



LEGAL STUDY OF INFORMED CONSENT LAW RELATED TO RIGHTS AND OBLIGATIONS FOR PATIENTS AND DOCTORS FROM THE ASPECT OF LAW NUMBER 17 OF 2023 CONCERNING HEALTH

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Article Info	Abstract
Article History Received: 2025-05-05 Revised: 2025-05-06 Published: 2025-06-06 Keywords: <i>Juridical Studies, Informed Consent Law, Rights and Obligations.</i>	Informed consent is essentially a communication process between a doctor and a patient regarding an agreement on medical procedures to be performed on the patient. The information provided by the doctor serves as the basis for the patient to give consent. This informed consent can also be a reason for a lawsuit against the doctor if there is a deviation in the doctor's practice. And for the doctor himself, it also serves as documentary evidence that can be accounted for if there is a claim in the future. Regarding informed consent, everything is regulated in detail in Law Number 17 of 2023 concerning Health. The implementation of this law has the potential to improve the quality of communication between doctors and patients, standardize informed consent procedures, and increase public health literacy. This study uses normative legal research, namely research that focuses on literature studies of laws and regulations, doctrines, and legal principles from primary, secondary, and tertiary legal materials with a qualitative descriptive analytical research method.

I. INTRODUCTION

Health is a form of Human Rights (HAM) guaranteed in the 1945 Constitution of the Republic of Indonesia and is upheld as a concrete manifestation of the government as a state of law. As explained in Article 28 H Paragraph (1) of the 1945 Constitution of the Republic of Indonesia (UUD 1945), the State guarantees that every person has the right to live a healthy and prosperous life, to have a good and healthy living environment and to have the right to receive health services.(Tutik 2017)

In providing these services, hospitals, doctors, and other healthcare professionals must work professionally, coordinate with each other, and act fairly without discriminating against ethnicity, religion, or specific groups. This attitude is essential to maintaining the quality of healthcare services and to foster public trust in hospitals and doctors as providers. It is on this basis of trust that a patient is motivated to provide informed consent for medical procedures.(Fazizullah, Marlina, and Sahlepi 2022)

Informed consent In the medical world, it serves as legal protection for patient rights and

the basis for the responsibility of healthcare professionals. Informed consent is a fundamental pillar of modern medical practice, serving as a bridge of communication between healthcare professionals and patients, but it also serves as a concrete manifestation of respect for patient autonomy in making decisions regarding their health. Everyone has the right to receive healthcare. Based on this right, physicians are obligated to provide the best possible service to patients. Patients have the right to be treated for their illnesses, and a physician is obligated to provide treatment and care as a form of responsibility.(Sidi 2020)

Informed consent is essentially a communication process between a doctor and a patient regarding an agreement on the medical procedure the doctor will perform on the patient. Signing a written informed consent form merely confirms what has been previously agreed upon and serves as legal evidence that can be relied upon in the future in the event of a lawsuit. In this case, the patient or the patient's family has the right to decide whether to accept or reject the procedure after receiving a complete explanation from the doctor.(Sidi 2020) A doctor is required to

provide complete and accurate information regarding the planned procedures and treatment plans for a patient, including any potential risks and side effects. The doctor is also required to respect the patient's decision to refuse treatment or treatment after receiving the information. Providing an explanation also serves as a basis for the patient to make an informed decision. (Salsabila, Nugroho, and Gusthomi 2024)

Article 351 of the Indonesian 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 long been considered noble because it is related to saving lives. However, all of this 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 the communication relationship between doctors and patients. In addition, informed consent also serves 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.

In Indonesia, regulations regarding informed consent have evolved in line with the dynamics of community needs and legal protection in healthcare. One important milestone in this regard is Law Number 17 of 2023 concerning Health. This law replaces Law Number 36 of 2009 and introduces various reforms, including aspects of the rights and obligations of patients and healthcare professionals. In Law Number 17 of 2023 concerning Health, informed consent is seen not only as a medical procedure but also as an integral part of fulfilling patient rights and legal protection for medical professionals. The patient's right to receive complete, honest, and easily understood information about upcoming medical procedures is emphasized in various provisions of Law Number 17 of 2023 concerning Health. Furthermore, the obligation of doctors to provide information and obtain consent before performing medical procedures is also emphasized as a form of professional and ethical responsibility.

However, in practice, the implementation of the principle of informed consent still faces

various challenges. Lack of understanding on the part of both patients and medical personnel, such as time pressures in healthcare services, and differing perceptions about what constitutes "sufficient information," often give rise to legal issues. Furthermore, the imbalanced relationship between patients and medical personnel can result in informed consent being merely a formality, without ensuring that patients fully understand what they are agreeing to. This situation has the potential to lead to legal conflicts if patients feel disadvantaged by medical procedures performed without legally valid consent. (Rahmadsyah and Sidi 2023)

An example of a case that went viral and illustrates the importance of informed consent is the 2023 Post-Tonsillectomy Brainstem Death Case in Jakarta. This controversial case occurred in Jakarta when a 5-year-old child became brainstem dead after undergoing tonsillectomy surgery. The patient's family took legal action, claiming they were not provided with adequate information about the risks of the surgery and lacked clear consent for further medical treatment after the operation. This case highlights the importance of comprehensive informed consent, not only for the initial procedure but also for possible follow-up procedures in emergency situations. Furthermore, this case also raises questions about how risk information should be communicated for procedures generally considered routine, as well as the importance of the medical team's preparedness in handling rare complications. (Rahmadsyah and Sidi 2023)

Then, there was the alleged malpractice case in Gunungkidul in 2024, where a patient experienced serious complications after undergoing surgery. The patient's family claimed they never received informed consent, either verbally or in writing, before the operation. This case highlights the importance of clear documentation in the informed consent process and transparent communication between medical personnel and patients or their families. Furthermore, this case also demonstrates the persistent gaps in the implementation of standard informed consent procedures across Indonesia. (Muttaqin 2020)

This case demonstrates that informed consent has long been an integral part of medical practice, yet its implementation still faces various challenges. Research conducted by Susilo in 2020 reinforces this fact, showing that there is still a gap in understanding between medical personnel and patients regarding the essence and procedures of

informed consent. This has the potential to give rise to legal and ethical conflicts in healthcare. Furthermore, a 2018 study conducted by Afandi in several hospitals in Indonesia found that although most medical personnel recognize the importance of informed consent, significant variation in its implementation remains. Several factors contributing to this variation include time constraints, high workloads, and patients' lack of understanding of medical terminology.

Therefore, researchers feel the need to conduct a comprehensive legal study of the legal regulations regarding informed consent, relating to the rights and obligations of patients and doctors, from the perspective of Law Number 17 of 2023 concerning Health. This analysis is crucial to assess the extent to which the law provides legal protection for patients' rights while guaranteeing legal certainty and legal protection for medical personnel in carrying out their profession. Therefore, this legal research aims to contribute to strengthening regulations and practices for the implementation of informed consent that are fair, balanced, and based on applicable positive law in Indonesia.

II. RESEARCH METHODS

This research is normative legal research, focusing on literature review of laws and regulations, doctrines, and legal principles. The research approach uses a statutory approach (statutory approach), which examines Law No. 17 of 2023 and other regulations, and a conceptual approach (conceptual approach), which analyzes the legal concept of informed consent and the legal relationship between patients and doctors from the perspective of law and medical ethics.(Yunanto and Helmi 2024)

The data used in this research comes from primary, secondary, and tertiary legal materials. Data collection was conducted through library research and online searches. The collected data were then analyzed qualitatively using the Qualitative Descriptive Analytical method, which analyzes, describes, and summarizes various conditions and situations from the collected data.

III. RESULTS AND DISCUSSION

A. Legal Regulations on Informed Consent in Law Number 17 of 2023 concerning Health

Informed consent is the delivery of information from a doctor or other medical

personnel to a patient before a medical procedure is carried out.(2019 Driver's License)This is important because every patient has the right to know the benefits and risks of the medical procedure they are about to undergo. Almost everyone has been ill and required certain medical procedures or treatments, such as surgery or an operation. However, before a medical procedure is performed, the doctor will first explain the steps, benefits, and risks of the procedure. After receiving and understanding the doctor's explanation, the patient can decide whether to accept or reject the recommended medical procedure. This is called informed consent. With clear and proper informed consent, the patient will understand all the benefits and risks, as well as the goals of the therapy the doctor will provide, including the success rate of a treatment or medical procedure. This is important to prevent misunderstandings about the consequences of their choices.(Siyen, Hadi, and Asriwati 2020)

Informed consent is essentially a communication process between a doctor and a patient regarding an agreement on a medical procedure the doctor will perform on the patient. The information provided by the doctor serves as the basis for the patient's consent. When such a relationship is established, a legal bond, known as a therapeutic contract, arises, which ultimately creates rights and obligations between the two parties. This agreement, formalized in the informed consent form, is legally binding, meaning it has the force of law and must be complied with by both parties.

This consent can be verbal or written. Signing a written informed consent form merely confirms what has been previously agreed upon. It's important to understand that informed consent is part of the medical record. The medical record must contain a complete record of consent for medical procedures. Medical records are the primary written evidence, making them useful in resolving legal, disciplinary, and ethical issues.(Hasna, Laila, and Andri 2023)

The position of informed consent in health services is regulated in Law No. 17 of 2023 concerning Health and its technical implementation 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 Approval of Medical Actions.

In Law Number 17 of 2023 concerning Health, provisions regarding informed consent for medical procedures are clearly regulated, especially in:

- a. Article 274 Letter (b) emphasizes that medical personnel and health workers are required to obtain approval from the patient or their family for the actions to be taken.
- b. Article 293 Paragraph (1) states that every individual health service action carried out by medical personnel and health workers must obtain approval.
- c. Article 293 Paragraph (5) explains that written consent must be obtained before carrying out invasive or high-risk actions.
- d. Article 293 Paragraph (9) explains that there are exceptions in emergency situations and if the patient is incompetent and there is no guardian, then medical action can be carried out without prior consent.

Law No. 17 of 2023 concerning Health provides a more comprehensive definition and rules regarding informed consent compared to previous regulations. Article 293 paragraph (1) of Law No. 17 of 2023 states that "Every health service action can only be carried out after obtaining approval from the patient or his/her family." This definition emphasizes the position of informed consent as a fundamental prerequisite in every medical action. Furthermore, Article 293 paragraph (3) details the elements that must be included in the informed consent process, namely an explanation of the diagnosis, its indications, the health service action carried out and its purpose, possible risks and complications, alternative actions and their risks, risks if the action is not carried out and the prognosis after receiving the action. Compared to previous regulations, Law No. 17 of 2023 concerning Health places greater emphasis on the aspect of patient understanding and the quality of the information provided. This is in line with Nouri's findings in 2019 which highlighted the importance of quality communication in the informed consent process to improve patient understanding and satisfaction.(TRP Lestari 2007)

The requirement to obtain informed consent is also stipulated in Articles 1, 2, and 3 of the Regulation of the Minister of Health of the Republic of Indonesia No. 290/Menkes/Per/III/2008 concerning Consent to Medical Procedures. For example, Article 2 states that:

- a. All medical actions to be carried out on patients must obtain consent,
- b. The approval referred to in paragraph (1) may be given in writing or orally,
- c. The consent referred to in paragraph (1) is given after the patient has received the necessary explanation regarding the need for medical action to be carried out.

From a legal perspective, the relationship between a doctor and a patient can be viewed as a form of contract (*Verbinten*) involving a consensual agreement between both parties regarding the provision of medical services. Therefore, the concept of informed consent falls into the category of contract within the doctor-patient relationship because it involves an agreement based on trust and mutual understanding between both parties.

Having an agreement strengthens patient compliance with the recommended medical procedure plan and the information provided. This helps uphold the rights and obligations of both the doctor and the patient involved and reduces the risk of misunderstanding. Furthermore, it also strengthens patient compliance with the recommended medical procedure plan. By establishing informed consent, the doctor has legal assurance that the patient has understood the information provided, which serves to support the rights and obligations of both the doctor and the patient concerned, reduce the possibility of misunderstanding and strengthen patient compliance with the recommended medical procedure plan.(Meher, Sidi, and Risdawati 2023)

In an emergency, a doctor may be required to perform high-risk medical procedures as quickly as possible in an effort to save a life. Under such stressful conditions, doctors are required to think clearly to determine the best medical treatment for their patient without compromising on any options.(Hasna, Laila, and Andri 2023) Legally, doctors do not need to hesitate to immediately provide the necessary medical treatment in emergency conditions because the medical actions carried out by the doctor are protected by clear legal grounds as stated in Law No. 17 of 2023 concerning Health, based on:

- a. Article 80 paragraph (3) states that in emergency conditions, medical action can be carried out without requiring prior approval,
- b. Article 275 paragraphs (1) and (2) provide an obligation for a doctor to provide first aid in emergency conditions

and guarantee legal protection for doctors in efforts to prevent disability or save lives.

- c. Article 293 paragraph (9) emphasizes that if a patient does not have the capacity to give consent and is facing an emergency situation without a guardian who can be asked for consent, then consent for the medical procedure is not required.

Article 293 paragraph (5) of Law Number 17 of 2023 concerning Health states that written informed consent is required before carrying out high-risk medical procedures. In non-emergency conditions, doctors have sufficient time to obtain informed consent, whereas in emergency cases requiring high-risk procedures, there is often insufficient time to obtain informed consent due to the need to immediately carry out medical procedures in an effort to save the patient's life. This is stated in Article 80 paragraph (3) and Article 293 paragraph (9) of Law Number 17 of 2023 concerning Health, which explains that there are exceptions to informed consent being not required in certain conditions, namely in emergency situations.(RD Lestari 2023)Doctors are still obliged to provide medical treatment even if the patient is unconscious and unable to give consent to the procedure. This is known as presumed consent. However, even though it is permissible to carry out medical treatment based on presumed consent, based on Article 293 paragraph (11) of Law No. 17 of 2023 concerning Health, it is emphasized that doctors must still immediately inform the patient after the patient is competent or their representative is present.(TRP Lestari 2007)

However, Article 440 paragraph (2) of Law No. 17 of 2023 concerning Health clearly states that a doctor who commits negligence resulting in the death of a patient can be sentenced to imprisonment or a fine, which is lurking among doctors from one side.(Mohamad 2019)Where, when a doctor dares to take action without delaying until the family has made a decision to carry out medical treatment for a high-risk medical procedure, but the expected results do not match the family's wishes and even hasten the patient's death, the doctor will be sued for medical negligence based on the patient's family's lack of understanding of the incident and vice versa. Basically, the negligence in question occurs because the doctor works not in accordance with professional standards, standard operating

procedures, and medical protocols that should be adhered to.

B. Rights and Obligations for Patients and Doctors

Seeing the relationship between the doctor and the patient that is established through a therapeutic transaction, this will certainly give rise to the rights and obligations of each party, namely the doctor as the service provider (Medical Provider) and the patient as the service recipient (Medical Receiver) and must be respected by both parties.(Meher, Sidi, and Risdawati 2023)The medical team, as medical providers, has an obligation to perform the best diagnosis, treatment, and medical procedures according to their knowledge, reasoning, and judgment. Likewise, the patient or their family, as medical recipients, have the right to determine the treatment or medical procedures to be performed on them (the patient).(Darwaman, Sidi, and Saragih 2023)Therefore, these rights and obligations create a conflict. As healthcare providers, doctors, based on their best judgment, may not align with what the patient or family desires or accepts. This is due to the nature of medical science, which means that not all patient care will be successful.(Alfina 2019)

The legal relationship between a doctor and a patient in medical care is based on agreement, ethics, and statutory regulations. The relationship typically begins with a therapeutic agreement. The doctor is obligated to provide medical services in accordance with professional standards, while the patient is obligated to provide honest information and, in some cases, to pay for the doctor's services. This agreement between the two parties constitutes a therapeutic agreement, which is formalized in the form of informed consent.(Pintabar, Rafianti, and Saragih 2024)

The matter of informed consent has been explained in legal regulations such as Minister of Health Regulation No. 290/MENKES/PER/III/2008 concerning Approval of Medical Actions and Law No. 17 of 2023 concerning Health. Article 273 and Article 274 of Law No. 17 of 2023 concerning Health explain the rights and obligations of doctors. where a doctor has the right to legal protection as long as he provides services according to standards and is entitled to receive a salary/wages for the services he provides to patients. In providing services, a doctor has the right to receive complete and correct information

from the patient and his family to assist the doctor in determining the diagnosis and providing appropriate treatment for the patient. In addition to rights, doctors also have obligations that they must carry out in providing services, namely doctors are obliged to provide health services according to professional standards, maintain patient health confidentiality, create and store a history of actions and treatments that have been carried out on patients in the form of medical documents, and most importantly, doctors are required to obtain prior approval for medical actions from the patient or their family before carrying out medical actions. At any time, a doctor is obliged to refer a patient to another medical professional who has the competence and authority appropriate to the patient's problem if necessary. (Harahap, Kusuma, and Gurning 2024)

Then, in articles 276 and 277 explain the rights and obligations of patients. Among them, patients have the right to receive services according to professional standards and their medical needs and have the right to receive complete information regarding their health and also the actions that will be taken on them. Most importantly, patients have the right to approve or reject the planned medical action that will be carried out on them after hearing an explanation from the doctor except in cases of preventing infectious diseases and handling KLB or epidemics. To achieve the desired results for patients in terms of treatment for their illnesses, patients are obliged to provide complete and honest information regarding their health problems, comply with the doctor's advice and the provisions applicable at the health care facility and are obliged to provide compensation for services received.

Some significant changes regarding informed consent in Law No. 17 of 2023 include:

1. **Emphasis on Patient Rights.** This law explicitly recognizes the patient's right to receive comprehensive information and to fully understand the medical procedures to be performed. This strengthens the patient's position as an active participant in patient decision-making, in line with the principle of patient autonomy proposed by Beauchamp and Childress in 2019.
2. **Stricter Documentation Requirements.** Article 293 Paragraph (4) requires that consent to medical procedures be given in writing and

signed by the patient or their family. This enhances legality and can serve as strong legal evidence in the event of a future medical dispute.

3. **Special Provisions for Emergency Cases.** This law provides clearer guidance regarding informed consent procedures in emergency medical situations, where consent can be given after the action has been carried out in accordance with Article 293 Paragraph (9). This provides a balance between the need for rapid action in an emergency and respect for patient rights.
4. **Emphasis on Patient Understanding.** This law emphasizes that information must be provided in a way that is understandable to patients, accommodating differences in educational and cultural backgrounds.

Then the potential impact of Law No. 17 of 2023 on the practice of informed consent, such as:

1. **Improving the Quality of Doctor-Patient Communication.** With more detailed regulations, medical personnel are required to improve the quality of their communication with patients. This can encourage the development of better communication skills among medical personnel.
2. **Standardization of Informed Consent Procedures.** This law could encourage the creation of more uniform national standards for informed consent procedures. This could help reduce variations in practice across healthcare institutions and increase consistency in protecting patient rights.
3. **Improving Public Health Literacy.** By emphasizing patient understanding, this law can indirectly encourage efforts to improve health literacy in the community. This aligns with the global trend of increasing active patient participation in medical decision-making.
4. **Potential Increase in Medical Litigation.** On the other hand, stricter regulations regarding informed consent also have the potential to increase the number of medical litigations if not implemented

effectively. Therefore, intensive education efforts are needed for medical personnel and healthcare institutions to ensure compliance with these new regulations.

IV. CONCLUSIONS AND RECOMMENDATIONS

1. Conclusion

Law No. 17The 2023 Health Law brings significant changes to informed consent regulations in Indonesia. This law strengthens informed consent as a fundamental patient right and an ethical-legal obligation for medical personnel, emphasizing the quality of information, patient understanding, and comprehensive documentation. Implementation of this law has the potential to improve communication between doctors and patients, standardize informed consent procedures, and enhance public health.

However, implementation challenges remain, particularly in terms of educating medical professionals and the public, as well as the potential for increased medical litigation. Therefore, collaborative efforts from various stakeholders are needed to ensure the effective and ethical implementation of this new informed consent regulation.

2. Recommendation

Collaborative efforts from various stakeholders are needed to ensure the effective and ethical implementation of this new informed consent regulation because challenges in implementing informed consent still exist, especially in terms of educating medical personnel and the public and the potential for increased medical litigation.

For further research, it is recommended to conduct empirical studies on the impact of Law No. 17 of 2023 on the practice of informed consent in the field, including the perceptions of medical personnel and patients, as well as the effectiveness of implementing this new regulation in improving the quality of health services in Indonesia.

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