LEGAL RESPONSIBILITIES OF THIRD PARTIES AND HOSPITALS REGARDING THE IMPLEMENTATION OF ELECTRONIC MEDICAL RECORDS

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Abstract

Medical records are simply a history of health services and illnesses faced by patients. The use of electronic medical records is predicted to be the most effective method of reducing errors, improving the quality of health services, and reducing costs. With the recommendation for the use of electronic medical records, many health service providers are implementing electronic medical records in an effort to improve service quality, increase patient satisfaction, and reduce medical errors. In Minister of Health Regulation no. 269 of 2008 Chapter II article 2 states that: (1) Medical records must be made in writing, complete and clear or electronically. (2) The administration of medical records using electronic information technology is further regulated by separate regulations. Before the issuance of Regulation of the Minister of Health of the Republic of Indonesia Number 24 of 2022 concerning Medical Records. The problem arises that to create an electronic medical record system, hospitals must entrust people or institutions who are competent to create a medical record system that can be accessed electronically. What about the confidentiality of the medical record history contained in it, can the third-party company access the electronic medical record system easily? Using normative juridical research methods, the author explores and learns from various sources the rules regarding the legal responsibilities of third parties and hospitals regarding the implementation of Electronic Medical Redord. The conclusion from this research is that in fact third parties are free from legal responsibility if later problems arise such as system leaks from the system that has been built. Please note that the warranty or maintenance period has passed, and the third party's connection cannot be proven.

Keywords: responsibility, electronic medical records, third parties.

INTRODUCTION

The flow of globalization has been unstoppable in entering Indonesia, technological developments have become increasingly sophisticated, the world is now entering the era of industrial revolution 4.0 which emphasizes digital economy patterns, artificial intelligence, big data and so on or what is called the phenomenon of disruptive innovation, this development of course extends to all sectors of life, including the health sector.

The world of health (medical) is an information intensive field, every day it produces data and information from the results of patient health service transactions. To balance the flow of information, a health service facility from primary to advanced level must have information and communication technology to support its management activities. All information relating to patient service transactions, starting from history taking, physical examination, support, diagnosis, procedures and other services must be recorded completely and clearly in a patient's medical record.

It is not surprising that medical records are now the spearhead in a health service facility. The process of recording, processing, storing data and information must also be accessible quickly. Electronic medical records are a big challenge in the application of

information and communication technology in health service facilities. According to Johan Harlan, the role of electronic medical records includes:

1. Patient data integration

   Electronic medical records can be used as a repository (data warehouse) for several components or parts in a health service facility.
2. As clinical decision support

   Electronic medical records can be used as a rule engine, which can be used to support clinical decisions such as warning systems, clinical protocols and so on.
3. As an integrated communication tool

   An electronic medical record will produce aggregate data that can be analyzed to support decision making. This data can be communicated in the form of text, images, sound and others.
4. As access to sources of knowledge

   Electronic medical records can be used as access to developments in medical science.
5. Entering clinician orders

   Electronic medical records can be used as a data capture tool and have the ability to access data and process data through aggregate data. From the discussion in the article above, we know that electronic medical records are a requirement for every health service facility to improve service quality. As for the key to successful implementation, EMR cannot be separated from the government's role in preparing standards and regulations regarding the use of EMR in health services.

The use of electronic medical records is recommended as a method to reduce errors, improve the quality of health services, and reduce costs. With the recommendation for the use of electronic medical records, many health service providers are implementing electronic medical records in an effort to improve service quality, increase patient satisfaction, and reduce medical errors. However, until now there are no government regulations that specifically regulate the administration of electronic medical records.

In Minister of Health Regulation no. 269 of 2008 Chapter II article 2 states that: (1) Medical records must be made in writing, complete and clear or electronically. (2) The administration of medical records using electronic information technology is further regulated by separate regulations.

Paragraph (1) indicates that medical records can and may be made electronically. However, referring to paragraph (2), until now there are still no further regulations that specifically discuss the administration of medical records using information technology.

The regulations that can be referred to currently governing electronic transactions in general are Law no. 11 of 2008 concerning Information and Electronic Transactions which we know as the ITE Law.

In the ITE Law, it is stated that there are the terms "electronic signature", "electronic certificate", and "electronic certification provider". Electronic signatures are attached to electronic certificates issued by electronic certification providers. The detailed contents of the law are:

Electronic Signature is a signature consisting of Electronic Information that is attached, associated or related to other Electronic Information that is used as a verification and authentication tool.

An electronic Certificate is an electronic certificate containing an Electronic Signature and identity indicating the legal subject status of the parties in an Electronic Transaction issued by an Electronic Certification Organizer.

Electronic Certification Provider is a legal entity that functions as a party worthy of trust, which provides and audits Electronic Certificates.

Next, it is explained that "Business actors who offer products through Electronic Systems must provide complete and correct information regarding contract terms, manufacturers and the products offered." Article 9 of Law Number 11 of 2008 explains that writing patient information including related matters in medical records must be appropriate, so complete data is very necessary. Legal protection for patient data regarding privacy, confidentiality and security of patient information in general still does not have a clear legal umbrella.

In Indonesia, the regulation of electronic medical records has not been specifically regulated (before the issuance of Regulation of the Minister of Health of the Republic of Indonesia Number 24 of 2022 concerning Medical Records) but in practice in the field there are already several hospitals that implement electronic medical records, so what is the power of electronic medical records for medical equipment? evidence in court when a medical dispute occurs. What are the legal regulations for administering electronic medical records in hospitals, what are the rights and obligations of third parties and hospitals in administering electronic medical records, what are the legal responsibilities of third parties and hospitals regarding the administration of electronic medical records. Some of the problems above are the focus of the author's research.

METHOD

This research is normative juridical research, namely research that reveals a problem, situation or event by providing a comprehensive, broad and in-depth assessment from the perspective of legal science, namely by examining legal principles, legal rules and legal systematics.

In collecting data, document study was used, namely by studying secondary materials, in the form of legislation, other regulations, court decisions regarding health cases as well as books, papers and journals related to what was studied. The data obtained is then analyzed qualitatively, namely a data analysis method that is not based on numbers or statistics, so that the data obtained in library research is then presented in logical sentences to obtain a description of the Legal Responsibility of Third Parties and Hospitals. Implementation of Electronic Medical Records.

RESULTS AND DISCUSSION

Regulation of Electronic Medical Records in Regulation of the Minister of Health of the Republic of Indonesia Number 24 of 2022 concerning Medical Records.

That since the birth of Regulation of the Minister of Health of the Republic of Indonesia Number 24 of 2022 concerning Medical Records, it is hoped that health services in this country will improve, which has replaced Minister of Health Regulation No. 269 of 2008 which is considered outdated and not updated. In particular, Regulation of the Minister of Health of the Republic of Indonesia Number 24 of 2022 concerning Medical Records adds 3 points from the old Minister of Health Regulation on electronic medical record systems, activities for administering electronic medical records, security and protection of electronic medical record data.

Article 18 Minister of Health Regulation No. 24 of 2022:

(1). Processing of Electronic Medical Record information as intended in Article 13 paragraph (1) letter d consists of:
   a. coding;
   b. reporting; And
   c. analysis.

(2). Coding as referred to in paragraph (1) letter a is the activity of assigning clinical classification codes in accordance with the latest international classification of diseases and medical procedures/International Statistical Classification of Disease and Related Health Problems, in accordance with the provisions of statutory regulations.

(3). Reporting as intended in paragraph (1) letter b consists of:
   a. internal reporting of Health Service Facilities; And
   b. external reporting from Health Service Facilities to the health department, Ministry of Health, and related stakeholders.

(4). The analysis as intended in paragraph (1) letter c is carried out on Electronic Medical Record data quantitatively and qualitatively.

(5). In addition to processing Electronic Medical Record information as intended in paragraph (1), Health Service Facilities which for certain reasons cannot maintain Electronic Medical Records must carry out indexing.

(6). Indexing as referred to in paragraph (5) is a data grouping activity at least in the form of an index:
   a. patient's name;
   b. address;
   c. the type of disease;
   d. operation action; And
   e. death.

Legal Responsibilities of Third Parties and Hospitals Regarding the Implementation of Electronic Medical Records

Medical records are an activity that is required in the provision of health services as regulated in statutory regulations which are the legal basis for implementing medical record activities. The legal basis for implementing electronic medical records is in addition to the statutory regulations governing medical records, more specifically regulated in Minister of Health Regulation No. 269 of 2008 concerning Medical Records article 2: (1) Medical records must be made in complete, clear writing or electronically, (2) The administration of medical records using electronic information technology is further regulated by separate regulations. According to statutory regulations, medical records must be kept and kept confidential because the data contained in the medical record belongs to the patient, this obligation is the responsibility of the doctor or dentist and the head of the health service facility.

The use of computers as a means of creating and sending medical information is an effort that can speed up and extend the movement of medical information for the sake of accurate medical procedures. However, on the other hand, it can create new problems in the field of patient confidentiality and privacy. If a patient's medical data falls into inappropriate hands, it will cause legal problems, and responsibility must be borne by the doctor or the hospital. For this reason, the standards for implementing and storing medical records that currently apply to paper files must also be applied to digital/electronic files. Generally, computerization does not make medical records paperless but only paperless. Some data such as identity data, informed consent, consultation results, radiology and imaging results must remain in paper form (print out). The Council of World Medical Associations in the field of ethics and law issued provisions in this field in 1994, some important guidelines are:

1) Medical information is only entered into the computer by authorized personnel.
2) Patient data must be closely guarded. Each particular personnel can only access certain data that is appropriate using a certain level of security.
3) No information can be disclosed without the patient's permission. Distribution of medical information should be limited to authorized persons only. These people are also not permitted to transfer this information to other people.
4) Data that exceeds the storage time limit can be deleted after notifying the doctor and the patient (or their heirs).
5) Online terminals can only be used by authorized people.

In article 6 of Minister of Health Regulation no. 269/2008, regulates the responsibility of doctors and dentists and/or certain health workers for medical records that have been carried out. Minister of Health Regulation No. 269/2008 also regulates ownership of media records in medical services or health services as regulated in article 12, namely:

(1) The medical record file belongs entirely to the health service facility.
(2) The contents of the medical record belong to the patient.
(3) Contents of the medical record as intended in paragraph (2) in the form of a summary of the medical record.

(4) *The summary of medical records as intended in paragraph (3) can be provided, recorded, or copied by the patient or person authorized to do so or with the written consent of the patient or patient's family who is entitled to do so.*

Medical records are confidential where doctors or hospitals or other health service personnel have an obligation to keep all medical record documents confidential as regulated in article 48 paragraphs 1 and 2 of Law no. 29/2004 namely:

(1) Every doctor or dentist in carrying out medical practice is obliged to keep medical secrets.

(2) *Medical secrets can be disclosed only in the interests of the patient's health, to fulfill the request of law enforcement officials in the context of law enforcement, the patient's own request, or based on statutory provisions.*

Apart from that, the confidentiality of medical records is also regulated in Article 322 paragraphs 1 and 2 of the Criminal Code (KUHP):

(1) Any person who deliberately discloses a secret which, according to his position or occupation, whether current or previous, he is obliged to keep, shall be punished by imprisonment for a term of nine months or a fine of up to Rp. 9,000.

(2) If this crime is committed against a specified person then the act is only prosecuted based on that person's confession.

In article 57 paragraphs 1 and 2 of Law Number 36 of 2009 concerning Health:

(1) *Every person has the right to keep their personal health conditions confidential which have been disclosed to health service providers.*

(2) *Provisions regarding the right to confidentiality of personal health conditions*as intended in paragraph (1) does not apply in the case of:

a) statutory orders;
b) court order;
c) relevant permits;
d) *community interests; or*
e) *that person's interests.*

The purpose of confidentiality of medical record documents is also to provide protection not only from the administrative aspect, the medical aspect but most importantly from the legal aspect, namely related to the position of media records as evidence in accordance with the provisions of KUHAP article 184 paragraph 1 letter c that letters are valid evidence. in criminal cases and in article 164 HIR which states that records can be used as written evidence in civil cases. Meanwhile, the medical aspect in it is used to measure media actions carried out by doctors that are in accordance with the Medical Professional Standards (SPM) because if the contents of the medical record are different from the medical actions carried out by the doctor it will have a negative impact on the patient's health, so it can be expected there has been a violation (malpractice) and legal action can be taken, either civil (related to the victim's material loss due to the doctor's error in carrying out the medical procedure), criminal (there is a criminal element of intent or unintentional action in the medical procedure so that the victim experiences a serious condition) , as well as

administration (related to the medical profession so that it can be reported to the medical ethics commission).

Nowadays, the use of electronic medical records can provide great benefits for health services such as basic and referral (hospital) service facilities. One of the benefits of using electronic medical records is increasing the availability of electronic patient records in hospitals. This is also beneficial for patients because it increases efficiency in the health care process.

Apart from that, for administrative staff, the use of electronic medical records can make it easier to retrieve patient information. So that health workers can easily access patient information. Doctors and health workers also benefit from providing health services due to the ease of accessing patient information which ultimately helps in making clinical decisions such as making a diagnosis, administering therapy, avoiding allergic reactions and duplication of medication.

From an efficiency aspect, the use of electronic medical records has the impact of reducing operational costs and increasing income in health service facilities, especially hospitals. Electronic medical records also make it easier for doctors and health services to access patient data in reading the patient's health history without having to manually check the files one by one, making it easier for patients to change doctors or hospitals.

This research was carried out before the issuance of Minister of Health Regulation No. 24 of 2022 last August. For this reason, in the author's opinion, it would be a bit confusing and not on target if the author did not include the latest Minister of Health Regulation regarding medical records, even though the author started this research long before this Health Regulation appeared.

In Article 21:

Electronic Medical Records stored by Health Service Facilities must be connected/interoperable with the interoperability and health data integration service platform managed by the Ministry of Health.

Article 22:

(1). In the event that there are limited resources at the Health Service Facility, the storage of Electronic Medical Records as intended in Article 20 can be carried out in collaboration with an Electronic System Operator that has domestic data storage facilities.

(2). Electronic System Operators as referred to in paragraph (1) must obtain recommendations from the work unit responsible for data and information management in the Ministry of Health.

(3). Electronic System Operators as referred to in paragraph (1) are prohibited from opening, taking, manipulating, destroying, utilizing data and other things that are detrimental to Health Service Facilities.

(4). The prohibition provisions as intended in paragraph (3) are stated in the form of an integrity pact or NonDisclosure Agreement which is attached when entering into a cooperation agreement with a Health Service Facility.

(5). Health Service Facilities that collaborate with Electronic System Operators that have domestic data storage facilities as intended in paragraph (1) must obtain unlimited access to the Electronic Medical Record data stored.

Part Four Security and Data Protection Article 29

(1). Electronic Medical Records must comply with data and information security principles, including: a. confidentiality; b. integrity; and c. availability.

(2). Confidentiality as referred to in paragraph (1) letter a is a guarantee of the security of data and information from interference by internal and external parties who do not have access rights, so that the use and distribution of data and information contained in Electronic Medical Records is protected.

(3). Integrity as referred to in paragraph (1) letter b is a guarantee of the accuracy of the data and information contained in the Electronic Medical Record, and changes to the data may only be made by people who are given access rights to make changes.

(4). Availability as intended in paragraph (1) letter c is a guarantee that the data and information contained in the Electronic Medical Record can be accessed and used by people who have access rights determined by the head of the Health Service Facility.

Article 30

(1). In the context of security and protection of Electronic Medical Record data, the leadership of the Health Service Facility grants access rights to Health Workers and/or other personnel at the Health Service Facility.

(2). Granting access rights as intended in paragraph (1) becomes part of the standard operational procedure policy for the implementation of Electronic Medical Records which is determined by the head of the Health Service Facility.

(3). The access right as intended in paragraph (1) consists of the right to:

a. data input;

b. data improvement; And

c. view data.

(4). Data input as referred to in paragraph (3) letter a is an activity to fill in administrative data and patient clinical data, which is carried out by Health Workers providing health services and administrative officers including Medical Recorders and Health Information in accordance with the authority of their respective fields.

(5). Data correction as referred to in paragraph (3) letter b is carried out if an error occurs in inputting administrative data and patient clinical data.

(6). Correction of data as intended in paragraph (5) can only be carried out by Health Workers providing health services and administrative officers including Medical Recorders and Health Information with a maximum time limit of 2x24 hours from the time the data is input.

(7). In the event that administrative data errors are found to exceed the deadline as intended in paragraph (6), data corrections are carried out after obtaining approval from the Medical and Health Information Recorder and/or the head of the Health Service Facility.

(8). Viewing the data as intended in paragraph (3) letter c is an activity carried out by internal staff at the Health Service Facility to obtain information related to data in the Electronic Medical Record for service or administration purposes.

(9). The access rights as intended in paragraph (1) are regulated in the policy of the leadership of the Health Service Facility by taking into account the principles of data and information security as intended in Article 29.

CLOSING

Currently, Indonesia does not have a law that specifically regulates electronic medical records. Therefore, violations of the protection of personal data in electronic medical records can refer to one part of personal rights (privacy rights) as regulated in the explanation of article 26 paragraph (1) of the ITE Law. In this case, the patient has the right to object to his medical records being entered online and the health service must be willing to delete them based on a court order as written in the preamble to the ITE Law. If this right is violated, the patient concerned can file a lawsuit for losses incurred according to law because in the use of Information Technology, the protection of personal data is one part of personal rights (privacy rights) as regulated in the explanation of article 26 paragraph (1) of the Law. ITE. Every person's knowledge of the secret of their personal health condition is regulated in Law Number 36 of 2009 concerning Health, article 57 paragraphs 1 and 2.

That there are two definitions of third parties here, firstly, the third party, as the one responsible for building the electronic medical record system, cannot be sued or escape legal entanglement if the agreement states that after the guarantee or maintenance period, the third party is free from system errors or leaks. On the other hand, if a third party is assigned by the hospital as the manager, not just the one who creates the system, then it could be that the third party is most responsible. Both third parties as data bank or hosting providers, this has been stated clearly in article 22 paragraph 3 concerning access rights, are prohibited from disclosing this data. Of course, if this is violated there will be consequences.

REFERENCES

Chnipper JELS, Inder JEAL, Alchuk MABP, Inbinder JOSE, Ostilnik ANP, Iddleton BLM, et al., “Smart Forms ” in an Electronic Medical Record : Documentation-based Clinical Decision Support to Improve Disease Management, Journal of the American Medical Informatics Association, 2008, ed. 15(4).

Cinthia Mutiara Hapsari, 2014, Kajian Yuridis Pemakaian Rekam Medis Elektronik Di Rumah Sakit, Magister Ilmu Hukum Program Pascasarjana Fakultas Hukum Universitas Islam Indonesia.

Cinthia Mutiara Hapsari, Ary Subiyantoro, 2019, Kajian Yuridis Pemakaian Rekam Medis Elektronik Di Rumah Sakit, Jurnal Ilmiah Ilmu Keperawatan Dan Ilmu Kesehatan Masyarakat, Volume 14 No. 1 Januari.

Departemen Ilmu Kedokteran Forensik dan Medikolegal, 2014, Kompilasi Peraturan Perundang – undangan terkait Praktik Kedokteran. Jakarta : Fakultas Kedokteran Universitas Indonesia.

Dinevski D; Bele U; Šarenac T., 2013, Clinical Decision Support Systems, Studies in Health Technology and Informatics.

Feby Erawantini, dkk, Rekam Medis Elektronik: "Telaah Manfaat dalam Konteks Pelayanan Kesehatan Dasar", Jurnal FIKI, Vol. 1 No. 1 Edisi 2013, Jogjakarta: IKM Fakultas Kedokteran Universitas Gadjah Mada

Fuad Anis, 2005, Persiapan Tenaga Medis dalam Persiapan RKE di Indonesia, Makalah dalam seminar sehari Rekam Kesehatan Elektronik, Jakarta.

Goodman, C., 2005. Savings in Electronic Medical Recors System? Do It for The Quality. Health Aff (Millwood), 24(5).

Guidelines for The retention Periods of Medical Records 2015 NIST Special Publication 800-145 The NIST Definition of Cloud Computing

Hasrul Buamona,2013, Kajian Yuridis Tentang Rekam Medis, , diunduh dari http://www.lbhyogyakarta.org/ 2013/05/kajian-yuridis-tentang-rekam-medis/, Diakses pada 24 Oktober 2022 Pukul 02.26 WIB.

Hendrik, 2014. Etika Hukum Kesehatan; Penerbit Buku Kedokteran EGC : Jakarta.

J. Guwandi,1999. Dokter dan Rumah Sakit. Jakarta ; Fakultas Kedokteran Universitas Indonesia.

Johan Harlan, Dari Rekam-Medik Kertas ke Rekam-Medik Elektronik, Presentasi, Pusat Studi Informatika Kedokteran, Universitas Gunadarma, Jakarta, without published year.

Muhamad Sadi Is, Etika Hukum Kesehatan Teori an Aplikasinya, Kencana, 2015.

Satria, beni. Redyanto Sidi, Hukum Pidana Medik dan Malpraktik (Aspek Pertanggungjawaban Pidana Terhadap Dokter Dalam pelayanan Kesehatan, CV. Cattleya Darmaya Fortuna, Medan. 2022.

Satria, beni. Redyanto Sidi, Pertanggungjawaban Pidana Rumah sakit atas kelalaian yang dilakukan oleh tenaga medis, Dewa Publishing, Nganjuk. 2022

Schenarts, P. J., & Schenarts, K. D, 2012, Educational Impact of The Electronic Medical Record. Journal of Surgical Education.

Sciences-New York [Internet], 2010;11–4, diunduh dari http://techhouse.brown.edu/ ~dmorris/ publications/ WishPatientDisplaysCHI 2010.pdf. Diakses pada 24 Oktober 2022 Pukul 02.43 WIB.

Sidi, redyanto, Hak Asasi Manusia Dalam Perspektif Hukum Kesehatan di Indonesia, Perdana Publishing, Medan. 2021.

Wilcox L, Using the Electronic Medical Record to Keep Hospital Patients Informed,

Undang-Undang nomor 19 tahun 2016 tentang Perubahan Atas Undang-Undang Nomor 11 tahun 2008 tentang Informasi dan Transaksi Elektronik

Undang-Undang nomor 29 tahun 2004 tentang Praktik Kedokteran

Undang-Undang nomor 39 tahun 1999 tentang Hak Asasi manusia

Undang-Undang nomor 25 Tahun 2009 tentang Pelayanan Publik

Peraturan Pemerintah Republik Indonesia nomor 82 Tahun 2012 Tentang Penyelenggaraan Sistem dan Transaksi elektronik

Peraturan Menteri Kesehatan Republik Indonesia Nomor 269 Tahun 2008 tentang Rekam Medis.

Peraturan Pemerintah nomor 96 Tahun 2012 tentang Pelaksanaan Undang-Undang Nomor 25 Tahun 2009 tentang Pelayanan Publik

Peraturan Menteri Kesehatan nomor 749a/Menkes/Per/XII/1989 tentang Rekam Medis

Peraturan Menteri Kesehatan nomor 269 / MENKES /PER /III / 2008 tentang Rekam Medis