

Arrangement of Informed Consent in Medical Record as Evidence for Patient's Civil Lawsuit at Court

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Abstract— *Informed consent is legal foundation of doctor-patients relationship in delivering health service. However, it has not been well-documented in medical records of patients. Informed consent should be a legal contract document between doctors and patients though it is stated as agreement statement from patients. Informed consent as written proof in civil lawsuit at court is very crucial for patients. However, it raises problems for patients because firstly, from administrative point of view, written proof is on the domain of health service facilities and technically, there has been unequal level of knowledge among doctors on health service delivery. Judges are required to take an active part in investigating health service lawsuit at court not by assigning the burden of proof on the part of patients but by applying shifting burden of proof system to give fair court decision.*

Keywords— *Informed Consent, Medical Record, Patient's Evidence, Court.*

I. INTRODUCTION

Informed consent is legal foundation for medical treatment given by doctors. Informed consent for medical treatment as legal documents reflecting legal relation between doctors and patients should be part of medical records. Normatively, medical record is set of files containing specific records and documents on patients' identity, examination that has been undergone, medication, treatment and other health services given to patients.¹ However, there has been no clear description on the position of informed consent as substance of medical records.

Medical records belongs to doctors, dentist or other healthcare facilities, but its contents belong to patients. Medical records should be kept confidential by doctors, dentist and the head of healthcare facilities. It is possible that medial treatments are not properly delivered or they are not based on appropriate procedures. It will raise conflict between doctors and patients resulting in lawsuit at court. Informed consent for medical treatment as legal documents containing details of contract between doctors and patients is part of medical records that is not in patients' possession.

During trial, patients need evidence for means of proof to prove their lawsuit. In civic law, principle of evidence evaluation is that "the one who argues should prove for the argument". In addition, informed consent for medical treatment as part of medical record is not clearly stated. Formally, medical records which are not in patients' possession will cause problem for patients in proving their arguments at court.

Burden of proof at civic lawsuit for medical treatment has special characteristics due to the uniqueness of contracts or agreements between doctor or dentist with patients which are

inspanning verbintenis in nature. According to article 132 of HIR or article 156 of RBg on principle of "active role on the part of judges", it is the judges weffho are responsible to determine what to prove and who has burden of proof. At present, examination of lawsuit on healthcare service are similar to other usual civic lawsuit. It results in unfair court decision because there has not been special procedures to examine healthcare lawsuit. Thus, burden of proof are dependent on the judge.

Based on legal problems described in background of study, then research problem in this study is "how is the arrangement of informed consent of medical treatment as means of proof on civic lawsuit at court?"

II. RESEARCH METHOD

This is a law study with legal approach by analysing positive norms of law in Indonesia namely, article no 45 on the arrangement of Informed consent for medical treatment and article no 47 on the arrangement of medical records as stated in Indonesia Law no 29 of 2004 on Clinical Clerkship. Legal data are gathered by collecting regulations related to the two articles, relevant guidelines, and other technical requirements which are relevant to research problem. In addition to legal approach, this study also employs principle of contract law concept and principle of burden of proof in civic law. Then, data are also analysed by using prescriptive analysis technique. It is expected that this study results in applied science namely informed consent as means of proof for patient. Systematic interpretation technique of analysis is also employed by cross-correlating article no 45 and 47 of Indonesia Law no 29 of 2004 on Clinical Clerkship.

III. RESULTS AND DISCUSSION

1. The Meaning of Informed Consent for Patients

Article no 45 verse (1) of Indonesia Law no 29 of 2004 on Clinical Clerkship states that "each medical treatment by

¹ General requirements of article 1 no 1 of Regulation of Health Minister of Indonesia no 269/MENKES/PER/III/2008 on Medical Records.

doctor or dentist should be approved by patients". Without patients' approval, all medical treatment should not be delivered. The approval reflects doctor-patients relationship.

Technically, informed consent for medical treatment is under Regulation of Health Minister no 290/MENKES/PER/III/2008 on Informed Consent for Medical Treatment as the implementation guideline of article no 45 of Indonesia Law no 29 of 2004 on Clinical Clerkship. Informed consent is agreement given by patients or close family after getting complete explanation on medical treatment by doctor or dentist to receive medical treatment². Informed consent is given in the form of:

- a. Oral approval from patients; all medical treatment to patients; however, there should be written approval if the oral one is considered doubtful³; informed consent for medical treatment might be given orally for treatments of low risk.
- b. Written approval from patients; it is given by patients for high risk medical treatment⁴. High risk medical treatments are those causing death based on certain probability level⁵.
- c. Without patients' approval; it is in emergency situation to save patients and/or to prevent disability on the part of patients. Proper explanation should be given to patients right after being conscious or to close family⁶. It is an exception but it is also an intervention from government to fulfil the right of citizen for healthcare service. The exemption is stated clearly at article 17 of regulation of health minister of Indonesia no 290/MENKES/PER/III/200 on Informed Consent of Medical Treatment that "approval might not be needed in case of situation in which medical treatment should be delivered for the sake of common people interest".

Written approval should be stated in the form of statements on special form⁷. There are no details on the form of relevant written approval. It must be in the form of "statement". In addition, there has no specific requirements on how to put informed consent on relevant document and also the stages for that. Also, there is no certain form of informed consent as legal documents.

Manual book of Informed Consent for medical treatment, which is so far used as guideline for doctor and dentist gives clear description on the form of Informed Consent, and stated that the form of Informed Consent is "statement of approval". However, the manual doesn't state clearly that informed consent is a legal documents reflecting doctor/dentist-patient relation.

² General requirements of article 1 no 1 of Regulation of Health Minister of Indonesia no 290/MENKES/PER/III/2008 on Informed Consent.

³ Article 2 verse (1) and article 3 verse (5) of Regulation of Health Minister of Indonesia no 290/MENKES/PER/III/2008 on Informed Consent.

⁴ Article 3 of Regulation of Health Minister of Indonesia no 290 /MENKES/PER/III/2008 on Informed Consent

⁵ General requirements of article 1 no 5 of Regulation of Health Minister of Indonesia no 290/MENKES/PER/III/2008 on Informed Consent.

⁶ Article 4 verses (1,2) of Regulation of Health Minister of Indonesia no 290/MENKES/PER/III/2008 on Informed Consent.

⁷ Article 3 verse (3) of Regulation of Health Minister of Indonesia no 290/MENKES/PER/III/2008 on Informed Consent

Each stage in healthcare service is legal stage⁸. Informed consents as form of legal relation reflecting patients' approval on certain medical treatment are stated in form of informed consent. Therefore, legal relation between doctor and patient is not unilateral action on the part of patient but it is a legal relation resulting in legal right and obligation on the part of doctor or dentist and patient. Doctor/dentist-patients legal relation is a contractual relation and form of informed consent is contract or agreement document between doctor or dentist with patient. In addition, form of informed consent for medical treatment is a document of legal contract or agreement between doctor or dentist with patient.

Definition of contract or agreement, as stated in article 1313 BW is "a agreement is a legal action in which one person or more bind him/themselves to one other/more persons". The definition reflects that there is only one party taking an active part. However, in business contract or agreement, the two relevant parties take active part to reach an agreement in order to obtain mutual benefit.⁹ Subekti states that "an agreement is an occurrence in which one specific person make an oath to other person or in which there two person take oath to each other to conduct certain thing."¹⁰

Doctor and patients are two interrelated subjects of law, based on agreement with forceful power due to norm of law. The agreement has a unique characteristics namely *inspanning verbintenis (agreement engagement)*, in which reward given is maximum effort with uncertain result. Contracts in healthcare service are urgent. The urgencies of contract in healthcare service are

- As the essence of contract as interchange of interest between relevant parties;
- As medium of law for relevant parties;
- As statement of right and obligation;
- As means of proof for the relation between the relevant parties;
- As means for law certainty.
- As mutualism symbiosis.
- To support conducive relation between relevant parties.

Informed consent for medical treatment doesn't eliminate law responsibility for the dereliction in giving medical treatment causing harm for patients¹¹. Each person who knows or whose interest is violated due to treatment given by doctor or dentist during his medical treatment might send written report to The Chair of Council of Medical Discipline of Indonesia. However, the council only examines and decide for the report concerning on discipline standard of doctor or dentist. In addition, the decision is irrelevant to the substance of patients' report which is the recovery of patients' loss. The

⁸ Agus Yudha Hernoko, "Karakter Hubungan Keperdataan Antara Rumah Sakit Dengan Pasien Di Bidang Jasa Layanan Kesehatan", Material presented at the event: Health Law Workshop, "Rumah Sakit Sebagai Bentuk Korporasi Dalam Hubungan Pelayanan Kesehatan"; Jimly School of Law and Government (JSLG) Surabaya, Hotel Elmy Surabaya, 14-15 Desember 2018.

⁹ Moch. Isnaeni, "Seberkas Diorama Hukum Kontrak", (Surabaya: Revka Petra Media, 2017), page. 24-25

¹⁰ Subekti, "Hukum Perjanjian", (Jakarta: Intermasa, 2002), page. 1

¹¹ Article no 6 of Regulation of Health Minister of Indonesia no 290/MENKES/PER/III/2008 Tentang Persetujuan Tindakan Kedokteran

decision is always in the form of discipline sanction in the form of:¹²

- a. Written warning;
- b. Recommendation to withdraw registry license or clinical clerkship license; and/or
- c. Obligation to take part in education or training in medical institution or dentistry education.

2. The Position of Informed Consent in Medical Record in Indonesia

Due to the increasing complexity of healthcare system in Indonesia, medical records play more crucial role. It gives big impact on the quality of healthcare service to patients.¹³ Thus, in during their clinical clerkship, doctors or dentists have to make medical records.¹⁴ In addition, medical records are crucial because they contain notes and documents on identity, examination, treatment and other services of patients.¹⁵ Notes on medical records are doctors' or dentists' writing on all kinds of treatment given to patients.¹⁶

Requirements of Health Minister of Indonesia no 269/MENKES/PER/III/2008 on Medical Records as the implementation of article 47 verse (3) of Indonesia Law no 29 of 2004 on Clinical Clerkship state that there are four types of medical records. They are:

- a. Content of medical records for outpatients in a healthcare centre;
- b. Content of medical records for inpatients and one-day treatment patients;
- c. Contents of medical records for emergency patients; and
- d. Content of medical records for catastrophic situation.

The four classifications of medical records contents elaborate minimum requirements of contents that should be put in medical records; however, they don't state the substance of informed consent as one of the components of medical record.

Medical records are in the possession of healthcare centre, and the contents of medical record belongs to patients to be used for:¹⁷

- a. "Health examination and treatment for patients".
- b. Means of proof for law enforcement, medical discipline and dentistry and for upholding medical ethics and dentistry ethics;
- c. Research and education;
- d. Basis of payment for health treatment; and
- e. Health statistical data".

Therefore, medical record has *administrative, legal financial, research, education and documentation* functions¹⁸.

¹² Article no 66, 67, 69 of Indonesia Law no 29 of 2004 on Clinical Clerkship

¹³ Sutarno, "Hukum Kesehatan : Eutanasia , Keadilan dan Hukum Positif di Indonesia", (Malang: Setara Press, 2014), page. 63

¹⁴ article 46 verse (1) of Indonesia Law no 29 of 2004 on Clinical Clerkship

¹⁵ Explanation of article 46 verse (1); it is also regulated in general requirements of article 1 no 1 of Regulation of Health Minister of Indonesia no 269/MENKES/PER/III/2008 on Medical Records.

¹⁶ General requirements of article 1 no 6 of Regulation of Health Minister of Indonesia no 269/MENKES/PER/III/2008 on Medical Records

¹⁷ Article 13 verse (1) point b, the regulation of Health Minister of Indonesia no 269/MENKES/PER/III/2008 on Medical record

¹⁸ Sutarno, "Hukum Kesehatan : Eutanasia , Keadilan dan Hukum Positif di Indonesia", (Malang: Setara Press, 2014), page 64

However, the requirements of medical record do not state clearly on the role of informed consent as the substance and proof of doctor/dentist-relation.

Medical record is the only document containing notes made by doctors and/or other healthcare practitioners, report of supporting examination result, observation notes, daily treatment and other types of records such as radiology image, digital imaging, and diagnostic electro records.¹⁹ In addition, medical record is not only regular documents but it is also legal document for health service which is very crucial to be used as means of proof for patients.

Informed consent as contract or agreement is a landmark of doctor/dentist-patient relation so it should be part of components of legal documents in healthcare service. Therefore, it can be inseparable part of medical records substance. Being a part of substance of medical record, then it is clear that medical records are in the possession of healthcare centre but their contents belong to patients.

Means of proof in civic law which is is under the regulation of article no 164 HIR, article no 284 RBg and article no 1966 BW are as follows:

- a. Proof of letter;
- b. Proof of witness;
- c. Presumptions;
- d. Confession;
- e. Oath.

As stated above that medical records are documents containing notes, and other records on patients' identity, undergone examination, treatment, medication and other services given to patients,²⁰ meaning that written medical records are equal to letter functioning as means of proof at court to deny patients' lawsuit²¹.

Medical record might also function as means of proof for law enforcement process, upholding medical and dentistry discipline and enforcing medical and dentistry ethics. Formally, it will be easier for patients to prove the existence of doctor/dentist-patients relation because informed consent is inseparable part of medical record substance which can function as means of proof.

3. The Position of Informed Consent for Medical Treatment as Means of Proof for Patients in Civic Lawsuit at Court

In civic law, the concept of proof is under the regulation of article 1865 BW stating that "each person arguing for having certain right must proof for the right or occurrence to uphold his own right or deny others' right concerning on certain occurrence". This article shows that if patient sues doctor for certain misconduct, then he or she has to prove that the doctor has committed fault or dereliction.²²

Proofs are needed to deny the opponents' argument on certain suit or to uphold certain right. Generally, lawsuit

¹⁹ General requirements of article 1 no 7 of Regulation of Health Minister of Indonesia no 269/MENKES/PER/III/2008 on Medical Records.

²⁰ Explanation of article 46 verse (1): it is also regulated in article 1 no 1 of Regulation of Health Minister of Indonesia no 269/MENKES/PER/III/2008 on Medical Records;

²¹ Anny Isfandyarie, "Tanggung Jawab Hukum dan Sanksi Bagi Dokter Buku I" (Jakarta : Prestasi Pustaka, first printing, 2006), page. 183

²² *Ibid*, page 182

occurs due to an occurrence or legal relation supporting certain right. Thus, what should be proven is the existence of relevant occurrence or legal relation. The truth on occurrence or legal relation is the aspect that should be proven. In case the defendant admits the suit, then the proofs are no longer needed²³.

Concerning written proof in modern era, companies make written contract containing right and obligation of each related parties stated in contract clauses²⁴. Informed consent which meant to be contract between doctor/dentist with patients is documented in certain format of informed consent functioning as legal contract document and it is crucial for patients' lawsuit at court. Informed consent which is intended to be contract between doctor or dentist with patients is legal guidance for doctor or dentist in giving treatment to patients. It contains clauses of right and obligation of each relevant parties. In addition, it ensures law certainty for each party in case of dereliction of giving treatment to patients. Therefore, one of the functions of contract is for means of proof for doctor/dentist-patient relation.

Informed consent, as part of medical records might be used as written proof. Medical record is also a kind of document which is made based on prevailing regulation namely Indonesia Law no 29 of 2004 on Clinical Clerkship and Regulation of Health Minister of Indonesia no 269/MENKES/PER/III/2008 on Medical Record. It is made by authorized officer (doctor) as part of his responsibility and for certain condition of patient. This criteria fulfils the requirements in article 187 of verse (4) of point b of Indonesian Civic Law stating that "document made by authorized officer as part of his responsibility based on certain regulation, and intended for proving certain things or condition"; therefore medical record might be means of document proof at court.²⁵

Burden of proof is regulated under the requirement of article 163 HIR or article 283 of RBg stating that "person claiming right or mentioning an occurrence for upholding his right or for denying others' right have to prove the existence of the right and occurrence". The two articles are about burden of proof but it is not clearly stated so it is difficult to decide whether burden of proof is on the defendant or litigant.²⁶

Contract as business frame ensures that benefit expected by the two parties will be obtained in line with the expectation and planned calculation. In case one party violates the contract, meaning that he (debtor) is unable to fulfil his obligation, then the creditor has to proof for that. Litigant has to proof that the defendant is fault, and it needs proof to win the lawsuit; in this case, to obtain certain claims, cost and interest though, it is hard to proof that the defendant is fault. However, the prevailing law provides adequate elaboration for

means of proof which is regulated under the article no 1866 BW for written proof.²⁷

Contract as instrument of law facilitates fair, firm and efficient exchange of right and obligation based on the agreement of those making contract.²⁸ The essence of contract legal relation for healthcare service is that law functions as guidance, solution for upcoming problem (legal solution), aiming at maintaining harmonious relation of relevant parties and at creating conducive business atmosphere.²⁹ In case of conflict in healthcare service resulting in a lawsuit at court, problem might come up for patients when they have to proof for the lawsuit. It is because informed consent as legal document is the landmark of legal relation, is part of medical record, and it takes a long process to obtain medical record from healthcare centre. Other problems is unequal level of knowledge of patients to that of doctor or dentist and therefore, it is hard for patients to prove the fault or dereliction committed by doctor or dentist.

There should be a deep review on article 283 of RBg to determine who takes the burden of proof. The article states that³⁰

- Those claiming right have to prove it. Usually, the litigant is the one claiming right, therefore, he or she have to take first burden of proof;
- Those mentioning certain occurrence for upholding his right have to prove it. If the litigant mentions the occurrence, then he or she has to prove it. Therefore, the burden of proof is on the litigant. On the other side, if the defendant mentions certain occurrence, then he has to prove it and takes the burden of proof;
- Those mentioning certain occurrence to deny others' right have to prove it. If the litigant mentions the occurrence, then the burden of proof is on him. However, if the litigant mentions it, then he takes the burden of proof;

Patients during lawsuit (as litigant) takes the burden of proof; however the position of patients and doctor is unequal especially in terms of their level of knowledge. Patients are not familiar with medical knowledge, then it puts them in trouble when they have to prove for things related to medical aspects. Therefore, it is very possible that they would fail to prove dereliction committed by doctor.

To solve the aforementioned problem, we may analyze article no 32 HIR or article no 156 RBg by using principle of "active role of judges". Based on the principle, it is the judges who are responsible to take the first burden of proof. In determining burden of proof, council of judges must be fair. Though burden of proof is on the patient as litigant in which they have to prove their right or to prove for certain occurrence, judges should give shifting burden of proof which

²⁷ Moch. Isnaeni, Op.Cit.

²⁸ Muhammad Syaifuddin, "Hukum Kontrak; Memahami Kontrak Dalam Perspektif Filsafat, Teori, Dogmatik, dan Praktik Hukum (Seri Pengayaan Hukum Perikatan)", (Bandung: Mandar Maju, 2012), page 9

²⁹ Agus Yudha Hernoko, "Karakter Hubungan Keperdataan Antara Rumah Sakit Dengan Pasien Di Bidang Jasa Layanan Kesehatan", Materi disampaikan pada acara: Whorkshop Hukum Kesehatan, "Rumah Sakit Sebagai Bentuk Korporasi Dalam Hubungan Pelayanan Kesehatan"; Jimly School of Law and Government (JSLG) Surabaya, Hotel Elmy Surabaya, 14-15 Desember 2018.

³⁰ Abdulkadir Muhammad, Op.Cit. page 127-128

²³ Abdulkadir Muhammad, "Hukum Acara Perdata Indonesia", (Bandung:Citra Aditya Bakti, 2008), page 126

²⁴ Moch. Isnaeni, "Pijar Pendar Hukum Perdata", (Surabaya: Revka Petra Media, 2014), page 108

²⁵ Anny Isfandyarie, Op.Cit. page 186

²⁶ Abdulkadir Muhammad, "Hukum Acara Perdata Indonesia", (Bandung:Citra Aditya Bakti, 2008), page 127

so far has not been used for conflict of healthcare service. Burden of proof would help patient to win the right and result in fair court decision.

IV. CONCLUSION

Juridically, informed consent should state patients' statement. However, as basis of legal relation, it should be intended as contract between doctor or dentist with patients. Informed consent as document is not clearly stated as substantive part of medical record. From administrative viewpoints, medical record might be used as means of proof for patients. However, patients find it difficult for technical verification at court.

V. SUGGESTIONS

There should be clear arrangement of informed consent as contract between doctor or dentist with patients and it should be put as inseparable part of medical record. When patients become litigant, it takes active role of judge to take unique characteristic of healthcare service conflict into account during examination and also to take patients' consideration into serious consideration by applying shifting burden of proof.

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