

Juridical Review of Approval of Medical Actions (*Informedconsent*) Based on Law Number 17 2023 Concerning Health as a Replacement of Law Number 36 of 2009

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Abstract

Along with increasing legal awareness among the general public, aspects of legal protection have become the center of attention in the health legal structure in Indonesia. Law Number 17 of 2023 concerning Health, which replaces Law Number 36 of 2009, represents a significant change in the legal framework for health in Indonesia. One of the main focuses of the implementation of this law is providing consent for medical procedures (informed consent), which is considered a legal protection tool for patients. Therefore, the aim of this research is to evaluate the provisions for providing informed consent in Law Number 17 of 2023 and their alignment with expert opinions. This research uses a normative juridical analysis method by examining the documents of Law of the Republic of Indonesia Number 17 of 2023 concerning Health. This legal review was carried out by referring to several legal materials and expert views. The research results show that Law Number 17 of 2023 establishes a stronger basis than the previous Law for the implementation of informed consent. Informed consent is explained as an obligation of medical personnel and a patient's right, with an emphasis on providing comprehensive information, before taking action. This change reflects a response to unequal access to health services and the need to strengthen the national health system, especially in emergency situations, Extraordinary Events (KLB), or epidemics. Many changes to informed consent regulations are in line with the opinion of several experts that informed consent should be based on *prima facie* principles, namely autonomy, beneficence, non-maleficence and justice.

Keywords: Informed Consent, Legal Protection

1. INTRODUCTION

According to A. Heuken (1973), control of health services in Indonesia is based on Article 34 Paragraph (1) The 1945 Constitution of the Republic of Indonesia, which emphasizes the state's obligation to provide health services, and Article 28 H Paragraph (1) which recognizes the right of citizens to receive health services. These two articles reflect fair and civilized human values, as well as social justice for the Indonesian people, with a focus on respect for human dignity and achieving equality in the provision of health services. Since the enactment of Law Number 17 of 2023 concerning Health, replacing Law Number 36 of 2009, the state has emphasized the right of every citizen to achieve a good, healthy and prosperous life. The preamble to this law emphasizes the state's responsibility to protect the entire Indonesian nation in accordance with the national goals in the 1945 Constitution of the Republic of Indonesia. Therefore, the presence of doctors is very important as the main implementer of development projects in the health sector which aims to ensure realization of general welfare. Initially, the relationship between doctor and patient was based on a form of paternalistic therapeutic relationship, which was like a family bond and based on trust. However, with the development of information facilities through mass media, privacy in medical practice is increasingly open. The growth of public knowledge about health, accompanied by a transformation towards higher levels of education in the health sector, is triggering a paradigm shift. Society is now more aware of personal responsibility for their health, so there is awareness to form a comparable relationship between doctors who are providers of health services and patients

who are recipients of services. Rano Indradi (2007) revealed that an individual in the role of a patient has a set of rights and obligations that should be understood when in the health service process. There are three fundamental rights of patients, namely the right to health care (the right to health care), the right to information (the right to information), and the right to participate in decision making (the right to determination). Koeswadi (1998) recognizes two models of doctor-patient relationships, namely the horizontal contractual and the vertical paternalistic model. In the vertical paternalistic model, the role of doctors as providers of health services is considered more dominant than patients who only act as consumers. In contrast, in the horizontal contractual model, both parties are considered equal in their position. Equality in these relationships forms the basis of contractual frameworks, where mutual agreement is required for contributions or services in the delivery of health services.

From this pattern of horizontal contractual relationships, the concept of approval for medical procedures emerged (informed consent) which is applied in service practices in the modern health sector. As a fundamental principle in medical practice, informed consent does not only involve medical aspects, but also involves legal dimensions. It is important to ensure that the patient fully understands the information conveyed, so that consent is given without any pressure or coercion. In Indonesia, the implementation of informed consent has become the main focus, especially since the enactment of Law Number 17 of 2023 concerning Health which replaced Law Number 36 of 2009 concerning Health. The enactment of Law Number 17 of 2023 concerning Health notes significant changes in the legal framework for health in Indonesia. By focusing on the principle of informed consent, this law presents innovations and adjustments regarding patients' rights to receive complete information and language that can be easily understood before agreeing to a medical procedure. Although Health Law Number 36 of 2009 previously established the basis for the principle of informed consent, evaluation of its implementation shows several obstacles and weaknesses in protecting patient rights. Therefore, the implementation of Law Number 17 of 2023 is very crucial to make improvements and introduce substantial changes in a more modern legal framework. By analyzing the differences and similarities between the two laws, this analysis provides a comprehensive picture of the development and status of informed consent within the health legal framework in Indonesia, as well as acting as a form of legal protection for patients. By detailing the background context described above, the author feels interested in conducting research in the form of a scientific paper with the title " *Judicial Review of Approval of Medical Procedures (Informed Consent) Based on Law Number 17 of 2023 concerning Health as a substitute Law Number 36 of 2009* ".

Raharjo (2000) believes that the function of law is to maintain people's security from various potential dangers and actions that could cause harm or suffering in their lives, whether from individuals, society or the government. Furthermore, law also has a role in providing justice and functions as a means to achieve prosperity for all citizens. The main focus of law on legal subjects, namely individuals who have rights and responsibilities, is protection, justice and welfare. According to Fitzgerald, as cited by Satjipto Raharjo (2000), the theory of legal protection is rooted in natural law theory. This theory was introduced by figures such as Plato, Zeno and Aristotle. The natural law perspective states that the source of law is from God, which is general and eternal, and the relationship between law and morals is something that cannot be separated. Adherents of this legal school believe that law and morals reflect rules in human life that originate from internal and external factors. Legal interests involve handling human rights and interests, so that the law is considered to hold the highest power in determining and also protecting human interests. Protection involves a series of actions, starting from the concept of legal protection which originates from legal provisions and also all regulations produced by society. This is essentially a mutual agreement between society with the aim of regulating relationships or behavioral interactions between members of society and also interactions between individuals and the government, who are considered representatives of society. The law is vital for individuals who are in a position that is not strong or weak economically, politically and socially, to ensure that they can achieve social justice. Protection is provided to the Indonesian population as a form of reflection of the implementation of the principle of recognition and also as protection for the honor and dignity of citizens which originates from Pancasila and Constitution of the Republic of Indonesia. Every individual is obliged to obtain legal protection, and all forms of legal relations must be guaranteed protection. In line with this, contractual relationships in health services must receive legal protection, especially in the context of the relationship between doctors and patients. When facing the dynamics in this relationship, Law Number 17 of 2023 concerning Health plays a key role in providing the basis and regulations that regulate the rights and responsibilities of both parties. One aspect that is important in this law is the practice of informed consent. Informed consent is a form of legal protection that ensures that patients are expected to obtain adequate understanding before finally deciding to accept or refuse medical treatment. These principles are in line with legally recognized ethics and norms, which provide a strong foundation for a mutually beneficial and safe relationship between doctors and patients. Therefore, informed consent is not only an ethical

obligation, but also an integral part of the legal protection regulated by the Health Law. This ensures that every medical procedure is carried out with fully informed consent and can be legally justified. Informed consent is a term consisting of two words, namely informed which indicates understanding of the explanation or information provided, and consent which means agreement or permission.

Therefore, informed consent reflects the concept that consent is given after the individual has received adequate information. Furthermore, informed consent can also be interpreted as permission given by the patient or their family after they receive an explanation regarding the medical procedure to be carried out, including the risks of the related action. All medical procedures carried out by a doctor must aim to maintain the patient's health and must not involve an element of coercion. Dahlan (2005) states that informed consent is a statement given by an authorized party, such as a patient, family or guardian, stating and giving permission or approval to medical personnel to carry out medical procedures after receiving adequate information. Komalawati (1989) explained that the use of the term informed consent is based on ethical, moral and patient autonomy principles. These two principles cover two main aspects, namely: (1) Everyone has the right to make decisions freely based on adequate understanding (2) These decisions must be taken without intervention or pressure from other parties, so that individuals can make choices completely freely. Due to the autonomous nature of individuals, information is crucial to provide a basis for consideration so that decisions are taken in accordance with these considerations. This concept is known as the doctrine of informed consent, which was first introduced in 1947 in the Nuremberg Code, rule 1. Basically, this doctrine explains the basic standards that must be followed when conducting experiments on humans. Based on Article 4 in Law Number 17 of 2023 concerning Health, it is explained that every individual has the right to receive balanced and responsible information and education regarding health, has the freedom to determine the health services needed independently and responsibly, has the right to receive or refuses part or all of the assistance measures after receiving and understanding information about the measures in full, and has the right to obtain information regarding his/her health data. Fulfilling patient rights requires that health workers or health facilities provide accurate, clear and comprehensive information to patients about their medical conditions, available treatment options, and their risks and benefits. This process is closely related to informed consent, where the patient must understand the information before giving consent. Informed consent is not only an integral part of fulfilling patient rights but is also the basis for legal protection. Without adequate informed consent, certain medical procedures or treatments may be considered a violation of the patient's rights. Based on the background of the problem above, the problem formulated is as follows: (1) What are the regulations for providing informed consent based on Law Number 17 of 2023 concerning Health as a substitute for Law Number 36 of 2009?; (2) What are the arrangements for informed consent based on Law Number 17 of 2023 concerning Health according to the opinions of experts?.

2. METHODOLOGY

The method used in this research is a normative juridical research method. According to Zainuddin Ali (2009), normative juridical research is an approach used to identify legal regulations, principles and legal doctrines with the aim of answering the legal problems faced. The process of collecting primary legal data is carried out through a statutory approach. In collecting primary legal material, the author used the law approach method by analyzing the documents of Law of the Republic of Indonesia Number 17 of 2023 concerning Health, which replaced Law Number 36 of 2009 concerning Health. The process of collecting secondary legal material in this research was carried out through library research, including references from books, legal journals, legal articles and various other literature that has relevance to the author's research. The secondary legal material is used as an explanation or support for the primary legal material. The legal review will be carried out by referring to several legal materials and the material collection methods that have been used. This analysis will be based on legislation to formulate detailed conclusions, with the aim of providing detailed answers to the problems being researched.

3. RESULTS AND DISCUSSION

The expansion of development and reform of the health sector in Indonesia was realized through the birth of Law Number 17 of 2023 concerning Health, which was signed on 08 August 2023 and replaced Law Number 36 of 2009. The formation of this Law was based on the consideration of Remembering, namely Article 20, Article 21, Article 28H paragraph (1), and Article 34 paragraph (3) of the 1945 Constitution of the Republic of Indonesia. This stems from the inequalities and imbalances that are still felt in the provision of health services in various regions. Although there has been a commitment to equalize health services, the reality on the ground shows that quality health services tend to be easier to reach in urban areas than in rural areas. On the other hand, low-income people experience difficulties in obtaining adequate health services. It is hoped that Law Number 17

of 2023 will provide a stronger legal basis for overcoming the problem of access to health services, so that all segments of society can enjoy their health rights fairly. This law changes the health system to achieve more equitable services, and quality, including promotional, preventive, curative and rehabilitative and palliative efforts. An important aspect of this law is to increase the availability and distribution of health services to all residents, regardless of social, economic, or geographic status. However, the implementation of this law still requires further efforts to overcome these inequalities and ensure the equal fulfillment of individual rights in the context of health services in Indonesia. In accordance with what is stated in Article 2, one of the principles is the basis for its formation. Law Number 17 of 2023 is the principle of legal awareness and respect for rights and obligations. In the context of health development, this means that development must treat people with respect for their rights and obligations, demonstrating equality under the law by recognizing patients' rights to obtain information and control their medical care, as well as considering the public interest and public health, the Law Number 17 of 2023 seeks to create a fair balance between personal rights and broader interests. This action is a significant step in safeguarding patients' rights to receive more dignified care, in accordance with their desires, needs and rights as individuals. As individuals subject to the law, every citizen holds the rights regulated by law. In order to maintain and fulfill the rights of legal subjects related to health, providing legal protection to citizens involved in health services is important. One of the legal protection instruments in the health services sector is informed consent or approval for medical procedures. Changes in aspects of legal protection are the main focus in Law Number 17 of 2023. Law Number 17 of 2023 adopts the term "Consent to Health Service Actions," which has a similar meaning to informed consent. This law updates various aspects of Law Number 36 of 2009. The position of informed consent is strengthened as a community right (Article 4) and as an obligation for medical personnel (Article 274). Informed consent is recognized as a basic element in the health care process, where each individual has the right to accept or refuse some or all medical procedures after receiving detailed information regarding the action. From the perspective of medical personnel, obtaining consent from both the patient and family regarding the medical action to be carried out is an obligation, which was previously carried out by providing information (informed) by health personnel, conveyed in language that is easy to understand. In Law Number 17 of 2023 concerning Health, there are two additional conditions that limit the obligation to carry out informed consent, an aspect that was not included in the previous regulation. These conditions involve emergency situations and Extraordinary Events (KLB) or epidemics. This change is interpreted as a response to the pandemic that occurred in 2020, namely Coronavirus Disease 2019 (Covid-19). The Covid-19 pandemic highlights the importance of strengthening national health systems, especially in emergency situations and disease outbreaks. These restrictions on the implementation of informed consent are not merely to curb patient rights, but are aimed at protecting public interests and public health. In emergency situations, emphasis is placed on medical action before obtaining approval, with the aim of reducing obstacles that could hinder life-saving efforts. Article 293 provides a more comprehensive explanation regarding the responsibilities of medical personnel in obtaining consent, details of the explanation that must be given, the format for informed consent given, the time for implementing the consent, the party who has the right to give consent, the presence of witnesses, and the steps taken in the situation when neither party can be asked for consent. The article details the aspects of informed consent carefully and in depth.

The regulations regarding informed consent in Law Number 36 of 2009 tend to be more concise and simple when compared to the law that replaces it. In this law, informed consent in the context of health services is only recognized as a patient's right, not as the responsibility of medical personnel. Article 5 confirms the right of every individual to independently determine the health services needed for himself. Apart from that, Article 56 which relates to patient protection guarantees the right of every individual to accept or refuse help after understanding comprehensive information about the action. On the other hand, Article 24 paragraph (1) approaches the discussion of informed consent as an obligation for medical personnel, by stating that health personnel are obliged to comply with ethical regulations, professional standards, rights of health service users, service standards and standard operational procedures. In terms of substance, Informed Consent in Law Number 17 of 2023 has received clearer clarification and legal certainty compared to previous regulations. As explained in Articles 274 and 293, informed consent is recognized as a process that requires the obligation to convey comprehensive information to the patient regarding the disease which includes diagnosis, prognosis, treatment options, risks, benefits, and even related costs. These two articles guarantee that patients must have sufficient understanding before giving consent to a medical procedure. Therefore, these regulations increase legal protection for patients and provide a stronger basis for preserving their rights within the framework of medical decisions. Based on Law Number 17 of 2023 Article 4 paragraph (1) point (f) which states that every person has the right to "determine for themselves the health services needed for themselves independently and responsibly" and point (h) "accept or reject some or all assistance actions that will be given to him after receiving and

understanding information regarding the action completely." This is in line with the opinion of Sang Gede Purnama (2016) that informed consent is based on the principles of autonomy, beneficentia and non-maleficentia. These principles are rooted in human dignity, where the patient's autonomy and personal integrity are priorities that are protected and respected. This is also mentioned in The Universal Declaration of Human Rights in 1948 which states that every individual has rights over himself and the right to determine his desires for himself (the right of self-determination). In accordance with this view expressed by Catherine Tay Swee Kian quoted by Fuadi (2018), every individual is considered an autonomous being, which means that everyone has the right to make their own decisions and no one should impose their will on other people, even institutions . , or even the state cannot violate it. In the context of patient autonomy, Guwandi (2006) added the term informed refusal, namely a refusal that comes from the patient to carry out a certain medical action and is decided after the doctor has provided information regarding something related to the action with confirmation that the patient already knows and understand all the consequences that may or will arise as a result of such refusal. In the Explanation section of Article 293 paragraph (1) of Law Number 17 of 2023, it is stated that "...if the patient is incompetent or is under guardianship (under curatele), approval or rejection of health service actions is given by the closest family, among others, by the husband/wife , biological father/mother, biological child, or adult sibling." Informed consent is a form of agreement. In this case, article 1320 of the Book.

Civil Law Law (Civil Code) states that one of the requirements for a valid agreement is the ability to make an agreement. Furthermore, article 1330 of the Civil Code states that the definition of "incompetent" to make an agreement is (1) a minor (less than 21 years old); (2) and people placed under guardianship. The transfer of power to consent to medical procedures does not merely take into account the patient's right to autonomy to be able to decide what is best for him. Leenen (1981), quoted by Ratman Desriza (2018), argues that based on the principle of legal fiction , someone who is unconscious will agree to things that a conscious person would normally agree to in the same sick condition. Another opinion by Van der Mijn (1984) mentions voluntary representation or *zaakwaarneming* , namely an action where responsibility is taken by medical personnel (doctors) by helping the patient, and if the patient is conscious, the doctor who helps must explain the action taken and ask whether treatment will continue or whether the patient wishes to get a second opinion. From simple legal logic, patients who are unconscious or seriously ill do not qualify as people who are capable of making valid agreements, as regulated in the Civil Code. However, on the one hand, informed consent is an obligation that must be given and explained to the patient so that medical action can be carried out. Therefore, to provide legal protection for health workers, while still providing assistance to patients, a solution was created to transfer the power of informed consent to the patient's family. In Article 4 Paragraphs (2) and (3) it is stated that the patient's independent right, in this case to determine his or her own health services independently, does not apply in emergency situations and/or overcoming an outbreak or epidemic. This is interpreted as conditions that do not require informed consent before medical treatment is carried out. This is in accordance with the opinion of Herkutanto (2007) who states that an emergency is a condition which, in every definition, includes the word "immediate" and indicates that the situation is "forced" because of "unusual" circumstances. Therefore, an emergency certainly has special characteristics because the action involves a risk to someone's life safety. From a legal perspective, especially in the field of Health Law, there are several exceptional situations that are different from normal conditions. Viewed from a health law and medicolegal perspective, emergency measures are different from non-emergency services because they have special characteristics. Some specific aspects of emergency health services require special legal regulations and may result in legal relationships that are different from non-emergency situations. Similar to the opinion of Guwandi (2006) which states that if a patient experiences an emergency that makes the doctor unable to ask for informed consent , Article 1354 of the Civil Code allows medical procedures without requiring permission from the patient. This action is called *zaakwaarneming* or voluntary guardianship, which can be explained as the act of a person voluntarily carrying out another person's affairs without being asked, either with or without that person's knowledge. This action commits him to continuing to take care of the matter, even if the person is able to take care of himself. In this situation, the doctor's obligation to look after the patient's interests is based on legal action, not the patient's consent.

Jesicca (2001) has a different opinion regarding when informed consent can be postponed. The answer depends on the extent to which violating the informed consent requirement would undermine the values the doctrine seeks to uphold. Delaying informed consent in emergency situations is done because of the time needed to convey and obtain a decision from the patient. This action needs to be "better addressed" to avoid harm to all parties involved. Thus, the urgency of the need for health services is the primary determinant of whether a particular situation should be classified as an emergency. Potential harm, whether disability or death, should be made the main priority in considering whether informed consent can take precedence. Article 293 paragraph

(3) details the things that must be explained when requesting approval for health service actions, which at least include: (a) Diagnosis; (b) Indication; (c) Health service actions carried out and their objectives; (d) Possible risks and complications; (e) Other alternative actions and their risks; (f) Possible risks and complications; (g) Other alternative actions and their risks; (h) Risk if action is not taken; (i) Prognosis after taking action. This is in line with the view of Veronica Komalawati (2002) who defines informed consent as the patient's consent or agreement to medical actions carried out by a doctor after the patient receives information from the doctor regarding medical procedures that can be carried out to help him, along with an explanation of all possible risks. happen. In line with opinion. Ampera Matippana (2018) states that the essence of the right to consent to medical procedures is actually a communication process between the doctor and the patient regarding the agreement regarding the medical action that the doctor will carry out on the patient, involving a detailed explanation from the doctor.

4. CONCLUSION

Informed consent reflects consent given after the individual has obtained sufficient information, based on the principles of patient autonomy and ethics. The right of patients to receive information and control their medical care is confirmed by Law Number 17 of 2023, except in certain circumstances such as emergencies or overcoming outbreaks or epidemics. The informed consent process is placed in a strong position, where medical personnel are obliged to provide complete information to patients regarding diagnosis, prognosis, treatment options, risks, benefits and costs. Law Number 17 of 2023 concerning health is in line with the opinions of experts under informed consent which must give each individual the right to be able to determine health services independently accompanied by a sense of responsibility, in accordance with *prima facie* principles, namely autonomy, justice, beneficence, and non-maleficentia. Informed consent is the main basis, where patients have the right to accept or refuse help after fully understanding the information.

REFERENCES

- Ali, Zainuddin. 2009. *Legal Research Methods*. Jakarta: Sinar Graphics.
- Dahlan, Sofwan. 2005. *Health Law (Guidelines for the Medical Profession)*. Semarang: Publishing Agency Diponegoro University.
- Fuady, Munir. 2018. *Legal Research Methods, Theoretical and Conceptual Approaches*. Depok: Rajawali Press
- Guwandi, J. 2006, *Informed Consent & Informed Refusal* (Jakarta, FKUI publishing house, 4th Ed)
- Herkutanto, "Medicolegal Aspects of Services Emergency," *Indonesian Medical Magazine* 57, no. 2(2007)
- Heuken, Adolf. 1973. *Political Encyclopedia of Pancasila Development*. Jakarta: Cipta Loka Caraka Foundation.
- Indradi, Rano. 2007. *Patient's Rights in Expressing Approval of Medical Action Plans*. Available from: Koeswadji, Hedijati. 1998. *Law*
- Komalawati, Veronika. 1989. *Law and Ethics in Medical Practice*. Jakarta: Sinar Harapan Library.
- Law of the Republic of Indonesia Number 17 of 2023 concerning Health
- Law of the Republic of Indonesia Number 36 of 2009 concerning Health
- Medicine: A Study of Legal Relations in Which the Doctor is One of the Parties. Bandung: Citra Aditya Bakti.
- National Law Department The Indonesian Judiciary collaborates with PERHUKI and PB IDI, Jakarta
- Raharjo, Satjipto. 2000. *Legal studies*. Bandung: PT. Aditya Bakti's image.
- Ratman, Desrizza. 2018. *Legal Aspects of Informed Consent and Medical Partners in Therapeutic Transactions*. Bandung: CV Keni Media
- Regulation of the Minister of Health of the Republic Indonesia Number 290/MENKES/PER/III/2008 concerning Approval of Medical Procedures
- Rushad, Zahir. 2018. *Patient Protection Law*. Malang: Setara Press Constitution of the Republic of Indonesia of 1945
- Van der Mij, 1984, "The Development of Health Law in the Netherlands", Paper presented at the One Day Seminar "Issues of Health Law", Medical Law Study Team, Development Agency [www.http://ilunifk83.com/tl43-inform-ed-consent](http://ilunifk83.com/tl43-inform-ed-consent). (accessed January 31, 2023)