

## Legal Responsibility for Misuse of Restricted Over-The-Counter Medicine Sold by Small Traders

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### Abstract

*The purpose of this legal research is to find out about the applications of doctors who perform telemedicine services and to find out the legal protection for doctors who perform telemedicine services. By using normative legal research method, this research uses statute approach and conceptual approach. Based on this research, a conclusion is obtained that refers to Law Number 36 of 2009 concerning Health, Minister of Health Regulation Number 20 of 2019 concerning the Implementation of Telemedicine Services Between Health Service Facilities, and Law Number 29 of 2004 concerning Medical Practice. However, these regulations have not provided legal protection for doctors who perform telemedicine services both in statutory provisions and the medical code of ethics. Legal protection should be provided through a new law on doctors who perform remote virtual services (telemedicine) which contains telemedicine authority so that there are limits to the authority of doctors to perform telemedicine services.*

**Keywords:** Legal Protection; Doctor; Telemedicine.

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## INTRODUCTION

In the era of globalization, the world is currently dealing with the emergence of developments in new medical technologies that allow doctors to be able to practice in an online scope. The development of technological innovation in question is telemedicine. The existence of telemedicine, health services are now easily accessible despite differences in distance, time, and place that are no longer a barrier to the therapeutic contract between patients and doctors, but can also be offered through audio, telecommunications, data, and visuals that can connect health facility services. Telemedicine services include the exchange of medical information and remote scientific discussions as well as aspects of care, diagnosis, consultation, and treatment. Telemedicine uses a call center system to interact with patients. The high number of mobile phone users connected to the internet in Indonesia is one of the factors for the presence of online medical services that utilize mobile applications as a medium.

The right to health means that the State must create conditions that enable a healthy life for all, adequate and affordable health services for the community, and responsibility for the provision of proper health services. Regarding health services, it can usually be said that the health care provider in this case is the doctor, while the recipient of health care is the patient. The relationship between doctor and patient is based on trust, this relationship is called a therapeutic agreement. Legally, a therapeutic agreement is a legal relationship between a patient and a doctor in professional health services, based on certain knowledge and skills in the field of health. Currently, doctors and patients have a democratic form of relationship, which has a horizontal contractual relationship or commonly called joint participation. The agreement between doctors and patients has a relationship called informed consent, which requires caution and professionalism among doctors to prevent misunderstandings between

patients and doctors. With informed consent, the patient understands all the benefits, risks and purposes of the treatment provided by the doctor, including the level of progress of the treatment or medical intervention. (Guwandi, 2006). The development of telemedicine or online-based medical services is closely related to health services, with legal references to Health Law Number 36 of 2009, which states, among others, as follows:

“Any activity and/or series of activities carried out in an integrated, integrated, and sustainable manner to maintain and improve the degree of public health in the form of disease prevention, health improvement, disease treatment, and health recovery organized by the government and/or the community.”

In practice, the doctor-patient relationship in telemedicine services solely offers interaction between patients and doctors. One form of interaction is health consultation, where patients can consult online remotely. Starting from the consumer side, the presence of telemedicine services provides convenience as a doctor in carrying out daily routines. The process is online, there is no face-to-face meeting and the doctor only conducts anamneses and diagnosis based on conversations on the phone and WhatsApp chat, only seeing photos that are not necessarily accurate. This online medical service is not strictly regulated by law and does not yet have functional standards set by the professional association of doctors or the Indonesian Doctors Association, as a result it does not rule out the possibility that when the public feels aggrieved it can at any time sue or expose the services of doctors who are considered malpractice.

Based on Ministry of Health Regulation Number 20/2019 on the Implementation of Telemedicine Services between Health Facilities, Telemedicine is a remote service provided by medical personnel using information and communication technology, including changes in information about diagnosis, treatment, illness, accidents, prevention, research and evaluation, as well as providers of continuing education in health services for the benefit of individuals and public health increases. Health is an important factor in a person's life, without health a person cannot fully enjoy life as a person. Apart from clothing, food and shelter, health is a basic human need. Without a healthy life, a person's life becomes meaningless as in a normal state of daily activities (Clinical Pathology, n.d.). Health problems that are biological problems are social problems caused by inappropriate environmental conditions that can destabilize the biological state of society. This includes the philosophical issue that health should be provided fairly, beneficially and safely in law, and at the level of legal substance and its implementation in various medical services.

The definition of telemedicine is telemedicine services between geographically separated health facilities in such a way that doctors and patients do not meet in person, but the discussion is carried out online using telecommunications and other information systems. The scope of telemedicine is quite broad and includes the remote use of health services (including educational services, clinical services and administrative services), through data transmission (voice, two-way interactive video calls, computers, and telementry) with the participation of doctors, patients, and other parties (Khalid Mustafa, 2009). These advances in technology have enabled patients living far away in one country to receive medical care from experts in another. Doctors using remote medical devices or telemedicine can instantly recognize digital images and hear the patient's heart movements and breathing sounds (audio signals and electronic stethoscopes) even when the doctor and patient are in two different locations.

Telemedicine promises many conveniences and opportunities that can be used as a solution to address health problems, but telemedicine unwittingly brings potential legal issues to the practice of medicine. Medical telemedicine has many legal implications, including registration, licensing, insurance, quality of privacy and confidentiality issues, and other risks associated with online health communication. Medical science knows how to estimate the

probability of success of medical actions to cure, alleviate the suffering of patients, and even calculate the time of death of patients due to certain diseases quickly (Supriadi WC, 2001). When a person's health is compromised, they take various steps to recover quickly. One of them requests treatment at available health facilities.

## **MATERIALS AND METHODS**

The research method is a procedure or process of how researchers collect and analyze the legal materials used. This type of normative legal research is used by examining theoretical approaches, concepts, and understanding related laws and regulations which will later answer future legal problems. Normative law is a type of research that functions to solve problems on existing legal issues. In answering the legal issues built by researchers, a statutory approach is needed, namely by examining from the point of view of the legislation of the Ministry of Health's decision and the law on medical practice.

Then the conceptual approach is a type of approach that is different from the views and teachings of legal science, the conceptual approach is also a legal study that offers a critical point of view to solve legal research problems from a jurisprudential perspective. Terms from the underlying law or even from the values contained in the standardization of regulations in connection with the terms used. In this study, the researcher focuses on the concept of legal protection rules for doctors who conduct telemedicine..

## **RESULTS AND DISCUSSION**

### **Regulations on Telemedicine License in Positive Law**

Positive law is a set of legal principles and principles that are in force today, whether oral or written. The validity of the law is binding and is usually controlled by a judicial body of legal or administrative authorities based in the country. Legislation must also be adapted to the realities of today's society or in other words, the government must respond to how society is developing. Nowadays, it is certainly easy to find public public service products that are based on IT information. Accessing distant internet areas in remote areas also allows people to enjoy the available internet. Online services related to public services are seen as a way of breakthrough in the midst of the current era. However, in relatively simple online services, the sophistication of information technology combined with public services is not necessarily acceptable to all citizens.

Telemedicine is a new type of healthcare service that has emerged in the healthcare industry as a result of technological advancements. Telemedicine is a kind of remote medical care in which actions, diagnosis and treatment assessments, and recommendations are made based on data, documents, and other information sent through communication networks. Telemedicine was developed to make it easier for people to access health information through electronic media and communication, overcome the problems of time and geographically limited health services, and introduce services and facilities to the wider community through the internet media. With its various advantages, telemedicine is basically identical to the type of services provided by the government sector, which also has some disadvantages. Privacy and confidentiality of electronic medical records are the most important issues that need to be considered.

Remote monitoring, asynchronous telemedicine, and synchronous telemedicine are three categories of telemedicine services. The real-time dissemination of medical data is referred to as synchronous monitoring. This can make it possible to have physical conversations with patients as well as medical professionals to provide care. Facilitated virtual meetings are another style of in-person or synchronous telemedicine visits. When the patient is in an

accessible location, such as a healthcare service with existing diagnostic tools and a distant medical practitioner, an assisted virtual visit can be conducted. In this case, the telefacilitator, which is a medical assistant or nurse, accumulates real measurements using devices such as thermometers, digital stethoscopes, pulse meters, etc. and sends this information to the service provider. The "store-and-forward" method is referred to as asynchronous telemedicine. The collection of medical history, images, and pathology reports by patients or doctors, which are then sent to specialized doctors for diagnosis and treatment. Last but not least, remote patient training requires continuous assessment of the patient's clinical condition, either through live video surveillance of the patient or by remote monitoring of collected tests and images.

Provisions for the fulfillment of Indonesia's telemedicine obligations and rights are defined by legal means in Permenkes No. 20 of 2019 concerning the Implementation of Telemedicine Services Between Health Facilities, Kepmenkes Number 489/2021 concerning Telemedicine During the Covid-19 Pandemic Through Health Service Guidelines (Kepmenkes 4829), For Health Services Through Telemedicine During the Covid-19 Pandemic (Kepmenkes 4829) and Regulation No. 74 of 2020 concerning Clinical Authority and Medical Practice Using Telemedicine During the Covid-19 Pandemic in Indonesia (Perkonsil 74/2020). Health facilities offer advice with the right to obtain medical and health information in the form of writing, images, audio or video in electronic form. In the rules of Fasyankes, it is limited to hospitals that are allowed to provide consultations. There is no specific regulation on the implementation of telemedicine at present. There are only licenses for the establishment of health care facilities such as licenses for the establishment of clinics, hospitals, and private doctors' practices. In Indonesia, telemedicine is often used for the first time. Telemedicine applications emerged and developed in 2016. After that, the Corona-19 outbreak that reached Indonesia in March 2020 contributed to the increasing demand for telemedicine-based health services. To reduce the amount of time doctors and patients spend in direct contact, telemedicine is one option.

The implementation of telemedicine services between health institutions is regulated in Permenkes Number 20 of 2019 which regulates the types of services to be provided, the rights, costs and obligations between health care facilities that provide consultations and those that request consultations, the financing derived from telemedicine services provided, and maintenance and control. This MOH regulation only organizes communication between medical institutions; it has nothing to do with how telemedicine is provided between doctors and patients. However, it is mentioned that telemedicine is the transmission of medical data through electronic means from one place to another for the purpose of improving patient health. Permenkes Number 20/2019 regarding telemedicine services used by doctors or medical facilities with patients is not covered by the rules. Wireless devices, email, two-way video calls, smartphones, and other forms of telecommunication technology are just some of the many services that can be used with telemedicine. There are currently no laws or regulations that specifically govern the delivery of comprehensive telemedicine between doctors and patients, which applies at all times, not just during the pandemic.

When there are no regulations, doctors who practice medicine do not receive legal protection and are prone to criminalization, although none have yet reached the realm of litigation. For example, if a patient has a fever and consults on a platform such as halodoc, the doctor may ask the patient to take their own temperature. Later, the temperature result is shown through a picture message or video call to the doctor. The doctor will then hand over recommendations for antipyretic or fever-relieving drugs. If the fever does not subside, the doctor advises the patient to go to the nearest health facility. As for skin diseases, the doctor can also conduct an examination by knowing the results of the diagnosis first physically using

pictures or video calls. However, the Halodoc platform says it is not responsible for any actions, omissions, negligence of doctors/patients, the Halodoc platform is only a tool for remote communication and information technology services between platform providers and users. Patients must first understand and comprehend the rules of the Digital Health Platform before applying its features.

Other topics relate to qualifications, accreditation, privacy and confidential information of electronic medical records, liability for medical malpractice, clinical policies, and health insurance/funding issues. (Mars M, 2020). There are various gaps in the laws governing this issue in Indonesia's current legislation. If there is a suspicion that a doctor made a wrong diagnosis, it is necessary to consider whether the doctor followed the instructions or not. Only health workers are responsible for their work and do not guarantee the final result. Prijo Sidipratomo also explained that the disciplinary standards for doctors are related to the standards set by the Indonesian Medical Council as a formal body determined by Law Number 29 of 2004 concerning Medical Practice. Evidenced is the suitability of the actions performed by the doctor, not the results obtained from the doctor's examination. (Prijo Sidipratomo, 2021).

#### Arrangement on License to Practice Medicine

The practice of medicine is a set of tasks performed by health professionals for a person in need of assistance in an atmosphere of mutual trust and filled with all the feelings, hopes, and concerns that humans have. Assistance as a lifesaving act motivated by compassion and performed with free choice and conscience must be legally justified. The practice of medicine today has developed rapidly. Doctors and patients have a relationship that forms a legal relationship in a therapeutic contract. Likewise, there is a relationship between doctors and patients in this telemedicine practice. Law Number 29 Year 2004 regulates the license to practice medicine. The Medical Practice Act (UUPK) is sometimes misinterpreted as a medical law, health law, or other types of medical laws. This viewpoint developed when the law was seen as limited to rules that responded to practical demands, i.e. to deal with social problems involving health workers whose main problems were related to the application of medical practices. Regulations governing medical practice are based on the principles of state, science, benefit, humanity and justice (Sri Siswati, 2015). A license is required for every doctor who has completed his/her studies and who will practice medicine. The word "license to practice" has two different meanings: "permission" as in "formeele bevoegdheid," or "permission" as in "material authority" (materieele bevoegdheid).

Licenses are granted in a non-verbal request-based form. Licensing bodies are also based on their ability to carry out medical-administrative and technical assessments. The granting of licenses is based on the principles of openness, order, thoroughness, good judgment, equality, trust, courtesy and fairness. Law Number 29 of 2004 states that a license is a written record issued by the state to doctors and dentists who begin to fulfill the requirements after practicing medicine. Therefore, the permit tool becomes one of the most important influences when a doctor wants to make a health center, because the permit tool can be used as evidence that the doctor concerned is qualified to carry out his medical practice. (Suganda Munandar, 2017). This practice letter permit is issued by the authorized district / city health office, of course this policy permit is issued by the health office which is where the doctor does medical work and has special authority. That is, if a doctor wants to obtain a license to practice medicine, he must meet the requirements, namely a license to practice medicine, a place of practice, and a recommendation from a professional association. The Certificate of Registration and License to Practice Medicine are requirements that must be possessed by a doctor while practicing as a doctor. The powers that a doctor must have at the time of practicing medicine and performing medical activities must have two authorities, namely during practicing medicine and

performing medical activities, doctors are not obliged to exercise the powers required by law at the time of practicing medicine and performing medical actions. the activities of the Registration Certificate (STR) and the Doctor's License (SIP) mean that there is a violation of the law committed by the doctor and will be subject to fines for his actions.

Professional standards are general completeness, namely the obligation of medical personnel in carrying out the therapeutic contract to do everything in the doctor's practice room carefully, thoroughly and reasonably, not carelessly, carefully. Medical negligence is usually measured by the thoroughness and diligence of the doctor in performing the same medical act (Mustajab, 2013). All doctors must have and practice the same care and diligence when performing the same medical operation. Thus, an objective culpa program that assesses whether there is culpa in the same circumstances of another person either in the same circumstances or in the same circumstances in performing the same act as the one who made it is in accordance with the general meticulousness criteria of doctors. Concurrent accuracy and thoroughness should be used when performing the same medical act, i.e. cesarean section, as a basis for measuring accuracy and thoroughness in standard procedures. The level of precision should normally be determined and measured by a physician who has similar experience with performing cesarean sections. It cannot be measured with equal accuracy by other medical personnel performing other medical health procedures. Usually, in the actions of a doctor, the standard operating procedures and professional standards, as well as the medical needs of the patient are the legal standards for his actions, so it is precisely both as a limitation for all actions, which also serves as a guideline or guideline, and as a limit, meaning that not all actions are allowed.

Health must be understood as a human right which is realized by offering various health interventions to all levels of society by implementing quality and accessible public health arrangements (Rahardjo Satjipto, 2010). Doctors and dentists are required to practice medicine, which is an integral part of various health service delivery functions that have high ethics and behavior/morals, competence and authority which are required to improve quality through continuous development such as providing certification, registration, licensing and training, guidance and examination so that medical practice is carried out in accordance with advances in science and technology. Every member of society needs access to quality health services, and doctors are obliged to provide these services in accordance with professional standards, operational guidelines and the patient's medical needs when carrying out medical procedures. This is because a doctor's job is to treat sick patients with the necessary knowledge and skills. As someone who has expertise in the medical field, a doctor has the appropriate authority and permission to provide health services and examine and treat patients who come to him in accordance with the provisions of the Health Services Law. Article 50 article 29 of 2004 concerning Doctors explains that the minimum skill limits set by the professional body which must be understood by a doctor independently in carrying out his profession are professional knowledge, skills and attitudes, therefore general knowledge, attitudes and skills.

The medical profession is a job that requires mastery of clinical knowledge and skills and whose practice is carried out in accordance with valid ethical rules and regulations. Doctors are required to have logical and structured skills or assumptions, this skill refers to dividing a problem in an orderly and systematic manner so that doctors can find the root of the problem. (Ravena Dey, 2010). Patient care must be consistent with competencies acquired during training; Family doctors do not limit their work to any particular disease or illness. You must be responsible for managing the facility, providing first aid to emergency patients, performing minor operations, providing first aid and ensuring patients are in a stable condition to prevent further complications. There are two forms with different but inseparable unity. The first is the

doctor's professional power, often referred to as professional or material power, which relates only to the individual; doctor; secondly, legal force; licensing.

## CONCLUSION

The practice of telemedicine in the form of remote online clinical consultations between doctors and patients is not regulated. Regulation of the Minister of Health Number 20 of 2019 concerning the Implementation of Telemedicine Services Between Health Institutions aims to organize telemedicine only when the framework of expert distance between doctors and specialists in different health institutions. New regulations are needed in accordance with the law that specifically regulates the practice of medicine through telemedicine, specifically in the form of remote medical consultations between doctors and patients. Those who practice medicine must also practice their profession in a professional manner and follow the professional standards and action guidelines established for the medical needs of doctors and patients in the course of treatment prescribed by doctors. Doctors must respond to the qualifications acquired during medical training and be professionally active in accordance with the doctor's training and expertise, if they are unable to carry out the legally prescribed examination or treatment, send the patient to another doctor or authorize another doctor in proportion to the doctor's qualifications.

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