

# The Completeness of Informed Consent form Filling and Protection of Consumer Rights in Hospital Healthcare Services

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## ABSTRACT

Fulfillment the completeness of filling out the informed consent form is one of the minimum service standards in hospitals, but until now there are some hospitals that have not complied this obligation. This study aims to understand the legal protection of patients' rights as consumers related to the completeness of filling out an informed consent form in medical record services in hospitals. This research uses a normative legal approach through descriptive analysis. The secondary data used in this study were obtained through a study of the literature. The results of the analysis in this study show that the fulfillment of the completeness of filling out the informed consent form is a form of obligation of business actors to fulfill consumer rights which include the right to be treated or served correctly and honestly and not discriminatory and the right to obtain advocacy, protection, and consumer protection dispute resolution efforts properly. The violation of the patient's right to obtain a minimum standard of health services in the form of incomplete filling of the informed consent form is a violation of consumer rights in health services. According to the provisions of the Consumer Protection Law, the settlement of disputes regarding violations of these rights can be carried out through providing compensation to patients by business actors, filing lawsuits by patients, and even criminal charges against business actors. The conclusion obtained in this study is that the completeness of filling out the informed consent form in the medical record service at the hospital contains protection of consumer rights in the form of the right to obtain health services in accordance with the standards in legislation and legal rights. As a protection for the rights of these patients, consumer protection legal instruments in Indonesia require business actors to provide compensation to patients. Consumers are also given the authority to file claims and lawsuits. Based on these conclusions, it can be said that this study provides a new formulation regarding the protection of patient rights as consumers regarding the completeness of filling out an informed consent form in medical record services in hospitals.

**Keywords:** Completeness of Informed Consent, Health Information Management, Consumer Rights, Health Services, Hospitals

## 1. Preliminary

The relationship between patients and health care providers is a relationship between legal subjects who should have the same position before the law. The existence of a commercial element in health services can be used as a basis for placing the relationship between the parties in the health service as a commercial transaction relationship between consumers and business actors. Thus, the provisions in Law Number 8 of 1999 Concerning Consumer Protection should also apply to health services.

The consequences of the legal relationship between consumers and business actors give rise to reciprocal rights and obligations of each party. This manifests itself in the issue of rights and obligations related to the administration of medical records in health services. The description of the quality of health services can be seen from how the documentation in the medical record is carried out. Good documentation in medical records can also make an important contribution to the interests of law, education, research and hospital accreditation

(Erlindai and Yunita, 2018). That is why Article 46 of Law Number 29 of 2004 Concerning Medical Practice in conjunction with Article 70 paragraph 2 of Law Number 36 of 2014 Concerning Health Workers states that the recording in the medical record must be completed as soon as possible by doctors, dentists, and other health workers after the patient or recipient of health services has received health services.

The informed consent form is one of the records documented in the medical record file at the hospital. Health care facilities such as hospitals are required to ensure that all informed consent forms documented in the medical record file are filled out completely. As regulated in the Regulation of the Minister of Health Number 129 of 2008 Concerning Minimum Service Standards for Hospitals, there are four minimum service standards in medical record services. One of the standards regulates the completeness of informed consent forms.

Hospitals need to give serious attention to the completeness of filling out the informed consent form. In order to meeting the hospital's national accreditation service standards, complete informed

consent forms are also required to fulfill patient rights. The existence of informed consent in health services is intended so that patients can freely and without coercion give consent to medical actions that will be carried out on themselves. Without the consent given by the patient, the doctor surely cannot touch the patient's body (Carr, 2013; Bertens, 2015). The informed consent that has been given by the patient, especially for risky medical actions, will then be documented on a special form and put together in the patient's medical record file (Suganda, 2017).

The completeness of informed consent form in the hospital in several regions of Indonesia is still not fulfilled optimally. One of the case can be seen in the research of Wulandari, Wasono, Lestari, & Maitsya (2019) which states that 70% of the 100 informed consent forms for surgery at Pertamina Bintang Amin Hospital in 2018 were incomplete. The description of the results of these studies shows that not only the medical record services do not meet the minimum service standards, but also the fulfillment of patient rights in health services.

There are several factors causing the incompleteness of informed consent form in several hospitals in Indonesia. Lack of understanding from health workers regarding to the standard operating procedures related to the informed consent forms filling is one of the reasons why the completeness of the informed consent form unfulfilled. In addition, the incomplete filling was also caused by the lack of understanding and lack of attention from the health workers regarding the importance of informed consent itself. The existence of time constraints due to the tight schedule of services to patients is also one of the contributing factors. Other fundamental factors that lead to compliance with the complete informed consent form still often encounter obstacles, namely hospital regulations that impose sanctions for health workers who do not complete an informed consent form (Kristina, Maulina, & Agnesia, 2018; Meyyulinar, 2019).

It should also be understood that people who receive health services at hospitals in Indonesia can not only be positioned as patients or recipients of health services, but should also be seen as consumers who receive health services. Patients as consumers have a number of rights which are regulated in Law Number 8 of 1999 Concerning Consumer Protection. Due to the existence of reciprocal rights and obligations in the legal relationship between consumers and business actors, these rights should be fulfilled by the hospital as a business actor. In the perspective of consumer protection law, the completeness of filling out the informed consent form is not complete. Of course, this can lead to a violation of the fulfillment of patient rights as consumers who receive health services in hospitals.

Based on the problems that have been described previously, this study aims to examine the legal protection of patients' rights as consumers related to

the completeness of filling out an informed consent form in medical record services in hospitals. According to the author's knowledge, until now, previous studies in the field of health information management are still limited to reviewing the technical aspects by analyzing the completeness of filling out the informed consent form in the hospital. These studies also explore the factors that cause incomplete filling of informed consent forms in medical record services in hospitals. Therefore, the results of this study are expected to provide a clear understanding of the legal arrangements related to the obligation to meet the standards for completing the informed consent form and the responsibilities of business actors for violations of these obligations according to consumer protection law in Indonesia. This research is organized into several parts. Literature review as the first part includes a review of the literature data relevant to the problems studied in this study. The methodology as the second part will explain the methods used and the collection of research data. The third part of this study contains an analysis of the research data and discussion. At the end, the conclusions obtained and the implications that are expected to arise from this research will be formulated.

## 2. Literature Review

### Completeness of Informed Consent form

Informed consent is a form of communication process between health care providers or researchers with patients or research subjects. The results of the communication process will manifest in the form of approval and authorization of certain procedures for medical intervention or research to be carried out. The process of informed consent involves many elements consisting of explanation, understanding, voluntary choice, and authorization (Grady, 2015; Erkan, Mayadagli, & Akbaba, 2017).

Consent can only be given after the patient or research subject has obtained information with certain criteria from health workers or researchers. The criteria for the information referred to among others must be good in terms of delivery, correct regarding the content of the information, and complete including the content of the entire content of the information. Such information is very necessary in order to let the patients make good and correct decisions. This is considering that understanding the information conveyed is one of the parameters to determine whether or not the consent is given, in addition to freedom and awareness. However, the parameter for complete informations is actually rather difficult to determine (Kusmaryanto, 2015). Article 45 of Law Number 29 of 2008 Concerning Medical Practice states that the information submitted in the informed consent process at least describes:

Diagnosis and procedures for medical action

The purpose of the medical action taken.

Alternative other medical actions that can be done.

Risks and complications that may occur from the medical procedure performed.

Prognosis of the medical action performed.

There are three forms of consent that can be given by patients as a form of authorization in the informed consent process, namely through implied consent, verbal consent, and written consent. Written consent is required for risky medical procedures involving the use of anesthesia or sedation, restorative procedures, and invasive surgical procedures, as well as the administration of drugs known to have a high risk. Giving consent through written consent is stated through the signing of an informed consent form. The existence of the signature can be used as evidence that the patient has agreed to the surgical procedure to be performed on his body (Bowman, Spicer, & Iqbal, 2012; Mirza, 2012).

Okupon et al. (2019) in his research stated that a well-filled informed consent document can be used as useful information and improve the quality of the relationship between patients and doctors as health care providers. In addition, the content in the informed consent can also help to ensure that the decision made regarding the medical action to be taken is a form of collective decision between the patient and the doctor. In addition, Hall, Prochazka, & Fink (2012) also explain in their research that informed consent also has an administrative function. As in the implementation of surgical procedures, patients will not just enter the operating room without first signing an informed consent form. However, the demand for efficient service flow can sometimes result in the approval process from the patient shifts to just getting a signature from the patient and is no longer a form of conversation between the patient and the doctor.

Based on the provisions in Article 3 of the Regulation of the Minister of Health Number 269 of 2008 Concerning Medical Records, it can be seen that the informed consent form is one of the records stored in the medical record file. Meanwhile, one of the standards regulated in the Minister of Health Regulation Number 129 of 2008 Concerning Minimum Service Standards is regarding to the completeness of the informed consent form in medical record services in hospitals. Analysis of the completeness of the informed consent form was carried out on a number of patients at the hospital who received medical treatment within a period of 1 month. The purpose of this analysis is to get an overview of the doctor's responsibilities in providing medical care explanation to the patient and obtain consent from the patient for the medical action taken. The regulation states that the standard for completing the informed consent form is 100%.

### Patients' Rights as Consumers in Health Services

Barapatre & Joglekar (2016) in their research stated that the regulation of consumer rights was made to ensure that these rights were not violated by business actors and service providers. The protection

of consumer rights can not only be applied in commercial trade but also in health services. Based on human, legal, and moral values, patients have the right to obtain all the benefits of the services provided for their health and well-being in health services. Thus, the understanding of consumer rights can be expanded to include patient rights in health services. The idea of the urgency of protecting patient rights as consumers is in line with the research of Samal, Mishra, Shrestha, & Joshi (2020) which emphasizes that protection of consumer rights is needed to provide better protection for the public interest. One of the parties whose rights need to be protected are patients who often do not understand their rights which have been violated in health services.

The results of research conducted by Singh, Patnaik, Kapoor, Chaturvedi, & Srivastava (2014) explain that the application of the Consumer Protection Act (CPA) as an effort to protect patients' rights does not only have a positive impact but also a series of negative impacts. The application of CPA in health services is considered to be able to erode the relationship between doctors and patients. This condition will eventually lead to the occurrence of defensive medicine due to concerns about the emergence of many lawsuits by patients in the future. However, there are a number of preventive measures that can be taken to prevent claims from patients. One form is through secondary prevention efforts by carrying out proper management of medical record files.

### The Relationship between The Completeness of The Informed Consent Form in The Medical Record File to The Protection of Patient Rights

Informed consent has several other functions, apart from administrative functions, which are related to moral, legal, and clinical aspects. Informed consent is morally needed as a form of respect for the patient's right to autonomy. Through this right of autonomy, the patient has the right to determine what should be done to his body. The existence of informed consent in a legal perspective is based on the understanding that touching the patient's body without consent, either intentionally or unintentionally, is a form of crime (battery) and negligence (tort). Therefore, as a form of justification for health workers to carry out certain medical actions on the patient's body, informed consent is needed from the patient which according to the Court of Appeal term is referred to as "Flak Jacket". Meanwhile, the function of clinical informed consent is to provide convenience in treatment. Through the provision of informed consent, the patient's cooperative attitude is expected to be formed and it surely will affect the success of treatment (Herring, 2012; Jackson, 2013).

According to Chintia & Kusumaningrum (2020), medical records can be used as evidence for letters and expert statements. Medical records that are



used as evidence without asking a doctor to make medical records in front of a trial can be categorized as evidence as contained in Article 187 of the Criminal Procedure Code. Doctors who make medical records who are asked to provide information before a trial by a judge, based on Article 186 of the Criminal Procedure Code are categorized as evidence of expert testimony. However, the obstacles that arise when medical records are used as evidence in the resolution of medical disputes between doctors and patients are incomplete medical records that are still often encountered, the lack of supervision carried out by the Health Service on medical records and the lack of strict sanctions given to medical officers who do not complete medical records.

Oktavia, Hardisman, & Eradius (2020) through their research stated that the completeness of filling out the informed consent form contained in the medical record is very important because it can be used for various purposes. These needs can be used as legal evidence, research and education materials as well as a tool to analyze and evaluate the quality of services provided by hospitals. If there is a lawsuit at a later date, informed consent can be used as legal evidence in court.

### 3. Research Method

This study questioned the legal basis for protecting patient rights regarding the completeness of filling out informed consent forms in hospitals according to the perspective of consumer protection law in Indonesia. This research took a juridical approach related to the problems studied, so this research is normative juridical research. Normative juridical research is a qualitative research method that approaches the legal norms contained in the legislation, the results of court decisions, and the law that lives in the community. The approach in this study formulates the concept of legal norms that will be used as a benchmark for humans to behave in relation to the problems studied (Ali, 2016).

Secondary data that is related to the problem being studied was used in the research with normative juridical approach. The use of secondary data was

used to formulate the legal doctrines that is both theoretical and scientific. The legal doctrines that have been formulated were then used to analyze the problems discussed. Secondary data used in legal research was library material which consisted of primary, secondary, and tertiary legal materials (Muhaimin, 2020).

This study used secondary data collected through literature and internet studies. Secondary legal materials in this study were primary legal materials in the form of laws and regulations in Indonesia related to the problems studied. Meanwhile, the secondary legal materials used in this research consist of explanations of primary legal materials, legal books, and research results related to the legal aspects of informed consent in the provision of health services and consumer protection law in health services. In addition, non-legal studies related to the management of the complete management of informed consent forms in hospitals were also used to help enhancing the analysis carried out in this study.

The analysis process in this study was carried out by first collecting secondary data through literature and internet studies. The secondary data that has been collected was re-selected to determine which data can be used to support this research. The data was analyzed to obtain conclusions regarding legal arrangements related to the obligation to meet the standard for completing the informed consent form for the hospital as a business actor. Then, the result of the analysis was also used to analyze the responsibility of business actors for the incomplete filling of the informed consent form to protect the rights of patients as consumers. Therefore, this research is analytical descriptive research which according to Ali (2016) is a form of research in which the determination of the content of legal norms is positioned as a guideline for finding solutions to the legal problems being studied.

### 4. Results and Discussion

#### Overview of Completeness of Filling Informed Consent Form for Surgical Action at Pertamina Bintang Amin Hospital in 2018

Table 1. Completeness of Patient Identification

No	Items	Completeness		Total		%	
	Yes	%	No			%	
1	Name	56	56	44	44	100	100
2	Place Date of Birth / Gender	56	56	44	44	100	100
3	Medical Record Number	47	47	53	53	100	100
4	Address	55	55	45	45	100	100
Average		53.5%				46.5%	

Based on the data in Table 1, it is known that in the patient identification (identity) component the highest percentage of completeness was found in the items Name and Place of Birth Date / Gender as many as 56 sheets (56%), and the average completeness was 53.5%. Meanwhile, the highest

percentage of incomplete filling was found in the Medical Record Number item as many as 53 sheets (53%) and the average incompleteness was 46.5%. Based on the results of the analysis, it was found that all items on Patient Identification Completeness were not completely filled out (Wulandari, Wasono, Lestari, & Maitsya, 2019).

**Table 2. Completeness of Important Reports**

Table 2: Completeness of Important Reports							
No		Items	Completeness		Total	%	
Yes		%		No		%	
Information							
1	Doctor's Name	89	89	11	11	100	100
2	giver	30	30	70	70	100	100
3	Receiver	4	4	96	96	100	100
4	Diagnosis	94	94	6	6	100	100
5	Basic Diagnosis	95	95	5	5	100	100
6	Action	89	89	11	11	100	100
7	Indication	93	93	7	7	100	100
8	Procedures	85	85	15	15	100	100
9	Objective	85	85	15	15	100	100
10	Risk	80	80	20	20	100	100
11	Complications	80	80	20	20	100	100
12	Prognosis	25	25	75	75	100	100
13	Alternative	22	22	78	78	100	100
Agreement							
14	Relationship with Patient	62	62	38	38	100	100
15	Recipient's name	81	81	19	19	100	100
16	TTL/JK	78	78	22	22	100	100
17	Address	74	74	26	26	100	100
Average			68.5%			31.5%	

Based on Table 2, it is known that in the important report components the highest percentage of completeness of filling in the information group is found in the Basic Diagnosis item as many as 95 sheets (95%), the agreement group is found in the Recipient Name item as many as 81 sheets (81%) and the average completeness by 68.5%. While the highest percentage of incompleteness in filling out the information group was found in the Receiver item as many as 96 sheets (96%), the agreement group was found in the Patient Relations item as many as 38 sheets (38%) and the average incompleteness was 31.5%. (Wulandari, Wasono, Lestari, & Maitsya, 2019).

**Table 3. Authentication Complete**

No	Items	Completeness		Total		%	
Yes		%		No		%	
1	Giver's Signature	98	98	2	2	100	100
2	Recipient's Signature	96	96	4	4	100	100
3	Date/Time	87	87	13	13	100	100
4	Recipient's Signature	100	100	0	0	100	100
5	Witness Signature 1	53	53	47	47	100	100
6	Signature of Witness 2	15	15	85	85	100	100
Average		74.8%		25.2%			

Based on Table 3, it is known that in the authentication component the highest percentage of completeness is found in the Signature item The recipients were 100 sheets (100%), and the average completeness was 74.8%. While the highest percentage of incomplete filling is found in the Signature item S action 2 is 85 sheets (85%) and the

average incompleteness is 25.2% (Wulandari, Wasono, Lestari, & Maitsya, 2019).

### Protection of Patients' Rights As Consumers through Complete Fillment of The Informed Consent Form In Health Services in Indonesia

People who receive health services from doctors or dentists in the context of medical practice in Indonesia are referred to as "patient". Article 1 number 10 of Law Number 29 of 2004 Concerning Medical Practice explains that a "patient" is every person who consults on his health problems to obtain the necessary health services, either directly or indirectly to a doctor or dentist. About The definition of "patient" in Article 1 point 4 of Law Number 44 of 2009 Concerning Hospitals is explained as anyone who consults on his health problems to obtain the necessary health services, either directly or indirectly at the hospital. Meanwhile, in the context of the practice of health workers in general, people who receive health services are referred to as "health care recipients". Article 1 number 18 of Law Number 36 of 2014 Concerning Health Workers explains that "recipients of health services" is every person who conducts consultations on health to obtain the necessary health services, either directly or indirectly to health workers. There is no significant difference between the two terms because the emphasis is only on who provides the health services. However, what needs to be asked is whether patients in consumer protection law settings in Indonesia can be considered as consumers?

Kusumaningrum (2016) in his writing states that the Indonesian Consumers Foundation (YLKI) views that patients are consumers in health services. This statement is based on the assumption that the economic element is attached to health services. This economic element is seen through the existence of costs charged to patients for health services that have been provided from doctors or hospitals.

The argument that mentioning the finance element in health services as stated by the Indonesian Consumers Foundation (YLKI) is actually quite reasonable. Regarding the financing itself, whether in the context of medical practice or the practice of health workers, it is regulated in the laws and regulations in Indonesia. Article 53 letter d of Law Number 29 of 2004 Concerning Medical Practice states that providing compensation for services that have been received is one of the obligations of the patient. In addition, in the context of the practice of Health Workers, it is also stated in Article 57 letter c of Law Number 36 of 2014 Concerning Health Workers that health workers who carry out their practice are entitled to receive compensation for services. The existence of the regulations shows that there are economic elements in the implementation of health services which according to Government Regulation Number 47 of 2016 Concerning Health Service Facilities, including health efforts consisting

of promotive, preventive, curative, and rehabilitative efforts.

Another factor that can also be used as an argument to explain the position of patients as consumers can be seen through the existence of elements of health service promotion. Promotion as described in Article 1 point 6 of Law Number 8 of 1999 Concerning Consumer Protection is a form of activity aimed at introducing or disseminating information regarding goods and/or services with the aim of attracting consumers to buy goods and/or services that will and/or is being traded. Meanwhile, Article 1 number 1 of the Regulation of the Minister of Health Number 1787 of 2010 Concerning Health Service Advertisements and Publications explains that health service advertisements are a form of persuasive communication or introduction/promotion of health policies, programs, and/or services through images, sounds, and /or writing whose purpose is to attract interest and facilitate the public. According to the provisions of Article 1 point 3 of the Regulation of the Minister of Health Number 1787 of 2010 Concerning Health Services Advertising and Publication, advertising is a form of information that contains commercial elements and is of service to the public regarding the availability of services, goods, and ideas that can be utilized by the public with or without compensation. to the broadcasting institution concerned. It is very clear that these provisions indicate that a commercial element is also inherent in health services. Thus, every individual who receives information from advertisements and publications of health services to generate interest in getting what is informed should be viewed as a consumer (Ramadianto, 2021).

The existence of health workers as the spearhead of health services cannot be separated from the implementation of health services. This is considering that health services are a form of collaboration from various health professional professions that work together to complement each other in order to provide the best health services for the community. Based on the provisions in Article 11 of Law Number 36 of 2014 Concerning Health Workers, the professions included in the health workforce include doctors, dentists, and medical recorders.

The implementation of health services, of course, also requires a place to oversee the implementation of health services in the community. That is why, apart from health workers, the existence of health service facilities is also needed to support the success of health services. Based on the details in Article 2 of Government Regulation Number 47 of 2016 Concerning Health Service Facilities, it can be seen that the hospital is one type of health facility that provides health services for the community. Then, Article 20 paragraph 1 in conjunction with Article 21 of Law Number 44 of 2009 Concerning Hospitals states that hospital management can be classified into public hospitals and private hospitals. Meanwhile, private houses must be managed in the

form of a legal entity in the form of a Limited Liability Company with the aim of making a profit. Regarding the definition of Business Actor in the context of consumer protection law in Indonesia, it is explained in Article 1 number 3 of Law Number 8 of 1999 Concerning Consumer Protection. The provision explains that a business actor is any individual or business entity in the form of a legal entity or not a legal entity that is given and domiciled or carries out activities within the jurisdiction of the Republic of Indonesia, either alone or jointly through an agreement to carry out business activities in various economic fields. .

Based on the explanations that have been described previously, it can be clearly understood that patients in the perspective of consumer protection law in Indonesia are consumers. Meanwhile, health service providers consisting of health workers and hospitals are business actors who provide health services to patients. According to the legal perspective in Indonesia, these parties are two legal subjects who have equality before law. Thus, the relationship between the parties formed in the implementation of health services should be viewed as a legal relationship, each of whose rights and obligations are regulated in the legal provisions for consumer legal protection in Indonesia which are codified in Law Number 8 of 1999 Concerning Consumer Protection.

Regulation of the Minister of Health Number 129 of 2008 Concerning Minimum Service Standards for Hospitals states that the items contained in the informed consent form in the service of medical records in hospitals must be completely filled out. As explained in the research of Oktavia, Hardisman, & Eradius (2020), the completeness of the informed consent form in health services has various aspects of interest which include administrative, legal, educational, and research aspects. The administrative completeness of the informed consent form can clearly be used as one of the benchmarks for evaluating the quality of services in hospitals which will be used as one of the assessment parameters in medical audits and hospital accreditation. That is why the role of the medical recorder profession is also needed to ensure the quality of medical record files in hospitals.

Article 5 paragraph 2 of Law Number 36 of 2009 Concerning Health states that everyone has the right to obtain safe, quality, and affordable health services. This regulation is binding to all health workers and health care facilities in Indonesia who provide services to the community as patients. That is why as stated in Article 29 paragraph 1 letter b of Law Number 44 of 2009 Concerning Hospitals in conjunction with Article 2 paragraph 1 letter b of Regulation of the Minister of Health Number 4 of 2018 Concerning Obligations of Hospitals and Patients, hospitals have an obligation to provide services safe, quality health, anti-discrimination, and effective by prioritizing the interests of patients in accordance with hospital service standards. One of



the consequences for the hospital as a business actor is to ensure that the informed consent form is filled out completely within 1 month. This action must be carried out by business actors considering the provisions in Article 7 letter e of Law Number 8 of 1999 Concerning Consumer Protection which states that business actors have an obligation to guarantee the quality of goods and/or services produced and/or traded based on standard provisions. the applicable quality of goods and/or services. The existence of this regulation arises as a consequence of the arrangement in Article 4 number of patient rights which is as regulated in Article 4 point 7 of Law Number 8 of 1999 Concerning Consumer Protection which states that consumers have the right to be treated or served correctly and honestly and non-discriminatory.

Fulfilling the completeness of the informed consent form is not only to fulfill the rights of consumers to obtain services that meet the standards but also as a form of fulfillment of the legal rights owned by consumers. Article 4 point 5 of Law Number 8 of 1999 Concerning Consumer Protection states that consumers have the right to obtain advocacy, protection, and efforts to resolve consumer protection disputes properly. In the context of health services, these provisions indicate that patients as consumers in health services have the legal rights to be protected. One of the legal rights in question is to use an informed consent form that is documented in the medical record file as legal evidence to defend their rights that are allegedly violated by business actors.

It is undeniable that the practice of providing health services at hospitals in Indonesia does not always run smoothly. The existence of a conflict of interest between patients and health care providers will not infrequently cause problems. When the problem that has occurred cannot be resolved through mediation, it will be very possible for the patient as one of the disputing parties to exercise their right to resolve the case through the courts. As regulated in Article 44 letter q of Law Number 44 of 2009 Concerning Hospitals, patients have the right to sue the hospital either through civil and criminal law if it is suspected that the hospital provides services that are not in accordance with standards,

The existence of legal evidence is needed as an instrument to resolve legal cases in court. As stated in Chintia & Kusumaningrum's research (2020), medical records can be used as legal evidence in the form of letters or expert statements according to the provisions in Article 186 in conjunction with Article 187 of the Criminal Procedure Code. The informed consent form as regulated in Article 3 of the Regulation of the Minister of Health Number 269 of 2008 Concerning Medical Records is one of the records that must be documented in the medical record file. This requirement applies especially to the medical record files of patients who receive medical intervention in the form of surgery.

As stated by Oktavia, Hardisman, & Eradius (2020)

in their research, the completeness of filling out the informed consent form from the legal aspect clearly plays an important role as legal evidence to resolve legal cases between patients and health workers and/or hospitals. When there is a legal conflict between patients and health workers, of course, this condition will also drag the hospital which has a role as a health facility that oversees the implementation of health services provided to these patients. That is why as a form of defense against patient demands and/or lawsuits, hospitals as health service providers need to ensure that the services provided meet service standards. One of them concerns the issue of the completeness of filling out the informed consent form. This action needs to be taken because as stated by Singh, Patnaik, Kapoor, Chaturvedi, & Srivastava (2014) that one of the preventive measures that can be taken to prevent claims or lawsuits from patients is to carry out proper management of medical record files.

### Legal Responsibility of Business Actor for The Incompleteness Filling of Informed Consent Form on The Medical Record Services in Indonesia

The description of the data from the analysis of the completeness of filling out the informed consent form at Pertamina Bintang Amin Hospital in 2018 shows that the medical record service at the hospital has not met the minimum service standards as stated in the Regulation of the Minister of Health Number 129 of 2008 Concerning Minimum Service Standards for Hospitals. The incomplete informed consent form clearly violates the provisions in Article 29 paragraph 1 letter b of Law Number 44 of 2009 Concerning Hospitals in conjunction with Article 2 paragraph 1 letter b of Regulation of the Minister of Health Number 4 of 2018 Concerning Obligations of Hospitals and Patients who require hospitals to provide health services in accordance with hospital service standards. In addition, failure to comply with the standard for completing the informed consent form, according to the perspective of consumer protection law in Indonesia, is a form of violation by business actors of the provisions in Article 8 paragraph 1 letter a of Consumer Protection Act which states that business actors are prohibited from producing and/or trading goods/services that do not meet or are not in accordance with established standards requirements and provisions of laws and regulations.

Violations by the hospital as a business actor not only result in the violation of the patient's right to obtain quality health services. The best fulfillment of the completeness of filling out the informed consent form resulted in the violation of the legal rights of the patient. The informed consent form, of course, cannot be used as legal evidence. Such conditions of course cause harm to patients who are suspected of being victims of malpractice. Without a complete informed consent form, it can be difficult for the patient to prove any kind of patient's rights violation,

although this can also exacerbate the mistakes of business actors.

Article 19 paragraph 1 of Law Number 8 of 1999 Concerning Consumer Protection states that business actors are responsible for providing compensation for losses, whether in the form of damage, pollution, and/or consumer losses. The loss must of course be caused because the consumer has consumed the goods and/or services produced or traded by the business actor. Article 19 paragraph 2 of Law Number 8 of 1999 Concerning Consumer Protection also explains that the form of compensation provided by business actors can be in the form of refunds or replacement of goods and / or services of a similar type or value of equivalent, or can also be in the form of health care and / or compensation provided in accordance with applicable laws and regulations. As stipulated in Article 19 paragraph 3 of Law Number 8 of 1999 Concerning Consumer Protection, the grace period for giving compensation must be met within 7 days after the transaction is made.

Patients who suffer losses due to the violation of these rights, as regulated in Article 19 of Law Number 8 of 1999 Concerning Consumer Protection, have rights to receive compensation, compensation and/or reimbursement for having received health services that do not meet the standards stipulated in the legislation. Therefore, business actors are obliged to provide compensation for material losses to patients as consumers, both the fulfillment of the right to obtain a completely filled out informed consent form and loss of costs arising from being affected by the violation of these rights. In addition, business actors should also provide compensation for immaterial losses suffered by patients. Fulfillment of compensation for the patient's loss must be given by the business actor not later than 7 days from the first time the patient finds out that the informed consent form related to certain medical actions that have been carried out on him is not completely filled out.

If the claim is rejected and/or there is no response and/or compensation is not fulfilled, then according to the provisions of Article 23 of Law Number 8 of 1999 Concerning Consumer Protection, the patient as a consumer can file a lawsuit against the business actor through the Consumer Dispute Settlement Agency (BPSK) or through the court where position of the plaintiff. Based on the provisions in Article 45 paragraph 1 of Law Number 8 of 1999 Concerning Consumer Protection, patients as consumers can file a lawsuit against the perpetrator through other institutions authorized to resolve disputes between consumers and business actors outside the court (non-litigation) or through general courts (litigation). Article 45 paragraph 2 of the Law Number 8 of 1999 Concerning Consumer Protection states that the settlement of disputes between consumers and business actors, whether it is carried out through a court or through an institution outside the court, must be based on the voluntarism of the parties to

the dispute. Article 45 paragraph 3 of Law Number 8 of 1999 Concerning Consumer Protection also states that the criminal responsibility of business actors for the violation of the patient's right to obtain the contents of the medical record cannot be immediately eliminated even if the dispute resolution is carried out out of court. Submission of a lawsuit by a patient through the court, as regulated in Article 45 paragraph 4 of Law Number 8 of 1999 Concerning Consumer Protection, can only be conducted if the dispute resolution efforts outside the court are declared to have produced no results by one of the parties or the parties in dispute.

Unlike in Civil Law regulation, the Consumer Protection Law adheres to the rebuttable presumption of liability principle. Thus, the business actor as the defendant is charged with the obligation to prove that the loss suffered by the patient was not his fault (Heriani, 2018). The application of this principle is regulated in Article 28 of Law Number 8 of 1999 Concerning Consumer Protection which states that proving the presence or absence of an element of error in a claim for compensation is the burden and responsibility of the business actor.

If the business actor cannot prove that the loss suffered by the patient as a consumer is not caused by the element of negligence and intentional negligence on the part of the defendant, the business actor is obliged to compensate the patient who filed the lawsuit. The burden of proof that is delegated to business actors in the context of health services is of course quite beneficial for patients. This is given that only business actors fully understand how the flow of service procedures should be carried out at the health facilities where health services are provided.

The Consumer Protection Act does not provide any restrictions regarding which legal subjects can be sued when a patient suffers a loss. Consumers who are harmed can file a lawsuit against all parties declared as business actors by the Consumer Protection Law (Heriani, 2018). Thus, lawsuits can be filed either to doctors, dentists, other health workers, and even to health facilities when patients feel aggrieved because of the violation of the right to obtain health services that comply with minimum service standards and legal rights are not fulfilled. In principle, every party involved in the violation of the patient's rights must be held responsible for the mistakes that have been made

The Consumer Protection Act does not specifically regulate what kinds of evidence can be used in proof. Thus, the general provisions in the Civil Procedure Code regarding the types of evidence that can be used as evidence in civil cases apply. The defendant may use witness statements and suspicions to assist him in proving his denial of wrongdoing that results in harm to consumers (Sutedi, 2008).

Based on the provisions in Article 19 paragraph 4 in conjunction with Article 61 of Law Number 8 of 1999 Concerning Consumer Protection, criminal charges



due to violation of the patient's right to obtain record contents cannot be simply dismissed even if the business actor has fulfilled the compensation for the patient. These criminal charges can not only be imposed on doctors, dentists, or other health workers, but can also be imposed on health facilities who took part in the violation. However, of course the violation of the patient's rights can only be a offense as long as the criminal elements in the case can be proven by the authorities. As regulated in Article 62 paragraph 1 of Law Number 8 of 1999 Concerning Consumer Protection, violation of the obligations of business actors, one of which is regulated in Article 8 of the Consumer Protection Law, will result in consequences in the form of imprisonment for a maximum of 5 (five) years or a criminal fine. with a maximum amount of Rp. 2,000,000,000.00 (two billion rupiah).

## 5. Conclusion

The completeness of filling out the informed consent form in the medical record service at the hospital contains the protection of the patient's rights as consumers. Violation of these rights can lead to a violation of the consumer's right to obtain health services in hospitals that meet the standards in the legislation. In addition, a failure to ensure the completeness of filling out the informed consent form is the same as ignoring the legal rights of consumers. In order to protect the rights of these patients, consumer protection legal instruments in Indonesia require business actors to provide compensation to patients. Consumers are also allowed to file claims and lawsuits. Based on these conclusions, it can be said that this study provides a new formulation regarding the protection of patient rights as consumers regarding the completeness of filling out an informed consent form in medical record services in hospitals.

Through this research, the government of the Republic of Indonesia is expected to be able to immediately reform Law Number 8 of 1999 Concerning Consumer Protection as a legal instrument of consumer protection in Indonesia. It is also necessary to update the legal regulations to expand the scope of consumer protection to include the protection of patient rights in health services. The researcher also wants to suggest that the laws and regulations related to health services should be summarized as a legal instrument in order to better fulfill legal certainty and minimize multi interpretations.

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## 6. Regulations