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ORIGINAL RESEARCH

Legal protection of the patient's right to access medical records in Indonesia

Rano Indradi Sudra[1,2], Sarsintorini Putra[2], Inge Hartini[3]

[1] Politeknik Rukun Abdi Luhur, Kudus, Indonesia;
[2] Universitas 17 Agustus 1945, Semarang, Indonesia;
[3] Universitas Katolik Soegijapranata, Semarang, Indonesia.

Corresponding author: Rano Indradi Sudra;
Address: Universitas 17 Agustus 1945, Semarang, Indonesia.
E-mail: rano.indradi@gmail.com

Abstract

Background: Patient access rights to medical records are related to the retention period because they can only be accessed as long as they have not been destroyed. The study aims to identify the corresponding regulations to assess the legal protection of the patient's right to access her/his medical record.
Methods: Tracing and identifying primary legal sources in regulatory content related to patient rights of access. An analysis was conducted on the clarity and consistency of the contents identified.
Results: Regulations identified regarding patients' rights to access their medical records are Law number 29 of 2004, Government Regulation number 47 of 2021, and Minister of Health Regulation number 269 of 2008. The regulations governing the retention period of medical records are Law number 11 of 2008, Law number 44 of 2009, Government Regulation number 46 of 2017 and number 71 of 2019, Minister of Health Regulation number 269 of 2008, number 82 of 2013, and number 46 of 2017.
Conclusions: The condition of disharmony and inconsistency among regulations governing patient access rights and the retention period of medical records creates uncertainty for patients to access their medical records.

Keywords: *Indonesia, legal protection, medical records, patients' rights.*

Conflicts of interest: None declared.

Background

Health as a human right must be realized by offering various health efforts to the entire community through the implementation of quality and affordable health development by the community (1). Health service facilities are required to provide the necessary services in administering and keeping adequate medical records. The International Federation of Health Information Management Associations (IFHIMA), in its 2019 edition of 'Learning module-1' defines medical records as "A collection of written information about patients since the patient arrived at the hospital, clinic or primary healthcare. The medical record is a record of all procedures performed on a patient, containing the patient's past medical history, including opinions, investigations, and other details relevant to the patient's health". Medical records contain notes and documents about the patient's identity, examination, treatment, action, and other services that have been provided to the patient (2). The medical record, as stated in the Medical Record Manual of the World Health Organization (WHO), must contain sufficient data to be used to identify the patient, support the diagnosis or state the main reason the patient came to the health care facility, validate the reason for offering the procedure and document all the results accurately (3).

Patient access rights in Indonesia:

Chapter VIII, Article 29 paragraph 1 (h) in Law number 44 of 2009 concerning Hospitals in Indonesia states that "Every Hospital has an obligation to maintain medical records." The explanation of the paragraphs states that "What is meant by the administration of medical records in this paragraph is carried out in accordance with standards that are gradually revised to reach international standards." The Hospital Accreditation Commission (KARS) in the National Hospital Accreditation Standard (SNARS) edition 1.1 of 2019 states that "Medical records are written evidence (paper/electronic) that record various patient health information such as assessment findings, care plans, details of care implementation and treatment, integrated patient progress records, and discharge summaries prepared by the care professional (PPA)" (4). Article 7 of Law Number 36 of 2009 concerning Health states that "Everyone has the right to get information and education about balanced and responsible health." Furthermore, in article 8, it is stated that "Everyone has the right to obtain information about his health data including actions and treatments that have been or will be received from health workers." In this provision, it is also explained that health information in the context of this provision is private health information so that only those entitled have access, especially the patient concerned (5).

Article 12 paragraph (3) of the Regulation of the Minister of Health number 269 of 2008 concerning Medical Records states that the contents of the medical record belong to the patient in the form of a summary of the medical record which can then be given, recorded, or copied by the patient or person who is authorized or has written consent from the patient or the patient's family (2). Article 47 paragraph (1) of Law number 29 of 2004 concerning Medical Practice also states that the contents of the medical record are the patient's property. Article 52 (e) states that the patient has the right to obtain the contents of the medical record and not only in the form of a summary of the medical record (1). As the owner of the information in the medical record, the patient has the right to obtain his/her information and determine the parties who are authorized to participate in accessing the information in his/her medical record (2). If the health service facility already uses electronic medical records, then the technique for obtaining information in the medical record is realized by accessing the electronic medical record system. Access to an electronic system, including electronic medical records, can only be done if a person is authorized by the electronic medical record system (given the right to access).

Present regulations for storage

In order for something to be accessible, it must exist. The existence of medical records is related to the arrangement of the shelf life or retention. Regulations regarding the retention

period of medical records are contained in articles 8 and 9 of the Regulation of the Minister of Health number 269 of 2008 concerning Medical Records, Circular (SE) of the Director-General of Medical Services no. HK.00.06.1.5.01160 dated March 21, 1995, concerning Technical Instructions for Procurement of Record Forms Basic Medical and Destruction of Medical Record Archives in Hospitals, article 55 of the Republic of Indonesia Law number 44 of 2009 concerning Hospitals, and article 21 paragraph (5) of Government Regulation of the Republic of Indonesia number 46 of 2014 concerning Health Information Systems. The regulations related to the retention period of medical records mentioned above still do not harmoniously regulate the period of storage (retention), types of medical records (paper or electronic), active/inactive medical record groups, and which data/sheets are stored/destroyed.

Actual regulatory developments

Consistent regulation of patient access rights to medical records is essential and urgent considering the strategic plan of the Ministry of Health for 2020-2024 as stated in Minister of Health Regulation number 21 of 2020. The plan targets all hospitals in Indonesia to apply integrated electronic medical records. If medical records "can" be destroyed after a retention period of 10 years, patients will lose their access rights. This study aims to identify patient access rights to medical records and regulations related to the retention period of medical records to assess the legal protection for patients' rights to access their medical records.

Methods

This research is empirical juridical research using secondary data collected through document studies on various legal materials and non-legal materials that support the focus of this study. The data and information obtained in this study will be presented and developed comprehensively in descriptive narratives to support the conclusion.

Results

The author's initial survey of 50 hospitals participating in the readiness assessment and development of electronic medical records in 2018-2019 (divided into six training batches) showed that none of these hospitals provided patients with access to electronic medical records and did not even plan to provide these features.

Although it has been stated in the Minister of Health Regulation number 269 of 2008 concerning Medical Records and Law number 29 of 2004 concerning Medical Practice that the patient is the owner of the contents of the medical record and has the right to access his property, the regulation does not contain the patient's access rights.

A complete and good medical record must include all information about the patient's health and treatment during the period of service and be easily accessible. Medical records must be kept for a predetermined period so that they can be used for:

a. communication needs between service providers and patients and between service providers,
b. source of continuity of service and patient care data,
c. evaluation of patient care,
d. medicolegal needs,
e. the need for health service statistics,
f. sources of research and education data, and
g. history-related needs (6).

Article 46 paragraph (1) of Law number 29 of 2004 concerning Medical Practice states that what is meant by "medical record" in the situation of Indonesia: It is a file containing records and documents regarding patient identity, examination, treatment, action, and other services that have been provided to patients. Regarding the manufacture of medical records, Regulation of the Minister of Health number 269 of 2008 concerning Medical Records Article 2 paragraph (1) states that "Medical records must be made in writing, complete and clear or electronically." A good medical record is a medical record that contains all the required information, whether

obtained from the patient, the doctor's thoughts, examinations, and actions of the doctor, communication between medical/health personnel, informed consent, and other information that can be evidence in the future, which arranged sequentially (chronologically). Medical records also show what health service providers have done, which can be compared with what should be done as stated in professional standards and standard operating procedures, which is proof of whether or not there is a violation of obligations and the presence or absence of losses resulting from it (7).

Medical Record Ownership

As a document containing notes about the patient's medical history, ownership of medical records is regulated in Article 47 paragraph (1) of Law Number 29 of 2004 concerning Medical Practices and Article 12 of Regulation of the Minister of Health Number 269 of 2008 concerning Medical Records which states that the medical record file belongs to the health service facility and its contents belong to the patient in the form of a summary of the medical record, this summary of medical records can be provided, recorded, or copied by the patient or person authorized or written consent of the patient or patient's family who is entitled to it.

Access to Electronic Data and Information

In the Kamus Besar Bahasa Indonesia (KBBI), data is defined as: 1) true and real information; and 2) real information or material that can be used as the basis for a study (analysis or conclusion). Meanwhile, information is defined as "the whole meaning that supports the message seen in the parts of the message." Article 1 paragraph (1) of Law number 19 of 2016 concerning Amendments to Law number 11 of 2008 concerning Electronic Information and Transactions states that "Electronic Information is one or a set of electronic data, including but not limited to writing, sound, images, maps, designs, photographs, electronic data interchange (EDI), electronic mail (electronic mail), telegram, telex, telecopy or the like, letters, signs, numbers, Access Codes, symbols, or processed perforations that have meaning or can understood by those who can understand it." In paragraph (4), it is stated that "Electronic Document is any Electronic Information that is created, forwarded, sent, received, or stored in analog, digital, electromagnetic, optical, or similar forms, which can be seen, displayed, and/or heard through a computer or electronic systems, including but not limited to writing, sounds, pictures, maps, designs, photographs or the like, letters, signs, numbers, access codes, symbols or perforations that have a meaning or can be understood by people who are able to understand them."

Article 1 of Law Number 14 of 2008 concerning Disclosure of Public Information states that what is meant by information is "…information, statements, ideas, and signs that contain values, meanings, and messages, both data, facts, and explanations that can be seen, heard, and read which is presented in various packages and formats in accordance with the development of information and communication technology electronically or non-electronically. "From this understanding, electronic medical records meet electronic documents and information criteria. In the concept of national law, health information is one type of public information that is formulated in several statutory provisions, one of which is formulated in the Law on Public Information Disclosure as described above (8).

Regulations Regarding Access to Medical Records

In the fourth amendment to the 1945 Constitution of the Republic of Indonesia, the provision of articles on human rights (HAM) as a form of guarantee for their protection is stated in a separate chapter, namely in Chapter XA with the title "Human Rights." Regarding the protection of personal rights, it is regulated in the 1945 Constitution of the Republic of Indonesia Article 28G paragraph (1), which states that "Everyone has the right to the protection of his personal, family, honor, dignity, and property under his control, and has the right to a sense of security and protection from the threat of fear to do or not do

something which is a human right." Data protection laws such as the European Union Data Protection Directive (EU DP Directive) distinguish data based on the level of harm that will be felt to individuals in the event of unauthorized processing of data into "sensitive data" and "non-sensitive data. "Sensitive" data usually get better legal protection. For example, consent must be explicitly stated in a written statement. The European Union Data Protection Directive prohibits the processing of sensitive data unless express consent has been obtained from the data owner. The data includes information regarding ethnicity, political opinions, religion and beliefs, membership of trafficking organizations as well as data related to a person's health and sex life (9). The protection of the patient's medical history is contained in Article 57 paragraph (1) of Law Number 36 concerning Health which recognizes the right of everyone to the confidentiality of his personal health condition that has been presented to the health service provider. Furthermore, Article 57 paragraph (2) regulates the provisions for the exception to the confidentiality of personal health conditions which do not apply in terms of 1. statutory orders; 2. court order; 3. the permit in question; 4. public interest; or 5. the interest of the person.

Discussion

A right is a claim that one person can make to another up to the limits of the exercise of that right. Rights contain protection and interests and will. Meanwhile, rights are protected by law, while interests are individual, or group demands expected to be fulfilled. Interest essentially contains the power guaranteed and protected by law in carrying it out. Rights are normative elements inherent in every human being, and their application is within the scope of equal rights and freedoms related to their interactions between individuals or institutions (10).

Rights are something that must be obtained. There are two theories about this. The first theory, which states that granting rights is to be done, owned, enjoyed, or has been done. The second theory states that granting full rights is an integral part of a valid claim (the benefits obtained from the exercise of rights accompanied by the implementation of obligations). Thus, benefits can be obtained from the exercise of rights when accompanied by the implementation of obligations (11).

There is an interaction between service providers and health service recipients (patients) in health services. Article 32 of Law number 44 of 2009 concerning Hospitals, in letter (i), regulates patients' right to obtain privacy and confidentiality of the illness they suffer, including their medical data. Letter (l) in this article requires hospitals to provide true, clear, and honest information regarding the rights and obligations of patients. Whereas in letter (m) this article requires hospitals to respect and protect patients' rights. This medical secret is further regulated in the Regulation of the Minister of Health number 36 of 2012 concerning Medical Secrets. This Regulation of the Minister of Health was prepared to comply with Article 48 paragraph (1) of Law No. 29 of 2004 concerning Medical Practice and Article 38 Paragraph (3) of Law No. 44 of 2009 concerning Hospitals. Article 4 of this Regulation of the Minister of Health confirms that all parties involved in medical services must maintain patients' medical confidentiality using data and information about patients. The obligation to keep medical secrets applies forever, even if the patient has died (12). In article 52, paragraph (e) of Law number 29 of 2004 concerning Medical Practice, it is stated that patients have the right to obtain the contents of the medical record in receiving services in medical practice.

The Health Insurance Portability and Accountability Act (HIPAA) states that patients have the right to view and obtain copies of their medical records. In this regard, HIPAA allows healthcare providers to charge a reasonable fee to provide these copies. Such costs may include only the costs of labor and materials required to copy and transmit and may not include the costs of locating and retrieving the information. Supporting and facilitating patient access to health information through patient portals is perhaps the most significant cultural shift for the health

information management (MIK) profession since the emergence of prospective health care payment methods and DRG (13).

The right of access to electronic medical records requires terms and conditions in its implementation, including (but not limited to):

a. Access subject
b. Access permission policies and procedures
c. How to access
d. Place and means of access
e. Accessed data area
f. Access time limitation
g. Activity restrictions on access
h. Access activity audit trail

Ownership is defined as "the ability to exercise complete sovereignty over information, to disclose, sell, destroy, alter, or determine who will have access to the information." Given this potential complexity, it is necessary to redefine the concept of "ownership" regarding access, use, and control of health data by each entity that creates, produces, or stores health information. The question of "Who can do what for what data and under what circumstances" is the main question that must be asked in determining the rights and responsibilities of each stakeholder (14).

The definition of access is an activity to interact with an Electronic System that is stand-alone or in a network. Access activities may include (but are not limited to) open, view, add, crop/reduce, edit, delete, copy, cut, paste, move, send / forward, and print. This access activity is associated with ownership of the thing being accessed, for example, information in electronic medical records. As the owner of the contents of the medical record, the patient has the right to access his electronic medical record. Access to electronic medical records can be set individually, time, duration, area accessed access method, the time limit for access. The system developed should record and track access activities to the system (audit trail), including (but not limited to) access date, access hours, accessor identity, information area accessed, activity during access (15). Interoperability is one of the keys to access to electronic medical records.

In addition to interoperability, patient education and additional tools that can help make it easier for patients to coordinate their information and care are also very important (16). When they leave the health facility, treatment plan sheets, discharge summaries, and data transfers should be provided to patients. Other information should be accessible to the patient within a few days, and when requested during admission and care, up-to-date information should be shared with the patient (17). There needs to be harmonization and equalization (standardization) to provide patient health information in electronic standards that are easy for patients to use. Greater access to usable electronic health information in standardized formats could improve health literacy, communication between patients and health care providers, coordination of care, and overall quality of care (18). The regulation that regulates the contents of medical records as belonging to patients is Article 12 paragraph (3) of the Regulation of the Minister of Health number 269 of 2008 concerning Medical Records, which states that the contents of medical records belong to the patient in the form of a summary of medical records which can then be given, recorded, or copied. by the patient or person authorized or written consent of the patient or patient's family who is entitled to it. It should be noted here that a summary of medical records is made at the end of the service episode. This summary is only available after the patient has finished undergoing his service episode. This can create uncertainty regarding ownership of medical records when patients are undergoing service episodes. Does it mean that the patient is considered not to have the contents of the medical record while undergoing an episode of service? If at the time of undergoing an episode of service, the patient is placed not as the owner of the contents of the medical record (because the summary sheet of the medical record has not been made and will only be made after the episode of service is completed), does it mean that the patient does not have the right to access the contents of his medical record before the episode of service is

completed? If so, then who is the owner of the contents of the medical record at that time? This condition is different from what is stated in Article 47 paragraph (1) of Law Number 29 of 2004 concerning Medical Practice, which states that the contents of the medical record are the property of the patient, and Article 52 (e) states that the patient has the right to obtain the contents of the medical record and not mentioned in the form of a summary of the medical record. Referring to this article means that the patient has been the owner of the contents of the medical record since the medical record was made. The inconsistency between the regulations mentioned above can create legal uncertainty regarding the ownership and access rights of patients to their medical records. With a retention period of 10 years for the discharge summary sheet (which is also a summary of the medical record), it means that this sheet can be destroyed after being stored for ten years from the date the sheet was made (Regulation of the Minister of Health number 269 of 2008 concerning Medical Records Article 8). After this sheet is destroyed, how is the patient's right to the contents of the medical record which according to Article 12 paragraph (3) of the Regulation of the Minister of Health number 269 of 2008 states that this patient's right is given in the form of a summary of the medical record? Does it mean that the patient no longer has the right to access his medical records after the discharge summary sheet is destroyed?

Conclusions

Present regulations in Indonesia governing ownership and access rights of patients to their medical records have not clearly and firmly defined all necessary aspects of access to medical records in writing or electronic.

The disharmony and inconsistency of regulations can create uncertainty in the legal protection of patients' rights to access their medical records. The electronic medical record system that has been developed and/or implemented does not yet provide a feature that allows patients to access their electronic medical records so that the patient's access rights to the electronic medical record cannot be realized. Hospitals as medical record managers (paper-based and electronic-based) need to improve their understanding of the implementation of regulations related to the retention of medical records and the rights of patients to access medical records.

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