
LEGAL POSITION OF INFORMED CONSENT IN THE FIELD OF CIVIL AND CRIMINAL MEDICAL LAW

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Abstract

Informed consent is a crucial element in medical services that provides legal protection for both parties, namely patients and doctors. In the criminal realm, informed consent protects medical personnel from accusations of abuse or malpractice, while in the civil realm, informed consent is evidence of fulfillment of legal and ethical obligations and the basis for protection against claims of breach of contract or unlawful acts. The informed consent process involves aspects of *ius contractu* and *ius delicto* in civil law, which establish the basis for the rights and obligations between doctors and patients. In addition, this process also regulates legal responsibility in cases of violation of legal norms. In the context of criminal law, the principle of legality requires valid consent and comprehensive information, in accordance with the provisions of Article 274 and Article 293 of Law No. 17 of 2023. This study uses a normative juridical approach that only examines library research or document studies that refer to legal rules in the order of statutory regulations and principles in applicable law in Indonesia using the Qualitative Descriptive Analysis method.

Keywords: Legal Status, Informed Consent, Medical Crime.

INTRODUCTION

As health services and medical services increase, the role of law becomes crucial. Health services can be carried out in various forms of promotive, preventive, curative and rehabilitative approaches, both aimed at individual health services and community health in the wider community. This is stated in Law Number 17 of 2023 concerning Health. Medical personnel and health workers are authorized to carry out health efforts professionally, with knowledge and skills to provide the best health services for the community. (2019 Driving License)

Everyone has the right to receive health services. Based on this right, there is an obligation for those who work as doctors to serve patients as well as possible. (Hasna, Laila, and Andri 2023) Patients have the right to be treated for their illness and a doctor is obliged to provide treatment and care as a form of his responsibility as a doctor. The relationship between a patient and a doctor is a relationship between someone seeking treatment and someone who will provide treatment based on trust. (Siyen, Hadi, and Asriwati 2020) The relationship is first born when the patient comes with the intention of getting help from the doctor and continues until a therapeutic agreement is established between the two called informed consent. The position of the doctor is considered higher than the position of the patient, where the legal relationship between the doctor and the patient is based on a paternalistic vertical relationship pattern like a father and son who adhere to the principle of "Father knows best", namely a doctor is considered to know more and is able to provide treatment for the disease suffered by the patient and has an important role in patient care. Thus, the doctor is required to provide complete information to the patient so that the patient can consciously decide to continue medical treatment or refuse it because all medical actions to be performed on the patient must obtain approval with informed consent, from minor surgery to major surgery and other medical actions.

Informed consent is an agreement regarding the medical action that will be carried out by the doctor on the patient. This agreement can be in oral or written form. In essence, informed consent is a communication process between a doctor and a patient regarding the agreement on the medical action that will be carried out by the doctor on the patient. Signing the written informed consent form

is only a confirmation of what has been agreed upon previously and becomes legal evidence that can be accounted for in the future if there is a lawsuit. In this case, the patient or the patient's family has the right to decide to accept or reject the action to be taken after hearing a complete explanation from the doctor. A doctor is required to provide complete and correct information regarding the plan for the action and treatment to be carried out by the patient and all possible risk effects, and the doctor is also required to respect the patient's decision if they refuse treatment or action after the information is given. The purpose of providing a complete explanation is so that the patient can determine his own decision according to his own choice (informed decision). Therefore, the patient has the right to refuse the recommended medical action and the patient also has the right to ask for the opinion of another doctor (second opinion), and the doctor who is treating him. (Sidi 2020)

In the Regulation of the Minister of Health Number 290/Menkes/Per/III/2008 Concerning Approval of Medical Actions, and Law Number 17 of 2023 Concerning Health, it is explained that doctors must obtain medical approval from their patients or informed consent, because without it doctors can be legally blamed for their actions. Although basically doctors in carrying out their medical duties have noble reasons, namely to maintain people's bodies so that they remain healthy or to make sick people healthy or at least reduce the suffering of sick people. However, all of that must begin with a therapeutic agreement in the form of informed consent which aims to provide comfort and support for patients to make choices for themselves and to improve communication between doctors and patients. In addition, informed consent also functions as written evidence for legal protection against the risk of lawsuits that are often related to failures in medical actions or maximum services that have been provided by hospital health workers including doctors. (Rahmadsyah and Sidi 2023)

Article 351 of the Criminal Code states that if a doctor injures a patient without informed consent, the doctor's actions are considered abuse and have violated the points in the article. For doctors, the many claims for damages from patients are something that is highly avoided and even feared because it concerns their good name and credibility as a professional who has always been considered noble because it is related to saving lives. Thus, informed consent plays an important role in protecting medical personnel and health workers in providing medical services and can be used as documentary evidence if there is a lawsuit in the future. Based on this, the researcher wants to explore more deeply the legal position of informed consent in the realm of civil law and medical data related to the legal relationship between doctors and patients, the rights and obligations of each party and the important role of informed consent in medical services as part of civil and criminal law that provides legal protection for both.

METHOD

This research will be presented in the form of Qualitative Descriptive Analysis, namely analyzing, describing, and summarizing various conditions and situations from various data collected from several literature reviews. This research uses a normative legal approach that only examines library research or document studies that refer to legal rules in the order of statutory regulations and principles in applicable law in Indonesia that are related to the title being studied. (Salsabila, Nugroho, and Gusthomi 2024)

RESULTS AND DISCUSSION

Legal Relationship Between Doctors and Patients in Medical Services

In daily practice, various things can be seen that cause the relationship between doctors and patients. This relationship occurs for several reasons, one of which is because the patient himself comes to the doctor to ask for help in treating his illness. In such a situation, there is an agreement of

will between the two parties. This means that both parties have fully agreed to enter into a legal relationship. This legal relationship is established on the basis of the patient's trust in the doctor so that the patient is willing to give consent to medical treatment (informed consent), namely the patient's agreement to accept the medical efforts that will be carried out on him. This is done after he has received a complete and correct explanation from a doctor regarding the medical efforts that will be carried out to help him, including obtaining an explanation of all kinds of risks that may occur and all other forms of alternatives that can be done to him in terms of treatment. (Salsabila, Nugroho, and Gusthomi 2024)

The legal relationship between a doctor and a patient in medical services is a relationship based on agreements, ethics, and laws and regulations. The relationship between a doctor and a patient usually begins with a therapeutic agreement. The doctor is obliged to provide medical services in accordance with his professional standards while the patient is obliged to provide honest information and in some cases pay for the doctor's services. The agreement made by both parties is a form of therapeutic agreement which is confirmed in the form of informed consent. The matter of informed consent has been explained in Permenkes No. 290/MENKES/PER/III/2008 Concerning Approval of Medical Actions and Law No. 7 of 2023 Concerning Health. (Siyen, Hadi, and Asriwati 2020)

In general, there are two conditions that can be the basis for an agreement between a doctor and a patient, namely the patient is in fact willing to carry out medical procedures in order to treat his/her illness and with or without a real agreement. Where the patient shows an attitude that can be concluded that the patient has signed his/her consent. So it can be concluded that the patient approves of the medical procedure so that rights and obligations arise between the doctor and the patient in two directions. The patient has a very big opportunity to take advantage of the patient's right to know all the procedures that will be undergone by him/her. The relationship between doctor and patient in this era is certainly different from the paternalistic nature of the previously dominant doctor-patient relationship where the patient only follows the decisions given by the doctor and carries out the procedures that have been planned by the doctor. In such circumstances, the patient has the right to ask and obtain as much information as possible before deciding to follow a planned action by the doctor. In addition, a doctor has a full obligation to explain the decision starting from the considerations used in determining the action, how the stages of the action are, and the planning after the action until the patient recovers. All processes that take place between the doctor and the patient in a therapeutic transaction must be carried out carefully and precisely.

Legal relations in therapeutic transactions give rise to the rights and obligations of each party, both the patient and the doctor. An agreement is said to be valid if it meets the requirements as stipulated in Article 1321 of the Civil Code which explains that "no agreement is valid if the agreement is given due to an error or obtained by coercion or fraud". Based on this article, it can be concluded that legally the validity of an agreement is determined by the agreement of the parties who bind themselves, without any error, coercion or fraud. This agreement is an agreement made by both parties where both parties have a match of will in a therapeutic transaction as the patient agrees to be treated by the doctor, and the doctor also agrees to treat his patient. (Alfina 2019) In order for this agreement to be legally valid, then in this agreement the parties must be aware (no mistake) of the agreement made, there must be no coercion from either party, and there must be no fraud in it. That is why Informed Consent is needed or what is also known as "Medical Action Consent".

Another reason that causes the relationship between a doctor and a patient is in an urgent or emergency situation to immediately get help from a doctor. For example, because of a traffic accident, a natural disaster, or because of a situation that causes the patient's condition to be critical so that help is needed. In this case, it is difficult for a doctor to know what his patient wants. However, the doctor can immediately take the necessary medical action to save the patient without having to get the patient's consent because he is in an emergency situation. This is also explained in Law Number 17 of 2023 in Article 275 paragraph 2 that medical personnel or health workers who provide health services for first aid in the event of an emergency or natural disaster are exempt from claims for compensation. In addition, in circumstances like this, doctors can also do what is called *zaakwaarneming* (voluntary

representation) as regulated in Article 1354 of the Civil Code, namely a form of legal relationship that arises not because of prior approval of medical action but because of compelling circumstances or an emergency. The relationship between the doctor and the patient that occurs is a therapeutic transaction that differentiates it from ordinary agreements as regulated in the Civil Code. (Naili et al. 2022)

When a relationship is established between a doctor and a patient, an agreement arises to do something by the doctor. In accordance with Article 1601 of the Civil Code which states that a doctor has agreed to try with all his ability to fulfill the contents of the agreement, namely to treat or cure the patient. While the patient is obliged to comply with the rules determined by the doctor including providing compensation for services. With this agreement through informed consent, an agreement has been achieved that gives rise to reciprocal rights and obligations. This agreement which is confirmed in this informed consent sheet has binding power in the sense that it has legal force that must be obeyed by both parties.

Before the therapeutic transaction occurs in the doctor-patient relationship. The existence of informed consent can be used as a form of legal protection that can provide a sense of security both by doctors who will perform medical actions as an effort to cure the patient's illness, as well as a defense if the results of medical actions are not in accordance with the wishes of the patient or the patient's family. Even so, patients can still file a lawsuit against health workers, if the health workers and doctors or dentists concerned do not perform actions in accordance with professional standards properly.

Informed consent is not only for the purpose of writing a contract, but is quite broad in scope to protect both parties. Therefore, it is the doctor's responsibility to ensure the integrity of the entire process from the start. The basis of a doctor's work is consent and it is hoped that the relationship between the doctor and the patient will contribute to the healing process and also the safety of the patient. Doctors will be punished if they do not obtain medical consent from the patient or their family regarding the medical action to be carried out both in the civil and criminal legal realms and also administration with discipline by the MKDKI (Indonesian Medical Discipline Honorary Council). (Mohamad 2019)

Legal Position of Informed Consent in the Field of Civil and Medical Criminal Law.

In essence, informed consent is a communication process between a doctor and a patient regarding an agreement on medical actions that will be carried out by the doctor on the patient. With informed consent, every person (patient) has the right to determine for themselves to accept or reject some or all of the assistance that will be given to them after receiving and understanding complete information about the action. The position of informed consent in health services is regulated in Law No. 17 of 2023 concerning Health and Law No. 29 of 2004 concerning Medical Practice. In addition, technically the implementation of informed consent in health services, especially for patients in hospitals or other health service centers, is regulated in the Regulation of the Minister of Health of the Republic of Indonesia Number 290/Menkes/Per/III/2008 concerning Consent to Medical Actions. (Sidi 2022)

The following are several regulations governing Informed Consent or approval of medical procedures in Indonesia:

- 1) Law No. 17 of 2023 concerning Health, in article 293 states that every individual health service action carried out by medical personnel and health workers must obtain approval from the patient after receiving adequate explanation including diagnosis, indications, health service actions carried out and their objectives, risks and complications that may occur, alternative actions and their risks, risks if not carried out and prognosis after receiving the action. The consent is given in writing or verbally which must be obtained before the invasive and/or high-risk action is carried out.
- 2) Law No. 29 of 2004 concerning Medical Practice. Article 45 states that every medical or medical action performed by a doctor or dentist on a patient must obtain approval after

- receiving a complete explanation of at least the diagnosis and procedures for the medical action, the purpose of the medical action performed, alternative actions and their risks, risks and complications that may occur and the prognosis.
- 3) Regulation of the Minister of Health of the Republic of Indonesia No. 290/MENKES/PER/III/2008 Concerning Consent for Medical Procedures, in Article 1 has defined informed consent as consent for medical procedures which is consent given by the patient or the closest family after receiving a complete explanation regarding the medical or dental procedures to be performed on the patient.
 - 4) Regulation of the Minister of Health of the Republic of Indonesia No. 1419/MENKES/PER/X/2005 Concerning the Implementation of Doctors' and Dentists' Practices, which in Article 17 states that doctors and dentists in providing medical or dental services must first provide an explanation to the patient about the medical action to be performed and obtain the patient's consent which is carried out in accordance with statutory provisions.
 - 5) The Indonesian Hospital Code of Ethics (KODERSI) 2022, in Article 20 concerning Consent for Medical Procedures, states that hospitals are required to request patient consent or refusal before performing medical procedures. Patient consent is only given after the patient has received and understood information including the diagnosis and procedures for medical procedures, the purpose of medical procedures, alternative procedures, risks and complications that may occur, and the prognosis for the procedures performed and the estimated cost of treatment.
 - 6) The 2006 Indonesian Medical Council Manual for Consent to Medical Procedures, outlines the meaning of consent to medical or dental procedures as follows:
 - a. The consent of the patient or his/her legal representative for the planned medical or dental action proposed by the doctor or dentist, after receiving sufficient information to be able to make the consent,
 - b. Consent to medical or dental procedures is a unilateral statement from the patient and is not an agreement between the patient and the doctor or dentist, so it can be withdrawn at any time.
 - c. Consent for medical or dental procedures is a process and result of effective communication between the patient and the doctor or dentist, and not simply signing a consent form.

In the provisions above, it is stated that doctors in performing medical actions must ask for approval from the patient or his/her family. The patient referred to here is a competent patient. This means that if the patient cannot be asked for approval, the patient's family can take the patient's position to provide choices or approval for the patient's good.(Hasna, Laila, and Andri 2023)

As stated above, in order to treat a patient, the patient must consent to the treatment verbally, signed or in writing. In criminal law, whatever a person wants to do, they must provide evidence to justify their actions so as not to cause problems. Likewise, doctors must follow the patient's consent to medical decisions when carrying out treatment or therapy. In the realm of substantive criminal law, the patient's consent to treatment is based on torture. If a doctor performs invasive procedures such as surgery and radiation therapy without the patient's consent, the doctor can be sued for misusing the method.(Naili et al. 2022)Abuse is punishable by a maximum imprisonment of two years and eight months or a fine. If the practice causes serious harm, the perpetrator can be sentenced to up to five years in prison. If the behavior causes someone's death, the perpetrator can be imprisoned for up to seven years. Abuse has an impact on someone's health.(Sidi 2020)Judging from the purpose of carrying out an approved medical procedure, the condition for carrying out an approved medical procedure between the doctor and the patient is to protect the beneficiary in all medical procedures.

In Criminal Law, anything done by a person requires supporting evidence as a form of justification for what he did so as not to get problems later. Likewise, doctors in carrying out treatment or therapy must be based on the consent of medical action given by the patient.

The presence of informed consent in the world of health aims to protect patients and also their doctors if there is a medical dispute in the future. In carrying out his professional responsibilities as a doctor who has legal provisions, he can be legally accounted for under criminal law, civil law and administration. In the realm of civil law, the relationship between a doctor and a patient in the form of informed consent occurs due to two events, namely *Ius Contractu* and *Ius Delicto*. *Ius Contractu* or agreement is a branch of law that regulates agreements or contracts between the parties involved. This includes the formation of contracts, implementation of obligations, dispute resolution, and legal action in cases of breach of contract. In other words, *Ius Contractu* focuses on the rights and obligations arising from agreements and the legal rules that govern them. While *Ius Delicto* is a law that regulates violations or unlawful acts. This includes the definition of a crime, legal responsibility, sanctions, the principle of causality, and responsibility related to actions that are considered violations of legal norms. (Sustainable 2021)

Furthermore, informed consent in the realm of criminal law must adhere to the principle of legality. The principle of legality in informed consent emphasizes the importance of ensuring that every medical procedure or health action involving patients must be based on legally valid consent. In this context, the provision of information to patients must cover all relevant aspects, such as diagnosis, risks, and other treatment alternatives. Patients must give consent voluntarily in a state of full consciousness without any elements of pressure and coercion. The patient's understanding of the information provided is also the main focus, ensuring that the decisions taken are based on adequate knowledge. The process of providing informed consent should always be documented in accordance with the law. This creates a clear and valid record related to patient consent. In addition, the principle of legality requires health service providers and medical personnel to comply with applicable health regulations and standards. Thus, this principle provides a strong legal basis aimed at providing patient rights and ensuring integrity in the process of providing informed consent in the field of health services. The principle of legality is stated in Article 23 of Law no. 17 of 2023 on health, namely health workers who are tasked with carrying out health processes in accordance with their expertise and authority. This means that the legality of health services can be implemented if the health services have fulfilled the requirements and permits that have been regulated in laws and regulations, namely having a registration certificate and a practice permit. (Sustainable 2023)

Informed consent can be given in writing, verbally, or by gesture. In the original language, the latter is called implied consent which is usually given in emergency situations. In this case, the medical decision is approved. However, the patient or his family cannot provide verbal or written consent at that time. However, for high-risk medical procedures, written consent is required and signed by the patient regarding the agreement between the medical procedure carried out by the patient and the doctor. Legal Aspects of Informed Consent are:

- 1) The civil law aspect is related to the law of contract, the essence of which is that there must be an agreement between the two parties. Which means there must be information between the two, namely the patient and the doctor.
- 2) The criminal law aspect is that patients must give consent to medical actions such as surgery. Because if it is associated with Article 351 of the Criminal Code concerning abuse, then surgery by a doctor such as stabbing a patient's body without prior consent can be subject to criminal sanctions because it can be categorized as an act of abuse.
- 3) The legal administrative aspect is that the hospital provides approval in the form of informed consent, such as carrying out medical actions for hospital administration purposes, so it is mandatory to do so as per the regulations regarding medical actions in PMK 290 of 2008.

In an emergency Informed consent remains the most important thing even though it is recognized as the lowest priority. The highest priority is life-saving action. (NOVITA 2022) Although still important, Informed consent should not be a barrier or obstacle to the implementation of emergency care because in critical conditions where the doctor is racing against death, he does not have enough time to explain until the patient is truly aware of his condition and needs and makes his

decision. The doctor also does not have much time to wait for the patient's family to arrive. Even if the patient's family has arrived and then does not agree to the doctor's actions, then based on the doctrine of necessity, the doctor must still perform medical action. This is explained in the Regulation of the Minister of Health Number 585/Men.kes/Per/IX/1989 Concerning Consent to Medical Actions, that in an emergency, Informed consent is not required. In accordance with the Regulation of the Minister of Health Number 290/Menkes/Per/III/2008 Concerning Consent to Medical Actions, that in an emergency, to save the patient's life and/or prevent disability, consent to medical action is not required

CONCLUSION

Informed consent is a crucial element in medical services that provides legal protection for both parties, namely patients and doctors. In the criminal realm, informed consent protects medical personnel from accusations of abuse or malpractice while in the civil realm, informed consent is evidence of fulfillment of legal and ethical obligations and the basis for protection against claims of breach of contract or unlawful acts.

The position of informed consent in the civil law realm as legal protection from claims of breach of contract and as evidence that health workers have fulfilled their obligations to provide information and respect patient rights and patients can sue if there is a failure to fulfill their agreement. While the position of informed consent in the criminal law realm as a defense tool for medical personnel to show that the actions taken have obtained the patient's conscious and voluntary consent and as evidence that medical personnel have not committed unlawful acts or abuse.

The absence of Informed Consent in medical procedures can result in administrative sanctions in the form of revocation of the doctor's practice license and can be prosecuted under civil and criminal medical law. By signing the Informed Consent, it indicates that the patient or the patient's family has understood, realized and accepted all actions that will be taken by the doctor concerned as well as the risks that may occur to him/her.

Suggestion:

1. In carrying out informed consent, doctors and patients must understand that each individual has rights and responsibilities that must be fulfilled. This must be understood so that there are no problems in the future that endanger and harm all parties involved.
2. Between patients and doctors should be able to improve communication, because with good communication, the implementation of informed consent can run well. In addition, with good communication, the risk of malpractice in the medical field will be minimized.
3. For the sake of legal certainty in the medical field, as well as the guarantee of rights and obligations between doctors and patients, it would be better if the Minister of Health Regulation No. 290/Menkes/Per/III/2008 which regulates informed consent for medical procedures is raised to the level of a Government Regulation, and strict sanctions for violators of the provisions on informed consent for medical procedures are added.

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