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Competency of Legal Subjects in Informed Consent as a Standard Agreement

Argo Sudarga Yohanes [a], Dola Ramalinda [b], Laras Eka Pertiwi [c], Amalia Putri Kumalawijaya [d], Fedryan Syach Rahmawan [e] Sukmawati Nurdin [f], Mohamad Febrinur Ilyasa [g], Harish Fauzan [h]

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Corresponding Author [a]

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Abstract

The purpose of this study is to describe the process of health care that involves a triad of legal subjects, namely doctors, patients, and hospitals. The relationship between the three legal subjects is placed in a standard contract called informed consent. This research method uses a quantitative approach, which is measured by statistics. Necessary to carry out medical actions, legal subjects are doctors or hospitals, as drafters of agreements that contain the rights and obligations of all parties. The results of the analysis in practice in hospitals indicate an indication of competency gaps between legal subjects. The doctor or hospital must explain as easily as possible to the patient or the patient's family, leading and a complete understanding. Unclear from the patient or the patient's family, on the explanation of the hospital doctor. That informed consent is the legal basis for the rights and obligations of each.

Contents

[a] Politeknik Kesehatan YBA Bandung, Indonesia
[b] Politeknik Kesehatan YBA Bandung, Indonesia
[c] Politeknik Kesehatan YBA Bandung, Indonesia
[d] Politeknik Kesehatan YBA Bandung, Indonesia
[e] Politeknik Kesehatan YBA Bandung, Indonesia
[f] Politeknik Kesehatan YBA Bandung, Indonesia
[g] Politeknik Kesehatan YBA Bandung, Indonesia
[h] Politeknik Kesehatan YBA Bandung, Indonesia

1 Introduction

In simple terms, a legal subject or reaches subject is anyone who has the capacity as a supporter of rights and obligations so that he is declared authorized or reaches bevoegheid. In contemporary developments, there are several categories of legal subjects, namely humans as original legal subjects or naturlijke persons, legal entities as artificial legal subjects or rechts persons, and fetuses in the womb if their interests so desire. The Indonesian Civil Code (KUH-Perdata) stipulates this in Article 2 which states, "A child in the womb of a woman is considered to have been born if the interests of the child so desire it on condition that when it is born it is alive. If the child dies during birth, it is considered there never was". Thus the child in the womb if born alive is categorized as a legal subject or a supporter of rights and obligations.

A standard agreement or standard contract is generally understood as an agreement where all the requirements needed have been standardized by one legal subject so that other legal subjects lack an adequate bargaining position. However, it needs to be understood that until now there are still differences of opinion between experts between standard agreements and standard clauses. Standard agreements always contain several clauses of agreement material that have been prepared unilaterally by one of the legal subjects, where there are only two choices, namely to be accepted or rejected by other legal subjects. While the standard clause is an understanding that focuses on certain things that involve certain conditions and conditions that cannot be changed. The debate between the standard agreement and the standard clause was finally ended with the issuance of the Indonesian Supreme Court Decision No. 267/K/Pdt.Sus/2012 which confirms that there is no difference between a standard agreement and a standard clause as long as the contents of the agreement include clauses on prohibited items as contained in Article 18 of the Law of the Republic of Indonesia No. 267/K/Pdt.Sus/2012. 8 of 1999 concerning Consumer Protection, which stipulates that business actors are prohibited from formulating standard clauses containing several things such as the transfer of responsibility for business actors; refusal to return goods/money already paid; require consumers to comply with new rules, changes and continuations determined unilaterally by business actors; formulate the power of attorney for business actors to take unilateral action against consumer installment goods; reduce the benefits/wealth of consumers and regulate consumer evidence for the loss of the use of goods or the use of services purchased by consumers (Humayun et al., 2003; Arbabshirani et al., 2017).

Informed Consent or in Indonesian can be interpreted as a statement or approval of medical action, generally made in the form of a standard or standard that has been prepared by the legal subject of a doctor or hospital. Informed consent essentially contains the consent of the patient or the patient's family to take medical activities related to the illness. The medical action in question has a purpose, nature, and risk which will be explained by the doctor so that the patient or the patient's family should fully understand (Stevens et al., 2010; Speight et al., 2015). Statements or consent from the patient or the patient's family must be made with full awareness and without coercion from any party.

The brief picture that we can catch from the description above is that informed consent is substantially a standard agreement that always requires full awareness of the legal subjects involved to truly have adequate competence (Okura et al., 2004). Considering the human character as the original legal subject has a plurality of understanding, then the issue of the competence of legal subjects in making approvals in the medical field as informed consent should be considered seriously with full wisdom.

Literature review

Legal subject

Conceptually, Mochtar Kusumaatmadja and B. Arief Sidharta stated that the legal subject) is the holder or bearer of rights and obligations. In a legal relationship, the rights of one party are the obligations of the other party. In positive law, supporters of the rights and obligations to carry out certain legal actions are called legal subjects. Legal subjects in the modern legal order consist of two types, namely humans as original legal subjects and legal entities as artificial or artificial legal subjects. Right is the freedom to do or not do something related to certain legal subjects without hindrance or interference because it has a foundation and is protected by law. Meanwhile, obligations are obligations stipulated by law to do or not to perform certain actions, which if not fulfilled will lead to certain legal consequences (Paterick et al., 2008; Joffe et al., 2001).

Meanwhile, Achmad Ali introduced that the elements that must exist in every legal subject are rights and obligations. Rights always reflect the existence of obligations, and conversely, obligations always reflect the existence of rights. Further added by CST. Kansil, that the enactment of humans as legal subjects, begins at birth and ends at death. A person in the womb can be considered a legal subject if his interests require it, provided that he is alive at birth. Meanwhile, legal entities as legal subjects and their existence are very dependent on the willingness of their management.

Indonesian law very clearly recognizes that every human being is a legal subject as stated in the Indonesian Civil Code (KUH Perdata Indonesia). Article 1 paragraph (1) of the Civil Code states that enjoying citizenship rights does not depend on state rights. This implies that the position as a citizen is not at all related to certain conditions set by the state. Recognition of humans as legal subjects has started since humans are in the womb until they die. While Article (2) of the Civil Code states that a child in the womb of a woman is considered to have been born if the interests of the child so desire. Similarly, Article 3 of the Civil Code states that there are no penalties resulting in civil death, or the loss of all citizenship rights. Humans as legal subjects mean that every human being has rights and obligations. Humans as legal subjects which means they can support rights and obligations are referred to as humans who have authority. However, having authority is not synonymous with having the authority to act to carry out rights and obligations (Miller et al., 2007).

The authority of a legal subject to act to defend the rights and obligations requires the subject concerned to have the ability to act. This is regulated in Article 1320 of the Indonesian Civil Code which states that for a valid agreement to be valid, among other things, it must meet the requirements for the ability to make an engagement. In full, Article 1320 of the Civil Code states: "a valid condition for an agreement is that they agree that those who bind themselves are capable of agreeing, regarding a certain matter and a lawful cause". Meanwhile, the skills of a child are subject to the following arrangements: (a) Article 330 of the Civil Code, a child is only capable of agreeing if he is at least 21 years old or has previously been married; Article 29 of the Civil Code, to be able to enter into a marriage for a man must be at least 18 years old and for a woman, a minimum of 15 years; Article 7 of the Law of the Republic of Indonesia Number 1 of 1974 concerning Marriage (Law No. 1 of 1974), a new man may marry when it is 19 years old and for women, it is 16 years old.

Standard agreement

According to Subakti (2018), explaining that in the agreement certain conditions must be met by business actors, without involving the patient as a consumer in making a contract, so that consumers may not have other choices, which are under the supervision of officers. Although until now no comprehensive research has been conducted, it is suspected that most of the agreements in the business world are in the form of standard agreements or standard agreements. A standard agreement can also be said as an agreement whose contents have been formulated by a party in the forms of forms. What is meant by standard clauses are the articles contained in standard agreements. For consumers, there is only the choice of agreeing or disagreeing with the contents of the agreement. From this, it can be assumed that the consumer is in a very weak bargaining position. Consumers become vulnerable to contractual abuse concerning producers.

Concerning the standard clauses contained in the standard agreement, for example, it can be seen in the financial services sector. In the agreement, there is a clause in the form of unilateral terms which states: "Banks are allowed to change the interest rate on loans received by the debtor at any time without prior

notification or approval from the debtor. Such conditions seem to have reached an agreement that the debtor agrees to all unilateral decisions taken by the bank. Article 18 Paragraph 1 of the Law of the Republic of Indonesia Number 8 of 1999 concerning Consumer Protection, basically prohibits the inclusion of standard clauses in an agreement. The imposition of this prohibition is intended to protect the position of consumers so that they are equal to business actors based on the principle of freedom of contract. For this reason, it is necessary to pay attention to several opinions regarding the position of standard agreements as follows: (a) Sluijter: "standard agreements are no longer agreements. Business actors have acted as private legislators (Legio particuliere whatever)"; (b) Pitlo: "the standard agreement violates the law, but is required by the community in practice"; (c) Hondius: "tolerable because it is a habit in trade; (d) Stein: "the existence of an agreement due to fiction which is supported by the will and trust, where acceptance means that the consumer has agreed".

There are so many opinions circulating regarding the existence of standard agreements, but the important thing that always demands attention is the arrangement of agreements contained in the Civil Code, especially Article 1320 and Article 1338 paragraph (1) of Civil Code. Article 1320 of the Civil Code has regulated the conditions for the validity of an agreement, namely: (a) There is an agreement; (b) Existence of skills; (c) There are certain objects, and (d) There is a halal clause. Meanwhile, Article 1338 paragraph (1) of the Civil Code provides the basis for freedom of contract, namely: (a) Freedom to make any type of agreement; (b) Freedom to regulate its contents; (c) Freedom to adjust its shape. These freedoms may be exercised on the condition that they do not conflict with the law, morality, and public order. The question that arises in practice is whether the standard agreement has complied with the provisions of Article 1320 and 1338 paragraph (1) of the Civil Code. In this regard, the following opinions arise: The standard agreement does not meet the provisions of Article 1320 and Article 1338 paragraph (1) of the Civil Code; (b) The standard agreement complies with the provisions of Article 1320 and Article 1338 paragraph (1) of the Civil Code.

The final note related to the discussion regarding standard agreements is those standard agreements are made by one party so that the other party does not have the opportunity to express there will freely. In the standard agreement, there is no bargaining over the contents of the agreement as required by the principle of freedom of contract. Such conditions have given birth to the adage, "take it or leave it contract", which implies, "if you agree, please take it, and if not leave it".

Informed consent

Whereas Informed Consent consists of two words, namely "informed" which means data, and information, and "consent" which means giving permission and approval. So thus, that Informed Consent is an agreement that is given after getting information. So it can be concluded that Informed Consent is a patient statement authorized by law, which contains an agreement on a medical action plan carried out by a doctor, after receiving sufficient information and data to be used as approval or refusal to be returned.

Some parties translate the Informed Consent into Indonesian as approval for medical action. So in general, informed consent can be interpreted as an agreement given by a patient to a doctor for a medical action to be taken, after getting clear information. With informed consent, the patient will understand all the benefits, risks, and levels of success that will be given by the doctor (Haines et al., 2006; Wang & Luo, 2005).

This needs to be emphasized to prevent patient misunderstandings so that the perception of a medical action as malpractice does not arise if the results are not as expected. Informed consent is generally in the form of a written form containing: (a) the Identity of the patient and doctor; (b) The name of the disease or information regarding the patient's diagnosis or medical condition; (c) The type of examination or treatment procedure recommended or to be performed by the doctor; (d) The risks and benefits of the medical action to be taken; (e) The risks and benefits of alternative courses of action, including not opting for the procedure; (f) Expected cure or success rate; and (g) Estimated cost of medical treatment and treatment (tentative). After the patient or the patient's family reads and agrees to the informed consent material, the patient is asked to sign the consent. If the patient refuses, the doctor or nurse can ask the patient to sign a letter of refusal to take medical action and understand the consequences of his choice.

Approval of medical action is regulated in Article 45 Law of the Republic of Indonesia No. 29 of 2004 concerning Medical Practice. It is stated that every medical or dental procedure that the doctor or dentist will do for the patient must get approval. Approval is given after the patient has received a complete explanation,

at least including diagnosis and procedures for medical action, the purpose of the medical action taken, alternative actions and risks, risks and complications that may occur, and prognosis of the action taken. The consent can be given either in writing or orally. It states that any medical or dental procedure that contains a high risk must be given with written consent signed by the person entitled to give the consent. Regulation of the Minister of Health of the Republic of Indonesia No. 290/Menkes/Per/III/2008 concerning Approval of Medical Action states as follows:

Article 1: (a) Approval for medical treatment is the approval given by the patient or next of kin after receiving a complete explanation regarding the medical or dental action to be performed on the patient; (b) The closest family is husband or wife, biological father or mother, biological children, siblings or guardians; (c) Medical or dental action, hereinafter referred to as medical action, is a medical action in the form of preventive, diagnostic, therapeutic or rehabilitative treatment performed by a doctor or dentist on a patient; (d) Invasive action is a medical action that can directly affect the integrity of the patient's body tissues; (e) Medical action that contains a high risk is a medical procedure which, based on a certain level of probability, can result in death or disability; (f) Doctors and dentists are doctors, specialists, dentists and specialist dentists graduates from medical or dental education both at home and abroad who are recognized by the government of the Republic of Indonesia in accordance with the laws and regulations; (g) Competent patients are adult patients or non-children according to statutory regulations or have/have been married, are not disturbed by their physical awareness, are able to communicate properly, do not experience mental retardation and do not experience mental illness so that they are able to make decisions freely (Nataliia et al., 2021).

Article 2: (a) All medical actions to be carried out on patients must obtain approval; (b) The approval as referred to in paragraph (1) may be given in writing or orally; (c) The approval as referred to in paragraph (1) is given after the patient has received the necessary explanation regarding the need for medical action to be carried out. Article 3: (a) Every medical procedure that contains a high risk must obtain a written agreement signed by the person entitled to give the consent; (b) Medical actions that are not included in the provisions as referred to in paragraph (1) may be given with oral consent; (c) The written approval as referred to in paragraph (1) is made in the form of a statement contained in a special form made for that purpose; (d) The approval as referred to in paragraph (2) can be given in the form of an affirmative statement or a nodding head gesture which can be interpreted as an expression of agreement; (e) If the verbal consent given as referred to in paragraph (2) is deemed dubious, a written approval may be requested.

In the event of a violation of the Informed Consent, it has been regulated in the Regulation of the Minister of Health of the Republic of Indonesia Number 290 of 2008 concerning Approval of Medical Actions (Permenkes RI No. 290 of 2008 concerning Approval of Medical Actions) Article 19, it is stated that doctors who perform medical actions without informed consent may be subject to sanctions in the form of verbal warnings, written warning up to the revocation of the Practice License.

2 Materials and Methods

The study was conducted through a normative juridical approach by using secondary data in the form of primary legal materials, secondary legal materials, and tertiary legal materials (Bungin, 2017). The discussion will link the available legal materials and the phenomena encountered.

The nature of this study is analytical descriptive, which means that the research results will only provide an overview of the analysis of legislation, legal concepts, and medical concepts in informed consent. Secondary data in the form of legal materials that will be used in this research study are (a) Primary Legal Materials: Law of the Republic of Indonesia Number 29 of 2004 concerning Medical Practice and Regulation of the Minister of Health of the Republic of Indonesia Number 290 of 2008 concerning Approval of Medical Actions, Law No. Law of the Republic of Indonesia Number 8 of 1999 concerning Consumer Protection, and the Civil Code of the Republic of Indonesia; (b) Secondary Legal Materials: Consists of various pieces of literature related to health law, medical law, hospital law, and civil law; (c) Tertiary Legal Materials: Consists of references in the form of dictionaries, encyclopedias, newspapers, scientific journals, and relevant and urgent instructions with the main discussion.

3 Results and Discussions

It can be said that almost everyone had fallen ill and needed action medical. Procedurally before a medical procedure is performed, the doctor will explain in advance the steps, benefits, and risks of the action to be taken. After getting an explanation and understanding it, the patient can decide to agree or refuse to take the action. Informed consent is the delivery of information from a doctor or nurse to a patient before a medical action done.

Informed consent should be given before medical action is carried out. Several medical procedures that generally require informed consent from the patient are: (a) Administration of anesthetic or anesthetic, (b) Blood transfusion and blood donation, (c) Radiation therapy or radiotherapy and chemotherapy, (d) Suturing of wounds, (e) Immunization, Psychiatric medical examination, (f) Certain supporting examinations, eg biopsy, bone marrow aspiration, lumbar puncture and HIV or VCI testing, (g) Organ donation and acceptance procedures. However, under certain conditions, informed consent can be given after medical action is carried out.

This needs to be done, for example in emergency or emergency cases, because delays in patient handling can cause disability or even death. Informed consent is generally given to legally mature patients, who can understand the doctor's explanations well, are fully aware, and have a healthy mental condition. If deemed unable to decide on informed consent, the patient can be represented by a family member. Several conditions of informed consent that can be represented include: (a) Minor patients: for young patients, such as infants and children, or adolescents under the age of 18 years, the consent/informed consent can be represented by parents or guardians; (b) Conditions that are not. possible: For patients with conditions of loss of consciousness, such as fainting or coma, so that it is not possible to be given an explanation or asked for their opinion, the informed consent agreement can be represented by the family or guardian. Informed Consent can also be represented in patients with thinking disorders, such as Alzheimer's disease or mental disorders.

The results of data collection at a hospital consisting of 302 respondents related to an explanation of medical procedures were obtained as follows: Age 17-25 years: very clear 7 respondents, quite clear 5 respondents, less clear 1 respondent, not clear 0 respondents. Age 26-35 years: very clear 21 respondents, quite clear 15 respondents, less clear 2 respondents, not clear 0 respondents. Age 36-45 years: very clear 35 respondents, quite clear 29 respondents, less clear 7 respondents, not clear 0 respondents. Age 46-55 years: very clear 29 respondents, quite clear 31 respondents, less clear 9 respondents, not clear 0 respondents. Age 56-65 years very clear 34 respondents, quite clear 27 respondents, less clear 18 respondents, not clear 0 respondents. Age 65 years: very clear 7 and above, quite clear 15 respondents, less clear 8 respondents, not clear 0 respondents. An understanding of the explanation of the disadvantages of medical treatment stated as follows: very clear 121 respondents (40.1%), 131 respondents said quite clear (43.4.3%) said quite clear, said less clear 50 respondents (16.5%), while 0 respondents (0.0%).

An understanding of the explanation of the benefits of medical procedures are stated as follows: very clear 0 respondents, quite clear 1 respondent, less clear 1 respondent, not clear 0 respondents. Age 17-25 years, very clear 7 respondents, quite clear 4 respondents, less clear 2 respondents, not clear 0 respondents. Age 26-35 years very clear respondents, quite clear 21 respondents, less clear 2 respondents, not clear 0 respondents. Age 36-45 years very clear 27 respondents, quite clear 32 respondents, less clear 12 respondents, not clear 0 respondents. Age 46-55 years very clear 32 respondents, quite clear 28 respondents, less clear 9 respondents, not clear 0 respondents. Age 56-65 years very clear 30 respondents, quite clear 33 respondents, less clear 16 respondents, not clear 0 respondents. Ages 65 years and over are very clear 10 respondents, quite clear 12 respondents, less clear 8 respondents, not clear 0 respondents.

4 Conclusion

1) Informed Consent is a statement or agreement in the form of a standard agreement between a doctor/hospital legal subject and a patient's legal subject for medical action. Before the informed consent is carried out, the legal subject of the doctor/hospital is obliged to explain to the patient/patient's family as clearly as possible, especially related with the advantages, disadvantages, risks, and hope of recovery related to the patient's condition.

2) The reality of practice in the field by taking several respondents at a hospital shows that there are still legal subjects of patients who state "less clear" on the information of legal subjects of doctors/hospitals. For this fact, it is not appropriate to blame each other, but it is necessary to make joint corrections to all the subjects involved, especially concerning the method of conveying information from subject to subject.
3) Informed consent if carried out procedurally, will be able to protect all rights and obligations of the legal subjects involved. For this reason, the competence of legal subjects must be able to understand the entire series of events needed so that the signing of informed consent can be carried out properly. Competent parties mean that the legal subjects involved will agree to have the skills to act as determined by legislation

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Biography of Author

Argo Sudarga Yohanes
Head of Medical Record and Health Information Study Program; Lecturer of Health Law and Anti-Corruption Education Course at Health Polytechnic Foundation for Administrative Development, Bandung, Indonesia
Email: yohanesargo@poltekkesyba.ac.id