# Patient Consent Regarding Use of Their Medical Resume for Health Information Exchange According to the Minister of Health Regulation number 21/2020

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**Abstract:** Minister of Health Regulation number 21/2020 announced that the application of integrated electronic medical records (EMR) must reaches 100%. This condition is targeted to be able to support data exchange between hospitals based on medical resumes (health information exchange/HIE). For this need, the patient's consent as the owner of the information in the medical record is required as stated in the Minister of Health Regulation number 269/2008 on Medical Records. This research is qualitative research. The research focuses on the depth of material related to documentation standards in medical resume electronic health records (EHR) enriched with literature reviews to formulate clear and harmonious regulatory content related to documentation standards in the EHR medical resume. This research is normative juridical and aims to identify regulations related directly or indirectly to patient consent for the use or release of information in their medical records, including and especially the use of medical resumes for HIE. The results of this study indicate that there are no regulations that explicitly and clearly regulate patient consent for the use and release of medical record information by hospitals in the form of medical resumes for HIE needs as targeted in Regulation of the Minister of Health number 21/2020. There needs to be a regulation that explicitly and clearly regulates patient consent for the use and release of their medical resume for HIE needs as stated in the Minister of Health Regulation number 21/2020.

**Keywords:** Patient Consent, Medical Resume, Information (HIE)

#### Introduction

In Law Number 17 of 2007 concerning the National Long-Term Development Plan for 2005—2025, it is stated that health development is essentially an effort carried out by all components of the Indonesian nation which aims to increase awareness, willingness, and the ability to live a healthy life for everyone to achieve the highest degree of public health, as an investment for the development of socially and economically productive human resources. Every health service must be documented in the form of a medical record. The contents of medical records include non-medical and medical data. Non-medical data, for example data related to patient demographics, meanwhile medical data can include history, physical examination results, results of supporting examinations, medical actions that have been performed, therapy, and diagnosis (KEMENKES, 2008).

Given the function of the medical record that can be used to identify patients, support diagnosis or state the main reason the patient came to a health care center, validate the reasons for giving actions and document all the results accurately, it is as stated in the Medical Record Manual of World Health. Organization (WHO), medical records must contain sufficient data to support these various needs (WHO, 2006). The obligation to make medical records is mandated by Law No.44 of 2009 concerning Hospitals in chapter VIII article 29 paragraph 1 which states that "Every hospital has the obligation to maintain medical records. The explanation section states that "What is meant with the administration

of medical records in this paragraph is carried out in accordance with standards that are gradually being strived to achieve international standards (Law No.44, 2009).

The Hospital Accreditation Commission (KARS) in the 2019 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's). 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 (KARS, 2019). The use of electronic medical records (EHR) is expected to increase and strengthen the benefits of medical records. The use of EHR is primarily for the benefit of patient services, including clinical (Medical) and administrative services. The information generated from EHR is also useful for education, drafting regulations, research, community health management, policy support, and to support referral health services (Rano, 2020).

Acourding to regulation of the Minister of Health 46 (2017), that national e-health is a comprehensive approach to planning, developing, implementing, and evaluating the use of information and communication technology in the national health sector. In e-health, information and communication technology is utilized for health services and information, primarily to improve the quality of health services and work processes that are effective and efficient. E-health in general consists of health informatics (Health informatics) and long-distance health efforts (Tele-health). Increasing the accessibility and sustainability of quality health services for all Indonesians is the vision of e-health. One of the e-health applications is EHR. Until now, there is no specific and comprehensive regulation regulating EHR. Several articles in several regulations related to EHR also have the potential to be out of sync. Given the rapid development and wide potential for the implementation of information technology in health services, it is necessary to harmonize and reconstruct regulations to regulate EHR. 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.

#### **Methods**

This research is qualitative research. The research focuses on the depth of material related to documentation standards in medical resume electronic health records (EHR) enriched with literature reviews to formulate clear and harmonious regulatory content related to documentation standards in the EHR medical resume. This research uses a sociolegal approach, namely non-doctrinal legal research that examines law by combining legal and social sciences. 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 research uses a constructivist paradigm, which is to reconstruct regulations related to documentation standards in the EHR medical resume so that it is in line with the EHR development goals as stated in Permenkes number 21 of 2020.

#### Result

Electronic health record (EHR) occupies an important position from the concept of health and e-health information systems. Given this, it takes seriousness to design and apply an EHR.

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

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

An EHR system covers the scope from data recording (Capturing), data storage (Storing), data processing (Processing), safeguarding aspects of information security (Privacy & security), communication and presentation of data (Release of Information/RoI), to destruction. data on the required conditions (Destructing). The content of EHR has been formulated by the Health Information Management Systems Society's (HIMSS) in 2006, including, among others: patient demographic data, patient progress notes, problems that arise, drugs and other therapies administered, vital signs (temperature, respiratory pulse, etc.), past medical history, immunization history, laboratory examination results, radiological examination results, consultation results, other related supporting data (HIMSS, 2006).

The use of EHR 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. 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 "when recording medical records uses electronic information technology, the obligation to sign can be replaced by using a personal identification number". 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 statutory provisions". Article 17 points 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) of this government regulation states that "Every Health Service Facility must operate its own electronic medical record system.

In the Regulation of the Minister of Health number 82 of 2013 concerning Hospital Management Information System (SIMRS) article 3 paragraph (1) it is stated that "Every hospital is obliged to hold SIMRS". The attachment part of this Minister of Health Regulation states that medical records are one of the variables in SIMRS. According to article 1 in this Minister of Health Regulation, the definition of SIMRS is "a communication information technology system that processes and integrates the entire hospital service process flow 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 the Health Information System is agreed 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. "

In article 1 of Law number 19 of 2016 concerning Amendments to Law number 11 of 2008 concerning Electronic Information and Transactions, it is stated that "Electronic Documents are any Electronic Information that is created, forwarded, sent, received, or stored in analog, digital form., 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, photos or the like, letters, signs, numbers, codes Access, symbols or perforations that have meaning or meaning or can be understood by those who are able to understand them ". With this in mind, the documentation of health service results (medical records) stored in electronic form (EHR) meets the criteria as an electronic document.

Article 3 paragraph (2) in the Regulation of the Minister of Health number 269 of 2008 concerning Medical Records states that there is a discharge summary. Discharge summary (also known as medical resume) is a sheet containing significant data items related to the patient's main diagnosis, including the condition from the time the patient entered care until the patient was discharged / discharged. Article 4 paragraph (2) Regulation of the Minister of Health number 269 of 2008 concerning Medical Records states that: The contents of the summary of return as referred to in paragraph (1) shall at least contain:

- 1. Patient identity;
- 2. Admission diagnosis and indication of the patient being treated;
- 3. Summary of the results of physical examination and support, final diagnosis, treatment and follow-up; and
- 4. Name and signature of the doctor or dentist providing health services.

Unlike other medical record sheets that are kept for at least 5 years, Article 8 paragraph (3) of the Minister of Health Regulation number 269 of 2008 concerning Medical Records states that home summaries are stored for 10 years from the date of manufacture. The National Hospital Accreditation Standard (SNARS) edition 1.1 which was compiled and started to be used by the Hospital Accreditation Commission (KARS) since January 1, 2020 in standard 15 on Information Management and Medical Records (MIRM) states that patients discharge summary include:

- 1. Medical history, physical examination and diagnostic examinations,
- 2. Indications for hospitalization, diagnosis and other comorbidities,
- 3. The therapeutic procedures and measures that have been performed,
- 4. Drugs given, including drugs after the patient is discharged from the hospital,
- 5. The patient's health condition (status present) when going home to the hospital,
- 6. Follow-up instructions,
- 7. Described and signed by the patient and family.

The strategic plan of the ministry of health as stated in the Regulation of the Minister of Health of the Republic of Indonesia number 21 of 2020 concerning the Strategic Plan of the Ministry of Health for 2020-2024 states that: improving the SIK through the Integrated Referral System (SISRUTE) which is applied as an information system for the implementation of IT-based integrated health services aims to improve the referral system between First Level Health Facilities (FKTP) and Advanced Level Referral Health Facilities (FKRTL). Development is also being made on an electronic medical record system that can support the exchange of patient medical resume data between hospitals (Smart care).

#### Discussion

The regulations related to medical resume/discharge summary mentioned above do not yet regulate standard language, abbreviations, symbols, and units for documentation in medical resumes. The existing regulations also do not explain things related to the data dictionary for each data item in a medical resume, especially an electronic-based medical resume. This is important to support the function and utilization of medical resumes in EHR as a source of data in health information exchange. Given the position of EHR as the entry point for data in the concept of e-health where it is possible to have a health information exchange (HIE), the existence of documentation standards and data dictionary is absolutely necessary. This standard will establish the same steps in documenting and uniformity of understanding in the use of EHR-based information.

Thus there is no difference in meaning interpretation due to the variety of languages, abbreviations, symbols, and/or units used in documentation. Determining the items in the medical resume will also ensure the adequacy of information when the medical resume is used for various needs, for example to support SISRUTE. In SNARS 1.1, part of MIRM standard 15 regarding the discharge summary sheet has explained the items that should be included in it and also the obligation to explain its contents to the patient. However, MIRM standard 15 has not explained the obligation to explain to patients regarding the plan to use the discharge summary on their behalf. One of the agendas in the Minister of Health Regulation number 21 of 2020 concerning the Strategic Plan of the Ministry of Health 2020-2024 is the application of integrated electronic medical records (EHR) in all hospitals (100%) with medical resumes as a source of health information exchange (HIE). As an integral part of medical records, medical resumes are also confidential and require some regulation in their use. The HIE plan in this integrated EHR requires regulations to further regulate the manufacture and use of medical resumes related to HIE activities. The existing regulations regarding medical resumes do not yet regulate the use of medical resumes for HIE needs.

The use of medical resumes for HIE needs in an integrated EHR as stated in the Minister of Health Regulation number 21 of 2020 concerning the Strategic Plan of the Ministry of Health 2020-2024 requires affirmation and arrangements regarding patient consent as the owner of information in medical records. The patient has the right to self-determination, his options including the release of his health information. On the other hand, the implementation of the strategic plan stages of the ministry of health related to integrated HIE and EHR requires and uses a medical resume (Also known as discharge summary) as a basis for information that will be integrated between hospitals. With the direction of this strategic plan, some things that should be considered include (But are not limited to):

- 1. Does it mean that the patient is obliged to consent to the use of his medical resume for HIE in the integrated EHR?
- 2. Or is the patient considered to agree with the use of his medical resume if he goes to the hospital?
- 3. Is it necessary and mandatory to explain to patients about the use of their medical resume to support HIE in an integrated EHR?

Patient consent regarding the use of his medical resume still depends on the contents of the medical resume to be used. Because it is integrated between hospitals, it will also require the development of a standard medical resume design between hospitals so that data can be exchanged.

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According to SNARS edition 1.1, the concept of medical record management starts from the time the patient arrives, as long as the patient receives service until the patient goes home (discharge), and is continued with further processing and management according to their needs. In this regard, patient consent is required from the time the patient is admitted to the hospital until the end of his service episode and includes the use of his medical resume. This required patient consent includes (but is not limited to):

- 1. The patient's consent to be admitted to the hospital,
- 2. The patient's consent to be treated in a specific room (eg ICU or isolation room),
- 3. The patient's consent to comply with hospital regulations,
- 4. The patient's consent to fulfill his obligations as a patient,
- 5. The patient's consent to the medical action plan,
- 6. The patient's consent regarding information on his presence in the hospital,
- 7. The patient's consent regarding the use and release of his information,
- 8. The patient's consent to be consulted with a particular department or specialist,
- 9. Patient consent to be referred.

The things mentioned above need harmony in policy and implementation. Patients also need to be educated regarding patient consent in order to understand the various consequences of their decisions. Apart from being used for the benefit of continuous service to patients, medical resumes also have the potential for various other things, such as statistical needs, quality reviews, education, research, law, and so on. With regard to the intended use of this medical resume, patient consent is required that clearly states the scope of use of the medical resume. Likewise, the consent regarding whether the patient's identity is disclosed for a certain type of use (anonymization or de-identification). According to I Gede Atmadja, legal certainty means that the formulation of legal norms is clear and does not have multiple interpretations, is applied in accordance with the principle of "similia-similibus" (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 the existence of general rules individuals can know what the State may impose or do against individuals (Dewa, 2018).

Regarding the use of medical resumes as data sources in an integrated EHR, legal certainty is required, medical resume standardization, anonymization options. Legal certainty in terms of patient consent related to the use of medical resumes for HIE in this integrated EHR also needs clarity and clarity about the parties who have the authority to provide statements. There is also a need for certain criteria regarding competent patients, patient caregivers, patient families so that the implementation of patient consent for the use of medical resumes for HIE in this integrated EHR is clearer.

#### Conclusion

The use of medical resumes as a data source for HIE in an integrated EHR as stated in the Minister of Health Regulation number 21 of 2020 concerning the Ministry of Health's Strategic Plan 2020-2024 requires the support of patient consent as the owner of information in medical records. Patient consent in this regard, requires clarity of regulations, standardization, and education to related parties (Patients, service providers, service providers, third parties related to law; education; research; management, and also the general public).

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