

# Legal Certainty of Patients' Right to Autonomy Protection in High-Risk Health Services

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## ABSTRACT

The relationship between medical personnel and patients in health services should be viewed as a legal relationship between humans who have equal rights. There are two basic human rights in health services, the right to autonomy and the right to information. The results of the study indicate that the protection of patients' autonomy rights is one of the principles in biomedical ethics used as the moral basis for the provision of health services. The form of protection of patients' autonomy rights in health services is realized through regulations related to Informed Consent in Law Number 17 of 2023 Concerning Health and Minister of Health Regulation Number 290 of 2008 Concerning Consent to Medical Actions. Meanwhile, regulations related to the protection of patients' autonomy rights for high-risk health care actions have not met legal certainty because the health care actions are not classified as high-risk.

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## 1. INTRODUCTION

Frans Magnis Suseno stated that humans are individual beings and also social beings (Mumtazinur, 2019). Humans as individual beings clearly have certain interests, which are none other than to fulfill their life needs. Fulfillment of these needs is a must so that humans can continue their lives (Wajiyati, 2018). However, life in the midst of human civilization is not always friendly. There are times when various forms of threats lurk in life so that they can create obstacles for humans in fulfilling their interests (Yuhelson, 2017).

The existence of interests to fulfill primary needs is one of the main reasons for humans to live together in society (Kansil,

1984). Through cooperation between humans that is established in life, it will certainly make it easier for humans to fulfill and protect their interests (Daeng, 2018). One form of primary needs that has a vital role in human life is health.

Health is a form of socio-cultural rights which is part of human rights (Aprita & Hasyim, 2020). Health is a prerequisite for realizing welfare and quality of life. Good health conditions are the basic capital for humans to be able to exercise other basic rights. Health in a broader context is also positioned as a prerequisite for producing good economic growth. It is difficult for humans to work well, effectively, and productively without being accompanied by good health conditions. Without a good level

of health, humans will face difficulties in being able to maximize their potential as humans. On that basis, why is the right to health seen as a fundamental human right (Kusmaryanto, 2015). On the basis of this understanding, it can be said that obtaining access to quality and affordable health services is one of the health rights possessed by every citizen.

The relationship between medical personnel and patients in health services should be seen as a legal relationship between humans who have equal rights. Komalawati stated that in principle the relationship between medical personnel and patients is based on two types of human rights which are basic human rights, namely: the right to autonomy and the right to information (Suganda, 2017).

Through the right to information, patients have the right to obtain clear and complete information regarding their medical condition and the health care actions that will be taken on them. Fulfillment of the right to information will be an instrument that will help patients fulfill the right to autonomy (Ratman, 2013).

The right to autonomy is a right that is owned by every dignified human being. Through the right to autonomy, humans have the right to determine what is best for themselves. Likewise in health services, patients have the right to autonomy to determine what is best for themselves. Giving approval or refusing health care actions recommended by medical personnel or health workers is a manifestation of this right to autonomy.

It can be understood that the patient's right to autonomy is very important in the implementation of health services. Violation of the patient's right to autonomy is a form of insult to the patient's dignity as a human being. Thus, protection of the patient's right to autonomy is also regulated in laws and regulations in Indonesia.

Based on this description, this study aims to examine 3 (three) things. First, to understand the concept of the principle of respecting the patient's right to autonomy in

biomedical ethics. Second, to understand the protection of patient autonomy rights in positive legal arrangements in Indonesia. Third, to understand the urgency of legal certainty in protecting patient autonomy rights for high-risk health care actions.

## 2. METHODS

This study aims to examine the legal certainty related to the protection of patient autonomy rights in high-risk health care services. This research is normative legal research, because it takes a legal approach related to the problems studied in this study. Normative legal research is qualitative research that takes an approach to legal norms contained in laws and regulations, court decisions, and laws that exist in society. The approach in this study formulates the concept of legal norms that will be used as a benchmark for how humans should behave in relation to the problems studied (Ali, 2016).

Secondary data that is related to the problems studied is used in research that uses a normative legal approach. The use of secondary data is carried out in order to formulate legal doctrines that are theoretical and scientific in nature. The legal doctrine that has been formulated will then be used to analyze the problems discussed. Secondary data used in legal research is library materials which are generally in the form of primary, secondary, and tertiary legal materials (Muhaimin, 2020). This study uses primary legal materials in the form of laws and regulations and secondary legal materials consisting of explanations of primary legal materials, law books, and research results related to legal certainty, protection of patient autonomy rights, and medical risks in health services. Secondary data collection is carried out through literature studies. The study conducted in this study was carried out by first analyzing the principle of respecting patient autonomy rights in biomedical ethics which is the moral basis for legal regulations related to the protection of patient autonomy rights in health services. Then, the analysis is continued by examining legal certainty

related to the protection of patient autonomy rights in high-risk health services. Thus, this study is an analytical descriptive study. The analytical descriptive research referred to in the context of legal research is a form of research in which the content of legal norms is determined which is positioned as a guideline for finding a solution to the legal problem being studied (Ali, 2016).

### 3. RESULTS AND DISCUSSION

#### 3.1 *Principle of Respecting Patients' Right to Autonomy in Biomedical Ethics*

Biomedical ethics is a form of applied ethics that serves as a moral guide in the health sector. The existence of biomedical ethics initially seemed to only be applied in the medical field. However, over time it can be seen that at the practical level, not only doctors and dentists have a role in health services, but also other health professions. That is why biomedical ethics should also be applied in the provision of health services in general.

As in other branches of applied ethics, biomedical ethics uses many methods and approaches. However, as stated in the book *Principles of Biomedical Ethics* published in 1979 by Tom Beauchamp and James Childress, biomedical ethics is structured using four basic principles. These principles basically also apply in general ethics studies that examine the general moral context. However, in the medical field, these principles have a very important role. The four principles referred to in biomedical ethics consist of respect for autonomy, beneficence, non-maleficence, and justice (Bertens, 2015).

The principle of respecting autonomy is based on the inherent autonomous nature of every human being. Autonomous humans have the freedom to act based on considerations and decisions made by themselves. This arises when humans in a certain situation are faced with various choices, each of which has certain consequences. Human freedom that is correlated with autonomy can be seen as a

form of moral rights. Moral rights in the form of autonomy rights owned by every human being must of course always be respected by fellow humans themselves. The consequence is that no one has the right to hinder or interfere with every choice and decision based on the right to autonomy (Jackson 2013).

The application of the principle of respecting autonomy in health services emphasizes the obligation for medical personnel or health workers to promote the patient's right to autonomy. This can be achieved by increasing the patient's freedom to determine choices and decisions for themselves (Herring, 2012). In this case, patients must be given the opportunity to carefully consider every option offered by health workers. In addition, patients are also expected to be able to consider the benefits and risks of each option. In order to achieve such an ideal condition, every decision and choice that patients should make must be based on the provision of adequate information by health workers (Fauziah & Triwibowo, 2013).

The idea that underlies the principle of respecting autonomy can also be based on an understanding of the existence of intrinsic values inherent in every human being. As stated in the preamble to the human rights charter, humans have intrinsic values that must be recognized by all humans if humans want to live freely, fairly, and peacefully. The existence of these intrinsic values means that humans should not be viewed only as objects in the form of tools to achieve certain goals. Humans with their intrinsic values must be treated as subjects in themselves.

The existence of these intrinsic values makes humans dignified beings. The existence of this dignity does not exist because it is given by someone, society, or even by the state. Humans are dignified because they are human. Humans in themselves have value, so there is no need for the existence of other things that are other external factors to make humans dignified as humans (Kusmaryanto, 2015).

Human dignity is very important in various areas of life because it is the basis for

thinking about human rights. Dignity makes humans different from other creations and at the same time places humans with other humans in the same position. Human dignity is often used in politics and government in official documents and in everyday practice, for example in matters of opposing slavery, opposing human cloning, opposing sexual exploitation, and so on.

Immanuel Kant argued that humans must respect the dignity of other humans because humans are the only creatures that are ends in themselves. Humans can use physical objects to fulfill human goals. Animals can also be used as long as they are useful for fulfilling human goals. However, humans remain ends in themselves that should not be subjugated to other goals. This is due to the fact that humans are the center of independence. Thus, humans are free and autonomous creatures who are able to think in order to make their own decisions.

Whatever the reason and for whatever purpose to be achieved, human dignity should never be violated. The existence of human dignity that resides within itself gives rise to a moral consequence that humans must be respected as humans. Respect for humans should not be based on reasons of social status in society, heredity, wealth, or so on, but solely because of their dignity as humans (Bertens, 2022).

### ***3.2 Protection of Patients' Right to Autonomy in Positive Legal Regulations in Indonesia***

Moral values need to be realized in real terms if they are to be applied in people's lives (Bertens, 2017). One form is to make these moral values in the form of a code of ethics so that these moral values become moral obligations. The code of ethics which is a moral guideline applies within the scope of certain professions, such as doctors or dentists, and should be obeyed and carried out by those who work in these professions. However, the characteristics of the code of ethics which have relatively light sanctions for violations because they are only in the form of guidance make these moral guidelines

sometimes ignored. Of course, this has the potential to cause disruption to the public interest considering that professions in the health sector often intersect with the interests of society (Hanafiah & Amir, 2007). That is why in order to protect the public interest, the state 'intervenes' by institutionalizing moral values in the code of ethics of the profession into a legal form so that they can be stated and regulated in a concrete and detailed manner. Through the nature of the law that regulates (orders or prohibits), binds, forces, and contains strict sanctions (physical punishment or compensation) it is hoped that it can realize the moral values that are expected to apply so that order in society can be maintained as well as possible (Kansil, 1984).

The principle of respecting the patient's right to autonomy in health services is closely related to respect for human dignity. Protection of human dignity, in general, has been expressly stated in the second amendment to the 1945 Constitution. This is one of the efforts to realize one of the ideals of the state contained in the Preamble to the 1945 Constitution, namely to protect the entire Indonesian nation and all of Indonesia's territory. As stated in Article 28G paragraph 1 of the 1945 Constitution, everyone has the right to protection of themselves, their families, honor, dignity, and property under their control, and has the right to a sense of security and protection from the threat of fear to do or not do something that is a basic right.

Protection of human dignity as part of human rights is also confirmed in Law Number 39 of 1999 concerning Human Rights. Article 29 paragraph 1 of Law Number 39 of 1999 concerning Human Rights states that everyone has the right to protection of themselves, their families, their honor, their dignity, and their property.

Protection of patient autonomy rights is also a major concern in the provision of health services in Indonesia. Respect for human dignity as stated in the principle of respect for autonomy plays an important role in the medical field. This is manifested in the form of the application of the concept of informed consent in medical services. The

principle of respect for autonomy as stated in the concept of informed consent is universal and applies to health professions throughout the world. In order to be implemented properly, this principle is adopted into professional ethics which function as moral guidelines in the health profession, especially for the professions of doctors and dentists. Moral guidelines for the medical profession to respect patient autonomy are contained in Article 5 of the Indonesian Medical Code of Ethics which states, "Every act or advice from a doctor that may weaken psychological or physical endurance must obtain the consent of the patient/family and is only given for the benefit and good of the patient". Meanwhile, for the dental profession, it is contained in Article 10 of the Indonesian Dental Code of Ethics which reads, "Dentists in Indonesia are required to respect the patient's right to determine their choice of treatment and confidentiality". Efforts to protect human dignity in the health sector that are manifested through Informed Consent are also regulated in laws and regulations in Indonesia. The scope of Informed Consent regulations in Indonesia includes issues of approval in the implementation of donors, health research, and health service actions. Informed Consent regulations related to health service actions were previously contained in a number of laws and regulations related to the implementation of health services such as Law Number 36 of 2009 concerning Health, Law Number 29 of 2008 concerning Medical Practice, Law Number 44 of 2009 concerning Hospitals, and Law Number 36 of 2014 concerning Health Workers. Meanwhile, technical regulations related to the implementation of Informed Consent for health service actions refer to the regulations in the Minister of Health Regulation Number 290 of 2008 concerning Consent to Medical Actions. However, legal regulations in the health sector have undergone major changes since the enactment of Law Number 17 of 2023 concerning Health on August 8, 2023.

Through the provisions of Article 454 of Law Number 17 of 2023 concerning Health,

11 laws have been declared revoked and are no longer valid. Law Number 17 of 2023 concerning Health currently does not have implementing regulations that serve as technical guidelines for implementing the provisions in the law. However, Article 453 of Law Number 17 of 2023 concerning Health emphasizes that the laws and regulations that serve as implementing regulations for the 10 laws that have been declared revoked and are no longer valid in Article 454 of Law Number 17 of 2023 concerning Health, remain in effect as long as they do not conflict with the provisions of Law Number 17 of 2023 concerning Health. Thus, the provisions related to Informed Consent in the provision of health services are currently regulated in general in Law Number 17 of 2023 concerning Health. Meanwhile, technical provisions related to the implementation of Informed Consent in health services currently still refer to the Minister of Health Regulation Number 290 of 2008 concerning Consent for Medical Actions. Article 293 paragraph 1 of Law Number 17 of 2023 concerning Health stipulates that medical personnel and health workers are required to obtain consent in carrying out every health service action intended for individuals. In principle, the party who has the right to give consent is the patient. However, there are certain conditions where the patient is considered legally incompetent or is under guardianship (under curatele), so that consent for health service actions can be given by the closest family including father/mother, husband/wife, biological child or adult sibling. Regarding this matter, it is regulated in Article 293 paragraph 7 of Law Number 17 of 2023 concerning Health, which states that when a patient is not capable of giving consent, then consent for health service actions can be given by the person representing the patient.

It should be understood that Informed Consent is a process carried out through providing an explanation and a statement of decision (authorization). This explanation needs to be conveyed to the patient so that they can make the right decision for themselves based on a complete

understanding of the health service actions that will be carried out on them. Regarding the patient's right to obtain an explanation from medical personnel and health workers in the process of obtaining Informed Consent, it is regulated in Article 293 paragraph 2 of Law Number 17 of 2023 concerning Health, which expressly states that consent can only be given by the patient after receiving adequate explanation from medical personnel or health workers.

To be said to be adequate, the explanation provided by medical personnel or health workers to the patient must meet the criteria in Article 293 paragraph 2 of Law Number 17 of 2023 concerning Health in conjunction with Article 7 paragraph 3 of the Minister of Health Regulation Number 290 of 2008 concerning Consent to Medical Actions. These provisions outline that the explanation provided to the patient must contain a number of information that needs to be known and understood by the patient. There is some information that needs to be conveyed to the patient in the Informed Consent process, including:

- a. Diagnosis;
- b. Indication;
- c. Health Service Actions to be performed and their purpose;
- d. Possible risks and complications;
- e. Alternative actions and their risks;
- f. Risks if the action is not performed;
- g. Prognosis after receiving a diagnosis; and
- h. Estimated costs.

An important thing to note in providing an explanation is the patient's understanding of the information. The patient's understanding of the information is important because informed consent is invalid if the patient/guardian gives consent without understanding the information provided by the doctor (Bertens, 2015). Article 9 of the Minister of Health Regulation No. 290 of 2008 states that the explanation given to the patient must be given completely in a language that is easy to understand or in

another way that aims to facilitate understanding.

If the patient has received an explanation and understands the information that has been provided by medical personnel or health workers, the Informed Consent process continues to the decision statement stage. The decision statement is manifested in the act of giving a statement by the patient to medical personnel or health workers to carry out the recommended health service actions. The decision is given by the patient after obtaining information and recommendations from the doctor (Kusmaryanto, 2015).

The provisions in Article 293 paragraph 4 of Law Number 17 of 2023 concerning Health in conjunction with Article 2 paragraph 2 of the Minister of Health Regulation Number 290 of 2008 concerning Consent to Medical Actions regulate the statement of decision given by the patient in the Informed Consent process. As stated in the regulation, the statement of decision given by the patient can be in the form of consent stated in writing or verbally. Based on Article 293 paragraph 5 of Law Number 17 of 2023 concerning Health in conjunction with Article 3 paragraph 1 of the Minister of Health Regulation Number 290 of 2008 concerning Consent to Medical Actions, it is explained that written consent must be given for high-risk health care services.

Regarding the statement of consent given verbally, according to Article 3 paragraph 2 of the Minister of Health Regulation Number 290 of 2008 concerning Consent to Medical Actions, this can be given for health care services that do not have a high risk. Furthermore, Article 3 paragraph 4 of the Minister of Health Regulation Number 290 of 2008 concerning Consent for Medical Actions explains that the verbal statement given by the patient can be in the form of an agreement or in the form of a nod of the head indicating that the patient gives consent. However, it is also stated in Article 3 paragraph 5 of the Minister of Health Regulation Number 290 of 2008 concerning Consent for Medical Actions that if the statement of consent given verbally

is considered still doubtful, then written consent can be requested from the patient.

### ***3.3 The Urgency of Legal Certainty in Protecting Patients' Right to Autonomy for High-Risk Health Service***

Legal certainty correlates with the implementation of clear, permanent and consistent laws where the implementation cannot be influenced by subjective circumstances. Lawrence M. Friedman argues that to realize "legal certainty" at least it must be supported by the following elements, namely: legal substance, legal apparatus, and legal culture. Maria S.W. Sumardjono also explains that regarding the concept of legal certainty, namely that "normatively, legal certainty requires the availability of a set of laws and regulations that operationally and support its implementation. Empirically, the existence of these laws and regulations needs to be implemented consistently and consequently by supporting human resources" (Manan & Magnar, 2017).

Legal certainty is a concrete form of legal regulations in written and unwritten form containing general rules that serve as guidelines for everyone to behave in society. These regulations become limitations and references for society in taking action against other parties. The existence of such rules and the implementation of the rules are a form of legal certainty (Marzuki, 2008).

A regulation is made and enacted with certainty because it regulates clearly and logically. Clear in the sense that it does not cause doubt (multi-interpretation) and is logical so that it becomes a system of norms with other norms that do not conflict or cause norm conflicts. Norm conflicts arising from the uncertainty of the rules can take the form of norm contention, norm reduction or norm distortion. True legal certainty is when laws and regulations can be implemented in accordance with legal principles and norms. According to Bisdan Sigalingging: "between the certainty of legal substance and the certainty of law enforcement should be in line, not just clarity (Halilah & Arif, 2021). Legal

certainty will guarantee that someone behaves in accordance with applicable legal provisions, conversely without legal certainty, a person does not have standard provisions in carrying out behavior. Thus, Gustav Radbruch stated that certainty is one of the goals of law. In the order of community life, it is closely related to certainty in law. Legal certainty is in accordance with normative nature, both provisions and judge's decisions. Legal certainty refers to the implementation of a way of life that is clear, orderly, consistent, and consequential in its implementation and cannot be influenced by subjective circumstances in the life of society. The law is tasked with creating legal certainty because it aims to create order in society. Legal certainty is a characteristic that cannot be separated from law, especially written legal norms. Legal certainty is defined as the clarity of norms so that they can be used as guidelines for the community that is subject to these regulations. A regulation is made and enacted with certainty because it regulates clearly and logically. Clear in the sense that it does not cause doubt (multi-interpretation) and is logical so that it becomes a system of norms with other norms that do not clash or cause norm conflicts.

Gustav Radbruch put forward 4 (four) basic things related to the meaning of legal certainty, namely:

1. The law is positive, meaning that positive law is legislation;
2. The law is based on facts, meaning it is based on reality;
3. Facts must be formulated in a clear way so as to avoid errors in interpretation, in addition to being easy to implement;
4. Positive law must not be easily changed.

Gustav Radbruch's opinion is based on his view that legal certainty is certainty about the law itself. Legal certainty is a product of law or more specifically of legislation. Based on this view, according to Gustav Radbruch, positive law that regulates human interests in society must always be

obeyed even though the positive law is unfair (Aris, Setiawan, & Hartana, 2024).

Authorization as a form of statement of consent given by the patient after receiving adequate explanation in the Informed Consent process can be stated in writing or verbally according to statutory regulations. The provisions in Law Number 17 of 2023 concerning Health and Regulation of the Minister of Health Number 290 of 2008 concerning Consent to Medical Actions stipulate that written authorization must be made for high-risk health care services.

Regulations related to the protection of patient autonomy rights in health services have been regulated in laws and regulations. As previously explained, the protection of patient autonomy rights is realized through regulations related to Informed Consent which are generally contained in Law Number 17 of 2023 concerning Health. Meanwhile, how the Informed Consent process is implemented in health services has also been technically regulated in Regulation of the Minister of Health Number 290 of 2008 concerning Consent to Medical Actions. However, when looking further into the mandatory regulations. This description shows that normatively the protection of patient autonomy rights in health services has been regulated in positive law.

It should be understood that every medical action carried out in health services will always be accompanied by the emergence of certain risks referred to as medical risks. Medical risks that can occur in health services can be complications or things related to unexpected medical conditions that cannot be completely ruled out by the patient or the treating doctor (Tsanie & Kusumaningrum, 2018). The probability of medical risks arising is inherent in the health service action (inherent risk of treatment) (Kholib, 2020).

Medical risk has a fundamental difference with medical negligence. There are several benchmarks to determine whether a failed medical procedure result can be categorized as a medical risk or medical negligence. The result of a medical procedure that does not meet the patient's expectations

can only be categorized as a medical risk if the medical procedure is carried out with great care and in accordance with standard operating procedures, professional standards, and the opinions of the profession itself (Ilahi, 2018).

Misunderstandings related to medical risk and medical negligence by patients can be avoided through the implementation of medical risk management. Medical risk management is needed to reduce adverse events and dissatisfaction from patients and families, prevent poor management by doctors and dentists, waste of time and money from medical personnel, as an effort to prevent public demands for accountability for medical negligence (Siregar, 2023).

Real efforts of medical risk management to avoid misunderstandings related to medical risk and medical negligence are by emphasizing the importance of providing information to patients in the Informed Consent process. In order to avoid misunderstandings about the emergence of risks that are detrimental to patients, clear and complete information is needed by doctors in language that is easy for patients to understand and by remembering where the communication is carried out. Regarding the obligation to provide information to patients regarding medical risks that will arise in health services, it has been regulated in Article 293 paragraph 2 of Law Number 17 of 2023 concerning Health in conjunction with Article 7 paragraph 3 of Minister of Health Regulation Number 290 of 2008 concerning Approval of Medical Actions. Another effort that can be made is to ensure that the authorization stating approval regarding high-risk health service actions from the patient or patient's family is stated in writing. This is in accordance with the provisions in Article 293 paragraph 5 of Law Number 17 of 2023 concerning Health in conjunction with Article 3 paragraph 1 of Minister of Health Regulation Number 290 of 2008 concerning Approval of Medical Actions, which explains that written approval must be given for high-risk health service

actions. However, until now what is meant by medical risk is explained in Law Number 17 of 2023 concerning Health, Minister of Health Regulation Number 290 of 2008 concerning Approval of Medical Actions, and laws and regulations related to the provision of health services in Indonesia. In addition, the laws and regulations have not clearly outlined what health care actions are included in the high-risk category. Thus, it can be said that the regulation related to written consent for high-risk health care actions does not fulfill the principle of legal certainty.

Determining which medical actions are included in the group of high-risk health care actions is something that is difficult to do. This is because the success of a medical action is very dependent on the severity of the disease, the patient's systemic condition, the experience of the medical personnel providing the health care action and the patient's body response to the medical action and treatment carried out on him. In other words, the level of risk of a particular medical action tends to be subjective for each medical personnel.

In order to avoid subjectivity regarding the level of risk of health care actions, medical personnel need to have a dialogue to produce a uniform understanding and agreement in each profession regarding what is meant by high-risk medical actions. This agreement is needed to determine the types of medical actions that are generally considered to be high-risk health care actions

according to the understanding of each profession.

Uniformity of understanding and agreement regarding the classification of health service actions that have been made can be used as material for the formation of laws regarding Informed Consent. The types of health service actions that are classified as having a high level of risk can be detailed in the technical provisions for the implementation of Informed Consent in health services. Thus, legal certainty regarding the protection of patient autonomy rights for high-risk health service actions can be fulfilled. Through this legal certainty, medical personnel have a kind of clear guideline for implementing the Informed Consent process, especially for health service actions that are considered high-risk.

#### 4. CONCLUSION

There are three conclusions obtained from the analysis and discussion in this study. The protection of patient autonomy rights is one of the principles in biomedical ethics that is the moral basis for the implementation of health services. Indonesian legislation has regulated the protection of patient autonomy rights in health services. Medical personnel need to create a uniform understanding and general agreement in their respective professions regarding the classification of high-risk health service actions that can be clearly detailed in technical legislation.

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