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# *The Urgency of Regulation Regarding Standardization of Documentation in Electronic Medical Records*

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***Abstract--Medical records are documents that must be made in every health service. As an electronic form of medical records, electronic medical records (EMR) do not just transfer content from paper to computer screens, but many adjustments are needed including standardizing documentation. Standardization related to documentation in EMR is also important and urgent given the need for the health information exchange (HIE) between health service providers and the rapidly growing need for integration between health care facilities. This study aims to identify regulations related to the standardization of documentation in EMR. This study was conducted by searching and examining various regulations that are directly or indirectly related to EMR. The results of this study indicate that there are no regulations governing the standardization of documentation in the EMR for both medical and non-medical data components. It is recommended to immediately formulate regulations related to the standardization of documentation in EMR.***

***Keywords- documentation; electronic medical record; EMR; regulation; standardization***

## I. INTRODUCTION

Medical records are a form of documenting health services. Medical records contain both non-medical and medical data. Non-medical data, for example, is about patient demographic data, while medical data includes (but is not limited to) the results of anamnesis, physical examination, investigations, medical measures, therapy, and diagnosis.

Medical records, as stated in the Medical Record Manual of the World Health Organization (WHO), must contain sufficient data to be used to identify patients, support diagnosis or state the main reason patients come to health care centers, validate the reasons for giving. action and document all results accurately.[1] Law no.44 of 2009 concerning Hospitals in chapter VIII article 29 paragraph 1 (h) states that "Every hospital has the obligation to maintain medical records." In the explanation of the paragraphs it states that "What is meant by the administration of medical records in this paragraph is carried out in accordance with standards that are gradually being strived to achieve international standards ".

The Hospital Accreditation Commission (KARS) in the 2020 edition of the National Hospital Accreditation Standards (SNARS) 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 discharge summaries prepared by care professionals (PPA). This standard also states that medical records can be made electronically as stated in the Minister of Health Regulation number 269 of 2008 concerning Medical Records. [2]

The use of Electronic Medical Records (EMR) is expected to produce complete medical record records to support the needs of service activities and service management and to be able to produce information and reports according to needs. As well as medical records, the EMR which contains administrative data and medical data must be safe, contain up-to-date data, and be patient-centric. An EMR is also expected to be able to bridge communication needs between health workers so as to accelerate the service process for 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 abandon the principles and basic nature of medical records, but instead enhances and strengthens the benefits of these medical records. The use of EMR is primarily for the benefit of patient service, including clinical (medical) and administrative services. In addition, the information generated from EMR is also useful for education, drafting regulations, research, community health management, and policy support. [3]

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 long-distance health efforts (tele-health). The vision of e-health is to increase 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 quality, accessibility and sustainability of health services in Indonesia by growing and implementing e-health innovations and providing an electronic health system that is effective, reliable, safe, and innovative to support. all components of the health system. One of the applications of e-health is EMR. Until now, there are no specific and comprehensive laws and regulations governing EMR. Several articles in several laws and regulations related to EMR also have the potential to be out of sync. This condition requires harmonization and reconstruction of regulations to regulate EMR given the rapid development and wide potential for the implementation of information technology in health services. In the concept of e-health, release of information and health information exchange is a necessity. In order for the system to communicate with each other, standardization is needed in various aspects ranging from input, process to output.

The conditions of the COVID-19 pandemic have also encouraged the development of the application of telemedicin. Several regulations related to the application of information and communication technology in health services include Regulation of the Minister of Health number 20 of 2019, Circular of the Minister of Health number HK.02.01 / MENKES / 303/2020, Decree of the Honorary Council of Medical Ethics number 017 / PB / K.MKEK / 05/2020, and Regulation of the Medical Council (Perkonsil) number 74 of 2020.

## II. PROBLEMS

What are the applicable regulations related to standardization of documentation in electronic medical records?

## III. RESEARCH METHOD

This is a qualitative research. This research focuses on the depth of material related to documentation standards in electronic medical records (EMR), enriched with literature reviews to formulate clear and harmonious regulatory content related to documentation standards in EMR.

In this study, a sociolegal approach was used, namely non-doctrinal legal research that examines law by combining law and social science. The approach related to legal science is used for textual analysis as well as articles in the regulations under study. Approaches related to social sciences are used to study non-legal (external) social aspects that influence the operation of law within the context of the study.

This study uses a constructivist paradigm, which is to reconstruct regulations related to documentation standards in electronic medical records (EMR) to make it clearer, more harmonious, and provide legal certainty to health facilities.

The constructivism paradigm includes the following aspects:

- ontology, namely the form and nature of reality, and what can be known about this. Several problems in terms of regulations related to documentation standards in EMR include provisions on language standards, abbreviations, symbols, and units.
- epistemology, the nature of the relationship or relationship between an individual or group of people with the environment or everything outside of him, including what can be known about this. Problems that arise in terms of regulations related to documentation standards in the EMR will be discussed and analyzed to produce ideas as an alternative solution to the solution.
- methodology, how individuals or groups of people get answers to what they want to know. The methodology in this study was used to explore existing regulations regarding documentation standards in EMR.

According to Erlyn, the paradigm is actually an 'umbrella' philosophical system which includes a particular ontology, epistemology, and methodology. Each of them consists of a series of 'basic beliefs' or worldviews that cannot be easily exchanged (with 'basic beliefs' or worldviews from ontology, epistemology, and other paradigm methodologies).

According to I Gede Atmadja, legal certainty means that the formulation of legal norms is clear and does not have multiple interpretations, is applied according to the similia-similibus principle "(the same rule of law is applied to the same case).

According to Utrecht, legal certainty contains two definitions, namely first, the existence of general rules that make individuals know what actions are allowed or not to be done, and second, in the form of legal security for individuals from government abuse because with these general rules individuals can know what the State may impose or do against individuals.

This research was conducted by exploring and identifying applicable regulations that are related either directly or indirectly to standardization of documentation in electronic medical records (EMR). This documentation standard includes the

standard for documenting administrative data and medical data. These regulations then identified the scope of their content against the need for standard documentation in the EMR.

## IV. DISCUSSION

To equate a correct understanding of EMR, it is necessary to equate a correct understanding of medical records. As stated in the Medical Record Manual from WHO, medical records must contain sufficient data so that they can be used to identify patients, help determine the diagnosis or formulate the main cause of patients needing health services, serve as the basis for giving action and also document all services that have been provided.

Law no.44 of 2009 on Hospitals in chapter VIII article 29 paragraph 1 (h) states that "Every hospital has the obligation to maintain medical records." in this paragraph is carried out in accordance with standards which strive to achieve international standards ".

The Hospital Accreditation Commission (KARS) in the National Hospital Accreditation Standard (SNARS) edition 1.1 of 2020 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 discharge summaries prepared by care professionals (PPAs).

The placement of electronic medical records (EMR) as an important part of the concept of health and e-health information systems shows the importance of seriousness in designing and implementing EMR according to these objectives.

Regarding 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 level and the population level, by the authorities;

• appropriate / relevant to the need for knowledge and decision support systems that improve the quality, safety and efficiency of patient care;

• support the efficiency of the health service process.

An EMR system covers the scope from data recording, data storage, data processing, safeguarding aspects of information security, communication and data presentation (Release of Information / RoI), to data destruction 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 the EMR, including: patient demographic data, records of patient progress, problems that arise, drugs and other therapies given, signs -Vital signs (temperature, breath pulse, etc.), past medical history, immunization history, laboratory examination results, radiological examination results, consultation results, other relevant supporting data.

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

Regarding the making of electronic-based medical records, the regulation that states this is Permenkes number 269 of 2008 concerning Medical Records Article 2 paragraph (1) "Medical records must be made in writing, complete and clear or electronically".

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

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.

Indonesia 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 the provisions of laws and regulations". Article 17, point b of this regulation 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.

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 hold SIMRS". The attachment section of the Minister of Health Regulation includes medical records as one of the variables in SIMRS. Meanwhile, the definition 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 service processes in the form of a network of coordination,

reporting and administrative procedures to obtain accurate and accurate 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."

Observing the contents of 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 Electronic Information that is created, forwarded, sent, received, or stored in analog form. , 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, images, maps, designs, photographs or the like, letters, signs, numbers , Access Codes, symbols or perforations that have meaning or meaning or can be understood by those who are able to understand them ", health service outcome data (medical records) stored in electronic form (EMR) meets the criteria as an electronic document.

According to the understanding of 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, when opened and provided to applicants for public information, can reveal personal secrets.

In terms of managing this electronic data, the Indonesian Government Regulation number 71 of 2019 concerning the 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.

The above regulations indicate the existence of electronic medical records as an alternative and development of conventional medical records (paper-based). In the aforementioned regulations, the standard language, abbreviations, symbols and units for documentation in the EMR have not been regulated. Given the position of EMR as the entry point for data in the e-health concept in which a Health Information Exchange (HIE) is possible, the existence of this documentation standard is absolutely necessary. This standard will establish the same steps in documenting and uniformity of understanding in the use of EMR-based information. Thus there is no difference in meaning interpretation due to the variety of languages, abbreviations, symbols, and / or units used in documentation.

## V. CONCLUSION

The current regulations regarding the manufacture and documentation of health services in electronic medical records (EMR) have not clearly and firmly stipulated documentation standards in terms of the use of language, abbreviations, symbols, and units, both for administrative data and medical data.

The existence of regulations that regulate documentation standards in the EMR is very much needed and urgent to be in place immediately considering the rapid development of information and communication technology implementation in health services. In addition, considering the direction of development of national health development policies in Indonesia.

## REFERENCES

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