Juridical Analysis Of Approval Of Medical Acts

Bagus Indra¹, Rudi Hafiz²

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ABSTRACT

Approval of Medical Action (informed consent) in health services is a matter that must be done by doctors to patients in terms of legal aspects. For this reason, it is necessary to pay attention to the implementation of the approval of the medical act. So to note also the obstacles and solutions overcome in the implementation of health services to patients, so that there is legal protection for both doctors and patients.

INTRODUCTION

The success rate of health service quality can be seen from three subjects, namely 1) users, 2) organizers and 3) health service funders. For health care users, the quality of Service is more related to the dimensions of responsiveness of officers to meet the needs of patients, the smooth communication of officers with patients. For health service providers, the quality of Health Services is more related to the dimension of the suitability of services held with the development of Science and technology and/or professional autonomy in the implementation of Health Services. As for health care funders, it is more related to the dimensions of efficient use of funding sources, fairness of health financing, and/or the ability of health services to reduce losses of health care funders. 
Along with the development of health services and medical services, the role of law in health services and medical services is increasing. According to Article 52 of Law No. 36 of 2009 on Health, which states that health services consist of individual health services and public health services. The health service according to this law includes activities with promotive, preventive, curative, and rehabilitative approaches. 
Health services are divided into two kinds, namely 1) Public Health Services (Public Health Service) and 2) Medical Health Services (Medical Service), for medical services can be held alone with the main purpose is to treat (curative) disease and restore (rehabilitative) health and the main target is the individual. While public health services are generally held together in an organization, it must even include the potential of the community and prevent disease and the main target is the community as a whole. In addition to health services, there are also medical services where these services include all efforts and activities in the form of prevention (preventive), treatment (curative), improvement (promotive), and recovery (rehabilitative) of health based on individual relationships between experts in the field of medicine with individuals who need it.

Based on rights, each patient has the right to know how the treatment procedure will be experienced, including the risks that must be borne as a result of certain treatment methods. In addition, the patient also has the right to know whether there are other alternatives, including the risks. There are also those who argue that the patient has the right to know things that are outside the scope of health, but which are related, for example, social factors. That is what is commonly called "informed consent", which is consent given after getting more information.
Informed consent is an agreement regarding the conduct of medical actions by a doctor to his patient. This agreement can be in oral or written form. In essence, informed consent is a communication process between the doctor and the patient regarding the agreement of medical actions that will be carried out by the doctor to the patient. The signing of the informed consent form in writing is only a confirmation of what has been agreed before. The purpose of a complete explanation is for the patient to determine his own decision in accordance with his own choice (informed decision). Therefore, the patient also has the right to refuse the recommended medical measures. The patient also has the right to seek the opinion of another doctor (second opinion), and the doctor who treats him. The obligation to provide explanations or information to the patient is the person responsible for the care of the patient, for example a doctor. In certain circumstances the doctor may delegate his authority to other health workers, but legal responsibility remains with him. Legally, a nurse is not actually authorized to carry out the "informed consent" process. This is the duty of the doctor, and if there is delegation of authority, then the doctor must be sure that the nurse who was given the task really mastered the problem and was able to give an explanation that was understood by the patient. Therefore, from a legal point of view, the responsibility for "informed consent" remains with the doctor.

METHOD

Legal research requires accurate data obtained through legal approach procedures and field approaches in order to produce research that can be justified. In achieving the purpose of the research mentioned above, it is necessary to use several research methods first, the approach method, the empirical juridical approach method is used and supported by normative juridical research. The approach in this way is carried out considering that in this study starting from the normative aspects governing banking institutions. Second, the types and sources of data used include primary and secondary data. Primary data is data received directly from the public, while secondary data is data obtained from library materials.

RESULTS AND DISCUSSION

Implementation of informed consent in health services

According to R. Subekti, a covenant is an event where one person promises to someone else or where two people promise each other to carry out a covenant.
sufficient to give birth to an agreement on the principal matters concerning the agreement and the agreement is binding at the time of consensus.

d) the principle of personality, that the scope of validity of the agreement is only on the parties who make the agreement only. Parties outside the agreement cannot claim any rights under the agreement.

A therapeutic agreement is an agreement between a doctor and a patient that authorizes the doctor to carry out activities to provide health services to patients based on the expertise and skills possessed by the doctor. In the Preamble of the Indonesian Code of Medical Ethics attached to the decree of the minister of Health No. 434 /Men.Kes / X / 1983 on the enactment of the Indonesian Code of Medical Ethics for doctors in Indonesia, lists therapeutic transactions as follows: "therapeutic transactions are relationships between doctors and patients and patients carried out in an atmosphere of mutual trust (confidential), and always overwhelmed by all emotions, expectations and concerns of human beings".

Legal relationship in therapeutic transactions arise the rights and obligations of each party, both for the patient and the doctor. An agreement is said to be valid if it meets the requirements as stipulated in Article 1321 of the Civil Code which explains: "no agreement is valid if the agreement is given because of an error or obtained by force or fraud". In accordance with the aforementioned article, it can be concluded that judicially the validity of an agreement is determined by the agreement of the parties that bind themselves, without any oversight, coercion or fraud. This agreement is an agreement made by both parties in which both parties have a willing rapprochement in the therapeutic transaction as the patient agrees to be treated by a doctor, and the doctor also agrees to treat his patient. In order for this agreement to be valid according to the law, then in this agreement the parties must be aware (no error) of the agreement made, there should be no coercion from either party, and there should be no fraud in it. For this reason, it is necessary to have Informed Consent or also known as "approval of medical measures".

The requirements for the ability to make an engagement / agreement are regulated in articles 1329 and 1330 of the Civil Code as follows:

Article 1329: every man is able to make alliances, if he is not declared incompetent by law.

Article 1330: not being able to make a deal is:
1. Immature people;
2. Those placed in custody;
3. Those women, in matters stipulated by law and in general all persons to whom the law has prohibited making certain treaties. Based on the sound of Article 1329 of the Civil Code above, then judicially what is meant by the ability to make an engagement is the authority of a person to bind themselves, because it is not prohibited by law. In therapeutic transactions, the recipients of medical services can include various age groups, and various types of patients, consisting of those who are capable of acting and those who are not capable of acting. This must be realized by the doctor as one of the parties who bind themselves in therapeutic transactions, so as not to cause problems in the future.

Recipients of medical services who are not able to act (may not make an agreement, or an agreement made can be considered invalid), among others:
1. Adults who are incapable of acting (eg: lunatics, drunkards, or not aware), then required the consent of the forgiver (who may make an engagement with the doctor is the forgiver).
2. Minors, consent from their guardians or parents is required.

Maturity according to the Minister of Health Regulation Number 585/Men.Kes/Per / IX / 1989 Article 8 on approval of medical measures paragraph (2) is 21 years old or married. So for a person under the age of 21 years and not married, then the therapeutic transaction must be signed by his parents or guardians who are the parties entitled to give consent. According to Article 1320 of the Civil Code, the object of the agreement consists of "a certain thing" and must be "a cause that is lawful or permissible to be agreed upon". In therapeutic transactions, certain things that are agreed upon or as the object of the agreement are efforts to cure diseases that are not prohibited by law.

The law of engagement is known for 2 kinds of agreements, namely:
1. Inspanningverbintenis, namely effort agreement, meaning that both parties promise or agree to make maximum efforts to realize what was promised.
2. A covenant is a covenant or a promise.

Therapeutic agreements or therapeutic transactions are included in inspanningverbintenis or effort agreements, because doctors are unlikely to promise healing to patients, what doctors do is perform health services as an effort to cure patients. In making this effort, doctors must do with full seriousness by exerting all the abilities and skills they have by referring to professional standards. Meanwhile, the patient as the other party who receives medical services must also make maximum
efforts to realize his recovery as promised. Without the help of the patient, then the efforts of the doctor will not achieve the expected result. Uncooperative patients are a form of contributory negligence that cannot be accounted for by doctors. If the therapeutic transaction has fulfilled the terms of the validity of the agreement, then all obligations arising are binding for the parties, both the doctor and the patient.

The specificity of the therapeutic agreement when compared with the agreement in general is as follows:
1. The subjects of the therapeutic transaction consist of the doctor and the patient. Doctors act as professional medical service providers whose services are based on the principle of providing assistance. While patients as recipients of medical services who need help. The doctor has certain qualifications and authority as a professional in the medical field who is competent to provide the help needed by the patient, while the patient because he does not have the qualifications and authority as owned by the doctor is obliged to pay an honorarium to the doctor for the help that has been given by the doctor.
2. The object of the agreement is in the form of professional medical measures characterized by the provision of assistance.
3. The purpose of the agreement is the maintenance and improvement of family-oriented health, including health-improving activities (rehabilitative), disease prevention (preventive), disease healing (curative), and health recovery (promotive), to realize the optimal degree of Health.

The nature or characteristics of therapeutic transactions as mentioned in the Preamble of the Indonesian Code of medical ethics are:
1. Special therapeutic transactions regulate the relationship between the doctor and the patient.
2. The relationship in this therapeutic transaction should be carried out in an atmosphere of mutual trust (confidential) which means that the patient must trust the doctor who conducts the therapy, and vice versa the doctor must also trust the patient. Therefore, in order to maintain this mutual trust, the doctor must also make maximum efforts for the healing of patients who have entrusted their health to him, and the patient must provide clear information about his illness to the doctor who is trying to do therapy on him and obey the doctor’s orders that need to achieve the expected healing.
3. This hope is also expressed as "always overwhelmed by all the emotions, hopes and worries of human beings". Considering the condition of patients who are sick, especially patients with chronic diseases or severe disease, the patient's emotional condition, concern for the possibility of recovery or not the disease accompanied by the hope of wanting to live longer, raises a special relationship that distinguishes this therapeutic transaction different from other transactions in general.

Because the therapeutic transaction is a legal relationship between doctors and patients, then the therapeutic transaction also applies some underlying legal principles, which according to Veronica Komalawati concluded as follows:
- a. Principles Of Legality
- b. Principles Of Balance
- c. Principle On Time
- d. Principles Of Good Faith
- e. Principles Of Honesty
- f. Precautionary principles
- g. Principles of openness

Effective and successful medical services can only be achieved if there is openness and good cooperation between doctors and patients based on mutual trust. This attitude can grow if there is open communication between doctors and patients where patients obtain explanations or information from doctors in transparent communication.

Literally Consent means consent, or more "sharply "again,"permission". So Informed consent is the consent or permission by the patient or family who has the right to the doctor to perform medical actions on the patient, such as physical examination and other examinations to make a diagnosis, give medication, do injections, help with childbirth, do anesthesia, perform surgery, follow-up in case of difficulty, etc. Furthermore, the word Informed is related to information or explanation. It can be concluded that Informed Consent is the consent or permission by the patient (or family entitled) to the doctor to perform medical actions on him, after he by the doctor concerned is given complete information or explanation about the action. Getting a full explanation is one of the patient's rights recognized by law so in other words Informed consent is consent after explanation (PSP).

Meanwhile, according to the Minister of Health Regulation No. 585/Men.Kes/Per / IX / 1989 on medical approval, approval of medical action is the consent given by the patient or his family on the basis of an explanation of the medical action to be performed on the patient. According To The Minister Of Health Regulation No. 290/Menkes/Per/III / 2008 on approval of medical treatment, approval of medical treatment is the approval given by the patient or next of kin after receiving a complete
explanation of the medical or dental treatment to be performed on the patient.

There are 2 forms of approval of medical measures, namely:

a. Implied Consent (considered given)
Generally, implied consent is given under normal circumstances, meaning that the doctor can capture the approval of the medical action from the gesture given/done by the patient. Similarly, in the case of emergency, while the doctor requires immediate action while the patient is unable to give consent and his family is not in place, the doctor can perform the best medical action according to the doctor.

b. Expressed Consent
Can be expressed orally or in writing. In medical actions that are invasive and contain risks, doctors should get approval in writing, or commonly known in hospitals as operating licenses.

The function of Informed Consent is:
- Promotion of the right to individual autonomy;
- Protection of patients and subjects;
- Prevent fraud or coercion;
- Cause stimulation to the medical profession to hold introspection against yourself;
- Promotion of rational decisions;
- Community involvement (in advancing the principle of autonomy as a social value and conducting supervision in biomedical research).

Informed Consent itself according to the type of action / purpose is divided into three, namely:

a. Which aims to research (patients are asked to be the subject of research).
b. It's about finding a diagnosis.
c. Aimed at therapy.

The purpose of Informed Consent according to J. Guwandi is:

a. Protect the patient against all medical procedures performed without the knowledge of the patient;
b. Provide legal protection against unexpected and negative consequences, for example against the risk of treatment that cannot be avoided even though the doctor has tried as much as possible and acted very carefully and carefully.

In an emergency situation Informed consent remains the most important thing even though the priority is recognized as the lowest. The top priority is to save lives. Although it is still important, Informed consent should not be a barrier or obstacle to the implementation of emergency care because in a critical situation where the doctor is racing to death, he does not have enough time to explain until the patient is fully aware of his condition and needs and gives his decision. Doctors also do not have much time to wait for the arrival of the patient's family. Even if the patient's family has been present and then does not approve of the doctor's actions, then based on the doctrine of necessity, the doctor must still take medical measures. This is spelled out in regulation of the Minister of Health number 585/Men.kes/Per / IX / 1989 on approval of medical measures, that in an emergency is not required Informed consent. In accordance with the regulation of the Minister of Health No. 290/Menkes/Per/III/2008 on approval of medical measures, that in an emergency, to save the life of the patient and/or prevent disability is not required approval of medical measures.

The absence of informed consent can lead to malpractice actions of doctors, especially when there is harm or intervention to the patient's body. Common law in many countries states that the result of the absence of informed consent is equivalent to negligence. However, in some cases, the absence of informed consent is equivalent to intentional acts, so the degree of guilt of the doctor who committed the act is higher.

The malpractice actions of doctors that are considered equivalent to intentional are as follows:

a. The patient had previously expressed disapproval of the doctor's actions, but the doctor continued to take these actions.
b. If the doctor deliberately misleads about the risks and consequences of the medical measures he takes.
c. If the doctor deliberately conceals the risks and consequences of the medical measures he takes.
d. Informed consent is given to medical procedures that differ substantially from those performed by physicians.

CONCLUSION
Implementation of informed consent in health services. The approval of medical measures is regulated in various laws and regulations, namely law No. 36 of 2009 on health, law No. 44 of 2009 on hospitals, law No. 29 of 2004 on the practice of Medicine, the Civil Code (Civil Code), Permenkes No. 290/Menkes/per / III / 2008 on approval of medical measures. Any action that will be taken in the implementation of Medical Action approval is based on existing laws and regulations, based on the standard medical action approval form.

Implementation of informed consent in health services. The necessity of Informed Consent in writing signed by the patient before the medical action, because it is closely related to the documentation into the medical record (Medical Record). This is because the hospital where the
medical action is carried out, in addition to meeting the standards of hospital services must also meet the standards of medical services in accordance with those specified in the decree of the Minister of Health No. 436/MENKES/SK/VI / 1993 on the enactment of service standards in hospitals. Thus, the hospital is also responsible if the requirements of Informed Consent are not met. If the medical action is done without Informed Consent, then the doctor concerned may be subject to administrative sanctions in the form of revocation of a license to practice, meaning, the necessity of Informed Consent in writing is intended for the completeness of the administration of the hospital concerned. Thus, the signing of Informed Consent in writing by the patient is actually intended as an affirmation or confirmation of the consent that has been given after the doctor provides an explanation of the medical action he will do. Therefore, with the signing of Informed Consent in writing, it can be interpreted that the signer is responsible for handing over part of the patient's responsibility for himself to the doctor concerned, along with the risks he may face.

Obstacles and solutions to overcome them in the implementation of informed consent in health services. Obstacles encountered in the implementation of medical action approval is that the medical action approval form is not signed by the patient himself when the patient is conscious. In addition, the information obtained by the patient from the nurse, also in the form of approval of medical measures there are doctors who do not sign.

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