

# Harmonization of Regulations Related to the Medical Record Retention Period (Paper-Based & Electronic-Based)

Rano Indradi Sudra<sup>1</sup>

<sup>1</sup> Universitas Nasional Karangturi, Semarang - Indonesia  
E-mail: rano.indradi@unkartur.ac.id

**ABSTRACT**--Medical record is a file that contains records and documents about patient identity, examination, treatment, actions, other services that have been provided to patients. Health service facilities are required to provide the necessary facilities in the context of organizing medical records, from patients coming to patients returning and continuing with data processing, reporting, including storage and maintenance (retention) of medical records. Whatever type and model of medical record is developed, WHO states that determining retention periods is a matter that must be considered to meet legal, medical, management, education, research, and so on, in accordance with the regulations in force in the country concerned. The selection and determination of which data will be retained and for how long is a critical step to think about. The retention period for medical records has been regulated in several regulations, including laws, government regulations, regulations of the minister of health, circular of director general of Yanmed, and so on. The regulation of retention of medical records has not been harmonized so far both for the length of the retention period and the types of data retention, both for paper-based and electronic-based medical records. This condition has the potential to cause legal problems because the medical record is a document that is regulated by law for its manufacture, use and management. This study aims to identify various regulations that exist and apply to date related to the regulation of medical record retention. The study was conducted by searching the document and analyzing the document content. From the results of this study it can be concluded that various existing and current regulations relating to retention of medical records have not shown harmony in the regulation of medical record retention periods or types of data retention. This happens both for paper-based and electronic-based medical records. Harmonization and reconstruction steps are needed to clarify and reinforce regulations related to medical record retention.

**Keywords:** regulation, retention, medical record

## I. INTRODUCTION

### A. Background

Health development is intended to increase awareness, willingness, and ability to live healthy for everyone in order to realize optimal health status as one of the elements of general welfare as referred to in the Preamble of the 1945 Constitution of the Republic of Indonesia.

Health as a human right must be realized in the form of providing various health efforts to the whole

community through the implementation of quality and affordable health development by the community.

Health service facilities are required to provide the necessary facilities for the organization of medical records. Medical record is a file that contains records and documents about patient identity, examination, treatment, actions, other services that have been provided to patients.

World Health Organization (WHO) states that in the current health information system, the data received often does not support the decision making process because the data is incomplete, inaccurate, untimely, and not as needed (unrelated). In this book, WHO also formulated five basic problems in the health information system that were developing at that time, namely: (1) the information available was irrelevant, (2) the quality of the data was still poor, (3) duplication and non-uniformity, (4) delays in reporting & feedback, and (5) suboptimal use of information. The problems mentioned above are expected to be overcome in the development of subsequent health information system models, including the application of electronic medical records (EMR) as an important part of the health information system.[3][6]

The use of EMR is expected to produce a complete record of medical records to support the needs of service activities and service management and be able to produce information and reports according to needs.

As is the case with medical records, the EMR containing administrative and medical data must be safe, contain the latest data, and be patient-centered. An EMR is also expected to bridge the communication needs between health workers so as to speed up the process of service to patients.

In addition to direct service needs for patients, EMR is also used for other needs such as billing, service quality management, reporting of service results, resource planning, and community health management.

So, the use of EMR does not leave the principles and nature of the medical record, but instead enhances and strengthens the benefits of the medical record.

The use of EMR is primarily for the benefit of services to patients, including clinical (medical) and administrative services. In addition, information generated from EMR is also useful for education, drafting regulations, research, community health management, and policy support.[1]

The national e-health strategy is a comprehensive approach to planning, developing, implementing and

evaluating the use of information and communication technology in the national health sector.

E-health is the use of information and communication technology for health services and information, primarily to improve the quality of health services and improve effective and efficient work processes. In general e-health consists of health informatics (health informatics) and remote health efforts (tele-health). The vision of e-health is to improve the accessibility and sustainability of quality health services for all Indonesians. This vision is supported by the mission of building e-health as an integral part of the transformation and improvement of the quality, accessibility, and sustainability of health services in Indonesia by growing and implementing e-health innovations as well as providing an effective, reliable, safe and innovative electronic health system to support all components of the health system.

One application of e-health is an electronic medical record (EMR). Until now there is no statutory regulation that specifically and comprehensively governs EMR. There are also several articles in several laws and regulations related to EMR which are potentially out of sync.

This condition requires the harmonization and reconstruction of regulations to regulate EMR given the rapid development and implementation of information technology in health services.

#### B. Research Objectives

The purpose of this study is to identify regulations related to the creation of EMR and identify regulations related to determining the retention period of EMR.

## II. RESEARCH METHOD

This research is normative juridical, that is research which refers and bases on legal norms and norms, applicable laws and regulations, theories, legal doctrines, jurisprudence, and other library materials relevant to the research topic. The collection of legal materials is done by literature study.

## III. FINDINGS AND DISCUSSION

### A. Medical Records Concept

To get a correct understanding of EMR, it is first necessary to have a correct understanding of medical records. The medical record, as stated in the Medical Record Manual from WHO, must contain enough data to be used to identify patients, support the determination of diagnosis or state the main reasons for patients to come to the health service, validate the reasons for giving actions and document all the results accurately.[4]

Law no.44 of 2009 concerning Hospitals in chapter VIII article 29 paragraph 1 (h) states that "Every Hospital has an obligation to hold medical records". In the explanation of the paragraphs it is stated that "What is

meant by organizing medical records in this paragraph is carried out in accordance with the standards which are gradually strived to achieve international standards".

Hospital Accreditation Commission (KARS) in the National Hospital Accreditation Standards (SNARS) 1<sup>st</sup> edition 2017 states that medical records are written evidence (paper-based / electronic-based) that records various patient health information such as findings of assessment results, care plans, details of care implementation and treatment, integrated patient development records, and patient discharge summaries made by professionals care giver (PPA).

#### Definition of Electronic Medical Records (EMR)

The Institute of Medicine (IOM) in 2003 formulated EMR as a system that has the following elements:

- Electronic based collection of ongoing health information about a patient;
- Ready at any time, can immediately display electronic-based information, both at the personal and population level, by the authorities;
- Appropriate / relevant to the needs of knowledge and decision support systems that improve the quality, safety, and efficiency of patient services;
- Supports the efficiency of the health service process.

An EMR system covers the scope from data recording, data storage, data processing, maintaining aspects of information security, communication and data presentation (Release of Information / RoI), and to destruction of data in the required conditions.

The Health Information Management Systems Society's (HIMSS) in 2006 has also formulated things that can be included or recorded in EMR, including: patient demographic data, records of the patient's condition development, problems arising, medications and other therapies given, signs vital signs (temperature, breathing rate, etc.), past medical history, immunization history, laboratory results, radiological examination results, consultation results, other relevant supporting data.

The use of EMR is expected to produce a complete record of medical records to support the needs of service activities and service management and be able to produce information and reports according to needs.

As is the case with medical records, the EMR containing administrative and medical data must be safe, contain the latest data, and be patient-centered. An EMR is also expected to bridge the communication needs between health workers so as to speed up the process of service to patients.

In addition to direct service needs for patients, EMR is also used for other needs such as billing, service quality management, reporting of service results, resource planning, and community health management.

So, the use of EMR does not leave the principles and nature of the medical record, but instead enhances and strengthens the benefits of the medical record.

Regulations Regarding the Making of Electronic Medical Records

Regarding the making of electronic medical records, the regulation that states this is Minister of Health

Regulation number 269 of 2008 concerning Medical Records article 2 paragraph (1) "Medical records must be made in writing, in full and clear or electronically".

In Law number 29 of 2004 concerning Medical Practices, the elucidation section of article 46 paragraph (3) states "if in the recording of medical records using electronic information technology, the obligation to give a signature can be replaced by using a personal identification number".

In addition, the existence of EMR is also listed in the attachment of Minister of Health Regulation number 46 of 2017 concerning the National e-Health Strategy.

Republic of Indonesia Government Regulation number 46 of 2014 concerning Health Information System article 14 also states that "Health Data and Information sourced from Health Service Facilities obtained from electronic and non-electronic medical records are carried out in accordance with statutory provisions". Article 17 point b also states that "the implementation of medical records includes electronic medical records and non-electronic medical records". Article 40 paragraph (1) in this government regulation states that "Every Health Service Facility must operate its own electronic medical record system.

Minister of Health Regulation number 82 of 2013 concerning Hospital Management Information System (SIMRS) article 3 paragraph (1) states that "Every Hospital is required to hold a SIMRS". The attachment section of the Minister of Health Regulation lists medical records as one of the variables in SIMRS. While the understanding of SIMRS according to article 1 in this Minister of Health Regulation is "a communication information technology system that processes and integrates the entire flow of hospital services in the form of a network of coordination, reporting and administrative procedures to obtain information precisely and accurately, and is part of the Health Information System. "In this regard, the notion of the Health Information System is referred to as "a set of arrangements that include data, information, indicators, procedures, technology, tools, and human resources that are interrelated and managed in an integrated manner to direct actions or decisions that are useful in support health development. "

Data on the results of health services (medical records) stored in electronic form (EMR) meet the criteria as electronic documents as contained in article 1 of Law number 19 of 2016 concerning Amendments to Law number 11 of 2008 concerning Information and Electronic Transactions that read "Documents Electronics are any Electronic Information that is created, transmitted, sent, received, or stored in analog, digital, electromagnetic, optical, or the like, which can be seen, displayed and / or heard through a Computer or Electronic System, including but not limited to writing, sound, pictures, maps, designs, photos or the like, letters, signs, numbers, Access Codes, symbols or perforations that have meaning or meaning or can be understood by people who are able to understand it".

In Law number 14 of 2008 concerning Openness of Public Information, article 17 h, the medical record is

included in the excluded information that is as public information which if opened and given to the public information applicant can reveal personal confidentiality.

In the case of managing electronic data, the Republic of Indonesia Government Regulation number 71 of 2019 regarding the Implementation of Electronic Systems and Transactions article 99 paragraph (2) states that the health sector is included in institutions or institutions that have strategic electronic data that must be protected.

The regulations above show the existence of electronic medical records as an alternative and development of conventional (paper-based) medical records.

#### Regulations Related to Electronic Medical Record Retention Periods

Regarding EMR retention period, WHO defines retention as "The maintenance and preservation of information". Whatever type and model of EMR is developed, WHO states that determining retention periods is a matter that must be considered to meet legal, medical, management, education, research, and so on, according to the regulations in force in the country concerned. The selection and determination of which data will be retained and for how long is a critical step to think about.[5]

Because EMR is an electronic form of medical record, the rationale for the EMR period is the same as the retention period for medical records, except if there are regulations that clearly and expressly stipulate otherwise.

Concerning the retention of medical records, Minister of Health Regulation number 269 of 2008 concerning medical records article 8 regulates this matter, which is a minimum of 5 years for inpatient medical records at the hospital starting from the last date the patient was treated. After passing this period, it can be destroyed except for a discharge summary and informed consent (kept 10 years from the date the sheet was made).

Article 9 of the Minister of Health regulation regulates medical records at non-hospital health service facilities to be kept for a minimum of 2 years from the date the patient was treated.

The two articles (articles 8 and 9) do not mention and / or limit the form of medical records, both paper and electronic medical records.

Arrangement of medical record retention period is also mentioned in Circular Letter (SE) of the Director General of Medical Services No. HP.00.06.1.5.01160 dated March 21, 1995 concerning Technical Guidelines for Procurement of Basic Medical Records Form and Destruction of Medical Records Archives in Hospitals. In this SE the medical record retention period is regulated as active medical records (generally 5 years) and inactive (generally 2 years). In addition, the Circular Letter also regulates the retention period of medical records based on diagnosis groups and provides an opportunity for hospitals to regulate the retention of medical records based on other interests, such as medicolegal cases (kept for at least 23 years after a legal provision), educational needs, and research.

Act number 44 of 2009 article 55 states that hospitals must keep medical records for a certain period.

In this article also does not mention the form of medical records (paper or electronic), limits on the period of active and inactive, as well as data or sheets that are stored / destroyed.

The medical record manual of the Indonesian Medical Council (KKI) in 2006 states that medical records must be kept for a minimum of 5 years and for discharge summary for a minimum of 25 years.

Republic of Indonesia Government Regulation number 46 of 2014 concerning Health Information System article 21 paragraph (5) states that "Health Data and Information Storage is carried out for a minimum of 10 (ten) years for nonelectronic Health Data and Information and for a minimum of 25 (twenty-five) years for Electronic Health Data and Information according to the archive retention schedule ". This regulation does not mention EMR but "electronic health data and information". It still needs to be agreed again whether what is meant by "electronic health data and information" is the same as EMR. If it is the same, it can be interpreted that the EMR retention period according to this regulation is at least 25 years.

Regulations related to the retention period of medical records mentioned above still do not harmoniously regulate the retention period, types of medical records (paper or electronic-based), active / inactive medical record groups, and which data / sheets are stored / destroyed. Only Republic of Indonesia Government Regulation number 46 of 2014 concerning Health Information Systems regulates EMR retention periods. The retention period is also not yet harmonious between one regulation and another.

#### IV. CONCLUSION

1. Regulations related to the making of EMR, namely RI Law number 29 of 2009 concerning Medical Practice, Law number 19 of 2016 concerning Amendment to Law number 11 of 2008 concerning Information and Electronic Transactions, Law number 14 of 2008 concerning Openness of Public Information, Indonesian Government Regulations number 46 of 2014 concerning Health Information Systems, Republic of Indonesia Government Regulation number 71 of 2019 concerning Operation of Electronic Systems and Transactions, Minister of Health regulation number 269 / MENKES / PER / III / 2008 concerning Medical Records, Minister of Health regulation number 82 of 2013 concerning Hospital Management Information Systems, and Minister of Health regulation number 46 of 2017 concerning the National e-Health Strategy.
2. Regulations related to determining the EMR retention period, namely Law no.44 of 2009

concerning Hospitals, Minister of Health regulation number 269 / MENKES / PER / III / 2008 concerning Medical Records, Circular of the Director General of Medical Services number HK.00.06.1.5.01160 date March 21, 1995 regarding Technical Guidelines for Procurement of Basic Medical Record Forms and Destruction of Medical Records in Hospitals, and Medical Records Manual from Indonesia Medical Council 2006. These regulations have not clearly stipulated the period of EMR retention in terms of storage period, procedure, and data retention. The retention period and regulated in these regulations are not the same.

#### A. Suggestions

1. Regulatory harmonization related to making EMR is needed.
2. Regulatory harmonization related to the retention period of paper-based and electronic-based medical record is needed.

#### REFERENCES

- [1] Rano Indradi S, *Rekam Medis*, Tangerang Selatan: Penerbit Universitas Terbuka, 2014.
- [2] Rano Indradi S, *Sistem dan Teknologi Informasi Kesehatan*. Dalam: Pedoman Manajemen Informasi Kesehatan di Sarana Pelayanan Kesehatan. Hatta, GR, editor. Jakarta, UI Press, 2014.
- [3] World Health Organization, *Design and Implementation of Health Information System*, 2000.
- [4] World Health Organization, *Medical Record Manual – a Guide for Developing Countries*, 2006.
- [5] World Health Organization, *Electronic Health Records – Manual for Developing Countries*, 2006.
- [6] WHO Regional Office for the Western Pacific. *Developing Health Management Information Systems - A Practical Guide for Developing Countries*. 2004.
- [7] Law of the Republic of Indonesia number 29 of 2009 concerning Medical Practices.
- [8] Law number 19 of 2016 concerning Amendment to Law number 11 of 2008 concerning Information and Electronic Transactions.
- [9] Law number 14 of 2008 concerning Openness of Public Information.
- [10] Law no.44 of 2009 concerning Hospitals.
- [11] Government Regulation of the Republic of Indonesia number 46 of 2014 concerning Health Information Systems.
- [12] Government Regulation of the Republic of Indonesia number 71 of 2019 concerning Operation of Electronic Systems and Transactions.
- [13] Regulation of the Minister of Health number 269 / MENKES / PER / III / 2008 concerning Medical Records.
- [14] Minister of Health Regulation number 82 of 2013 concerning Hospital Management Information System
- [15] Minister of Health Regulation number 46 of 2017 concerning the National e-Health Strategy.
- [16] Circular of the Director General of Medical Services number HK.00.06.1.5.01160 dated March 21, 1995 concerning Technical Guidelines for Procurement of Basic Medical Record Forms and Destruction of Medical Records Archives in Hospitals.
- [17] Indonesian Medical Council, *Manual Rekam Medis*, 2006.