A JURIDICAL REVIEW OF INFORMED CONSENT BASED ON LAW NUMBER 17 OF 2023 CONCERNING HEALTH AS A REPLACEMENT FOR LAW NUMBER 36 OF 2009

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ABSTRACT

In contemporary times, with the increasing legal awareness among the general public, the aspect of legal protection has become a focal point in the healthcare legal framework in Indonesia. The Law Number 17 of 2023 concerning Health, replacing Law Number 36 of 2009, illustrates significant changes in the healthcare legal structure in Indonesia. One of the primaries focuses in the implementation of this law is informed consent, which serves as a legal protection tool for patients. Therefore, this study aims to explore the regulation of informed consent in Law Number 17 of 2023 and its implementation among healthcare professionals or facilities. This research employs a normative juridical analysis method by examining the document of the Republic of Indonesia Law Number 17 of 2023 concerning Health, which replaces Law Number 36 of 2009 concerning Health. Legal reviews are conducted by referring to various legal sources and expert opinions. The research findings indicate that Law Number 17 of 2023 establishes a stronger foundation compared to the previous law for the implementation of informed consent. Informed consent is emphasized as both a medical duty and a patient's right, with an emphasis on providing comprehensive information. These changes reflect responses to the unequal access to healthcare services and the need to strengthen the national healthcare system, particularly in the context of emergencies, extraordinary events, or outbreaks. The study notes that there is still a need for adaptation and thorough understanding from healthcare professionals and facilities to maintain a balance between patient rights and the public health interest. Further issues to be addressed include aspects of informed consent that are not elaborated in detail in this new law, such as medical expansion procedures and decisions regarding life-sustaining treatment cessation or postponement.

Keywords: Healthcare Law; Informed Consent; Legal protection.
INTRODUCTION

According to A. Heuken (1973), the regulation of healthcare services in Indonesia originates from Article 34, Paragraph (1) of the 1945 Constitution of the Republic of Indonesia, which asserts the state's responsibility for healthcare services, and Article 28, Paragraph (1) H, which acknowledges the citizens' right to receive healthcare services. These articles reflect the values of fair and civilized humanity, as well as the principle of social justice for the people of Indonesia, with a focus on upholding human dignity and achieving equity in the provision of healthcare services.

With the enactment of Law Number 17 of 2023 concerning Health, which replaces Law Number 36 of 2009, the state reaffirms the right of every citizen to attain a good, healthy, and prosperous life. The preamble of this law reaffirms the state's responsibility to protect all Indonesians and their descendants, in accordance with the national goals set forth in the 1945 Constitution of the Republic of Indonesia. Therefore, the presence of doctors becomes essential as the primary implementers of development projects in the healthcare sector, ensuring the attainment of the common welfare.

Initially, the relationship between doctors and patients followed a paternalistic therapeutic model, characterized by familial closeness, and built on trust. With the advancement of information dissemination through mass media, privacy within the medical profession became increasingly transparent. The public's growing knowledge of health, accompanied by a transformation towards higher levels of education in the healthcare field, has triggered a paradigm shift. People have become more aware of their responsibility for their own health, leading to an awareness of the need to establish a balanced relationship between doctors as

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healthcare providers and patients as recipients of care.\(^6\)

Rano Indradi\(^7\) highlights that individuals as patients have rights and responsibilities that deserve to be understood during the healthcare delivery process. There are three fundamental rights in this regard: the right to access healthcare, the right to information, and the right to decision-making.

Koeswadji\(^8\) identifies two models of doctor-patient relationships: the vertical paternalistic model and the horizontal contractual model. In the vertical paternalistic model, the doctor's position as a healthcare provider is considered higher than that of the patient, who is seen merely as a consumer.\(^9\) Conversely, in the horizontal contractual model, both parties are considered equal in status. This equal relationship forms the basis for the contractual framework, thus requiring mutual agreement for contributions or services in healthcare provision. From this contractual horizontal relationship pattern, the concept of informed consent emerges in medical practice, where doctors provide healthcare services to patients as recipients.\(^10\)

Informed consent, as a fundamental principle in medical practice, encompasses not only medical aspects but also legal considerations. It is essential to ensure that patients understand the information provided so that consent is given without pressure or coercion.\(^11\)

In recent years, the evolving landscape of healthcare in Indonesia has witnessed a surge in legal awareness among the populace, highlighting the imperative need for robust legal frameworks to safeguard patient rights and ensure healthcare providers' accountability. Amidst this backdrop, the enactment of Law Number 17 of 2023 concerning Health, replacing its predecessor, Law Number 36 of 2009, marks a significant milestone in the legal trajectory of Indonesian healthcare. However, this transition has unearthed a nuanced discourse concerning the congruence between the normative legal

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\(^8\) Hukum Kedokteran: Studi Tentang Hubungan Hukum Dalam Mana Dokter Sebagai Salah Satu Pihak (Bandung: Citra Aditya Bakti, 1998).


provisions (das solen) and their practical application (das sein), particularly concerning the pivotal aspect of informed consent. While the law underscores the centrality of informed consent as a cornerstone of patient autonomy and protection, the practical implementation of these provisions unveils various complexities and discrepancies. This juxtaposition between legal mandates and their real-world enactment underscores the exigency for a comprehensive juridical review to discern the efficacy, adequacy, and potential gaps in the regulatory framework surrounding informed consent within the ambit of Law Number 17 of 2023.

In Indonesia, the implementation of informed consent has become a primary concern, especially since the enactment of Law Number 17 of 2023 concerning Health, which replaces Law Number 36 of 2009 concerning Health. The legal framework for health in Indonesia has undergone a substantial transformation with the enactment of Law Number 17 of 2023 concerning Health. This law introduces changes and improvements regarding patients' rights to have sufficient information prior to giving their consent for a medical procedure, with an emphasis on informed consent. While Law Number 36 of 2009 concerning Health established the basis for the principle of informed consent, assessments of its application have shown a number of challenges and inadequacies in safeguarding patients' rights.\(^\text{12}\)

Therefore, the enactment of Law Number 17 of 2023 becomes highly significant to rectify and bring about significant changes in the newer legal framework. By identifying the differences and similarities between the two laws, this analysis provides a comprehensive overview of the development and status of informed consent within the legal framework of health in Indonesia, serving as legal protection for patients.\(^\text{13}\)

In the context of replacing Law Number 36 of 2009 with Law Number 17 of 2023 concerning Health in Indonesia, there is a profound need to evaluate the implementation of informed consent among healthcare professionals and facilities. The problem statement to be considered in this research includes: (1) To what extent do the requirements of informed consent stipulated in Law Number 17 of 2023 reflect the need for legal protection for patients? (2) How is

\(^{12}\) Zahir Rusyad, Hukum Perlindungan Pasien (Malang: Setara Press, 2018).

\(^{13}\) Desriza Ratman, Aspek Hukum Informed Consent Dan Rekan Medis Dalam Transaksi Terapeutik (Bandung: CV Keni Media, 2018).
the implementation of informed consent in daily healthcare practices by healthcare professionals and facilities in Indonesia, and to what extent does it meet the standards set by the law? By deepening the understanding of the discrepancy between legal mandates and field practices, this research aims to identify potential improvements in Indonesia's new healthcare legal system.

METHOD

The method employed in this research is normative juridical research method. According to Zainuddin Ali, normative juridical research is an approach to identify legal regulations, legal principles, and legal doctrines with the aim of addressing legal issues at hand. The process of collecting primary legal data is conducted by applying a legislative approach.

In gathering primary legal materials, the author adopts the method of statutory approach by examining the document of the Republic of Indonesia Law Number 17 of 2023 concerning Health, which replaces Law Number 36 of 2009 concerning Health. The process of collecting secondary legal materials in this research is carried out through literature review involving books, legal journals, legal articles, and various other relevant literatures to the author's research, serving as explanations, or supporting materials for the primary legal materials.¹⁴

Legal review will be conducted by referring to several legal materials and methods of collecting materials that have been used. The analysis will be based on the law to obtain detailed conclusions, in order to provide answers to the issues faced in this research.

RESULTS AND ANALYSIS

The development of transformation and reform in the healthcare sector in Indonesia has been extended through the enactment of Law Number 17 of 2023 concerning Health, signed on August 8, 2023, replacing Law Number 36 of 2009. The basis and foundation of the formation of this Law are based on the considerations, namely Article 20, Article 21, Article 28H paragraph (1), and Article 34 paragraph (3) of the 1945 Constitution of the Republic of Indonesia.

The basis and foundation for the establishment of this Law are rooted in the considerations outlined in Article 20, Article 21, Article 28H paragraph (1), and Article 34 paragraph (3) of the 1945 Constitution of the Republic of Indonesia.

Constitution of the Republic of Indonesia. These constitutional provisions underscore fundamental principles such as the right to health, the protection of human rights, and the promotion of public welfare. This analysis examines the complex intersection between constitutional mandates and specific provisions in the law. It explains how the law translates these constitutional principles into actionable steps within the health sector, ensuring the protection of patients' rights, equitable access to health services, and improvement of the national health system. In addition, the analysis also describes potential discrepancies or areas that require further refinement to uphold the constitutional integrity and coherence of the law.

This stems from the disparities and imbalances still felt in healthcare services in the regions. Despite commitments to equalize healthcare services, the field reality shows a significant variation in healthcare quality between regions. With the accreditation and supervision system in place, not all healthcare services implement service standards due to insufficient information and knowledge from the resources available to healthcare workers.

Law Number 17 of 2023 is expected to provide a stronger legal basis to address issues of access to healthcare services, ensuring that all segments of society can enjoy their health rights fairly. The Law transforms the healthcare system to achieve more equitable and high-quality services. This includes promotive, preventive, curative, and rehabilitative and/or palliative efforts. Various considerations in this Law aim to improve access and equal distribution of healthcare services to the entire population, regardless of social, economic, or geographical status. However, the implementation of this Law in the field still requires further efforts to address these disparities and ensure that individual rights are evenly fulfilled in the context of healthcare services in Indonesia.

As stipulated in Article 2, one of the principles underlying the formation of Law Number 17 of 2023 is the principle of legal awareness and respect for rights and obligations, which means that health development must be carried out

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respecting the rights and obligations of the community as a form of legal equality.¹⁶

By acknowledging patients' rights to information and control over their medical care, while also considering the public interest and public health, Law Number 17 of 2023 seeks to create a fair balance between individual rights and broader interests. This is an important step in safeguarding patients' rights to dignified care, in accordance with their wishes, needs, and rights as individuals.¹⁷

As legal subjects, every citizen is entitled to rights regulated by the Law. In order to protect and fulfill the rights of legal subjects in the field of health, legal protection is needed for citizens involved in health services. One of the legal protections in the field of health services is informed consent or consent to medical procedures. The transformation in the aspect of legal protection receives special attention in Law Number 17 of 2023.¹⁸

Law Number 17 of 2023 concerning Health uses the term "Consent to Health Service Procedures," which has the same meaning as informed consent. This law updates many aspects of Law Number 36 of 2009. The position of informed consent is emphasized as a right of the public (Article 4) and an obligation of medical personnel (Article 274). Informed consent becomes a fundamental part of the healthcare process. Everyone has the right to accept or refuse some or all medical procedures provided to them after receiving information about the procedures. From the perspective of medical personnel, consent from the patient or family for the procedures to be performed is an obligation, preceded by the provision of information by healthcare professionals, presented fully and in easily understandable language.¹⁹

The statement highlights a significant shift in terminology from "informed

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¹⁹ Baroto SP, “Presumed Consent Atas Tindakan Medis Berisiko Tinggi Pada Kegawatdaruratan: Perspektif Undang-Undang Nomor 17 Tahun 2023.”
consent" to "Consent to Health Service Procedures" within Law Number 17 of 2023 concerning Health, indicating a nuanced evolution in the legal framework governing healthcare practices in Indonesia. This change underscores a deliberate effort to modernize and align legislative language with contemporary healthcare standards and practices. The term "Consent to Health Service Procedures" is essentially synonymous with informed consent, emphasizing the importance of patient autonomy and the right to make informed decisions about their medical care. By updating this terminology, the law aims to enhance clarity and precision in articulating the expectations and responsibilities of healthcare providers and patients in the consent process.

Moreover, the mention of the update in Law Number 17 of 2023 in comparison to Law Number 36 of 2009 suggests a comprehensive reform of the healthcare legal framework. This reform likely encompasses various aspects beyond terminology, reflecting broader advancements, adaptations to evolving healthcare practices, and responses to emerging challenges or gaps identified in the previous legislation. Therefore, a thorough analysis of the changes introduced by Law Number 17 of 2023 is essential to understand its implications for healthcare delivery, patient rights, legal obligations of healthcare professionals, and the overall functioning of the healthcare system. This analysis should delve into the specific amendments, their rationale, potential impacts on stakeholders, and the extent to which they address existing shortcomings or align with international best practices in healthcare regulation. Additionally, it should explore any implications for the implementation of "Consent to Health Service Procedures" in practice, including potential challenges, ambiguities, or areas requiring further clarification or guidance from regulatory authorities.

Before the enactment of Law Number 17 of 2023, in the context of implementing informed consent, there were still elements that could potentially lead to medical disputes: (1) regulations regarding the provision of information related to medical procedures; (2) uncertainty about the legal status of orally conducted informed consent; (3) obtaining informed consent in emergency situations.20

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20 Eduardus Raditya Kusuma Putra, “Informed Consent Pada Pasien Sectio Caesarea Dengan Metode Enhanced Recovery After Caesarean Sectio (ERACS),” *Jurnal Sehat Indonesia*
The statement underscores several key challenges surrounding the implementation of informed consent prior to the enactment of Law Number 17 of 2023 in Indonesia. Firstly, there existed ambiguity regarding regulations governing the provision of information pertinent to medical procedures, potentially leading to disparities in the quality and comprehensiveness of information provided to patients. Secondly, uncertainty surrounded the legal status of orally conducted informed consent, raising questions about the adequacy of verbal agreements in ensuring patient understanding and protection. Lastly, the complexity of obtaining informed consent in emergency situations posed a considerable challenge, as time constraints and medical exigencies often limited the feasibility of comprehensive patient consultation. These elements collectively contributed to a heightened risk of medical disputes, highlighting the imperative need for legislative reforms to address these gaps and enhance the efficacy and clarity of informed consent processes in the healthcare domain.

A case study by Sosiawan regarding the implementation of Informed Consent in hospitals in Surabaya revealed that two out of three hospitals still did not adhere to the standard implementation of informed consent (in this case, the study refers to Law Number 29 of 2004). The main shortcomings were found in providing information before medical procedures, the prognosis of the procedures performed, and clarity regarding the contract between the patient and the procedure operator. These shortcomings certainly have the potential to lead to medical disputes if there is a breach of contract resulting in healthcare professionals being subject to prosecution under Articles 359 and 360 of the Criminal Code.21

Research by Bagaskara22 on the completion of informed consent at the Regional General Hospital of Dr. Abdoer Rahem Situbondo found that almost 56-74% of medical procedures performed did not have complete informed consent. An analysis of the factors contributing to the suboptimal implementation of informed consent in Indonesia revealed the lack of awareness among medical personnel regarding the consequences of not

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22 “Permasalahan Informed Consent Dalam Dokumentasi.”
obtaining informed consent and the failure of hospitals to conduct socialization and monitoring of standard operating procedures related to informed consent.

The potential for medical disputes arising from the regulation of informed consent in the previous laws can be exemplified by the case of doctor A's breach of contract (Case study from the Supreme Court decision No. 79 PK/PID/2013) when performing an emergency Cesarean section operation that resulted in the patient's death. In this case, the emergency situation was cited as the reason for doctor A performing the surgery without obtaining informed consent beforehand. However, on the other hand, doctor A never conveyed the risks and prognosis of the procedure to the patient's family orally.23

In Law Number 17 of 2023 concerning Health, there are two additional conditions that limit the obligation to implement informed consent, which were not present in the previous laws. These conditions are emergency situations and Extraordinary Events (KLB) or outbreaks. These changes are interpreted as a response to the Coronavirus Disease 2019 (COVID-19) pandemic that occurred in 2020. The COVID-19 pandemic has highlighted the importance of strengthening the national healthcare system, particularly efforts during emergencies and outbreaks. Limitations on the implementation of informed consent are not merely a violation of patients' rights, but are intended to protect the public interest and public health. During emergencies, medical actions take precedence over consent, aimed at minimizing barriers that could impede life-saving processes.

Article 293 provides a more comprehensive overview of the obligations of medical personnel to obtain consent, the explanations that must be provided, the form of informed consent given, the timing of consent, the parties entitled to give consent, the presence of witnesses, and the actions to be taken if no one can be asked for consent. This article explains the aspects of informed consent in more depth and detail.24

The mention of Article 293 within the legislative framework signifies a notable enhancement in the provisions governing


informed consent within the healthcare sector. This article offers a comprehensive delineation of the obligations incumbent upon medical personnel in obtaining consent, encompassing the provision of detailed explanations, the requisite form and timing of consent, and delineating the parties authorized to give consent. Additionally, it addresses procedural aspects such as the presence of witnesses and delineates protocols to be followed in scenarios where consent cannot be readily obtained. By delving into these intricacies, Article 293 endeavors to provide a robust legal framework that not only emphasizes the significance of informed consent but also seeks to mitigate potential ambiguities or uncertainties that may have existed in previous iterations of healthcare legislation. This heightened clarity and specificity not only serve to bolster patient autonomy and protection but also provide healthcare practitioners with clearer guidelines, ultimately contributing to a more transparent, accountable, and patient-centered healthcare system.

The regulations concerning informed consent in Law Number 36 of 2009 are relatively shorter and simpler compared to its replacement law. Informed consent in healthcare services under this law is only mentioned as a patient's right, not as a duty of medical personnel. Article 5 asserts that every individual has the right to independently and responsibly determine the healthcare services needed for themselves. Additionally, Article 56, relating to patient protection, guarantees the right of every individual to accept or refuse assistance after understanding complete information about the procedure. Meanwhile, the article approaching the discussion on informed consent as a duty of medical personnel is Article 24 paragraph (1), stating that healthcare providers must adhere to the provisions of the code of ethics, professional standards, patient rights, service standards, and standard operating procedures.  

Substantively, Informed Consent in Law Number 17 of 2023 obtains a clearer position and legal certainty compared to the previous law. As mentioned in Articles 274 and 293, informed consent is enforced as a process involving the obligation to provide comprehensive information to patients regarding diagnosis, prognosis, treatment options, risks, benefits, and even costs. These two articles ensure that patients must have sufficient

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understanding before consenting to a medical procedure. Thus, these regulations strengthen legal protection for patients and provide a more solid foundation for safeguarding their rights in the context of medical decision-making processes.\textsuperscript{26}

The assertion regarding the substantial improvements in the positioning and legal certainty surrounding informed consent within Law Number 17 of 2023 vis-à-vis its predecessor reflects a significant stride in healthcare legislation in Indonesia. Articles 274 and 293 notably solidify the concept of informed consent as a comprehensive process, mandating healthcare providers to furnish patients with detailed information encompassing diagnosis, prognosis, treatment alternatives, associated risks, benefits, and financial implications. By delineating these requirements, the law ensures that patients are equipped with the requisite understanding to make informed decisions about their medical care, thereby bolstering their autonomy and rights within the healthcare system. This heightened legal protection not only safeguards patients against potential risks and uncertainties but also fosters transparency and accountability among healthcare practitioners. Moreover, the establishment of a robust framework for informed consent underscores the commitment of Indonesian legislators to uphold ethical standards and promote patient-centered healthcare practices, thereby contributing to the overall enhancement of the healthcare system's integrity and effectiveness.

In facing these changes, healthcare professionals need to understand and carefully implement every new aspect regulated in the law. One central point that requires special attention is the requirement of informed consent. Healthcare providers are expected to provide clear and comprehensive information to patients, ensuring full understanding of medical procedures, risks, and possible alternatives. In line with this, healthcare facilities are also required to revise and enhance their operational procedures to comply with the new standards mandated by the law, making healthcare services more transparent and patient-centered.\textsuperscript{27}


\textsuperscript{27} Indah Amelia, Herfiyanti, and Piki Ganesha Bandung, “Kelengkapan Pengisian Formulir Persetujuan Tindakan Operasi (Informed Consent)
This rapid and effective adaptation is a crucial step in maintaining the quality of healthcare services, providing legal protection for all involved parties, and ensuring that patients have optimal control over decisions regarding their health. Moreover, through the implementation of these new regulations, it is hoped that the overall healthcare system can deliver safer, higher-quality, and patient-centered services.\textsuperscript{28}

According to the author, there are several aspects of informed consent that have not been mentioned and further elaborated in Law Number 17 of 2023, including the aspects related to medical expansion procedures and the withholding or withdrawal of life support, which are actually addressed in the Minister of Health Regulation (PMK) of the Republic of Indonesia Number 290/MENKES/PER/III/2008 concerning medical procedure consent. Law Number 17 of 2023 does not mention these two aspects, which may potentially lead to future issues if situations related to them arise.

In Article 8 paragraph (2) of PMK Number 290, medical expansion procedures are mentioned as one of the medical procedures that require explanation during the process of informed consent. According to Ratman\textsuperscript{29}, medical expansion refers to situations where a procedure that has already been consented to requires additional actions due to specific circumstances that were not covered in the initial explanation of informed consent. In certain circumstances where time is limited and obtaining informed consent from the patient's family is not feasible, medical expansion procedures are performed with the aim of saving lives or preventing disabilities that may arise as a result of the situation.

Furthermore, Article 14 of Ministerial Regulation Number 290 elaborates on the act of withholding or delaying life support, which can be interpreted as the authority to cease life support measures. It is also stated that the decision to withhold life support from a patient must obtain consent from the patient's closest family members after they have been provided with explanations, and this consent must be obtained in written form.


\textsuperscript{29} Aspek Hukum Informed Consent Dan Rekan Medis Dalam Transaksi Teurapetik.
CONCLUSION

Juridical review of informed consent under Law Number 17 of 2023 marks a significant step forward in the legal framework governing healthcare in Indonesia. The meticulous examination of Articles 274 and 293 reveals a more robust and comprehensive approach to informed consent, ensuring patients' rights and autonomy are safeguarded through the provision of detailed information regarding their medical care. This evolution from Law Number 36 of 2009 reflects a concerted effort to address previous shortcomings and ambiguities, thereby enhancing legal certainty and transparency within the healthcare system. These regulatory enhancements not only serve to protect patients but also foster trust and accountability among healthcare providers, ultimately contributing to the advancement of ethical and patient-centered healthcare practices in Indonesia.

Furthermore, the juridical review underscores the importance of ongoing evaluation and adaptation of healthcare legislation to reflect evolving societal norms, technological advancements, and international best practices. While Law Number 17 of 2023 represents a substantial improvement in the regulation of informed consent, there remains a need for continued vigilance and refinement to ensure its effective implementation and alignment with the ever-changing landscape of healthcare. By remaining responsive to emerging challenges and feedback from stakeholders, Indonesian legislators can further strengthen the legal framework surrounding informed consent, ultimately enhancing the quality, accessibility, and integrity of healthcare services for all citizens.

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