtained from several library material, related to doctrinal practices and doctrinal from other countries regarding the legal protection of patients with telemedicine services, supervision and challenges. In addition, to obtain information about the application of telemedicine services, field studies were conducted in the cities of Bogor and Yogyakarta.

The research's secondary data came from a document analysis of legal sources, specifically laws and regulations pertaining to consumer protection, health, and digital/online transactions. Additionally, a description of the concepts, rules, doctrines, and principles associated with the study's subject is included. The study's findings also serve as non-legal documentation. This non-legal information is drawn from academic texts and research papers on the subjects of legal protection, consumer protection, the regulation of health care, and digital transactions.

At the next stage, the team looks at the main problems and makes recommendations for solving them. The qualitative approach was used to analyze the data that the authors obtained in this study. The conclusions in this study are made using the methods of deductive reasoning, namely the process of reasoning that begins with a general statement or thesis about the legal protection of consumer rights in the field of telemedicine services, in order to reach a specific conclusion about a specific subject, namely the form of legal protection for the patient, telemedicine and its supervision, both preventive and law enforcement. [9]

### 3. RESULTS AND DISCUSSIONS

This study that relies more on secondary data yields several findings at least two things, first about the concept of protection, legal protection, patients, business actors, and authorities related to this service sector. Second, related to implementation at the central and regional levels as well as comparisons in several ASEAN countries that have begun to regulate and protect their citizens from transactions for telemedicine services.

#### 3.1. Patient Legal Protection in the Field of Telemedicine Services and Its Implementation

Legal protection is a collection of rules or rules that can protect one thing from another. Related to consumer protection, it means that the law provides protection for consumer rights from something that results in the non-fulfillment of these rights. Consumer protection is all the efforts that are taken to make sure that legal rights are clear for

consumers to have protection from businesses. Consumers are everyone who uses goods and services available in the community, both for their own benefit and the benefit of others. They do not use these goods and services for trading purposes. From this definition, it can be interpreted that the patient is also a consumer.

During the pandemic, the World Health Organization has responded to the development of telemedicine transactions by compiling interim guidance which was published at the end of November 2020 and published again in May 2021. [10] The purpose of this guideline can be used as a basis for making decisions regarding the implementation of telemedicine in Member States, therefore Each country's strategy is needed to implement it, although efforts to develop telemedicine have been initiated since 2009. [11] At the ASEAN regional level the development of telemedicine has also been the subject of discussion even before the pandemic period related to the implications of using Information and Communication Technology (ICT), because telemedicine is considered to be able to covers a wide range of things from the very general to diagnosing patients, the general population, and administrative meetings. [12]

On a national scale, both Law 8/1999 on Consumer Protection (UUPK) and Law 36 of 2009 concerning Health (UUK) regulate consumer protection which is basically related to consumer rights and government responsibilities in health services sector. Regulations related to other health services are regulated in Law No. 29 of 2004 concerning Medicine, especially regarding the obligation of doctors who practice health services to have a registration certificate (STR) and a practice license (SIP) for a doctor or dentist, which is only given for a maximum of three (3) places of practice, both at service facilities health facilities owned by the government, private sector, and individual practice. In addition, there is also Law no. 44 of 2009 concerning Hospitals, where the Minister of Health has issued a technical regulation on trials of video-conferencing and tele-radiology-based telemedicine service programs. Considering the implementation of telemedicine services using online media, it is also necessary to pay close attention to Law no. 19 of 2016 concerning Amendments to Law No. 11 of 2008 concerning Information and Electronic Transactions as amended by Law no. 19 of 2016. At the implementation level, regulations are based on Government Regulation (PP) 71 of 2019 concerning the Implementation of Electronic Systems and Transactions, as well as Minister of Health Regulation Number 269 of 2008 concerning Medical Records also states that health service facilities must adhere to the principles of confidentiality and data security.

The dynamics of the community's need for fast health services during the pandemic was anticipated by the government by issuing several regulations from the Minister of

Health of the Republic of Indonesia No. 20 of 2019 concerning the Implementation of Telemedicine Services Between Health Service Facilities, which principally regulates the definition and types of telemedicine services. In addition, the Indonesian Medical Council (KKI), an autonomous, independent and non-structural body responsible to the President of the Republic of Indonesia, was established based on Article 7 UU no. 29 of 2004 concerning Medical Practice has issued KKI Regulation No. 74 of 2020 concerning Clinical Authority and Medical Practice Through Telemedicine During the Corona Virus Disease 2019 (Covid-19) Pandemic in Indonesia. This policy is pursued by the government to anticipate the development of telemedicine service transactions, which in practice there are already 17 telemedicine platforms in the community.

During its development, there were several incidents experienced by consumers, such as the phenomenon of a doctoroid (not a doctor but claiming to be a doctor), misdiagnosis doctors in telemedicine services, disclosure of patient data privacy, clarity of therapeutic agreements (informed consent), and standardization of tools to very varied service rates. In connection with this situation, it is necessary to know the legal relationship between the patient and the doctor as the provider of telemedicine services who have the obligation to provide compensation, compensation and/or reimbursement of costs for losses due to the use, use, and utilization of traded services. This compensation is a form of doctor's responsibility for services provided based on a therapeutic (therapeutic) agreement in the form of an agreement between a doctor and his patient in the field of Health which includes diagnostic, preventive, rehabilitative, and promotive; where the doctor tries his best to cure the patient (*inspaningsverbintenis*) is rarely a fixed contract (*resultaatsverbintenis*). This consent must be preceded by an approval of the doctor's action against the patient which is called informed consent. On the other hand, doctors also have an obligation to provide compensation for costs, losses, and interest, if they do not fulfill their promises.

Patient protection is also provided by the provisions of Law no. 36 of 2009 concerning Health, especially Article 56 related to the provision of complete information so that the patient can determine the action of help that will be given to him. Patients also have the right to protection for the confidentiality of their personal health conditions that have been disclosed to health service providers. Patient protection is also regulated in Law no. 29 of 2004 concerning Medical Practice which basically gives the right to get a complete explanation of medical actions. This provision is *mutatis mutandis* for transactions in telemedicine services.

To overcome the regulatory vacuum where people need telemedicine services, especially during the pandemic, the government has issued several policies, namely Minister

of Health Regulation No. 20 of 2019 concerning the Implementation of Telemedicine Services Between Health Service Facilities. This policy in addition to regulating the definition and scope of telemedicine, human resources, facilities/infrastructure/equipment, and applications. These three parties must register with the Ministry of Health and must comply with applicable laws and regulations. As for the guidance and supervision under the implementation of telemedicine, besides being carried out by the Ministry of Health, it also can involve the Ministry of Communication and Information. As a follow-up to this regulation, the Minister of Health also issued the Decree of the Minister of Health of the Republic of Indonesia No. HK.01.07/MENKES/4829/2021. In addition, the Indonesian Medical Council (KKI), an autonomous and independent institution responsible to the President, issued KKI Regulation No. 74 of 2020 concerning Clinical Authority and Medical Practice Through Telemedicine During the Corona Virus Disease 2019 (Covid-19) Pandemic in Indonesia. This regulation was formed as a form of technical implementation of the Minister of Health Regulation 20/2019. The doctor's obligation, among others, is to make medical records that are stored in health care facilities. In accordance with the provisions of Law No. 36/2009 concerning Health, the patient has the right to his personal health secret which is recorded in the medical record.

To support the digitization of consulting services and other related activities, the Ministry of Health issued Indonesia Health Services (IHS), which is a digital health ecosystem platform (a digital health ecosystem) that provides connectivity, analysis, and services to support and integrate various health applications in Indonesia. Micro services are grouped into modules according to service business processes, such as primary and secondary services, pharmacies, financing, health human resources, health resilience, biotechnology, internal management, and personal health records through hospitals, pharmacies, and laboratories according to specifications. standard business processes. The next step that will be formed by the government is to create a regulatory sandbox. The regulatory sandbox is a space where innovations in the health sector can pilot innovations or new business models in a safe environment that is monitored by regulators).

The implementation of the Regulatory Sandbox is also an input for the government in formulating policies based on the pilot experience of health innovation actors; and also become an instrument to realize IHS through compliance. (The implementation of the Regulatory Sandbox also serves as input for the Government in developing policies based on the pilot experience of health innovation actors; and also become an instrument to realize IHS through compliance).

The regulatory sandbox system has already been implemented in Singapore [13], by implementing telemedicine services that refer to remote health services through Information and Communications Technology (ICT) facilities. In general, telemedicine in Singapore covers 4 different domains, teleconsultation (teletreatment), telecollaboration, telemonitoring, and telesupport. Teleconsultation (teletreatment) is the interaction between health professionals, especially doctors and patients or their caregivers with the aim of providing direct clinical care that results in diagnosis and treatment;

Telecollaboration is the interaction and discussion of patient case files between health professionals for clinical purposes; Telemonitoring is the remote gathering of ICT-enabled patient data for Health monitoring purposes; and Telesupport is the use of online ICT-based services to support patients for non-clinical objectives. [14] The Ministry of Health has proposed new regulations governing the telemedicine system in Singapore. This regulation regulates the provision of such services by institutions outside the office (possibly outside the jurisdiction) that may not be affiliated with a medical clinic.

The main purpose of this regulation is to mitigate the risks of teleconsultation for the sake of patient safety, therefore the Ministry of Health stipulates that all medical practitioners who offer teleconsultation must obtain a license, and new provisions on the telemedicine system will come into force under the Healthcare Services Act (HCSA) in 2022. This law is expected to provide a stronger legal basis than the previous condition, where telemedicine regulations are spread across various laws such as the Health Products Law and the Personal Data Protection Law. In principle, all legal relationships based on contracts between service providers and patients, in this case the confidentiality of patient data are protected by law. Doctors who are allowed to consult must also be registered with the SMC (Singapore Medical Council) and must comply with the SMC Ethical Codes and Ethical Guidelines (ECEG).

With the establishment of a law-level regulation, the telemedicine service system has a strong legal basis, it can even impose criminal sanctions if in the future a violation that contains a criminal element is found, both in the provision of health services carried out by the medical team or by providers or platforms that provide telemedicine services.

### **3.2. Forms of Supervision of the Consumer Protection Authority and its Challenges**

Telemedicine services have been proven to help reduce the risk of COVID-19 transmission and help the community gain access to health. The challenges of the current use

of telemedicine are related to 1) human resources, 2) infrastructure and 3) ethics which result in the use of telemedicine still not being maximized. [15]

First, telemedicine services are currently receiving less attention by doctors and health policy makers to integrate the use of telemedicine into the national health system. [16] In addition, the use of telemedicine by doctors is still limited considering there is a need for doctors to learn new and complex consultation methods. From the juridical side, the competence of licensed doctors is indicated by the existence of a practice license (SIP) and a registration certificate (STR), so that there is a guarantee of certainty for patients to receive competent doctor services. This prevents the occurrence of a doctoroid which is detrimental to the patient and is contrary to Law no. 29 of 2004 concerning Medical Practice. In this case, the Ministry of Health is required to carry out its function in determining service standards, including the use of medical devices, administering medicines, issuing Practice Permits (SIP) and Registration Certificates (STR) up to standardization of tariffs for doctors. Ineffective supervision of telemedicine services because there is no authorized authority to impose sanctions on doctors' practices that have a negative impact on patients due to inadequate human resources in the medical field or even fraud by fake doctors (doctoroid practice). The rapid development of telemedicine services is now starting to be supported by the Ministry of Health by enforcing an effective regulatory sandbox, so that it is hoped that it will be able to encourage application business players to test products, services, business models and business service mechanisms that do not conflict with existing regulations.

Second, the next challenge is the issue of infrastructure. Currently, there are at least seventeen (17) telemedicine applications in collaboration with the Ministry of Health. The presence of many of these applications gave birth to a pattern of legal relationships between providers and providers and between patients and providers. [17] In general, these service providers can only be reached in urban communities which have better networks than in rural areas, so the government needs to expand network development to the rural level. In addition, according to the type of service, each provider must comply with the provisions of regulations in the field of telecommunications and informatics. The challenges currently being faced include the leaking of patient medical records which should be confidential. Other data that needs to be kept confidential is the therapeutic agreement (informed consent) between doctors and their patients, and the online fee payment system. Therefore, it is necessary to monitor confidential patient data; where this is the authority of the Ministry of Health and the Ministry of Communications and Information Technology. These two authorities need to synergize to ensure the security of patient data.



Third, is the challenge regarding ethics that should be guarded by all stakeholders, especially regarding the relationship between patients, doctors and providers. The most important thing for patients is related to ensuring the right to patient safety in accordance with the Health Law, the Medical Practice Law and the Consumer Protection Act. Doctors as health service providers are bound by the responsibility to provide their services, especially for confidentiality of health care to the commitment to meet patients directly when needed, considering that some cases encountered in practice were misdiagnosed by doctors when providing consultation and treatment through telemedicine services. Issues that arise from the provider and administrator are cross-cultural issues, one of which is related to language differences, responsibility for the availability of adequate transmission or network and correct data storage, so as to ensure the confidentiality of patient data. In addition, guaranteeing the competence, availability (adequacy) and willingness of doctors and medical personnel to provide telemedicine services will be a challenge in the future.

Facing the above challenges, the authorities can take anticipatory steps such as standardizing the agreement format, educating doctors about remote health consulting services, the responsibility to maintain the confidentiality and security of patient information by doctors and medical personnel, guarantee the expertise and eligibility of doctors, the existence of clear boundaries for health insurance through telemedicine, regular monitoring and inspection of standard medical equipment, the existence of adequate capabilities for telemedicine service providers who are subject to the law on information and electronic transactions.

#### 4. CONCLUSION AND RECOMMENDATION

The description above yields several conclusions, firstly, protection of patients with telemedicine services is guided by regulations at the level of law in the fields of Health, Medical Practice, and Information and Electronic Transactions. However, considering that the law does not specifically regulate telemedicine services, the Minister of Health has issued several policies that regulate telemedicine service activities. Likewise, the Indonesian Medical Council issued a regulation concerning Clinical Authority and Medical Practice through Telemedicine during the Corona Virus Disease 2019 (Covid-19) Pandemic in Indonesia. However, this policy has not provided clear sanctions for violations of telemedicine practices by doctors and providers, so that the provisions of the relevant law can be treated *mutatis mutandis* for health services in general.

Secondly, in its development, the community's need for telemedicine services is increasing, so it is necessary to prepare at least three (3) things, namely human resources in the field of health services, network infrastructure to remote rural levels and upholding health ethics that ensure patient safety and security.

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