

Informed Consent on Medical Action in the Beauty Sector Based on Legal Review

Franky Sumarlie

Magister of Law, Hang Tuah University, Indonesia

Corresponding Author: Franky Sumarlie

Email: frankysumarliedr@gmail.com



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Abstract

The development of medical action not only in clinics, but also in beauty clinics, requires a standard regarding informed consent. This study used 2 problem formulations, namely: 1. The essence of Informed Consent, 2. Informed Consent in Aesthetic Beauty Actions. This study used a Statue Approach, and a Conceptual Approach. The result of this study was that Informed Consent should be a process from the doctor explaining the action until the patient accepts/rejects the action, either in oral or written form. In practice, medical action for beauty at Aesthetic Beauty Clinic was carried out in accordance with professional standard and standard operating procedures. The relationship that arises between the doctor and the patient is called a therapeutic agreement. In this agreement, an approval for a medical action that is given by the patient appears as a form of approval for aesthetic beauty medicine action which is initiated by an offer of the doctor.

Introduction

Hippocrates said that the relationship between the patient and the doctor as a therapeutic transaction. This therapeutic transaction begins when the patient comes to the hospital to ask for help with his complaints. Then there is a contract or agreement between the doctor and the patient which is called a Contract or Engagement or a therapeutic transaction. This agreement give raise to a Business Engagement (inspannings verbintenis) because it is based on a business obligation, the doctor must do everything in his/her power to cure the patient. The interaction between doctor and patient give raise to a legal relationship in the therapeutic transaction relationship, namely the emergence of rights and obligations on each party. One form of doctor professionalism in the framework of protecting patient rights is the existence of Informed Consent as a patient's right to obtain medical information from the doctor/beauty clinic before receiving certain medical actions that affect the patient (Farnan et al, 2013; Whitney et al, 2004).

Nowadays, with globalization, beauty care has now become a necessity for everyone who wants healthy skin, especially women who want beauty. Until 2016, the growth of the beauty care industry is estimated to have increased by 20%. This is supported by data from the Surabaya City Health Office, as of December 31, 2017, beauty clinics that are registered in the city of Surabaya alone, both Primary and Main Clinics, are 96 clinics. The lifestyle of women at this time demands to pay more attention to appearance, for that skin care is very important for everyone. Moreover, to overcome various complaints that cause skin problems that can reduce beauty, so everyone needs the right products and care.

This proper treatment action is usually done by doctors. Not only limited to hospitals and doctor's practice, but also these beauty actions are carried out in beauty clinics. Beauty clinics

should prioritize quality care that has been clinically tested rather than prioritizing profit but patients do not get maximum results. Doctors and patients both have rights and obligations, namely a reciprocal relationship between the two parties (Giordano, 2007; Morgan, 1982). The relationship between doctor and patient that starts from a paternalistic trust relationship in its development includes the stages of the process in medical services, including medical services in the aesthetic sector. Each party has rights and obligations that must be respected. The right to receive that is owned by someone will intersect with the obligation of other parties to give, and vice versa.

In protecting the interests of patients, every medical action in a beauty clinic should carry out Informed Consent, so that the rights and obligations of both doctors and patients can be fulfilled. Not only running, doctors, patients, and health workers also need to understand related to informed consent.

Methods

This research method used 2 (two) problem approaches, namely: The first approach in this research was the statute approach. The statute approach is a legal research that puts the statute approach as one approach. The statute approach is carried out by examining all laws and regulations that are related to the legal issue being handled. In this writing, the required legislation includes BW, Medical Practice Laws, Health Law and Minister of Health Regulation of the Republic of Indonesia Number 290/MEN.KES/PER/II/2008 concerning Approval of Medical Action. The second approach used was the conceptual approach, which was carried out by looking for existing theories and doctrines to be used as a reference in order to understand views and doctrines in building a legal argument in solving the issue at hand.

Results and Discussion

Informed Consent Essence

Informed consent is the free consent given by patients for a medical action, after they have obtained all important information about the nature and consequences of the action. Informed consent is made based on the principles of autonomy, beneficentia and nonmaleficentia, which are rooted in human dignity where the autonomy and personal integrity of the patient is protected and respected. If the patient is incompetent, consent is given by the family or legal guardian. If the family/guardian is present but not competent, the medical personnel must decide for themselves to take certain medical actions according to the patient's situation. Informed consent is especially required in extraordinary means. However, for critical or emergency patients who need immediate medical action to save them, proxy consent is not required.

The term of informed consent in our Health Law does not exist, what is listed is the approval term, acceptance or refusal of help action after receiving and understanding information about the action. Informed consent or approval of Medical Action based on Article 1 paragraph (1) Permenkes No. 290/Menkes/Per/III/2008 concerning Approval of Medical Action provides the definition of consent to medical action is consent given by a patient or closest family after receiving a complete explanation regarding the medical/dentistry action to be performed on the patient.

The definition of Informed Consent is the consent given by the clients or their family on the basis of information and an explanation of the medical actions that will be taken against the client. Informed consent is a process that shows effective communication between doctors and patients, and the meeting of thoughts about what will and what will not be done to patients

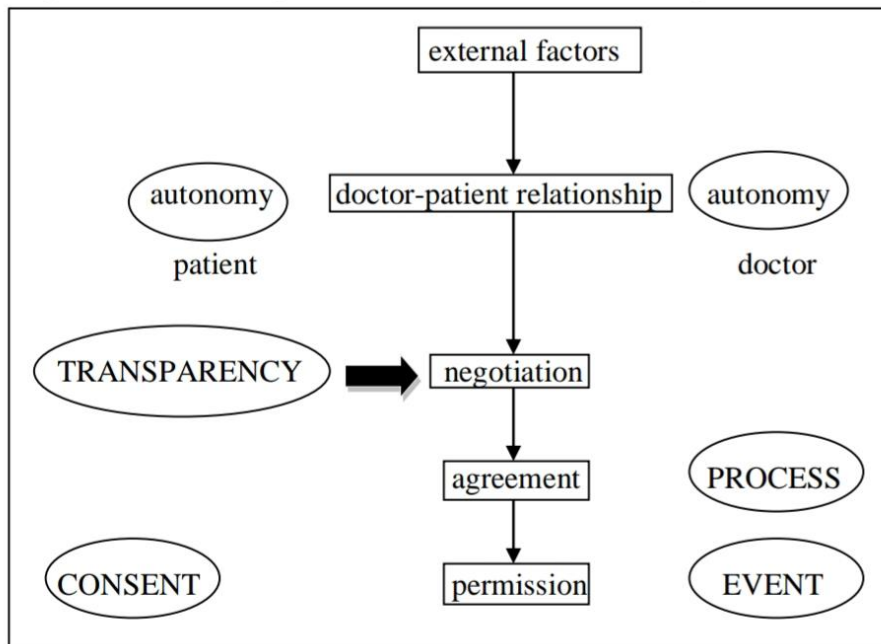


Figure 1. Informed Consent Processⁱ

The word consent comes from Latin, *consentio*, which means permit approval, consent, or a broader meaning is giving permission or authority to someone to do an informed consent, thus meaning a statement of consent or permission by the patient consciously, freely and rationally after obtaining the information that they understand from health workers/doctors about the disease. The word "understood" must be emphasized, because the understanding of information by a health worker or doctor is not necessarily understood by the patient. It must be remembered that what matters most is understanding by the patient. So if it is concluded, the patient or closest family has the right to approve or reject the medical action that will be carried out on the patient after the patient is given an explanation regarding the medical action that the doctor will take to the patient, and what things will happen after the medical action is carried out. Informed Consent is an agreement regarding medical action by doctors for their patient. This consent can be in the form of oral or written. In essence, Informed Consent is a process of communication between doctors and patients regarding the agreement on medical actions that the doctor will take against the patient. The signing of the Informed Consent form in writing is only an affirmation of what has been previously agreed. The purpose of a complete explanation is for the patient to make their own informed decision. Therefore, patients also have the right to refuse recommended medical action. Patients also have the right to ask for the opinion of other doctors (second opinion), and the doctor who treated them.

The explanation that is given by the doctor to the patient or patient's family based on Article 7 paragraph (1) Permenkes Number 290/Men.Kes/Per/II/2008 includes at least: Diagnosis that has been enforced, The nature and extent of the action to be taken, The benefits and urgency of the action, Risks and complications that may occur than the medical action, Consequences if the action is not carried out and are there other alternative treatment methods, and Costs related to the medical action,

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The doctor-patient relationship begins when patients come to the doctor to ask for help with their problems in the health sector, so that with this there is already a contract or agreement

between the doctor and patient which is called a therapeutic transaction. A therapeutic transaction is an agreement between a doctor and a patient, in the form of a legal relationship that creates rights and obligations for both parties. In therapeutic transactions, it is very different from the agreement in general, namely the difference that lies in the object of the agreement, where the result is not the main objective of the agreement, but lies in the efforts made to cure the patient (*inspanning verbintenis*). This is because a patient has characteristics that will differ from other patients, so that no two cases will be the same, because the human immune system factor is not the same. The legal relationship between doctor and patient is known as a Therapeutic Agreement, which occurs in ordinary circumstances the engagement or agreement occurs because of an agreement (Law on Medical Practice, Article 39). Medical practice is held based on an agreement between a doctor or dentist and a patient in an effort to maintain health, prevent disease, improve health, treat disease and restore health; in unusual circumstances (for example: medical emergencies), then an agreement or engagement occurs due to law, (Law on Medical Practice, Article 51 letter d). Perform emergency aid on a humane basis, unless he/she is sure that someone else is on duty and is able to do it.

Basically an agreement as a legal relationship between patient and doctor is a therapeutic transaction, which is a transaction between a doctor and a patient where each fulfills the legal conditions of the agreement. In order to assess the validity of the agreement, Article 1320 BW can be applied in transactions including: There is agreement from those who commit themselves; There is an ability between the parties to make the engagement; A certain thing that is allowed; and For some reason that is allowed. If the legal relationship between the doctor and the patient does not work well, it will create imbalances between the rights and obligations of both, which will result in legal consequences, usually the patients, in this case, feels more aggrieved, so that they can hold the doctor accountable.

The legal relationship between doctors and patients in health services is called a "Therapeutic Transaction", which is based on an agreement, that is, an agreement in which doctors do their best to cure the patient from their pain. This is in accordance with article 1320 BW. In this case what is demanded is not an agreement of results or assurance of a cure or success, but the agreement is in the form of the best possible effort or effort from the doctors in their efforts to heal their patient carefully and thoroughly based on proper science.ⁱⁱ More on the division of this Therapeutic Transaction in medical action:

Resultaatsverbintenis

namely an engagement based on achievement or work results. Doctors can promise the results of their work to patients, for example: a dentist who makes dentures, an orthopedist who makes foot prostheses, a cosmetic surgeon who fixes a sharp nose or other body parts. Even in Europe the operation which is considered easy, for which the result is promised, is included in the *resultaatsverbintenis*, whereas the operation which is complicated and difficult includes the *inspanningsverbintenis*. In this case, in the world of aesthetic beauty, what is included with the Results Agreement is an action that results. For example: Enlargement of body size with the intended size.

Inspanningsverbintenis

attempt/effort/endeavor agreement, namely an engagement based on maximum attempt/effort/endeavor to achieve a result. The patient gives full "trust" to the doctor that the doctor will make every effort, make every endeavor to cure the patient (*fiduciary relationship, trust, vertrouwen*). So doctors do not promise or guarantee that the patient will be cured. If the doctor can promise or guarantee the patient's recovery, then juridically *inspanningsverbintenis* switches to *resultaatsverbintenis*

In contrast to aesthetic services, the therapeutic transaction that occurs can be a result binding. This is because all actions are carried out as a mere aesthetic effort, namely to add to the beauty or shape of the organs of the body, (which results are measurable), not a treatment of organ function and damaged body tissue. In the doctor-patient relationship, the doctor gives a certain achievement, namely doing something in accordance with the agreement reached with the patient. Beauty clinic services even promise results before and after actions that show a change in the problem at hand.

Medical action is an effort to find, overcome health problems, and an effort to maintain, improve the health status of patients. To find the cause of the patient's health problems, doctors need to carry out a series of actions/examinations starting from an interview or what is called anamnesa, physical examination and supporting examinations. Recovery efforts can be done through administration of drugs or surgery. All of these efforts are medical actions, because they relate to medical care.

According to Law Number 29 of 2004 concerning Medical Practice (hereinafter referred to as the Medical Practice Law), there are rights and obligations of doctors. These are Doctor's Obligations based on Law number 29 of 2004 concerning Medical Practice article 50 and 5: Providing medical services in accordance with professional standard and standard operating procedures as well as patient medical needs; Referring the patient to another doctors or dentists who have better skills or abilities, if they are unable to perform an examination or treatment; Keep everything that they know about the patient a secret, even after the patient has died; Perform emergency aid on a humane basis, unless they are sure that someone else is on duty and able to do so; Adding knowledge and following the development of medical science or dentistry;

Doctor's Rights are consist of these: Obtain legal protection as long as they carry out their duties in accordance with professional standard with standard operating procedures, Providing medical services according to professional standard with standard operating procedures, Obtain complete and honest information from patients or their families, Receiving fees for services.

Article 44 states that in carrying out medical practice, every doctor is obliged to follow medical service standards. Therefore, every medical action must be based on Medical Service Standards and Standard Operating Procedures (SOP), one of the Medical Service Standards is to carry out the obligation to provide Informed Consent to patients. This is in accordance with the Minister of Health Regulation.

Informed consent is something that is required based on the Regulation of the Minister of Health of the Republic of Indonesia Number 290/MEN.KES/PER/II/2008 concerning Approval of Medical Action (hereinafter referred to as Permenkes Number 290/Men.Kes/Per/II/2008), which is used as a guideline for doctors to communicate with patients who will follow up. All medical actions to be performed on patients must receive written or oral consent. This has been regulated in Article 2 Permenkes Number 290/Men.Kes/Per/II/2008. Medical action here is not limited to medical action in the hospital, but also in beauty clinics where there are actions taken by doctors.

Informed Consent is essentially a process from the moment of the patient arrives, explains the process to be carried out, and the final result is an agreement from the patient, whether an agreement will be taken or refusal (Cohen, 2019; Kinnersley et al, 2013). Even though it is only regulated in the Permenkes, but Informed Consent is the basis for the relationship between patient and doctor before any medical action is taken(Mashdurohatun et al, 2020; Felt et al, 2009).

There is no difference in medical action in a beauty clinic, the action taken is still a medical action. According to the Minister of Health Regulation Number 290 of 2008 concerning Approval of Medical Actions (hereinafter abbreviated as Permenkes Number 290 of 2008) in Article 1 paragraph (3) states that medical action is a medical action in the form of preventive, diagnostic, therapeutic or rehabilitative action that is carried out by doctors on patients. To understand the legal aspects of medical action, it can be examined from the elements contained in medical action. The elements of medical action from the definition of medical action as meant by Permenkes Number 290 of 2008 are elements of medical action consisting of: Medical action, In the form of preventive, diagnostic, therapeutic or rehabilitative Performed by a doctor and Towards the patient. The elements above are the same as medical action in a beauty clinic, so that for every medical action, Informed Consent should be obtained, this not only protects the patient's rights, but is also the doctor's obligation and prevents doctors from malpractice.

Conclusion

Approval of medical action or what is commonly called Informed Consent must be given before the doctor gives action and after the doctor explains at least the diagnosis and procedure for medical action, the purpose of why the doctor gave the medical action, other alternative actions and their risks, complications and risks that may occur. Doctors cannot be sued as long as the doctor acts in accordance with the applicable code of ethics and has been determined by professional organizations and based on the discipline of medicine or dentistry. If they violate, the sanctions given can be in the form of disciplinary action, warning and recommendation to revoke the Registration Certificate. If there is a crime aspect, it can be subject to criminal sanctions, namely Article 351 of the Criminal Code concerning Persecution, and civil sanctions, namely being able to file a civil law suit on the basis of Article 1365 BW concerning acts of violating the law. In essence, the doctor's obligation to take aesthetic medicine actions in this case to beautify/change the appearance or just to treat or rejuvenate the skin or face must be done with great care, it must be based on Informed Consent as the basis for action (in accordance with existing regulations, in this case Permenkes). However, there is no standardization of regulations related to written Informed Consent. Medical action in a beauty clinic must have clear medical objectives and indications, as well as who is doing it, whether the doctors have competence according to their knowledge who can be accounted for in carrying out the medical action. Medical action in a beauty clinic is the same as medical action in general, so it must be based on Informed Consent for each action.

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