Juridical Analysis of Informed Concent and Ownership Rights Reviewed from Law No 17 of 2023 Concerning Health

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Abstract
This research aims to analyze informed consent in the context of Indonesian health law, specifically referring to Law No. 17 of 2023 concerning Health. Informed consent, which is consent given by the patient after receiving sufficient information, is a critical aspect of medical practice. This research examines the legal and ethical implications of informed consent and its ownership rights in medical records. This study uses normative juridical analysis methods, reviewing relevant legislation, literature and legal documents. The focus is on the interpretation of legal norms related to informed consent and analysis of cases related to medical records in health services. With a focus on discussing how to implement informed consent in health practice in terms of legal and ethical aspects according to Law No. 17 of 2023? How are ownership rights of medical records containing informed consent regulated?. Research shows that informed consent is not only a moral and ethical obligation, but also a legal one, which is strengthened by Law No. 17 of 2023 concerning Health. Effective implementation of *informed consent is essential in respecting patient autonomy and preventing malpractice.* Medical records, which include *informed consent* , are the property of the health facility but with access rights for the patient. This research emphasizes the importance of clarity and comprehensiveness of information conveyed to patients as well as regulating rights to medical records to guarantee patient rights and the responsibilities of health facilities. Health institutions should increase awareness and training about the importance of *informed consent* . There is a need to develop clear standards regarding the delivery of information and documentation of consent in medical records. Governments and health institutions need to ensure that relevant laws and regulations are implemented effectively to protect patient rights and ensure ethical medical practice.

Keyword: Informed consent, Ownership Rights, Medical Records

1. INTRODUCTION

Health services are nothing new in society, but as medical science and technology develop, ethical and legal aspects also experience changes and improvements. One important aspect of health services that is often in the spotlight is informed consent. The term informed consent was first introduced in the 20th century and has become an integral part of modern medical practice. In its development, the concept of informed consent was based on human rights, especially the right to regulate and determine everything regarding oneself. In a medical context, this means that patients have the right to receive complete and clear information regarding the medical procedures that will be performed on them, including the potential risks and benefits. This concept is firmly rooted in the principle of individual autonomy, where every individual has sovereignty over their body and self. According to Law of the Republic of Indonesia no. 29 of 2004 concerning Medical Practice, informed consent is defined as approval given by the patient after receiving information regarding the action that will be carried out on him. This means that informed consent is not just consent, but rather consent given after obtaining complete and adequate information. This mechanism is important so that patients can make the right decisions and according to their wishes. In providing health services, the existence of informed consent is a requirement that must be fulfilled. This is to protect the rights

of patients and also prevent the possibility of legal disputes that could harm the medical and medical parties patient. Any medical procedure performed without informed consent may be considered a violation of law and medical ethics.

So far, the mandatory element of informed consent in health services has been recognized and regulated in various legal regulations in Indonesia. Through Law of the Republic of Indonesia no. 29 of 2004 concerning Medical Practice, it is emphasized that before carrying out medical procedures, a doctor must obtain written consent from the patient or the patient's guardian. This document should contain complete information about the type of action, potential risks and benefits, and other available alternatives. The aim is clear: to ensure that patients have the opportunity to fully understand the procedure they are about to undergo and provide informed consent. Law No. 17 of 2023 concerning Health, as the latest regulation, reaffirms the importance of informed consent . According to the existing article, every medical action carried out must be based on the patient's consent after obtaining clear and complete information. This not only confirms the principle of patient autonomy, but also guarantees legal protection for medical personnel and health service facilities. Through this regulation, the responsibility of Health Service Facilities in storing and protecting medical record data, including informed consent, becomes stronger. Therefore, these old and new regulations show that the Indonesian government consistently emphasizes the importance of informed consent . However, there are significant differences in recent regulatory approaches. In Law No. 17 of 2023, the emphasis is more on aspects of data protection and accessibility. In other words, while the old law focused more on the doctor's obligation to obtain informed consent, the new law places more emphasis on the patient's right to access information and the responsibility of health care facilities in safeguarding those documents. Additionally, with Law No. 17 of 2023, there are new challenges for health service facilities. They must ensure that the system for storing and managing medical record data, including informed consent documents , is safe from the risk of loss, damage or leakage of information. This also raises questions regarding the extent of patients' rights to access and control their personal data, considering that medical records belong to health facilities but contain the patient's personal information. It cannot be denied that informed consent documents have an important role in the medical world. This document not only confirms the patient's consent to the medical treatment that will be received, but also becomes authentic evidence of the agreement between the medical personnel and the patient. Therefore, a deep understanding of ownership rights and access to these documents is necessary. The research with the title "Judicial Analysis of Informed Consent and Ownership Rights in View of Law No. 17 of 2023 concerning Health" was not raised without reason. In this modern era, a person's personal information, including medical records, has very important value. On the one hand, patients have the right to ensure that their personal information is properly protected. On the other hand, many parties may have an interest in this information, such as insurance companies, pharmaceutical companies, or even health research institutions. One case that occurred, where the insurance company was able to access a customer's medical history at a hospital, raised many questions. To what extent are third party access restrictions to patient medical records? What is the legal basis for the insurer to access this information? Does this not violate the patient's right to privacy? This case is a clear example that issues regarding ownership rights and access to informed consent are not only theoretical, but have direct implications in real life. This research is important because it will provide a clearer picture of the position of informed consent in the legal framework in Indonesia, especially after the issuance of Law No. 17 of 2023. Through juridical analysis, it is hoped that answers to the questions that have arisen can be found. Who actually has the right to informed consent documents ? Is it the patient, the hospital, or even another third party? Who has the right to access the information and in what context?

2. RESEARCH METHODOLOGY

This research examines *informed consent* and ownership rights in the context of Indonesian health law, specifically based on Law No. 17 of 2023 concerning Health, using a descriptive qualitative approach to obtain a holistic and in-depth understanding. Data collection methods through the study of legal documents and analysis of relevant cases, together with content analysis, allow the identification of the main themes and interpretation of this legal phenomenon in practice. Data triangulation and review by health law experts were used to ensure the validity and reliability of the study, which aims to provide a comprehensive juridical analysis of *informed consent* and its impact on patients and health care providers. The results of this research are expected to make significant contributions to the academic understanding and practice of *informed consent* in health law, offering insights for future policymaking and legal practice. These findings aim to

improve compliance with legal norms and strengthen patients' rights, while taking into account the obligations of health care providers, facilitating more effective dialogue between patients and medical professionals, and paving the way for further research in the field of health law.

3. RESULT AND DISCUSSION

The Urgency of Informed Concent in Health Services

Informed consent consists of two words, namely "informed" which means information or information and "consent" which means approval or giving permission. So the meaning of informed consent is an agreement given after receiving information. Thus, informed consent can be defined as a statement by the patient or his/her legal representative which contains the form of approval for the medical action plan proposed by the doctor after receiving sufficient information to be able to make an agreement or refusal. Approval of the action to be carried out by the doctor must be carried out without any element of coercion. For patients, informed consent is the realization of their right to receive complete information regarding medical conditions, actions to be taken, risks, alternative therapies, and prognosis. This research emphasizes the importance of doctors implementing informed consent effectively to reduce the knowledge gap between patients and doctors, thereby preventing malpractice. The recommendation from this study is to improve informed consent practices among medical professionals to ensure transparency and patient participation in medical decisions that impact them. With the development of patient awareness and demands for patient rights, informed consent has become not only an ethical but also a legal obligation for health practitioners. Effective implementation of informed consent helps in building a relationship of trust between doctors and patients, respects patient autonomy, and supports informed decision making. Additionally, given the complexity of medical procedures and the potential risks involved, informed consent helps ensure that patients fully understand what they are agreeing to, including the possible outcomes and consequences. Therefore, implementing comprehensive and systematic informed consent is the key to improving the quality of health services and reducing conflicts and misunderstandings that can lead to malpractice claims. This shows the urgency to continue to improve education and training for health professionals regarding the legal and communication aspects of their medical practice.

Informed consent in health care is a fundamental principle that supports patients' rights to make informed decisions about their medical care. It recognizes patient autonomy and the importance of transparency in the doctor-patient relationship. Effective implementation of informed consent allows patients to fully understand their medical condition, available treatment options, the risks and benefits of each medical procedure, and the potential outcomes that may occur. Thus, informed consent acts as a communication bridge between doctors and patients, reducing knowledge gaps, and ensuring that medical decisions are taken based on good understanding. In the Regulation of the Minister of Health of the Republic of Indonesia number 290/Menkes/Per/III/2008 concerning Approval of Medical Procedures, it is determined that informed consent is translated into Approval of Medical Procedures, which is regulated in Chapter I Article 1 which determines that consent is given by the patient or their closest family after receiving a complete explanation of the medical or dental procedures that will be carried out on the patient. Based on the definition above, informed consent contains two essential patient rights in their relationship with the doctor, namely the right to information and the right to consent. 11 Explanation of information regarding the action to be carried out on the patient must be given clearly and given directly to the patient, not to patient's family. This is regulated in Article 7 paragraph (1) Minister of Health Regulation no. 290/Menkes/Per/III/2008 which determines that explanations regarding medical procedures must be given directly to the patient and/or the patient's closest family, whether requested or unsolicited. Regarding the right to consent, it is contained in the Minister of Health Regulation. Article 2 of the same regulation stipulates that all medical procedures to be carried out on patients must obtain approval.

One thing that must be understood is that informed consent is part of the medical record. The medical record must contain a note regarding complete approval of the medical action. The legal aspects of medical records and informed consent have legal value because their content concerns the issue of guaranteeing legal certainty on the basis of justice in efforts to uphold the law and providing evidence to uphold justice. Medical records are the main form of evidence in written form, so they are useful in resolving legal, disciplinary and medical ethical issues. Informed consent is used as material for accountability and reporting by medical personnel if there is a legal claim from the patient or the patient's family. The information needs

to be provided and explained in simple words that the patient or family can understand. According to J. Guwandi, the information that needs to be conveyed to patients or their families includes:

a. The risks inherent in the action;
b. Possible side effects;
c. Other alternatives (if) exist besides the proposed action;
d. What might happen if the action is not taken.

Article 7 (3) Regulation of the Minister of Health of the Republic of Indonesia No. 290/Menkes/Per/III/2008 concerning Approval of Medical Procedures determines that explanations of medical procedures at least include:

a. Diagnosis and procedures for medical procedures;
b. The purpose of the medical action performed;
c. Other alternative actions and their risks;
d. Possible risks and complications;
e. Prognosis of the actions taken;
f. Cost estimation.

According to Guwandi informed consent can take the form of:

1. Expressed (expressed)
a. Verbally (orally)
b. In writing (written)
2. Implied or deemed to be given (implied or tacit consent)
a. Under normal circumstances (normal or constructive consent)
b. In an emergency situation (emergency).

When carrying out serious medical procedures, written approval for medical procedures is very important for both the patient and the doctor. If a medical risk occurs then legal problems arise, the doctor can say that this has been stated in the informed consent , but it turns out that the informed consent form that was made is not in accordance with the informed consent doctrine itself so that the informed consent form does not provide clear information so it cannot be used as evidence. which is strong to prove that the medical action carried out on the patient is correct. According to the Decree of the Directorate General of Medical Services No. HK.00.06.3.5. 1866 of 1999 concerning Guidelines for Consent to Medical Procedures. In establishing and implementing policies and procedures regarding informed consent , every hospital must pay attention to the following provisions:

(1) Arrangements for approval of medical procedures must be in the form of policies and procedures (Standard Operating Procedures/SOPs)
(2) Obtaining information and explanations is the patient's right and conversely providing information and explanations is the doctor's obligation;
(3) Informed consent is given for specific medical procedures;
(4) Informed consent was given without coercion;
(5) Informed consent is given by someone to a patient who is mentally healthy and who has the right to give it from a legal perspective;
(6) Informed consent is given after sufficient (adequate) information and explanation are required.

Furthermore, informed consent not only has an ethical dimension, but also a legal one. This reflects the legal recognition of the right of individuals to determine what happens to their own bodies, and the importance of protecting patients from unwanted or inappropriate medical procedures. Proper implementation of informed consent helps prevent medical malpractice, reduces potential legal conflicts, and builds trust in the doctor-patient relationship. These practices are also important for improving the quality of health care, ensuring patient compliance with treatment plans, and improving overall health outcomes. Given the complexity of medical procedures and their possible consequences, the urgency to strengthen informed consent practices in health systems is clear. This requires a commitment from health professionals to continually improve their communication skills and ensure that patients are provided with enough information to make informed decisions. Additionally, healthcare institutions and policymakers need to support an environment that promotes effective informed consent practices, including through policy development, professional training, and patient education. In this context, informed consent is not simply seen as an administrative formality, but as a critical element of quality patient care. This requires a holistic and integrated approach, involving all stakeholders in the health system, to ensure that the rights and

interests of patients are always a priority. Through increased awareness, education, and training, as well as the implementation of supportive policies, informed consent can continue to be an important pillar of ethical, patient-centered health care.

The doctrine of informed consent is a patient's human right in the implementation of health services in Indonesia

The right to obtain quality health services is a human right that is protected by law and is also explicitly protected in the Constitution of the Republic of Indonesia. Apart from that, the right to health is also mentioned in article 25 of the United Nations Convention, which essentially states that apart from having the right to health, humans also have the right to self-determination. In addition, Article 25 (1) of the Universal Declaration of Human Rights states: "Every human being has the right to an adequate standard of living, for the health of himself and his family, which includes food, shelter, clothing and health services as well as essential social services". The International Covenant on Economic, Social and Cultural Rights provides a very complete and detailed article regarding the right to health in international human rights law. There are two types of human rights in the health sector, namely basic social rights and basic individual rights . These basic rights are the basis for the emergence of other rights in the health sector. A prominent basic social right is the right to health care . The right to health care gives rise to one of the individual rights, namely the right to medical services. This is because social rights and individual rights support each other, do not conflict, at least run parallel. There are four factors related to implementing the right to health care, namely facilities, geographical factors, financial factors, and quality factors consisting of the quality of facilities and the quality of health workers. The second human right in the health sector is the basic right of the individual. The basic individual right that stands out is The Right of Self Determination. The Right of Self Determination is a source of individual rights in the form of the right to privacy and the right to one's own body. The right to privacy is a personal right, a right to personal freedom or liberty. The essence of the right to privacy is not to violate patient rights or patients have the right to ask (or not ask) hospitals and doctors to keep patient personal data or patient rights confidential other.

Confidentiality of patient personal data is an absolute patient's right, even the patient's husband or family does not have the right to be informed if they do not get consent from the patient themselves. However, this right will be lost if certain conditions occur so that the patient can no longer maintain this right, so the patient's family experts have the right to know thoroughly the patient's condition regarding the disease, the type of treatment that will be applied, the risks and chances of the patient's recovery. Privacy in health services is the recording of data in patient data status or medical records. The right to one's own body in the field of health takes the form of:

a. Approve or refuse a medical procedure;
b. Become a donor of human organs;
c. Become a blood donor;
d. Inheriting human organs after death;
e. Bequeathed his entire body to the anatomy laboratory;
f. Determining to be cremated after death.

In the basic principle of the right of self-determination, there is the right to determine one's own "fate" in the world of health, so that it can be correlated with the doctrine of informed consent . Informed consent is one of the basic rights is highly respected in the world of health. Informed consent is a reflection of the patient's right to autonomy. Patient autonomy must be respected ethically and most countries in the world place the doctrine of informed consent legally in their health legal systems. The principle of informed consent is to obtain approval from the patient in order to carry out or not carry out medical action on him or the patient who determines what is best for himself. However, before the patient agrees to this medical procedure, the patient must be given complete information regarding the type of treatment, treatment alternatives, risks and chances of recovery.

Ownership of Informed Concent in Health Services

Accessed in the Explanation of Article 173 of Law Number 17 of 2023 concerning Health. What is meant by "medical record" or also known as Informed Concent (part of the Medical Record) is a document containing patient identity data, examinations, treatment, procedures and other services provided. has been given to the patient using an electronic system intended for administering medical records. In the event that a

Health Service Facility cannot maintain electronic medical records due to technical obstacles, non-electronic medical records can be used until the obstacles are resolved, and medical record data can be re-entered into the electronic medical record system. In a legal context, Informed consent is considered a patient's right to obtain complete information about a proposed medical procedure, including benefits, risks, and available alternatives, so that they can make an informed decision about their care. This concept is supported by various international regulations, such as the Declaration of Helsinki issued by the World Medical Association, which emphasizes the importance of informed consent as an ethical principle in medical research involving human subjects. Furthermore, legislation in many countries has developed frameworks to ensure that informed consent practices are implemented effectively in health systems. For example, in some jurisdictions, national health laws specifically regulate informed consent procedures and documents , establish standards for communication between health care providers and patients, and outline the patient's right to refuse or consent to medical treatment after receiving adequate information.

Article 296

1. Every medical worker and health worker who provides individual health services is required to keep a medical record.
2. In terms of personal health services as intended in paragraph (1) is carried out at Health Service Facilities other than independent practice places, maintenance record medical is the responsibility of the Health Service Facility.
3. Medical records as intended in paragraph (1) must be completed immediately after the patient has finished receiving health services.
4. Each medical record entry must contain the name, time and signature of the Medical Personnel or Health Personnel providing the service or action.
5. Medical records as intended in paragraph (3) must be kept and kept confidential by Medical Personnel, Health Personnel, and leaders of Health Service Facilities.

Article 297

1. Medical record documents as intended in Article 296 belong to the Health Service Facility.
2. Every patient has the right to access the information contained in the medical record document as intended in paragraph (1).
3. Health Service Facilities are obliged to maintain the security, integrity, confidentiality and availability of data contained in medical record documents as intended in paragraph (1).

Law Number 17 of 2023 concerning Health stipulates that medical records belong to health service facilities, but gives patients the right to access the information contained therein. Articles 296 and 297 explicitly regulate the creation, storage and confidentiality of medical records, emphasizing the responsibilities of medical personnel and health service facilities in managing them. Furthermore, Article 298 assigns to the Ministry of Health the responsibility for managing medical record data as part of national health data management. This legal analysis shows the importance of medical records in the health system, not only as medical documentation but also as information assets that are tightly managed to maintain patient privacy and the integrity of the health system. Storing and managing medical records in accordance with this law ensures that patients' rights to privacy and access to information are fulfilled, while health care facilities and medical personnel fulfill their ethical and legal obligations.

4. CONCLUSION

The conclusion from the juridical analysis regarding *informed consent* and ownership rights based on Law No. 17 of 2023 concerning Health is that health service facilities are recognized as owners of medical records. This emphasizes the facility's responsibility to store, manage and maintain the confidentiality of medical records, while still providing patients with access rights to the information contained in the medical records. Suggestions that can be given are the importance of strengthening the legal framework and operational practices in health care facilities to ensure that patients' rights in accessing their medical information are fulfilled, in line with maintaining data privacy and security. Health care facilities must also increase patient awareness about their rights and responsibilities regarding medical records, as well as facilitate an easier information access process for patients.

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