Legal Certainty Regarding Electronic Medical Record Retention Period

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ABSTRACT

A medical record is a file containing notes and documents about the patient's identity, examinations, medication, actions, and other services that have been provided to patients. National hospital accreditation standards (SNARS) edition 1.1 states that health care facilities are required to provide the necessary facilities in the context of administering medical records, starting from the patient arriving to the patient returning home and continuing with data processing, reporting, including storage and maintenance (retention) of medical records. The World Health Organization (WHO) states that determining the retention period for medical records is something that must be considered in order to meet the needs of law, medical, management, education, research, and so on, in accordance with applicable regulations in the country concerned. Normative legal certainty is when a rule is made and promulgated because it regulates clearly and logically and not to cause doubts (multiple interpretations). Legal certainty provides clarity in carrying out legal actions. Legal certainty regarding the retention period of electronic medical records is needed to avoid legal problems considering that medical records are documents that are regulated by law for the manufacture, use and management. This research is normative juridical and aims to identify legal certainty related to the retention period of electronic medical records. From the results of this study it can be concluded that there is legal uncertainty regarding the retention period of electronic medical records. Regulatory harmonization is needed to create legal certainty regarding the retention period of electronic medical records.

Keywords: *electronic medical records, legal certainty, retention.*

I. INTRODUCTION

The Preamble to the 1945 Constitution of the Republic of Indonesia states that health development is aimed at increasing awareness, willingness and ability to live a healthy life for everyone in the context of realizing an optimal degree of health as an element of general welfare. As a human right, health must be realized in the form of providing various health efforts to the entire community. This will be achieved through the implementation of quality and affordable health development for the community. [1]

In this regard, health service facilities have the obligation to provide the necessary facilities, including the administration of medical records.

A medical record is a file containing notes and documents about the patient's identity, examination, treatment, actions, other services that have been provided to patients. [2] In the Medical Record Manual of the World Health Organization (WHO), it is stated that medical records must contain sufficient data so that they can be used to identify patients, support diagnosis or state the main reason patients come to health care, validate the reasons for giving action and document all results accurately. [3]

Law number 44 of 2009 concerning Hospitals in chapter VIII article 29 paragraph 1 (h) states that "every hospital has the obligation to maintain medical records." What is meant by the administration of medical records in this paragraph is that the administration of medical records is carried out in accordance with applicable standards which gradually strive to reach international standards ". [4]

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The National Hospital Accreditation Standard (SNARS) edition 1.1 of 2019 compiled and published by the Hospital Accreditation Commission (KARS) states that medical records are written evidence (paper/electronic) that records various patient health information such as assessment findings, care plans, details of the implementation of care and treatment, integrated patient progress records, as well as a patient discharge summary prepared by the professional healthcare giver (PPA). [5]

As stated by the World Health Organization (WHO) that the currently developing health information system, the data received often does not support the decision-making process because the data is incomplete, inaccurate, untimely, and unrelated. In this book, WHO also formulates five basic problems in the health information system that was developing at that time, namely: (1) the available information is irrelevant, (2) data quality is still poor, (3) duplication and non-uniformity, (4) delays. reports & feedback, and (5) less than optimal use of information. [6] [7] [8]

The development of the next health information system models, including the application of electronic medical records as an important part of the health information system, is expected to overcome the problems mentioned above.

Data items that can be entered or recorded in an electronic medical record include: patient demographic data, progress of the patient's condition, problems that arise during treatment, drugs and other therapies that have been given, patient vital signs (temperature, breath, pulse, etc.), past medical history, immunization history that the patient has obtained, laboratory examination results, radiological examination results, consultation results, and other related supporting data. [9]

The use of electronic medical records is expected to be able to produce quality documentation in medical records so that it can support the needs of health service activities for patients and service management and be able to produce information and reports according to the needs of various parties.

This electronic medical record containing administrative data and clinical data must be guaranteed safety, patient-centric, and contain up-to-date data. Electronic medical records are also expected to be used for communication needs between health workers so that the service process for patients can be faster, more efficient, and of high quality.

Apart from the things mentioned above, electronic medical records can also be used for other needs such as service quality management, reporting of service results, billing, resource planning, and community health management. The use of electronic medical records is in principle the same as paper-based medical records and actually increases the benefits of these medical records.

The use of electronic medical records is primarily for the benefit of patient services, including clinical (medical) and administrative services. In addition, the information generated from RME is also useful for education, drafting regulations, research, community health management, and policy support. [10]

The government has formulated a national e-health strategy which is an overall 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 long-distance health efforts (tele-health). [11]

One of the applications of e-health is electronic medical records. Because electronic medical records are an electronic form of medical records, the rationale for the period of electronic medical record retention is the same as the retention period for paper-based medical records, unless there are regulations that clearly and expressly regulate otherwise.

Regulatory certainty related to electronic medical records is important and urgent considering that in the strategic plan of the Ministry of Health it is targeted that 100% of hospitals in Indonesia apply integrated electronic medical records by 2024. [12]

II. PROBLEMS

What is the legal certainty regarding the retention period of electronic medical records?

III. RESEARCH METHOD

This research is normative juridical and aims to identify legal certainty related to the retention period of electronic medical records. Regulations related to the retention of medical records analyzed are Law number 29 of 2004 concerning Medical Practice, Law number 44 of 2009 concerning Hospitals, Regulation of the Minister of Health of the Republic of Indonesia number 269 / Menkes / Per / III / 2008 concerning Medical Records, Regulations The Government of the Republic of Indonesia number 46 of 2014 concerning Health Information Systems, Circular of the Directorate General of Medical Services number HK.00.06.1.5.01160 dated March 21, 1995 concerning Technical Instructions for Procurement of Basic Medical Record Forms and Destruction of Medical Record Archives in Hospitals, and Medical Records Manual from the Indonesian Medical Council (KKI) in 2006.

IV. DISCUSSION

A. *Regulations Related to the Making of Electronic Medical Records*

Regarding the making of electronic medical records (EMR), the regulation which states this is the Minister of Health Regulation number 269 of 2008 concerning Medical Records Article 2 paragraph (1) "Medical records must be made in writing, complete and clear or electronically". [2]

In Law number 29 of 2004 concerning Medical Practice, the explanation section of article 46 paragraph (3) states "when recording medical records uses electronic information technology, the obligation to sign can be replaced by using a personal identification number.". [1]

In addition, the existence of EMR is also listed in the attachment to Minister of Health Regulation number 46 of 2017 concerning the National e-Health Strategy. [11]

Government Regulation number 46 of 2014 concerning Health Information Systems article 14 also states that "Health data and information sourced from Health Service Facilities obtained from electronic and non-electronic medical records are implemented in accordance with statutory provisions". Article 17 point b also states that "the administration 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. [13]

Regulation of the Minister of Health number 82 of 2013 concerning Hospital Management Information System (SIMRS) article 3 paragraph (1) states that "Every hospital is obliged to organize SIMRS". The attachment section of the Minister of Health

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Regulation includes medical records as one of the variables in SIMRS. Meanwhile, the definition of SIMRS according to article 1 in this Regulation of the Minister of Health is "a communication information technology system that processes and integrates the entire flow of hospital service processes in the form of a network of coordination, reporting and administrative procedures to obtain accurate and precise information, and is part of Health Information System. " In this regard, the definition of a Health Information System is stated as "a set of structures 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 supporting health development. . " [14]

Medical records stored in electronic form (RME) 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 Electronic Information and Transactions which reads "Electronic documents are any information. Electronics that are made, forwarded, 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, voice, pictures, maps, designs, photographs or the like, letters, signs, numbers, access codes, symbols or perforations which have meaning or meaning or can be understood by those who are able to understand them". [15]

In Law number 14 of 2008 concerning Openness of Public Information, article 17 h, medical records are included in exempt information, namely as public information which, if opened and provided to applicants for public information, can reveal personal secrets. [16]

In terms of managing this electronic data, Government Regulation number 71 of 2019 concerning Implementation of Electronic Systems and Transactions article 99 paragraph (2) states that the health sector is included in agencies or institutions that have strategic electronic data that must be protected. [17]

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

B. *Regulations Regarding the Retention Period of Electronic Medical Records*

World Health Organization (WHO) defines retention as "The maintenance and preservation of information". Regardless of the type and model of EMR developed, WHO states that determining the retention period must be considered in order to meet legal, medical, management, educational, research needs, in accordance with applicable regulations in the country concerned. The selection and determination of which data will be retained and for how long is a critical step that needs to be considered. [18]

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

Regarding the medical record retention period, Minister of Health Regulation number 269 of 2008 concerning Medical Records article 8 regulates this, namely a minimum of 5 years for inpatient medical records at the hospital as of the last date the patient was treated. After passing this period, it can be destroyed except for discharge summary and informed consent

(stored 10 years from the date the sheet was made).

Article 9 of this Minister of Health Regulation regulates that medical records in non-hospital health service facilities are kept for a minimum of 2 years from the date the patient was last 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. [2]

Regulations for the medical record retention period are also mentioned in the Circular of the Directorate General of Medical Services no.HK.00.06.1.5.01160 dated March 21, 1995 concerning Technical Guidelines for Procurement of Basic Medical Record Forms and Destruction of Medical Record Archives at Hospitals. In this Circular Letter, the medical record retention period is regulated as active (generally 5 years) and inactive (generally 2 years) medical records. In addition, this Circular also regulates the retention period of medical records based on diagnosis groups and provides opportunities for hospitals to regulate medical record retention periods based on other interests, for example medicolegal cases (at least 23 years after a legal provision), educational needs, and research. . [19]

Law number 44 of 2009 article 55 states that hospitals are required to keep medical records for a certain period of time. In this article also does not mention the form of medical records (paper or electronic), limits on active and inactivity periods, and data or sheets that are stored/destroyed. [4]

The medical record manual from the Indonesian Medical Council (KKI) in 2006 states that medical records must be kept for a minimum of 5 years and for a medical record resume sheet at least 25 years. [20]

Government Regulation number 46 of 2014 concerning Health Information Systems article 21 paragraph (5) states that "Storage of Health Data and Information is carried out for at least 10 (ten) years for non-electronic Health Data and Information and at least 25 (twenty five) years for Data. and electronic Health Information according to an archive retention schedule". This regulation does not mention about RME but "electronic health data and information". It is still necessary to agree again whether what is meant by "electronic health data and information" is the same as RME. If they are the same, it means that the RME retention period according to this regulation is a minimum of 25 years. [13]

The regulations regarding the medical record retention period mentioned above are still not harmoniously regulating the retention period, type of medical record (paper or electronic), active/inactive medical record groups, and which data/sheets are stored/destroyed. Only Government Regulation number 46 of 2014 concerning Health Information Systems regulates the retention period of RME. The retention period is also not harmonious between one regulation and another.

V. CONCLUSION

Regulations related to the retention of medical records analyzed are Law number 29 of 2004 concerning Medical Practice, Law number 44 of 2009 concerning Hospitals, Regulation of the Minister of Health of the Republic of Indonesia number 269/Menkes/Per/III/2008 concerning Medical Records, Regulations The Government of the Republic of Indonesia number 46 of 2014 concerning Health Information Systems, Circular of the Directorate General of Medical Services number HK.00.06.1.5.01160 dated March 21,

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1995 concerning Technical Instructions for Procurement of Basic Medical Record Forms and Destruction of Medical Record Archives in Hospitals, and Manual Records Medical from the Indonesian Medical Council (KKI) in 2006. There is no legal certainty regarding the electronic medical record (EMR) retention period.

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